FINAL REPORT

NSW Government Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists

Evaluation of PATH-UTI

APRIL 2026

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

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EXECUTIVE SUMMARY

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Executive Summary

Healthcare systems are under pressure to adapt to the rising demands of populations, technological advancements, and the changing landscape of diseases. A key driver has been the impact of the COVID-19 pandemic [1], along with growing demand for primary healthcare services, application of technology and patient access to essential treatments [2, 3]. In response, governments are exploring health workforce reforms – including changes to legislation that allow pharmacists to play a larger role in patient care – as a way to improve access, efficiency, and deliver better health outcomes [4, 5]. In New South Wales (NSW) and the Australian Capital Territory (ACT), expanding the role of community pharmacists is part of a broader strategy to improve access to primary care in the community. As part of this shift, the NSW Government has funded pharmacist trials for the management of uncomplicated urinary tract infections (uUTIs), hormonal contraception and dermatological conditions [6]. These trials aim to assess whether pharmacist-led care is safe, effective and accessible for patients.

Evidence to support pharmacist-led management of uUTIs continues to grow and is mainly focused on establishing whether the service is safe, effective and acceptable to both patients and healthcare professionals [7-10]. Globally, studies on pharmacist management of minor ailments, including prescribing, have been conducted in clinical areas such as oral contraception [9, 10], hypertension [7] and urinary tract infection (UTI) [3, 8, 11-15]. A systematic review examined pharmacist prescribing [16] and concluded that it offers quicker, convenient access to treatment, and is well received by patients. Similarly, a 2018 study exploring attitudes toward pharmacist prescribing for three different conditions found positive sentiment among pharmacists, doctors, and patients in relation to the convenience of the service, especially for after-hours access when patients were unable to get a general practitioner appointment [12]. In a Canadian study of 692 pharmacists, the most commonly reported benefits of pharmacist prescribing included patient convenience, improved access to health services, increased efficiency for the health system, and improved patient understanding of the pharmacist's role [17-20]. Even though most studies report benefits in access and acceptability of pharmacy prescribing, many are relatively small, have not addressed broader outcomes and do not provide greater detail about both safety and effectiveness.

As the evidence continues to grow, an Australian review of health professionals' scope of practice has called for targeted reforms, particularly for those working in rural, remote, and underserviced areas [2]. The review suggested that innovation and interdisciplinary care need a specific evidence base to support new workforce models. It also highlighted that trust between key stakeholders is crucial to making reforms work [21, 22].

In 2023, NSW Health commissioned the University of Newcastle to lead a consortium in a 12-month trial testing pharmacist-led care for uUTI. The project began with a 2-month feasibility study (from 30 May to 30 July 2023) followed by the main trial, which ran from 31 July 2023 to 31 May 2024. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN – 12623000882628).

The aim of the research was to co-design and evaluate how effective and cost-efficient a pharmacist-led UTI service model could be when delivered by community pharmacists in NSW. The study focused on women aged 18–65 years presenting with urinary symptoms of an uUTI. The implementation process and sustainability of the service model was investigated using an implementation science approach.

In the tender requirements, the NSW Government highlighted the following specific objectives to:

- better understand, both qualitatively and quantitatively, the benefits of community pharmacists managing UTIs for a specific patient cohort (women aged between 18–65 years); and
- identify any specific risks that could be mitigated in a broader rollout of community pharmacists managing UTIs for a specific patient cohort across NSW after the trial was conducted.

The tender further outlined the following measures of success, including that community pharmacists' management of UTIs:

- provides timely access to patients presenting with symptoms and seeking care;
- provides confidence that patients are safe and those who do not meet the criteria for pharmacy-only management are appropriately referred to a general practitioner or hospital;
- promotes strengthened relationships between pharmacists and general practitioners, especially in regional/rural areas;
- is not shown to contribute to antimicrobial resistance; and
- does not adversely impact lower socio-economic patients in terms of out-of-pocket expenses [23].

In addition, the NSW Government added the following principles to be considered during co-design, including:

- 'Pharmacists are confident when to prescribe and when not to prescribe, including referral to a general practitioner or hospital.
- Understanding the patient base holistically – capturing data on all patients (i.e., including those who do not meet criteria), to help understand the broader patient cohort presenting with UTI symptoms and whether those with potentially more serious conditions are appropriately referred.
- Holistic understanding of prescribing patterns and patient outcomes through data linkage – Medicare data/Pharmaceutical Benefits Scheme (PBS) dispensing data and NSW Health routine data including hospitalisations and emergency department presentations.
- Connection to primary care – promotes/encourages clinical team relationships to strengthen patient centred care. This may include pharmacists uploading data to individual patient My Health Records as well as other pathways.
- Cost implications for patients – understanding how the cost associated with a pharmacy consultation and private prescription (non-PBS) impacts the patient demographic proceeding with a pharmacy prescription [23].'

The trial was supported by a consortium of academic, clinical and research institutions using a staged research approach. It included a feasibility study, full trial implementation (PATH-UTI), an economic evaluation, and a series of qualitative investigations. Targeted work was also undertaken with Aboriginal and Torres Strait Islander populations as well as rural and remote communities.

The study hypothesised a community pharmacy UTI service for women 18–65 years presenting with symptoms of an uUTI:

- is feasible and acceptable to participants and providers;
- will achieve high rates of self-reported symptom resolution rates at 7-day follow-up; and
- will not be associated with safety risks.

To test this hypothesis the following studies were conducted:

- an independent co-design process with stakeholders, undertaken by Deloitte Consulting, with guidance of the University of Newcastle research team;
- a feasibility study conducted by the University of Newcastle research team with advice from The George Institute for Global Health;
- a trial (PATH-UTI) in community pharmacy involving a consortium of Universities (University of Newcastle, University of Technology Sydney and the University of New England);
- an independent formative and summative evaluation of the trial undertaken by The George Institute for Global Health for clinical, patient satisfaction, and implementation outcomes;
- an economic evaluation for the PATH-UTI main trial by the Hunter Medical Research Institute health economics group;
- an implementation evaluation, undertaken by the University of Newcastle and the University of Technology Sydney;
- a study of the potential effect on community antimicrobial resistance (AMR) led by a team from Westmead Hospital, Sydney Children's Hospitals Network, with statistical advice from the University of Technology Sydney;
- a qualitative study undertaken for Aboriginal and Torres Strait Islander people by the Co-Design

Health Research and Innovation (CHRI) team at the University of New South Wales (UNSW); and

- a rural and remote qualitative study undertaken by the Rural Doctors Network and Charles Sturt University.

Co-design of PATH-UTI

The PATH-UTI trial was built on a foundation of stakeholder engagement and collaborative design. The co-design process with stakeholders was led by Deloitte Consulting, with oversight from the University of Newcastle research team. To ensure culturally appropriate engagement, a separate and dedicated consultation was conducted with Aboriginal and Torres Strait Islander peoples.

The co-design phase was critical in shaping the trial's foundation and focused on several key areas:

- the design of the feasibility study;
- the development of an evidence-based clinical management protocol; and
- the establishment of a robust governance framework.

Stakeholder input was collected through a structured process of interviews, workshops, and ongoing consultation held in March and April 2023. The co-design phase specifically aimed to:

- develop clinical management protocols to guide pharmacist-led UTI care;
- define the governance and operational components to support the delivery and oversight of the trial;
- document the trial's core design components to support both formative and summative evaluations; and
- investigate and capture diverse perspectives to collaboratively shape the service models, ensuring alignment with both clinical needs and operational realities.

The process involved multiple phases, including an international literature review, qualitative stakeholder interviews, and a series of co-design workshops that facilitated collaborative discussion and consensus-building among participants. Agreement was reached on key service elements such as eligibility criteria, management and referral criteria.

The data collected from the qualitative stakeholder interviews and co-design workshops were thematically analysed to identify common themes, challenges and opportunities that emerged across different stakeholders and groups. Key outputs from the co-design process included the finalised clinical management protocol and the detailed governance structure for the trial. These outputs informed the research protocol, which was subsequently registered with the Australian New Zealand Clinical Trials Registry. These outcomes reflect a collaborative approach and lay the foundation for future implementation and evaluation.

Clinical Evaluation of PATH-UTI

The PATH-UTI trial evaluated a pharmacist-led model for managing uUTI in women aged 18–65 years across community pharmacies in NSW and the ACT. Conducted over 10 months following a 2-month feasibility study, the trial aimed to improve access to timely care and assess the safety, effectiveness, and feasibility of community pharmacist management of uUTI, including prescribing. Specific objectives were to:

- assess uptake and implementation across community pharmacies, including reach, fidelity, adoption, participant characteristics, and variation in uptake by geographic region;
- evaluate clinical and experience outcomes for patients managed and/or treated by community pharmacists;
- assess the safety and identify any risks that need to be addressed for future rollout;
- evaluate acceptability and feasibility among pharmacists, other care providers and participants using the service; and
- identify contextual enablers and constraints to access, adoption, fidelity, delivery, impact, sustainability, and generalisability of the intervention.

The study hypothesised that the UTI service delivered by community pharmacists for women 18–65 years with symptoms suggestive of an uUTI would be feasible and acceptable to participants and providers, achieve high rates of self-reported

symptom resolution within 7 days and not be associated with safety risks.

A mixed-methods cohort study was used. Eligible pharmacies across NSW were invited to apply, and five ACT pharmacies were randomly selected (later expanding to 15). Participating pharmacists received structured training and ongoing implementation support coordinated by the University of Newcastle. The intervention had two components:

- Pharmacist enrolment, including preparatory training to support consultations, participant consent, patient recruitment, timely referral, and quality data collection. Follow-up training and ongoing support were provided as part of an implementation strategy.
- Structured consultation with the participant in a community pharmacy conducted by the pharmacist anticipated to take approximately 10 minutes, and applying a co-designed clinical management protocol. The consultation was guided by the MedAdvisor® IT program applying a clinical management protocol which considers the recommendations from the Australian Therapeutic Guidelines.

The criteria associated with the two above components were defined by the NSW Health Authority (Appendix 3.1).

Data for the study were collected from several sources. Pharmacists recorded consultation details using a purpose-built MedAdvisor® IT case registration form. Participant data was gathered through a survey sent by SMS or email 7 days after the pharmacy consult, with up to three reminders. This survey collected information on urinary symptoms, antibiotic use, adverse events, other medications taken, healthcare provider visits, hospital admissions, treatment costs, participant experience, and additional demographic details. NSW Health data was also linked, covering hospital admissions, emergency department visits, outpatient services, and death registrations from both NSW and ACT, with data collected from 12 months before the study start date to the most recent available period. Additionally, participants who consented provided access to their Medicare Benefits Schedule (MBS) and PBS data for a 2-year period spanning 1 year before and after registration. Qualitative data was collected through interactions with Practice Change Facilitators (PCFs) and through semi-structured interviews with a purposive sample of pharmacists, patients, and other stakeholders involved in the trial's design and implementation.

The primary outcome of the study was self-reported symptom-free rate at 7 days, defined as the complete resolution of UTI symptoms. Secondary outcomes included implementation measures (the proportion of pharmacies and pharmacists delivering the service, patient referrals, antibiotic supply, adherence, and use of first-line antibiotics), participant experience, and primary care use including general practitioner and specialist visits, as well as pathology testing rates. Medication use was evaluated by assessing antibiotic prescribing and switching patterns, both immediately after the pharmacy consultation and across the 12 months before and after the service. Hospital admission rates, along with causes, lengths of stay, and bed days were also analysed over the same time periods. Emergency department use was similarly evaluated. Adverse events were captured through self-reports at the 7-day follow-up, while serious adverse events included emergency department visits, hospital admissions, or specialist consultations within 7 days, based on both participant self-reports and linked health administrative data.

The trial commenced on 31 July 2023 after a 2-month feasibility study, and ran for 10 months, with recruitment closing on 31 May 2024. A total of 1,528 pharmacies expressed initial interest, of which 1,320 consented to participate. Among these, 1,028 pharmacies (77.9%) went on to recruit at least one participant. Fifteen pharmacies were from the ACT.

A total of 17,380 patients consented to participate and were assessed as eligible by the pharmacist. Of these, 830 participants (4.8%) used the service more than once. Sixty-seven eligible participants (0.4%) requested to withdraw from the study, leaving 17,313 participants who collectively accounted for 18,143 care episodes. Data were linked to NSW administrative datasets for 17,219 people. Of these, the most common age group was 46–65 years, representing 39% of participants, and the majority (72%) lived in metropolitan areas. Based on the Index of Relative Socio-Economic Advantage quintiles (derived from participant postcode), 38.4% of participants were from the 5th, most advantaged quintile, while 8.8% were from the 1st, most disadvantaged quintile. The remaining were distributed across the 2nd quintile (16.1%), 3rd quintile (21.2%) and 4th quintile (14.4%). Among those with follow-up survey data, 58% reported further education beyond Year 12.

Of the 18,143 care episodes provided, 14,671 had completed follow-up surveys at day 7, representing an 80.9% response rate. Among these, 79.4% participants reported complete symptom resolution at day 7, while a further 17.9% reported improved but not fully resolved symptoms. In 90.2% of cases, the prescribed antibiotic was taken as directed. Trimethoprim was the most commonly supplied antibiotic, used in 90.3% of all episodes. The median time to symptom resolution was 3 days, and antibiotics were taken for a median of 3 days.

Participants reported a median out-of-pocket cost of $20 for the full service, inclusive of medication costs. Pharmacists were remunerated an additional $20 consultation fee, which in NSW, was funded by NSW Health and not charged to participants. In 85.0% of care episodes, participants indicated that cost was not a barrier for future use of the service. However, 9.7% reported that cost may be a barrier, and 5.4% indicated that it would be a barrier. Following the transition of the service into usual practice, patients are expected to bear the cost of the consultation. This fee is estimated to range from $19.5 to $70.5 depending on the consultation duration, based on similar service provisions implemented in Queensland. As the service will be fully patient-funded in usual practice, cost may present a barrier to access, particularly for individuals from lower SES groups. Despite these considerations, most participants reported a positive experience with the service, with strong agreement or agreement across seven statements assessing service quality.

Pharmacists referred 7.3% of participants to see a general practitioner and/or the emergency department. Based on self-report, 14% of participants saw a general practitioner within 7 days of the initial pharmacy consult. MBS data suggested the proportion seeing a general practitioner was higher than indicated by self-report, with 10.5% of participants visiting a general practitioner within 2 days and another 12.4% within 3–6 days. Over the 28 days following the pharmacy consultation, 43.2% had a general practitioner consult: 25.1% had one consult, 11.6% had 2 consults, and 6.5% had >2 consults. Although the reasons for general practitioner consultation were not available, pathology data relating to urine samples may provide an indication of encounters related to a urinary condition. The proportion of patients who received a urine test was 5.4% within 0–2 days, 5.4% within 3–6 days, and 8.2% within 7–28 days. The proportion of general practitioner consults in which a urine test was ordered during these three time periods was 48.8%, 39.9%, and 19.0%, respectively. The mean weekly general practitioner consultation rate increased in the 6-month period post pharmacy consult compared to the 12 months pre consult (15.9 per 100 people vs 11.6 per 100 people, $p<0.001$).

Based on PBS data for those consenting to linkage, 4.3% were prescribed an antibiotic within 2 days of their initial pharmacy consult, and 7.1% within 3–6 days. At days 7–28, the figure increased to 11.8%. Mean weekly antibiotic prescription rates significantly increased over the same period (4.3 per 100 people vs 2.2 per 100 people, $p<0.001$). Among the 14,671 care episodes with follow-up surveys, the self-reported adverse event rate was 5.1%, with gastrointestinal symptoms being the most common. The incidence of side effects associated with pharmacist prescribing of antibiotics was consistent to those reported in several international and national databases and the literature.

Using data linkage to NSW health data for 17,219 people, there were minimal differences in the average weekly emergency department presentation rate 6 months after pharmacy consult compared to the 12 months before the consult (0.8 per 100 vs 0.6 per 100). There was an increase in the emergency department presentation rate in the first week after the consult (2.4 per 100 in week 1 vs 0.6 per 100 in the 12 months pre-consult). This represents an additional 1.8 presentations per 100 persons in the first week. It is important to note that this includes all emergency department visits, regardless of cause.

Following the first week of the service, there were a total of 409 recorded emergency department presentations, 170 of which were related to genitourinary conditions. As part of the clinical management protocol, pharmacists could directly refer to the emergency department when a high-risk factor was observed. Emergency department visits were more common among patients referred to a general practitioner by pharmacists compared to those who were not: 6.15% versus 1.01% at 0–2 days, and 1.66% vs 0.93% at 3–6 days after the pharmacy consultation (see Appendix 3.4 Table 3-4-4). These findings suggest that the pharmacist is supporting continuity of care by appropriately referring patients to the relevant level of care.

The average weekly hospital admission rate was similar in the 6 months after the pharmacy consult vs the 12 months before the consult (0.2 per 100 vs 0.4

per 100). There were also no differences in admission rates in the first week after the pharmacy consult (0.5 per 100 in week 1 vs 0.4 in the 12-months pre consultation). Based on MBS data, specialist consult rates were low in the 7 days following the pharmacy consult (1.7 per 100), although no data was available on the speciality type. According to the non-admitted patient data collection, no specialist visits related to genitourinary conditions were recorded in the public hospital system in the 7 days following the pharmacy consult.

For the primary outcome of self-reported complete symptom resolution, there was no statistically significant variation across any of the pre-specified sub-groups. These included age, socioeconomic status (based on participant postcode), geographic region (based on Modified Monash Model (MMM) categories), hospitalisation in 12 months prior to enrolment, state of pharmacy (NSW vs ACT), antibiotic type received from the pharmacy, and whether the patient used the service once or multiple times. Participants who were referred to a general practitioner by the pharmacist experienced higher rates of general practitioner consultations and antibiotic prescriptions than those who were not referred.

The qualitative interviews revealed insights from a diverse group involved in the trial, including 11 pharmacists, 10 service users, and two PCFs. In addition, feedback from 61 participant emails contributed to a thematic analysis. From this analysis, six key themes emerged as influential factors in the successful implementation of the service: participant incentives to use the service; pharmacist motivation to participate; participant perceptions of what constitutes a ‘good service’; pharmacist views on service quality; and the integration of the service with both the health system's ‘hardware’ (infrastructure and processes) and ‘values, culture and relationships’. These themes highlight the complex nature of successful service implementation and the importance of aligning user and provider perspectives with broader system support. An important cross-cutting theme related to equity of access. While the wide geographic distribution of pharmacies and the provision of ‘walk in’ care is potentially a strong enabler of equity of access, most participants were highly educated and proactive about their health care. Some participants had concerns about cost transparency and the lack of access to subsidised medications, particularly for concession card holders and those eligible under the Closing the Gap (CTG) scheme.

By combining quantitative and qualitative findings, four overarching domains related to service access, delivery, health system integration and equity were identified as core priorities in driving uptake, quality and sustainability of this service.

There are four main strengths to the clinical evaluation. First, it involved a large number of participants and pharmacists across diverse geographic settings, making it the largest such trial reported in the literature to date. Second, it achieved high follow-up rates, with 80.9% of participants completing the 7-day follow up survey. Third, linkage of records to NSW administrative data and federal Medicare data provided robust information to examine service use in the hospital and primary care sector. Fourth, the trial included a detailed qualitative evaluation of implementation barriers and enablers.

A key study limitation was the absence of a comparison group to assess outcomes against usual care. While a randomised controlled trial would have been the gold standard, this approach was considered logistically challenging and was likely to reduce participant engagement. Similarly, a quasi-experimental design with a matched comparison group from routinely collected data was considered, but participant self-selection introduced a high risk of bias. Symptom resolution rates were similar to that reported in other pharmacy trials, both in Australia and internationally.

The 10-month trial of a pharmacy-led care model for women with uUTI achieved high levels of uptake from both pharmacist and participant and is the largest such trial reported in the literature to date. Considering the high response rate from consumers, the overall data helped reassure trial sponsors that the trial was being conducted safely and that pharmacist management of uUTI appeared to be safe. Symptom resolution rates were consistent with existing literature, which are generally around 80–90%. Participant satisfaction with the service was high. The service was disproportionately used by women with higher levels of education and for those residing in wealthier areas. A minority of people reported cost as a potential barrier to future use of the service, with the limitations of most patients belonging to higher SES and that the consultation fee was being subsidised by NSW Health during the trial.

The trial offered valuable insights into care utilisation practices using linked data analyses. Around 1 in 14 people were referred by the pharmacist to see a general practitioner, 1 in 4 people actually saw a general practitioner within 1 week of the initial consult, and a urine pathology test was ordered in 1 in 10 consults. Around 1 in 8 people were prescribed an additional or alternative antibiotic within 1 week which is consistent with international literature. The referral rates to general practitioners and emergency departments suggest there was continuity of care for those that needed ongoing support. The serious adverse event rates, including emergency department presentations and hospital admission, were low. There was a rise in emergency department presentations in the first week post-pharmacy consults but minimal differences in overall utilisation rates in the 12 months pre- and 6 months post-consult. Several key factors related to sustaining access, supporting quality service delivery, promoting equity and enhancing health system integration should be addressed if the service is to be implemented after the trial.

Economic Evaluation of Value and Cost Redistribution

The economic evaluation addressed two questions: First, does the PATH-UTI service add value and second, how does this service redistribute costs across sectors, providers and patients. Specifically, the aim was to compare the costs and outcomes of the PATH-UTI service against pre-existing care pathways, including general practitioner services, urgent care clinics, emergency departments and self-care.

The evaluation compared the PATH-UTI model with standard care pathways that existed before its implementation, referred to as the 'pre-PATH-UTI' model. These existing pathways typically involved general practitioners, emergency departments or self-management. Using summarised patient-level data from the PATH-UTI trial and supplementary information from published literature and government fee schedules, researchers from the Hunter Medical Research Institute conducted a modelled economic analysis.

To determine if the service added value, a cost-effectiveness analysis using a decision-analytic model was conducted using SAS 9.4 and populated with data from a simulated cohort of 275,000 women aged 18–65 years who experience a UTI each year, divided equally between the PATH-UTI and pre-PATH-UTI groups. It was undertaken from a health services perspective (therefore excluding costs to patients) over a 7-day time horizon reflecting the typical clinical course of uUTIs.

The model evaluated three scenarios. The first included costs and outcomes from the initial presentation only. The second added average follow-up costs for those who presented again for a consultation (re-presented), adding linked data from NSW Health and MBS/PBS databases. The third scenario also used linked administrative data to estimate real-world re-presentation costs more accurately. For each scenario, the model estimated the total cost of care and the number of women who were symptom-free at 7 days. These were used to generate incremental cost-effectiveness ratios, which express the additional cost required to achieve an additional cure.

To assess uncertainty and robustness, researchers conducted 5,000 bootstrap simulations and plotted the results on a cost-effectiveness plane. Model inputs included cost data for pharmacist consultations (under trial conditions), general practitioner visits (in-person and online), emergency department presentations and urgent care visits, as well as the costs of antibiotics and over-the-counter treatments. Cure rates were derived from clinical data on different management strategies, and re-presentation rates were informed by both trial data and linked administrative records.

Across all scenarios, incorporating pharmacy care led to total healthcare system savings of $2.2–$2.3 million annually – even when re-presentation costs were included, as modelled in Scenario 3 using linked administrative data. This represents a conservative estimate compared to international data from Canada and the United Kingdom, where participation rates between 25–50% were assumed, indicating that actual savings could be even greater.

Across all scenarios, the economic evaluation found that offering pharmacy-led care for the initial treatment of uUTIs was likely to result in cost savings while achieving similar health outcomes. The modelling suggests that pharmacy-led care may reduce pressure on other parts of the healthcare system by diverting uUTI patients away from more costly providers and freeing them up for other patients.

To assess any changes in how costs were distributed, a further analysis was conducted to map pre- and post-service expenditure outlays aligned to the modelled scenarios, this time including costs to patients. The hypothesis being that PATH-UTI would produce a redistribution of spending between care settings and payers. In Scenario 1, the addition of PATH-UTI resulted in government costs across general practitioner, online general practitioner, urgent care and emergency department pathways, while patients paid more out-of-pocket when choosing pharmacy consultations. The sensitivity analyses, including scenarios with a portion of patients paying no pharmacy fee, showed similar distribution patterns. Scenario 2, which included re-presentations, maintained reductions in publicly funded non-pharmacy costs, especially emergency care, while costs attributed to the pharmacy pathway increased reflecting both initial and follow-up care. Overall, the analysis indicated that a model with community pharmacy management of uUTIs has the potential to bring about substantial cost savings to the health system for both State and Commonwealth payers. In doing so, some costs may be shifted to patients.

Enabling community pharmacists to manage uUTIs could potentially save money and reduce the workforce burden on general practitioners and emergency departments for treatment of this condition. At the same time, it has the potential to enable easier access to treatment for women. This economic evaluation supports the assertion that community pharmacy management offers a cost-effective addition, alongside traditional care models, with the potential for significant health system savings. It provides strong evidence to inform policy-making decisions regarding the support of community pharmacy-led care for uUTIs.

An Evaluation of Implementation Fidelity and Effectiveness

Translating health research in routine practice is often slow. On average, evidence-based practices take 17 years to become part of standard care, and only about 50% are successfully adopted [24]. This gap exists across various settings, disciplines and countries, highlighting the need for effective implementation strategies to maximise public health benefit. Implementation science addresses this challenge, focusing on strategies that support the integration of new practices into routine care [25]. A key part of this process is the role of PCFs, who provide expertise, mentorship, and support to organisations and service providers to help implement new services [26-28]. The Consolidated Framework for Implementation Research (CFIR) [29] categorises implementation determinants into factors that either hinder or facilitate the adoption of innovations. Strategies for overcoming barriers were selected based on their perceived feasibility and impact, using the Expert Recommendations for Implementing Change (ERIC) system to classify them [30]. The implementation outcomes included acceptability, appropriateness, feasibility, accessibility, adoption, and fidelity.

The primary objective of this evaluation was to assess how widely the intervention was adopted in community pharmacies, evaluate the contextual enablers and barriers influencing its effectiveness, and identify the strategies used to address these factors. PCFs received training at the start of the trial, which was reinforced throughout the study period. PCFs maintained regular contact with pharmacists to answer questions, support accurate data collection, and identify implementation barriers and facilitators using a checklist developed by the research team [29, 30].

Results showed that 69.3% of pharmacies received face-to-face visits from PCFs, with 97.6% of pharmacies having some form of contact. During these interactions, PCFs identified a total of 1,874 barriers and 4,648 facilitators during contact with pharmacies, with an average of 2.0 (±1.39) barriers and 5.2 (±3.25) facilitators per pharmacy. The most common barriers were pharmacist capability, resource availability, work infrastructure, patient engagement, physical infrastructure and Information Technology systems. When these factors were addressed, they acted as facilitators. Around 70% of these barriers were resolved through various strategies which included the development of formal implementation plans, material distribution, and feedback mechanisms.

The patient follow-up survey achieved a response rate of over 80%, with qualitative feedback highlighting that patients appreciated timely symptom resolution, affordability, trust, privacy, respect, and integration with healthcare services. Community pharmacists found the service feasible but emphasised the need for better integration with health systems, including information from pathology

services and general practitioners. Participation rates were similar across most geographic areas (based on Modified Monash Model (MMM) classifications), though pharmacies in remote and very remote areas (MMM6 and MMM7) had lower participation. The adoption rate was high: nearly a quarter of pharmacies conducting more than 20 consultations. Fidelity to clinical management protocols was also strong, with over 99% adherence. Only 0.08% of consultations involved protocol violations, mostly related to the referral of high-risk patients.

The pharmacist-led UTI management service demonstrated high uptake, protocol adherence, and patient satisfaction, especially in metropolitan, regional and rural areas. However, remote areas faced challenges in access, underscoring the need for efforts to reduce inequities in service availability. The role of PCFs was crucial in identifying and addressing barriers, emphasising the importance of tailored support in the rollout of services. Both pharmacists and patients reported positive experiences, supporting the service's relevance and potential sustainability within the broader healthcare system. Moving forward, integration with existing healthcare infrastructure, particularly in underserved areas, and continued support for workforce and systems will be essential to improving accessibility and equity in primary health care.

Evaluating Patterns and Drivers of Antimicrobial Resistance

The primary aim of this component of the research was to assess the prevalence of antimicrobial resistance (AMR) rates in uropathogens within NSW before and during the trial, and to determine if the program had any impact on community-level AMR rates. Key objectives include measuring differences in AMR rates immediately before and after the trial began and comparing these to a counterfactual estimate based on existing AMR trends.

This was a population-based study using routinely collected health data from private pathology providers, and data from the PATH-UTI trial. The datasets used were retrospective and prospective de-identified de-duplicated data on community uropathogens from patients/residents in NSW sourced from two of the largest private pathology providers. A third provider declined to participate in the study. De-identified data from the PATH-UTI trial were also used. The primary outcome was uropathogen resistance rates (urine cultures resistant to selected antibiotics/number of bacterial positive urine cultures).

Analyses of urinary isolates were conducted to describe overall antimicrobial resistance rates in line with the Australian Commission on Safety and Quality in Health Care specification for an antibiogram. Resistance categories included non-susceptibility to the following antibiotics: amoxicillin, amoxicillin-clavulanic acid, cefalexin, trimethoprim, norfloxacin or ciprofloxacin, and nitrofurantoin. The antimicrobials selected include amoxicillin, amoxicillin-clavulanate, cefalexin, ciprofloxacin, norfloxacin, nitrofurantoin, and trimethoprim, to represent standard 'first-line' testing in pathology laboratories.

A total of 165,466 samples were analysed in the Australian Clinical Labs dataset, and 433,580 samples were included in the Laverty Pathology dataset. 88% of the samples were from female patients in Australian Clinical labs, compared to 87% in the Laverty Pathology dataset. Males accounted for approximately 12% of samples in both datasets. The most frequently identified organism in both datasets was *Escherichia coli*, representing 79% of isolates in Australian Clinical Labs and 80% in Laverty Pathology.

The observed resistance trends for the study drugs – trimethoprim, nitrofurantoin, cefalexin – aligned with expected antimicrobial resistance trends, suggesting that the changes seen during the trial period were likely a continuation of pre-existing trends rather than a direct result of the UTI trial. The results in this report provide a preliminary update on AMR in the context of the NSW Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists. Data collection for the trial is ongoing, with future analyses expected to explore AMR changes after 12 months of surveillance data collection and comparator data. The current regression model includes data from 12 months before the intervention, but further analysis will extend this to assess the statistical significance of changes linked to the introduction of the pharmacist UTI trial in NSW.

A Qualitative Evaluation with Aboriginal and Torres Strait Islander Communities

Indigenous Australians face significant health disparities, including higher mortality rates from preventable causes compared to the broader population [2, 11, 31-35]. These gaps highlight the importance of improving access to health care, and pharmacist management of minor ailments, including prescribing, has been suggested as one way to address some of these disparities, particularly in providing easier access to medications. However, there is limited understanding of how Indigenous communities perceive pharmacist prescribing and the implications for their health care [16, 36].

This study aimed to understand the views of Indigenous community members, health organisations and community pharmacists regarding the trial and explore the risks and benefits of expanding the scope of practice for pharmacists in these communities.

The study used a co-design model validated for health research involving Indigenous populations, ensuring that local contexts and cultural considerations were prioritised. Three Aboriginal Community Controlled Health Organisations (ACCHOs) and four sites across NSW participated in the study. The research locations varied in remoteness, including very remote, rural, regional, and urban areas [37], and included the participation of both Indigenous and non-Indigenous staff, as well as local community members who self-identified as Indigenous.

A total of 63 participants were interviewed, including ACCHO staff, pharmacists, and Indigenous community members. The key finding was that Indigenous community members saw significant value in the service, with many identifying convenience and rapid access to medications for pain relief as key benefits. Some participants expressed interest in expanding the service to cover other conditions or medications. While most community members and pharmacists viewed the service positively, ACCHO staff were more cautious, particularly regarding the quality and continuity of care between primary health clinics and pharmacists.

Participants identified two primary concerns: quality and continuity of care and ensuring privacy during pharmacy consultations. ACCHO staff were particularly concerned about the potential disruption to the continuity of care between health clinics and pharmacies. Meanwhile, community members emphasised the importance of maintaining privacy during consultations. Additionally, participants identified two key factors that would help ensure equitable and safe access to the service for Indigenous people: aligning the service with the CTG program, which aims to reduce health disparities for Indigenous Australians, and providing cultural competence training for pharmacists.

Overall, the study found support among Indigenous community members – and the clinicians who care for them – for an expanded scope of practice for pharmacists. Like the broader population, Indigenous community members see potential benefits but also raise concerns about its implementation. While this study captured the perspectives of a small sample of Indigenous individuals, it highlights the importance of continuing to examine how such services impact Indigenous communities as they become more widely available in NSW. Further research into access, cultural considerations, and the long-term impact of the service will be crucial to ensuring its success and equity in healthcare delivery.

Qualitative Insights from Health Professionals in Regional and Rural Communities

Australians living in rural, remote and very remote communities generally have poorer access to health care than people in regional centres and metropolitan areas, often due to a lack of access to health services and the need to travel long distances for treatment [38].

This study explored the key drivers of collaboration and trust between pharmacists and general practitioners in regional or rural settings, focusing on how these relationships might influence the service model for pharmacist prescribing in such areas. A total of 21 semi-structured online interviews were conducted between October and December 2023, with 10 pharmacists and 11 general practitioners who had experience working in regional or rural Australia.

Four key themes emerged from the interviews: collaboration dynamics, communication, leadership, and patient-centred care. A major finding was the

critical role of communication in fostering collaboration between general practitioners and pharmacists. Many participants emphasised that 'trust between the professions is built on communication', underscoring the importance of clear and consistent exchanges of information. Regarding the NSW trials, most general practitioners acknowledged the need to communicate prescribing and consultation outcomes with patients' regular general practitioners. However, they also expressed concerns that the volume of communication could be burdensome and interfere with daily practice. Understanding and respecting the distinct roles and capabilities of each profession was highlighted as a vital aspect of building trust in interdisciplinary care.

Overall Discussion

The findings from six interrelated studies evaluating the PATH-UTI trial are presented under five strategic pillars: Access and Equity, Economic Sustainability, Safety and Efficacy, Implementation, and Practice.

During the PATH-UTI trial, over 17,000 women accessed pharmacists' management for uUTI across more than 1,000 pharmacies in a 10-month period. This made the PATH-UTI trial the largest pharmacy-led prescribing trial for the management of uUTI, nationally and internationally. The overall incidence of uUTI in women is challenging to estimate accurately due to many factors including self-treatment by women along with treatment by pharmacies, general practitioners and emergency departments. Previous research suggests an all-age annual incidence for uUTI in women at around 7%, with higher estimates for ages 20 to 24 and over 65 years [39]. Applying our estimate to the 2023 Australian Bureau of Statistics population data, approximately 175,000 women in NSW and 10,000 women in the ACT would have developed an uUTI in 2023 [40]. The PATH-UTI trial, having included 17,219 women in NSW and 787 in the ACT in the 10-month study, could have potentially covered up to 9.5% and 7.8% of all uUTI cases in this population for NSW and the ACT, respectively.

The data shows that most patients accessed the service in metropolitan areas (72%), while being employed (80%). Interestingly, the distribution of patient consultations was similar to the total distribution of pharmacies in NSW in relation to MMMs. For example, 14% of patient consultations occurred in pharmacies in larger rural towns (MMM 3), which house around 11% of all pharmacies registered in NSW [41]. Participation from more remote areas was limited: only three pharmacies in MMM6 (remote) provided consultations, and none from MMM7 (very remote), despite there being 17 pharmacies across MMM6 and MMM7 in NSW. In these areas, ongoing workforce challenges were reported, and additional concerns included the inability to conduct consultations in a separate room, as the sole pharmacist on duty could not leave the rest of the pharmacy unsupervised for the 10–20 minutes required for each consultation. These barriers highlight clear targets for future policy support and investment by stakeholders to enhance rural participation.

Accessibility is also affected by equity. Ensuring positive health outcomes for socio-economically disadvantaged populations, particularly Indigenous communities, while maintaining quality and continuity of care is essential. This study found that community members, including Indigenous participants, valued the convenience and rapid access to care and medications provided by pharmacies, particularly in rural and remote areas where doctor availability was limited. While participants generally did not see cost as a barrier to using the service, affordability remains a key concern, as out-of-pocket costs may deter Aboriginal and Torres Strait Islander patients from using pharmacy services. The Commonwealth CTG scheme was suggested as a potential strategy to reduce financial barriers and promote health equity nationally.

Among the trial population, affordability did not appear to be a major barrier to access. Over 85% of follow-up respondents reported that service costs did not impact their decision to access the pharmacy consultation. However, the data indicated that service usage was skewed toward higher-income and socioeconomically advantaged groups, based on postcode-level SEIFA (Socio-Economic Indexes for Areas) data. This suggests that while overall uptake was strong, patients from lower SES would require additional support to access the service.

The primary outcome, defined as the self-reported total absence of symptoms (or total symptom resolution) at 7 days after receiving the service, was achieved by 79.4% of the patients that completed the follow-up survey (11,654/14,671). An additional 17.9% (2,621/14,671) reported partial resolution of their symptoms. These are consistent with similar studies that have explored pharmacy

prescribing for uUTI, which show total resolution rates between 75–91% [42-44]. Comparable outcomes have been shown with physician-led care with symptom resolution rates ranging from 67–95% [45-54].

Pharmacists referred 7.3% of all patients to a general practitioner or emergency department based on the complexity of their condition. The most common high-risk factor prompting referral was the presence of systemic symptoms, such as fever. Among patients in PATH-UTI who had an MBS episode registered within 7 days after the intervention (n=3,831), approximately 44% had a urine sample sent for pathology testing (n=1,690), suggesting that most general practitioner visits may not have been related to UTIs, although this number could be underestimated. These rates are similar to those previously reported in pharmacy- and physician-led UTI interventions, which report follow-up pathology testing 15–42% of cases [45-54]. Studies have shown that nearly 40% of women aged 18–65 years who receive treatment for uUTI will return to a general practitioner for similar symptoms within the 6 months following their initial visit, with this figure rising to 60% after 12 months [45-54]. In PATH-UTI, the re-consultation rate was significantly higher in patients that were older, and in patients that were referred to a general practitioner by the pharmacist during the service. As a result, it may be said that PATH-UTI demonstrated expected re-consultation rates for patients with uUTI.

The PATH-UTI trial found minimal differences in hospitalisation rates or visits to emergency departments and urgent care clinics for genitourinary-related consultations before and after patients accessed the pharmacy-based service. In total, 409 emergency department presentations occurred after the first week of receiving the service, with 170 of these related to genitourinary conditions. Emergency department attendance was higher in patients referred by a pharmacist to a general practitioner compared to those non-referred (6.2% vs 1.0% at 0–2 days, and 1.7% vs 0.9% at 3–6 days after the pharmacy consultation) (see Appendix 3.4 Table 3-4-4). Follow-up data indicated that 147 patients had been referred either directly by a pharmacist or indirectly through a general practitioner, although no direct linkage was possible between these two groups. This suggests that pharmacists are supporting continuity of care by appropriately referring patients to the relevant level of care.

The average weekly hospital admission rate remained stable when comparing the 12 months prior to the pharmacy consultation (0.4 per 100 people) and 6 months post pharmacy consultation (0.2 per 100 people). In the first week after the pharmacy consultation, the admission rate was 0.5 per 100 people, indicating minimal differences in hospitalisations linked to the service. No deaths related to the pharmacy-led UTI service were identified through data linkage.

The rate of reported adverse events was low, at 5.1%, with the majority of cases involving gastrointestinal symptoms related to the antibiotics prescribed. This rate is in line with previous research, as gastrointestinal adverse events are common when antimicrobials are prescribed as an intervention [55]. One study by Beahm *et al*. reported that 7.2% (n=54) of patients experienced adverse events during their treatment, with gastrointestinal adverse events (59.3%), secondary vaginal infections (14.8%), other (14.8%) and headache (11.1%) being reported [42]. In the same study, a total of five (0.7%) reported adverse events resulted in a general practitioner or emergency department visit. The study revealed no statistically significant differences in adverse event rates between patients treated by pharmacists and those managed by general practitioners, as evidenced by p values greater than 0.1079 across all comparisons [42].

Approximately 88.5% (n=15,232) of patients in the PATH-UTI trial were prescribed trimethoprim, in line with the clinical management protocol, demonstrating high adherence to the guidelines. Smaller proportions of patients were prescribed cephalexin (2.5%) and nitrofurantoin (1.6%), while 7.4% of participants did not receive an antibiotic. Overall, pharmacists prescribed antibiotics in 92.6% of patient encounters, with trimethoprim being the primary agent (95%), aligning with first-line treatment recommendations in both the therapeutic guidelines and the trial's management protocol. In comparison, the AURA 2023 report, which examined a sample of general practices, found a 90.8% prescribing rate for UTIs, with only 42% using trimethoprim as the first-line treatment [56]. Furthermore, previous pharmacy studies present prescribing rates between 80–97%, and physician-driven trials have usually reported between 80–97% of antibiotic prescribing [45-54].

AMR was one of the key safety criteria for the trial due to the increased risk of complications that it could generate in the population. The resistance

levels observed for the antibiotics prescribed during the trial were consistent with the expected trends based on both previous and current laboratory data, with trimethoprim resistance at 27%. Given these results, it is highly unlikely that the antibiotics prescribed by pharmacists for UTIs had a significant impact on AMR, especially considering that fewer than 17,000 patients received prescriptions out of an estimated total antibiotic prescribing rate of 827 per 1,000 people per year in NSW [57]. The resistance patterns observed in this trial are consistent with ongoing developments in AMR, rather than any major deviation linked to the trial's interventions [56]. Given the current high levels of trimethoprim resistance in Australia, the therapeutic guidelines for UTI were updated at the end of March 2025. Trimethoprim has now been replaced with nitrofurantoin as first-line treatment, with fosfomycin as a second-line agent, and trimethoprim moved to a third line option [58].

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Glossary

ACCHO	Aboriginal Community Controlled Health Organisation
ACP	Australasian College of Pharmacy
ACT	Australian Capital Territory
AMR	Antimicrobial Resistance
ANZCTR	Australian New Zealand Clinical Trials Registry
APDC	Admitted Patient Data Collection
ATC	Anatomical Therapeutic Chemical
AUD	Australian Dollars
AURA	Antimicrobial Use and Resistance in Australia
BDM	Births, Deaths and Marriages
CAD	Canadian Dollars
CEA	Cost-Effectiveness Analysis
CEAC	Cost-Effectiveness Acceptability Curve
CFIR	Consolidated Framework for Implementation Research
CHeReL	Centre for Health Record Linkage
CI	Confidence Interval
CMA	Cost Minimisation Analysis
CMI	Consumer Medicine Information
CPD	Continuing Professional Development
CPI	Consumer Price Index
CTG	Closing the Gap
DSMB	Data Safety Monitoring Board
EBP	Evidence-Based Practice
EDDC	Emergency Department Data Collection
ERIC	Expert Recommendations for Implementing Change
GDS	George Data Systems
GLM	Generalised Linear Model
GPhC	General Pharmaceutical Council (UK)
HEAP	Health Economic Analysis Plan
HREC	Human Research Ethics Committee (University of Newcastle)
ICD	International Classification of Diseases
ICER	Incremental Cost-Effectiveness Ratio
ID	Identification
IHACPA	Independent Health and Aged Care Pricing Authority
IT	Information Technology

IUD	Intrauterine Device
MBS	Medicare Benefits Schedule
MMM	Modified Monash Model
NAP	Non-Admitted Patient
NPT	Normalisation Process Theory
NSW	New South Wales
OSCE	Objective Structured Clinical Exam
PATH-UTI	Trial: Effect of Management of Urinary Tract Infections in Women aged 18–65 years by Community Pharmacists on Self-reported 7-day symptom free rate
PATH-OC	Trial: Extended Supply of Oral Contraceptive Pills by Community Pharmacists
PBS	Pharmaceutical Benefits Scheme
PCF	Practice Change Facilitator
PPH	Potentially Preventable Hospitalisation
PSA	Pharmaceutical Society of Australia
PSC	Project Steering Committee
QALY	Quality-Adjusted Life Years
QALM	Quality-Adjusted Life Months
QR code	Quick Response Code
QCPP	Quality Care Pharmacy Program
RACGP	Royal Australian College of General Practitioners
RBDM	Registry of Births, Deaths and Marriages
SEIFA	Socio-Economic Indexes for Areas
SGLT2i	Sodium-Glucose Cotransporter-2 inhibitor
SNOMED	Systematized Nomenclature of Medicine
SSWG	Safety and Stewardship Working Group
STI	Sexually Transmitted Infection
SURE	Secure Unified Research Environment
TDF	Theoretical Domains Framework
TOR	Terms of Reference
UNSW	University of New South Wales
UTI	Urinary Tract Infection
UTIs	Urinary Tract Infections
uUTI	Uncomplicated Urinary Tract Infection
uUTIs	Uncomplicated Urinary Tract Infections
UTIPP-Q	Urinary Tract Infection Pharmacy Pilot – Queensland
WHO	World Health Organization

01

INTRODUCTION

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 1: Introduction

Scope of Practice

Healthcare systems worldwide are continuously evolving to respond to the growing demands of populations, technological advancements, and the changing landscape of diseases. Significant drivers have been the impact of the COVID-19 pandemic [1], an increased demand for primary healthcare services, application of technology and patient access to essential treatments [2, 3]. Many governments have re-evaluated their healthcare systems and delivery models, leading to legislative changes that enable more healthcare professionals to expand their scope of practice to include clinical management that may also involve prescribing of medications [4, 5]. Ensuring timely access to primary care with associated safety and effectiveness criteria has emerged as a priority for healthcare systems worldwide [59]. Historically, the authority to prescribe medications has been largely restricted to a select group of healthcare professionals, primarily general practitioners, physicians and, in some countries, nurses [60]. The aim of the policy change is to provide patients with timely access to services and to take full advantage of professional skills [61]. One key component of this transformation is the expansion of the scope of practice for healthcare professionals, including pharmacists.

The evolving role of pharmacists in healthcare systems worldwide has sparked significant discussions on scope of practice and its implications for patient care [31, 62]. Broadly defined, scope of practice refers to a health professional's *'knowledge, skills and experience'* encompassing all tasks and activities they undertake within their professional role [62, 63]. An Australian definition of scope of pharmacists' practice describes it as *'a time sensitive, dynamic aspect of practice which indicates those professional activities that a pharmacist is educated, competent and authorised to perform and for which they are accountable'* [64]. A pharmacist working to their full scope of practice is guided by individual training, experience, expertise and competency, while considering their practice setting, workplace policies and the healthcare needs of patients [31]. Countries such as New Zealand, the United Kingdom, Canada and the United States have implemented policies which expand the role of community pharmacists [65, 66]. Pharmacists in these regions fulfil essential roles in managing minor ailments, supporting personalised medicine, conducting health screening, administering vaccinations, contributing to chronic disease management, and promoting preventative health care [67].

Pharmacist Prescribing: International and National Context

Policies and legislation defining pharmacist prescribing vary across countries [68-71]. Conceptually, the various models can be divided into two main types:

- Independent prescribing – allowing pharmacists to assess patients, diagnose conditions, and prescribe medications autonomously [72]. This model is common in countries where pharmacists undergo additional training and certification to ensure competency in diagnosis and clinical decision-making.
- Supplementary (or collaborative) prescribing – involving a collaborative approach where pharmacists work under mutually agreed protocols and alongside physicians or other healthcare providers. This model encompasses several forms, such as prescribing by protocol, formulary, repeat prescribing, or collaborative prescribing [68].

An important distinction between these models is the degree of independence a pharmacist has from another prescriber, including their level of clinical decision-making authority and responsibility for prescribing decisions. In some contexts, the scope of prescribing is defined by the conditions and the medications authorised.

Countries apply different approaches to expanded scope of practice models, including prescribing, education and training standards, as well as registration requirements [73-75]. Local factors – including the political environment, education, health systems, remuneration systems and population needs – influence decisions regarding the

authorisation and legislation of pharmacist prescribing, including the scope and types of prescribing permitted [2]. In Canada, for example, prescribing authority, models, education and training requirements, and continuing professional standards vary across provinces and territories [73, 76]. Within the United Kingdom, each country has its own legislation, resulting in two models of expanded scope of practice, including pharmacist prescribing: supplementary/collaborative prescribing (structured) and independent prescribing (autonomous) [75].

In England, the General Pharmaceutical Council (GPhC), the body responsible for the regulation of pharmacists, has directed that by the end of 2026, all students graduating from programs meeting the 2021 education and training of pharmacists' standards will be able to practise as independent prescribers within a specified scope of practice [77]. Pharmacists who were previously registered will need to complete a GPhC-accredited pharmacist independent prescribing course. This accredited course allows pharmacists within their scope of practice to provide medication for any condition (excluding controlled substances or unlicensed medicines) [77]. Registered pharmacists who are not independent prescribers can offer extended services through separate schemes, such as treatment of minor ailments under the Pharmacy First program, delivered via the Community Pharmacy Contractual Framework [78].

In Canada, legislative amendments have facilitated pharmacist prescribing, with variations in requirements and criteria across provinces. All ten provinces allow pharmacists to manage uncomplicated urinary tract infections (uUTIs) [79]. Provinces such as British Columbia, Manitoba, Newfoundland and Labrador, Ontario, and Saskatchewan have requirements to complete continuing education modules to provide the service [80]. The scope varies between jurisdictions, with some focusing on ethical, legal and professional obligations when prescribing [80]. Alberta, New Brunswick, Nova Scotia, Prince Edward Island, Quebec and Yukon territory do not require registered pharmacists to undertake additional training in prescribing for uUTIs [79, 81, 82].

In New Zealand, the Pharmacy Council has established the competence and registration requirements for pharmacist prescribers. Pharmacists who are qualified, trained and working within a collaborative healthcare team are eligible to prescribe medicines. To become a pharmacist prescriber, a postgraduate qualification is required. The Pharmaceutical Society of New Zealand offers the Urinary Tract Infections Management Accreditation Training module, which enables pharmacists to prescribe antibiotics for uUTIs [83]. In addition, registered pharmacists can provide other extended services, such as prescribing for specific conditions, after completing the mandatory training relevant to each service [84].

In Queensland, Australia, the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) was introduced to trial pharmacist prescribing of antibiotics for uUTIs. Between 19 June 2020 and 30 September 2022, the pilot allowed pharmacists to prescribe antibiotics to women aged 18–65 years presenting with symptoms of an uUTI. The UTIPP-Q required pharmacists to undertake additional education and training to participate in the pilot [15]. The pilot delivered 10,270 urinary tract infection (UTI) services across 817 pharmacies [85]. Regulatory changes in October 2022 authorised trained pharmacists to prescribe antibiotics for UTIs under an Extended Practice Authority [86, 87].

In April 2024, a second initiative, the Queensland UTIPP-Q, commenced and, in August 2024, a separate training pathway was established enabling pharmacists to prescribe hormonal contraception [88-90]. The pilot covers autonomous prescribing for acute conditions such as gastro-oesophageal reflux, acute nausea and vomiting, allergic and non-allergic rhinitis, impetigo, herpes zoster, acute exacerbations of mild plaque psoriasis, mild to moderate acne, acute minor wound management, acute otitis externa, mild acute musculoskeletal pain, smoking cessation, travel health, and management of overweight and obesity, among others [88-90]. On 1 July 2025, pharmacist prescribing for these acute conditions became permanent in Queensland [91]. The pilot also covers protocol prescribing for chronic condition programs: cardiovascular disease risk reduction program for type 2 diabetes, hypertension and dyslipidaemia, improved asthma symptoms and chronic obstructive pulmonary disease monitoring [88-90]. The required training for pharmacists to participate includes both prescribing and clinical practice components. Accredited providers of such training include, but are not limited to, Queensland University of Technology, James Cook University and the Pharmaceutical Society of Australia (PSA) [88, 89, 92]. These providers are assessed by the Australian Pharmacy Council (APC). James Cook

University offers a Graduate Certificate of Advanced Practice and Prescribing for Pharmacists which includes both prescribing and clinical practice training [89]. It is delivered predominantly online, with on-campus attendance for residentials and Objective Structured Clinical Examination (OSCE) assessments and a duration of 1 year [89]. Enrolment in these courses is open to pharmacists across Australia [88-90].

In New South Wales (NSW) and the Australian Capital Territory (ACT), the expanded role of community pharmacists is guided by the need to increase the community's access to primary care. In this context, the NSW Government has funded pharmacist expanded scope of practice trials for the management of uUTIs, resupply of hormonal contraception and four common dermatological conditions [6]. It expects to reach a better understanding of the safety and efficacy of pharmacist prescribing.

Several other Australian jurisdictions including Victoria, South Australia, Western Australia, Northern Territory and Tasmania [22, 93-97] have also implemented pharmacist-led expanded scope initiatives. In Victoria, a program was introduced allowing pharmacists to provide treatment for uUTIs, resupply of oral contraceptives and treatment for two dermatological conditions. South Australia has also implemented a pilot program permitting pharmacist prescribing for UTIs. Pharmacists in Western Australia are authorised to prescribe for conditions such as UTIs and the resupply of oral contraceptive pill. The Northern Territory has adopted a similar model to Queensland, where pharmacists are authorised to supply certain medications for acute conditions following established guidelines. Tasmania launched its pilot program to enable pharmacists to manage common ailments, including UTIs, with the potential for future expansion contingent on measures of program success and demonstrated patient outcomes [7, 8].

Evidence in support of expanded scope of practice for pharmacists is evolving and primarily focuses on establishing the safety, efficacy and acceptability of the service [7-10]. Internationally, studies on pharmacist prescribing have been conducted in clinical areas such as oral contraception [9, 10], hypertension [7] and UTI [3, 8, 11-15]. A systematic review examined pharmacist prescribing [16] and concluded that it enables more timely and convenient access with positive feedback from consumers.

Stewart's (2018) qualitative study, exploring pharmacists', physicians' and patients' attitudes to pharmacist prescribing for three different conditions, highlighted similar positive sentiments regarding convenience, especially for after-hours access when medical practices were closed or when patients could not obtain an appointment with a general practitioner [12]. In a Canadian study of 692 pharmacists, the most frequently reported benefits of prescribing were patient convenience, enhanced access to healthcare services, increased efficiency for the health system, improved patient outcomes, and enhanced patient understanding of the pharmacist's role [17-20]. While most studies report benefits in access and acceptability of pharmacy prescribing, many of the studies are small scale, have not addressed broader outcomes and do not provide in-depth analysis of safety and efficacy.

Australian National Implications and Future Directions

An Australian review of health professionals' scope of practice recommended the implementation of adapted reforms for professionals in rural, remote and under-serviced areas [2]. The review suggested that innovation and interdisciplinary care required a specific evidence base to support the development of new workforce models, with suggestions that trust between key stakeholders enables reform effectiveness [97].

Work is currently underway in reviewing the national approach to the expanded scope of practice for community pharmacy in Australia. The Pharmacy Board of Australia recognises it has an integral role in developing safe, consistent and nationally coordinated endorsement for advanced practice and scheduled medicines for pharmacists. As part of this work, the Australian Pharmacy Council has been directed to develop accreditation standards and clinical performance outcomes [21, 22].

Research Overview for NSW and ACT

Research contract

In 2023, NSW Health contracted the University of Newcastle to lead a consortium to undertake a 12-month trial for the management by pharmacists for uUTIs. A 2-month feasibility study was undertaken

from 30 May 2023 to 30 July 2023, followed by the main trial which began on 31 July 2023 and concluded on 31 May 2024. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12623000882628).

Aim, objectives and timing

The aim of this research was to co-design and evaluate the clinical and economic effectiveness of a service model (intervention) delivered by community pharmacists in NSW managing UTIs for a specific patient cohort (women aged between 18–65 years) presenting with urinary symptoms suggestive of an uUTI. The implementation process and sustainability of the service model was investigated using an implementation science approach.

In the tender requirements, the NSW Government highlighted the following specific objectives:

- to better understand, both qualitatively and quantitatively, the benefits of community pharmacists managing UTIs for a specific patient cohort (women aged between 18–65 years); and
- to identify any specific risks that could be mitigated in a broader rollout of community pharmacists managing UTIs for a specific patient cohort across NSW after the trial was conducted.

The tender further highlighted the following measures of success, including that community pharmacists' management of UTIs:

- provides timely access to patients presenting with symptoms and seeking care;
- provides confidence that patients are safe and those who do not meet the criteria for pharmacy-only management are appropriately referred to a general practitioner or hospital;
- promotes strengthened relationships between pharmacists and general practitioners, especially in regional/rural areas;
- is not shown to contribute to antimicrobial resistance (AMR); and
- does not adversely impact lower socio-economic patients in terms of out-of-pocket expenses [23].

In addition, the NSW Government added the following principles to be considered during co-design including:

- Pharmacists are confident when to prescribe and when not to prescribe, including referral to a general practitioner or hospital.
- Understanding the patient base holistically – capturing data on all patients (i.e., including those who do not meet criteria), to help understand the broader patient cohort presenting with UTI symptoms and whether those with potentially more serious conditions are appropriately referred.
- Holistic understanding of prescribing patterns and patient outcomes through data linkage – Medicare data/Pharmaceutical Benefits Scheme (PBS) dispensing data and NSW Health routine data including hospitalisations and emergency department presentations.
- Connection to primary care – promotes/encourages clinical team relationships to strengthen patient-centred care. This may include pharmacists uploading data to individual patient My Health Records as well as other pathways.
- Cost implications for patients – understanding how the cost associated with a pharmacy consultation and private prescription (non-PBS) impacts the patient demographic proceeding with a pharmacy prescription [23].

Research team and governance

A team of 18 chief investigators collaborated with 13 project partners to undertake and/or advise on the research (Appendix 1.1). The role of the chief investigators was to oversee the research elements of the project and provide advice to the lead chief investigators. The project partners were divided into groups to address three research phases – Co-Design, Implementation and Evaluation. A governance structure was designed to facilitate collaboration across key stakeholders and health professionals, and to ensure external quality oversight of the project. The governance structure for the trial is described in Appendix 1.2.

Study hypothesis

The study hypothesis was that an intervention (UTI service) delivered by community pharmacists for women aged 18–65 years presenting with symptoms suggestive of an uUTI is feasible and acceptable to participants and providers, will achieve high rates of

self-reported symptom resolution rates at 7-day follow-up and will not be associated with safety risks.

To test this hypothesis, the following studies were conducted:

- an independent co-design process with stakeholders, undertaken by Deloitte Consulting, with guidance of the University of Newcastle research team (Chapter 2);
- a feasibility study conducted by the University of Newcastle research team with advice from The George Institute for Global Health;
- a trial (PATH-UTI) in community pharmacy involving a consortium of Universities (University of Newcastle, University of Technology Sydney and University of New England);
- an independent formative and summative evaluation of the trial undertaken by The George Institute for Global Health for clinical, patient satisfaction and implementation outcomes (Chapter 3);
- an economic evaluation for the PATH-UTI main trial by the Hunter Medical Research Institute health economics group (Chapter 4);
- an implementation evaluation, undertaken by the University of Newcastle and the University of Technology Sydney (Chapter 5);
- a study of the potential effect on community AMR led by a team from Westmead Hospital and the Sydney Children's Hospitals Network, with statistical advice from the University of Technology Sydney and trial advice from the University of Newcastle investigators (Chapter 6);
- a qualitative study undertaken for Aboriginal and Torres Strait Islander people by the Co-Design Health Research and Innovation (CHRI) team at the University of New South Wales (UNSW) (Chapter 7); and
- a rural and remote qualitative study undertaken by the Rural Doctors Network and Charles Sturt University (Chapter 8).

The discussion and conclusions of the overall research are provided in Chapter 9.

Evidence Specific to UTIs

UTIs may be classified as uncomplicated (occurring in a structurally and functionally normal urinary tract) or complex (occurring in an abnormal urinary tract or in the presence of other complicating factors) [98]. The diagnosis of an uUTI is based primarily on history and symptoms of dysuria, urgency and frequency [15, 99-102]. A meta-analysis by Bent *et al*. [101] found that in women who present with one or more symptoms of UTI, the probability of infection is approximately 50%. Specific combinations of symptoms (i.e., dysuria, urinary frequency or urinary urgency) and the absence of vaginal discharge) raise the probability of UTI to more than 90% [101].

UTIs occur more frequently in women than men, with 1 in 2 women and 1 in 20 men developing a UTI at some point in their lifetime [103], with premenopausal women being 20–40 times more likely to have a UTI than men of the same age [104]. There are over 3 million cases of UTIs diagnosed each year in Australia and UTIs have been reported to account for 1.2% of all problems managed in Australian general practice in 2015–2016 [105]. Interestingly, previous literature reports spontaneous resolution of symptoms associated with uUTIs in approximately 27–42% of patients who consulted their general practitioner [46–55]. There were 76,854 hospitalisations for kidney infections and UTIs in 2017–2018 [106]. The hospitalisation rate for kidney infections and UTIs among Aboriginal and Torres Strait Islander people is double the rate for the general Australian population [105].

The availability of services provided by pharmacists, at an international level, to treat UTIs has become increasingly common [3, 8, 11-15], becoming usual practice in the United Kingdom [102, 107-112], Canada [113-116], France [117], Ireland [118], New Zealand [119], Switzerland [120], the United States [113-116, 121, 122] and some states of Australia [15]. The treatment of UTIs varies across countries and regions, with key differences in patient eligibility, diagnostic protocols and treatment requirements.

A recent systematic review focused on studies involving community pharmacist management of uUTIs in women aged 16–65 years [123]. The review included studies from several countries including New Zealand (n=1), the United Kingdom (n=5), Canada (n=3) and Switzerland (n=1) [123]. An important finding from the review is that the rate of patients reporting 'curing' rates in the studies was

high, ranging from 84%–89%. High rates of patient satisfaction were reported in relation to accessibility of the service. One Canadian study included in the systematic review stated that patients receiving UTI treatment from pharmacist prescribing services received treatment approximately 1 day faster than those who consulted a medical practitioner [8]. Furthermore, most patients reported greater ease in securing an appointment with a pharmacist involved in prescribing treatment for UTIs than a medical practitioner [8]. In a Swiss study of community pharmacy prescribing for multiple minor conditions (4,256 consultations, 39.5% related to cystitis), the overall 3-day symptom resolution rate for all conditions was 84.7% [124]. In another Canadian study, of 750 patients with UTI symptoms that were treated by community pharmacists, symptom relief at 14 days was 88.9% [125]. There were also high rates of participant satisfaction in those studies that captured this information, both in terms of accessibility to the service, timeliness of receiving the service, and the quality of the service provided. Another systematic review similarly found that pharmacist prescribing for UTIs was associated with high rates of clinical improvement (4 studies), low rates of retreatment and adverse events (3 studies), and decreased healthcare utilisation (7 studies) [126]. In other studies, the implementation of pharmacist prescribing services for UTIs has been shown to improve patient experience outcomes [42, 126-130]. Among these positive findings however, it is important to note that the quality of included studies is variable [131].

In Queensland, of the 817 pharmacies involved in the UTIPP-Q pilot between 19 June 2020 and 30 September 2022, 588 (72.0%) provided at least one service [85]. Seven days after the initial consultation, pharmacists were required to conduct a follow-up call with participants. Follow-up rates were low, with most (n=5,320, 71%) participants lost to follow-up. The median time to follow-up was 6 days (range 1 day – 588 days), with 87.6% reporting that their UTI symptoms had resolved at this time, 7% reporting that their symptoms had not resolved but they had already sought other care, and 3.8% reporting unresolved symptoms and were verbally referred to their general practitioner by the pharmacist during the follow-up call. Participants who were followed up (n=2,409) were emailed a clinical service evaluation survey. Only 2.8% (n=61) of participants completed the survey, with 93% (n=63) reporting to be very satisfied and a further 7% (n=5) stating they were satisfied. The main reasons cited for using the pharmacy service were convenience and not needing to make an appointment. From 1 October 2022, pharmacists who successfully completed the required training were authorised under the Queensland Government Extended Practice Authority for pharmacists to prescribe for UTIs [86, 87].

02

CO-DESIGN OF PATH-UTI

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 2: Co-design of PATH-UTI

Introduction

Co-design is the process that combines professional expertise and stakeholders in the developmental process of health services [132, 133]. All stakeholders are equal collaborators and are encouraged to share their ideas, knowledge and expertise leading to higher quality services. Benefits of health service co-design are sustained in the longer term and may include improved relationships between service providers and their patients, and increased levels of support and enthusiasm for innovation and change [132, 133]. It assists in helping to inform intervention design and adaptation for future implementation and sustainability [134, 135].

The co-design process with stakeholders was managed by Deloitte Consulting. A separate consultation process was undertaken for Aboriginal and Torres Strait Islander people (see Chapter 7).

Objectives

The co-design phase focused on designing the feasibility study, developing best practice guidelines, and establishing a governance structure to ensure that stakeholders and health professionals were able to collaborate effectively. The process involved gathering feedback through interviews and workshops throughout March and April 2023, with the following objectives:

- to develop the clinical management protocol(s) that will underpin the service model(s);
- to define the governance and operational structure that will support the trial;
- to document the foundational design of the trial components that will underpin the formative evaluation; and
- to investigate stakeholder perspectives for the co-design and collaborative agreement on service elements and operational characteristics of a service model(s) (intervention) delivered by community pharmacists.

The goal was to create a robust, well-defined framework for the clinical trial that incorporated input from diverse stakeholders, ensuring that the trial reflects the realities of practice and the needs of the patient population.

Methods

The research was conducted in multiple phases, using tailored methodologies for each objective, including an international literature review, qualitative stakeholder interviews and co-design workshops. The workshops facilitated collaboration among stakeholders to refine key elements of the trial, while interviews provided individual perspectives on the trial design and potential challenges of implementing the service model. The co-design activities were sequenced to ensure that insights from the interviews informed the workshops. Feedback gathered from both interviews and workshops was integrated to develop a collaborative, evidence-based trial design and service delivery model that aligned with the needs of healthcare professionals and patients.

Literature review: clinical management protocol

The first objective was to develop clinical management protocols to support the service model. To achieve this, a comprehensive review of international and Australian literature was conducted to identify key components and best practices for managing acute uncomplicated urinary tract infections (uUTIs) in women aged 18–65 years. The findings provided the foundation for protocol development and informed discussions during the co-design workshops. The systematic review was of peer-reviewed and grey literature, along with customised website searches using targeted terms related to pharmacies and urinary tract infections (UTIs), browsing relevant health organisations' websites, and consulting professional organisations in the United Kingdom, New Zealand and Canada for additional protocols. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) process was followed, with documents reviewed for inclusion based on criteria such as being in English, relevant to community pharmacists,

and focused on managing acute uUTIs in women aged 16–65 years.

The clinical management protocols were analysed, extracting the key components. The components examined included decision-making algorithms, clinical pathways for diagnosis and treatment, escalation protocols, referral criteria, and patient communication strategies. These components were discussed during the co-design workshops to ensure that the protocols were evidence-based and aligned with the goals of the trial. Each of the clinical management protocols were assessed for quality using the AGREE (Appraisal Guidelines for Research and Evaluation) version II instrument. This tool is widely recognised for evaluating the methodological rigour and clarity of clinical guidelines and protocols. One reviewer conducted the quality appraisal for each protocol, ensuring a consistent and thorough evaluation of the protocols' strengths, limitations, and applicability in the community pharmacy setting.

Qualitative interviews and co-design workshops

The second and third objectives were to define the governance and operational structure for the trial and to document the foundational design of the trial components that would underpin the formative evaluation.

To achieve these objectives, stakeholder roles and responsibilities were initially mapped using a Responsibility Assignment Matrix (RACI model) to establish a framework of the individuals and organisations to be consulted. Additionally, five 60-minute semi-structured interviews were conducted with key stakeholders to develop an initial understanding of the clinical trial's study design. Participants included representatives from consumer organisations, a general practitioner, a practising pharmacist, a representative from a peak pharmacy organisation, and a rural healthcare representative.

A co-design workshop (Workshop 1) was held with 15 stakeholders, five research team members, and two facilitators. Participants included community pharmacists and pharmacy owners, general practitioners, representatives from peak pharmacy and medical bodies, academic partners, and individuals involved in trial evaluation. The workshop was designed to be interactive and participatory, creating an environment where stakeholders could contribute their expertise and provide input into the trial's governance framework and clinical management protocols. During the 2-hour face-to-face session, participants discussed and agreed on the governance structure, including the establishment of a governance model. The workshop also covered key components of the study protocol, data sources and metrics. Feedback gathered during the co-design workshop was collated and used to inform the study design. Following the workshop, all feedback was incorporated into a proposed governance model, which was further refined based on stakeholder input before finalisation. The insights gained from these processes provided a collaborative foundation for the trial's governance and operational framework.

The fourth objective was to investigate stakeholder perspectives for the co-design and collaborative agreement on service elements, specifically the clinical protocols and operational characteristics of the service model delivered by community pharmacists. A second, 4-hour face-to-face workshop (Workshop 2) was held to discuss and agree on the elements of the clinical management protocol. Prior to the workshop, a pre-read briefing paper was provided, which included a draft clinical management protocol developed through the international literature review mentioned above. The draft outlined key elements such as the treatment decision algorithm, escalation of care procedures, and referral points that pharmacists would follow during the trial. The workshop included a targeted group of seven frontline pharmacists and general practitioners, supported by four research team members and two facilitators. This session offered a structured environment to refine the protocol, ensuring it was evidence-based, practical, and aligned with real-world practice.

A third, 4-hour follow-up workshop (Workshop 3) involved a broader group of stakeholders, including consumer representatives, community pharmacists, general practitioners, representatives from peak pharmacy and medical bodies, academic partners, and research team members. The workshop, which included 16 participants, in addition to three research team members and two facilitators, focused on mapping the end-to-end consumer journey and linking key activities with the necessary data capture and information-sharing components to deliver the service. Discussions focused on finalising the clinical management protocol, agreeing on escalation processes, and referral points. The workshop also addressed the development of the service model, ensuring it aligned with the required authority for the

service. Participants identified the technological enablers necessary for the efficient execution of the process and determined the possible data points to be captured for evaluation purposes as part of the study.

The data collected from the qualitative stakeholder interviews and co-design workshops were analysed thematically to identify common themes, challenges and opportunities that emerged across different stakeholders and groups. Triangulating data from interviews and workshops aimed to ensure that the findings accurately reflected diverse stakeholder viewpoints.

Results

Literature review: clinical management protocol

The findings of the literature review, which informed the development of the clinical management protocol for the trial (first objective), have been published [136].

Qualitative interviews and co-design workshops

Several key insights emerged from both qualitative stakeholder interviews and the co-design workshops, informing the development of the governance framework, clinical management protocols, and overall trial design. The qualitative interviews, conducted with key stakeholders, revealed five main themes.

The first theme focused on prioritising patient-centric outcomes, accessibility, and the importance of delivering care that is effective and equitable. Stakeholders highlighted the need to engage consumers in a culturally respectful and safe manner. Accessibility for vulnerable populations, particularly those facing health disadvantages, was also identified as a key factor for the success of the trial.

The second theme, ensuring quality and safety in the care model, emphasised the necessity of clear care standards. Stakeholders agreed that clinical management protocols should include specific referral points and escalation processes, as well as clear distinctions between simple and complex UTI diagnoses. They further highlighted the need for training to mitigate risks associated with UTI diagnosis and treatment. Monitoring objective and measurable clinical outcomes, such as consultation numbers, prescription rates and referrals, was also seen as essential for ensuring safety and effectiveness.

The third theme, strengthening integrated care delivery, called for the development of efficient referral pathways and communication channels among healthcare professionals. The importance of a central platform for real-time information exchange between pharmacists and general practitioners was identified as critical for continuity of care. Clear communication channels and escalation processes were also identified as critical for safe and effective treatment delivery.

The fourth theme, considering professional autonomy, emphasised the need to maintain clear distinction between the roles of prescribing and dispensing. Particularly in rural and regional areas, stakeholders identified the importance of independent clinical verification processes, especially in settings with limited resources. Ensuring clarity in roles and responsibilities was seen as key to maintaining professional autonomy and the integrity of the trial.

The fifth theme focused on the challenges faced by pharmacists in completing required training for trial participation. To encourage broader participation, it was suggested that training sessions could count toward Continuing Professional Development (CPD) requirements. Additionally, stakeholders discussed how workflows might differ between small and large pharmacies, with potential implications for both pharmacists and pharmacy staff.

Workshop 1 included 15 stakeholders focused on developing a high-level governance model that included committees, advisory groups and communication channels. A structured governance framework was established during this phase (refer to Chapter 1 and Appendix 1.2), providing a collaborative foundation for the trial to ensure transparency, accountability, and stakeholder engagement throughout the trial.

Workshop 2 focused more specifically on the clinical aspects of the intervention. A core component of this workshop was the development and agreement of the clinical treatment protocol (see Appendix 2.1), and the service model (see Appendix 2.2). This included defining the key parameters that would allow pharmacists to prescribe treatments for UTIs within the trial framework. The group discussed the

treatment decision algorithm, which outlined the steps pharmacists would follow to diagnose and treat UTIs, as well as the process for escalating care or referring patients to other healthcare providers when necessary. Their feedback helped refine the treatment algorithm and clarify the roles and responsibilities of pharmacists within the trial. The clinical management protocol was refined to ensure the evidence-based management of uUTIs by community pharmacists (Appendix 2.1). This included a treatment decision algorithm identifying referral criteria (and whom to refer to), conservative management options, and options to address the current limitations where pharmacists are unable to order mid-stream urine testing.

Workshop 3 highlighted several critical factors in developing an effective and sustainable service delivery model and mapping the patient journey (see Appendix 2.3). Key guiding principles emerged, emphasising the importance of integrating care to avoid fragmentation, with a focus on extending services in accessible locations to reduce hospital admissions. Financial sustainability was another key consideration, balancing the costs of consultations with potential system-level savings through reduced emergency department visits. Furthermore, flexibility in models for Aboriginal and Torres Strait Islander communities, as well as the need for a sustainable workforce in rural and regional areas, emerged as pivotal elements in ensuring equity and long-term success.

An important consideration was the communication between general practitioners and pharmacists. Strengthened collaboration between general practitioners, emergency department clinicians and pharmacists was identified as essential, with clear referral pathways and escalation processes to facilitate timely and effective patient management. The journey of an uUTI patient was mapped to provide a foundational starting point for patient activities that would occur as part of the proposed service delivery model for the trial. Additional considerations were given to escalation points, required data for evaluation, and necessary technological enablers.

Discussion

The co-design process highlighted the complexities and opportunities associated with implementing a pharmacist UTI management service. The engagement of diverse stakeholders ensured that the trial design incorporated a breadth of perspectives, addressed patient priorities, professional concerns and system-level considerations. A key outcome of the co-design process was the establishment of guiding principles that ensured the service model aligned with best practices while remaining adaptable to real-world clinical settings (see Appendix 2.2). The emphasis on accessibility and equity underscored the importance of making UTI treatment more readily available, particularly in under-served and rural communities.

The workshops underscored the need for clear referral pathways and timely communication to ensure coordinated care. A structured process to ensure continuity of care, coupled with a defined governance framework, was identified as critical in facilitating decision-making and addressing clinical uncertainties. The need for professional autonomy was also emphasised, ensuring that pharmacists operate within well-defined clinical boundaries. Stakeholders refined the clinical management protocol, integrating clear referral points, conservative management strategies and therapeutic management options. Ensuring the protocol's feasibility and acceptability among frontline practitioners was a priority, and their feedback played a role in shaping the final clinical management protocol.

Digital health tools were identified as enablers of service delivery, facilitating patient tracking, data collection, and communication between healthcare providers. The integration of electronic referral systems and shared patient records was seen as essential to maintaining continuity of care. Furthermore, the importance of collecting both qualitative and quantitative data to evaluate the intervention's impact was highlighted.

A significant discussion point was the need to ensure the long-term sustainability of the pharmacist service. Workforce training and professional development emerged as crucial components, with stakeholders advocating for standardised education pathways and CPD recognition for participating pharmacists. Additionally, financial considerations, including consultation fees and reimbursement models, were explored to balance patient affordability with the economic sustainability of the service.

Conclusions

The co-design process produced the clinical management protocol (Appendix 2.1) and the governance structure for the trial (refer to Chapter 1 and Appendix 1.2). Additionally, the collaborative efforts led to an agreement on key service elements and valuable feedback incorporated into the research protocol, as detailed in the Australian New Zealand Clinical Trials Registry (ANZCTR) registration[1]. These outcomes highlight a collaborative approach and establish a strong foundation for future implementation and evaluation.

[1] *ANZCTR Trial Registration details are available at: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=385721*

03

CLINICAL EVALUATION OF PATH-UTI

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 3: Clinical Evaluation of PATH-UTI

Introduction

This chapter of the report provides a detailed description of the methods and results of the clinical evaluation of PATH-UTI, drawing upon data from the PATH-UTI trial, data linkage, and the available literature. Data collected from the trial were combined with external data sources through a comprehensive data linkage process to provide a robust analysis. The analysis was conducted by The George Institute for Global Health with feedback from the University of Newcastle team.

Objectives

The overall aim was to evaluate the clinical impact and implementation of a service model delivered by community pharmacists in New South Wales (NSW) and the Australian Capital Territory (ACT) over a 10-month period for women aged between 18–65 years presenting with symptoms consistent with an uncomplicated urinary tract infection (uUTI).

Specific objectives were to:

- assess implementation uptake of the intervention, including the reach, fidelity and adoption of the intervention in community pharmacies, participant characteristics, and variation in uptake by geographic region;
- assess the clinical and experience outcomes for patients managed and/or treated by community pharmacists;
- assess the safety of the intervention and identify any risks that need to be addressed for future implementation;
- evaluate acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service; and
- identify contextual enablers and constraints to access, adoption, fidelity delivery, impact, sustainability and generalisability of the intervention.

It was hypothesised that the urinary tract infection (UTI) service delivered by community pharmacists for women aged 18–65 years presenting with symptoms suggestive of an uUTI would be feasible and acceptable to participants and providers, achieve high rates of self-reported symptom resolution at 7-day follow-up and not be associated with safety risks.

Methods

Study design

A cohort study design, applying mixed methods (quantitative and qualitative research) to assess clinical, implementation and participant experience outcomes was adopted. It built on preparatory work to co-design the intervention and to assess implementation feasibility.

Pharmacy recruitment

All pharmacies in NSW were eligible to be in the trial and asked to submit an expression of interest if they were able to meet the minimum standards and the criteria related to an Authority set by NSW Health. This was verified by Practice Change Facilitators (PCFs) employed at the University of Newcastle, the University of New England and University of Technology Sydney. From pharmacies expressing interest in the ACT, five (and later, an additional 10) pharmacies were randomly selected across different geographical regions to participate.

Participant recruitment

The service was promoted in pharmacies by flyers displayed in prominent locations, through media releases promoting the start of the initiative, and through outreach by pharmacy staff to those women who presented to the pharmacy requesting products or advice for symptoms suggestive of a UTI. Pharmacy staff informed potentially eligible women in the pharmacy about the study and provided them with a QR code that directed them to a secure electronic consent form platform, George Data Systems (GDS) hosted by The George Institute for Global Health. The inclusion criteria were females aged 18–65 years presenting to consented, eligible pharmacies with symptoms associated with an uUTI.

Intervention description

The intervention had two components:

- Pharmacist enrolment, including preparatory training prior to service delivery for pharmacists to ensure efficiency in the consultation process, participant consent, recruitment of patients, timely referral, and quality data collection. In addition, there was follow-up training and ongoing support as part of a translational/implementation strategy. This was managed by the University of Newcastle. The clinical training for pharmacists who were members of the Pharmaceutical Society of Australia (PSA) or the Australasian College of Pharmacy (ACP) was a member benefit. There was no charge for the University of Newcastle training.
- Structured consultation with the participant in a community pharmacy undertaken by the pharmacist anticipated to take approximately 10 minutes, and applying a co-designed clinical management protocol.

The criteria associated with the two above components were defined by the NSW Health Authority (Appendix 3.1).

Pharmacy consultation

The consultation was guided by the MedAdvisor® IT program applying a clinical management protocol which considers the recommendations from the Australian Therapeutic Guidelines. The clinical management protocol was co-designed by community pharmacists and senior general practitioners. The intervention was provided under the NSW Health Authority (Appendix 3.1) allowing participating NSW pharmacists to supply medications as part of the trial. For the ACT, a discretionary licence https://www.act.gov.au/business/health-licenses-and-inspections/medicines-and-poisons-licences/apply-for-a-medicines-poisons-therapeutic-goods-licence-permit was approved for participating pharmacies (link no longer available). The structured consultation is summarised in Appendix 3.2. The medications prescribed by the pharmacist were via a private prescription and not provided under the Pharmaceutical Benefits Scheme (PBS).

Data sources

Community Pharmacy Data

During implementation of the intervention, information on the consultation was recorded in a purpose-designed case registration form completed by the pharmacist using a purpose-built MedAdvisor® IT program.

Participant Self-reported Data

A survey was sent to eligible participants via SMS and/or email at day 7 after the pharmacy consult. Three reminders were sent every 2 days thereafter if the survey had not been completed. The survey included the following:

- information on urinary symptom status and resolution;
- antibiotics prescribed and administered;
- number of days taking antibiotics;
- adverse events or complications, including from medications;
- details of any other medications used (either for UTI or any other condition);
- attendance at another healthcare provider in the last 7 days;
- admission to hospital for any reason in the last 7 days;
- treatment costs;
- participant experience ratings; and
- additional demographic information not asked at the consultation registration visit.

NSW Health Data

NSW Health administrative data were collected on hospital sector utilisation for participants enrolled in the trial. The NSW Centre for Health Record Linkage (CHeReL) performed linkage of the following trial datasets with NSW and ACT administrative records:

- NSW hospital separation data – NSW Admitted Patient Data Collection (NSW APDC);
- NSW emergency department data – NSW Emergency Department Data Collection (NSW EDDC);

- NSW Registry of Births, Deaths and Marriages (RBDM) death registrations – NSW RBDM-Deaths;
- NSW Non-Admitted Patient Data Collection – NSW NAP;
- ACT Admitted Patient Data Collection – ACT APDC;
- ACT Emergency Department Data Collection – ACT EDDC; and
- ACT Births, Deaths and Marriages (BDM) death registrations – ACT BDM-Deaths.

For APDC and EDDC data (for both NSW and the ACT), data were obtained from July 2022 (12 months prior to the start of the study) to 30 June 2024. For NSW RBDM-Deaths, ACT BDM-Deaths and NSW NAP data, data were obtained from July 2023 (start of the study) to 30 June 2024.

Medicare Benefits Schedule (MBS)/PBS

Participants were asked at the initial consult if they would provide consent to access their MBS and/or PBS data for a 2-year period (from 12 months prior to registration to 12 months post registration) using the Services Australia approved participant and information consent form.

Qualitative Data

PCFs: The collection of implementation data was undertaken through face-to-face visits and other contact channels (10–20 minutes) by PCFs. These data are held by the University of Newcastle and are reported separately in Chapter 5.

Semi-structured interviews: A purposive sampling technique was used to select a diverse range of pharmacies and patients for interviews, considering pharmacy-level factors (such as geography, engagement, and provision of trial services) and participant-level factors (such as age, geography, and utilisation and outcomes of pharmacy services). Other stakeholders involved in the design and implementation of the trial, including PCFs, NSW Government administrators and pharmacy. Medical and consumer peak bodies on the Steering Committee were also invited for interview.

At the time of initial consent into the trial, service users were asked if they were willing to be contacted further about their experiences with the service via an interview, and patients were selected for interview from those who agreed. At 9 months of implementation, the researchers obtained a list of community pharmacies enrolled in the trial along with the volume of UTI consults conducted at each pharmacy. Pharmacies were categorised as ‘high’ and ‘low’ recruiters based on the numbers of consults provided. Pharmacies in each of the Modified Monash Model (MMM) categories (urban city to small rural town), which were both high recruiting and had 50% interest from patient follow-up, were approached by PCFs and invited to nominate a pharmacist to participate in an interview to be conducted by The George Institute for Global Health. A total of 10 pharmacists from high recruiting pharmacies were invited to participate in interviews through this process. For the lowest recruiting pharmacies, participant lists where there had been at least five trial participants were inspected. However, due to small numbers of participants in these low recruiting pharmacies, only three pharmacies had at least two participants willing to be contacted for an interview. Of these three pharmacies, only one (from a small rural town) was willing and able to participate in an interview.

For community pharmacists, interview questions focused on implementation and contextual factors which may influence program outcomes [137-140], including sustainability considerations, staff experience and motivation to engage in the pharmacist-led UTI management model. When pharmacists indicated they were engaged in additional extended practice interventions, such as the resupply of the oral contraceptive pill, they were prompted to reflect on similarities and differences of their experiences of delivering these. Interviews ranged from 30 to 70 minutes (average 47 minutes). Upon completion of a pharmacist interview, patients attending the same pharmacy were invited to participate in an interview. To minimise recall bias, patients with the most recent encounter date were invited (no more than 6 weeks since the encounter). A total of 10 participant interviews were conducted across all pharmacies. Participant interview questions focused on experiences of health care, awareness and perceptions of services, including perceived barriers and facilitators for use, and effectiveness of the new service. Interviews ranged from 12 to 30 minutes (average 24 minutes). All interviews were conducted via phone call or videoconferencing, audio recorded, de-identified and professionally transcribed.

Participant feedback emails: A dedicated email address for the trial evaluation was provided to patients on the consent documentation to facilitate another avenue for consumer feedback and support. Emails were de-identified and incorporated into the thematic analysis.

Outcomes

Primary Outcome

Self-reported 7-day symptom-free rate, defined as the complete absence of UTI symptoms.

Secondary Outcomes

- **Implementation outcomes**
  - Proportion of pharmacies and pharmacists that provided consults.
  - Proportion of patients that received the service.
  - Proportion of patients referred to another health professional.
  - Proportion of patients supplied antibiotics by pharmacists.
  - Antibiotic adherence and completion of course
  - Proportion of first-line antibiotics supplied as a percentage of total antibiotic supply.
  - Rates of switching to alternative antibiotics by general practitioner (see medication utilisation section below).
  - 7-day follow-up rate.
- **Participant experience**
  - Self-reported responses at day 7
- **Primary care utilisation** (see Appendix 3.3 Table 3-3-1 for MBS items)
  - Rates of general practitioner visits per 100 people at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation.
  - Rates of general practitioner visits per 100 people up to 12 months pre and post pharmacy consultation.
  - Rates of specialist consults per 100 people at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation.
  - Rates of urine samples per 100 people sent for pathology testing at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation.
- **Medication utilisation** (see Appendix 3.3 Table 3-3-2 for Anatomical Therapeutic Chemical (ATC) codes)
  - Proportion prescribed an antibiotic at the initial pharmacy consultation.
  - Proportion of self-reported additional antibiotics prescribed/used within the 7-day follow-up period.
  - Rates of prescribed antibiotics per 100 people at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation, including switching rates to an alternative antibiotic.
  - Rates of prescribed antibiotics per 100 people 12 months pre and post pharmacy consultation (determined from PBS data), excluding those from the day of registration.
- **Hospital admissions** (see Appendix 3.3 Table 3-3-3 for International Classification of Diseases, 10th Revision (ICD-10) codes)
  - Rates of hospitalisation per 100 people (all-cause, acute, potentially preventable, genitourinary-related) at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation.
  - Rates of hospitalisation per 100 people 12 months pre and post pharmacy consultation.
  - Length of stay for acute hospital admissions per 100 persons.
  - Bed days for acute hospital admissions per 100 persons.
- **Emergency department utilisation** (see Appendix 3.3 Table 3-3-3 for ICD-10 and Systematized Nomenclature of Medicine (SNOMED) codes)
  - Rates of emergency department presentation per 100 people (all presentations, triage 3–5, genitourinary-related) at 0–2 days, 3–6 days and 7–28 days after the initial pharmacy consultation.
  - Rates of emergency department presentation per 100 people (all presentations, triage 3–5,

genitourinary-related) 12 months pre and post pharmacy consultation

Additionally, analyses were conducted to understand patient characteristics and treatments for proportion of patients lost to follow-up and rates associated with non-prescription of antibiotic, including eligibility and/or symptom/patient characteristics.

Adverse events and serious adverse events

Adverse events were defined as:

- self-reported adverse events at day 7 follow-up; and
- self-reported complications at day 7 follow-up.

Serious adverse events were defined as:

- self-reported attendance at an emergency department or urgent care clinic at day 7 follow-up;
- self-reported admission to a hospital at day 7 follow-up;
- attendance with a specialist within 7 days of initial consultation based on NSW non-admitted patient (NAP) and/or MBS data; and
- an adverse event that generated a hospital admission or emergency department presentation within 7 days of the initial pharmacy consultation based on the NSW Admitted Patient Data Collection (APDC) and Emergency Department Data Collection (EDDC) and the ACT APDC and EDDC.

Quantitative data analysis

Figure 3.1 outlines the data flows for each of the datasets generated from the study.

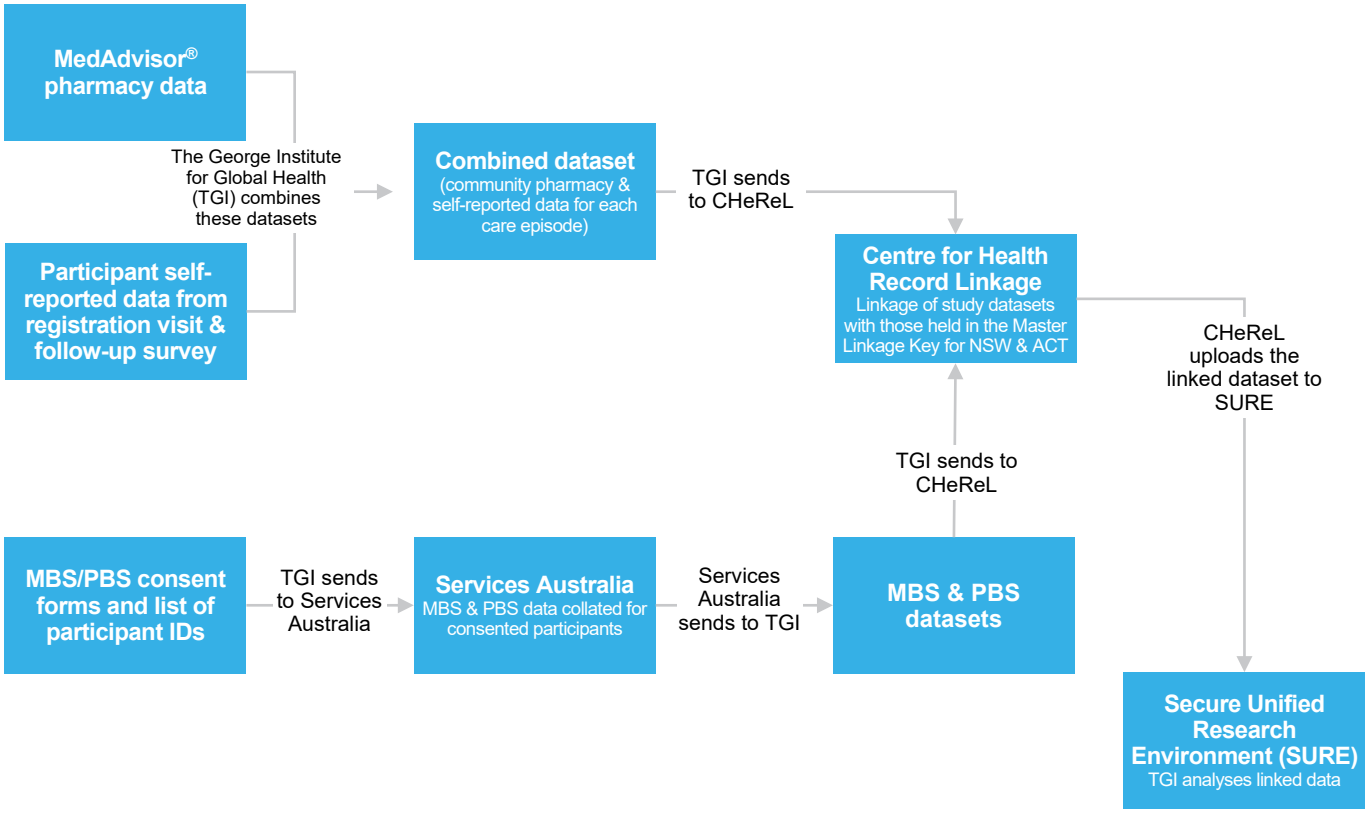


Figure 3.1: Study data flow

For linked data analyses, the Centre for Health Record Linkage (CHeReL) employs probabilistic record linkage methods to link multiple data sources [141]. They ensure privacy by separating identifying details from health-related content and using encoded personal information to create linkage keys. This process involves matching records from different datasets based on common identifiers, such as names and dates of birth, while maintaining confidentiality. The CheReL's probabilistic linkage procedures are designed to achieve a false positive rate of around 5/1,000. The de-identified linked dataset was then uploaded to the Secure Unified Research Environment (SURE) facility, hosted by the Sax Institute, for analysis.

A statistical analysis plan was developed by the research team and finalised prior to conducting the analyses of baseline data (participant demographics, clinical symptoms and antibiotics supplied), and self-reported 7-day follow-up survey data were summarised using frequencies and percentages. No imputation was performed for missing data. Baseline data were reported at the individual level using responses provided at the participant's first use of the service. The outcomes and experiences based on the 7-day survey were reported for each care episode.

MBS data were used to assess the proportion of participants who accessed a subset of services in the first month after participating in the study as well as over the 12 months pre-enrolment and 6 months post-enrolment[2]. Services of interest included general practitioner visit of any length, urine sampling or a specialist visit of any type excluding psychiatry. PBS data were used to assess the proportion of participants who were dispensed an antibiotic post-enrolment (at 0–2 days, 3–6 days and 7–28 days). All antibiotics were considered (ATC code J01) as well as the three specific antibiotics authorised for pharmacy prescription in this study – trimethoprim (J01EA01), cephalexin (J01DB01) and nitrofurantoin (J01XE01) (ATC codes in Appendix 3.3 Table 3-3-2). The NSW APDC and EDDC were used to analyse use of the NSW health services. Weekly rates of hospital service utilisation were calculated for the 12 months before and 6 months after the care episode.

A limited number of subgroup analyses were pre-specified and included age, socioeconomic status (based on Socio-Economic Indexes for Areas (SEIFA) and participant postcode), geographic region (based on MMM categories), hospitalisation in the 12 months prior to enrolment, state of pharmacy (NSW vs ACT), type of antibiotic received from pharmacy, and repeat vs single service users. Using the linked dataset in SURE, a multivariable regression model was developed to assess associations between these subgroup variables and the primary outcome, and also two secondary outcomes – visiting a general practitioner and receiving a PBS prescription for a new antibiotic. However, as postcode information is not permitted to be included in the linked dataset, SEIFA subgroup analyses were conducted on the combined dataset held at the George Institute.

All statistical tests were two-sided with a nominal level set at 5%. Analyses were conducted using SAS software (version 9.3 or above) and R software (version 4.3.1). The primary analyses used all available data with no imputation.

Qualitative data analyses

Qualitative data analyses were conducted by researchers who were independent of the main trial. The process began with familiarisation of transcripts, and an initial coding framework was developed using a combined inductive and deductive approach. This framework was iteratively refined over multiple coding rounds as patterns, inconsistencies and new insights emerged. Based on the analysis, and repeated questioning of the data, explanations about service providers' and women's experiences of the UTI trial, and how, why and for whom the trial achieved its effects in different local contexts, were formulated. Findings were contextualised using Normalisation Process Theory (NPT) and Weiner's theory of organisational readiness for change [142, 143]. NPT focuses on processes by which practices become routinely embedded. Weiner's theory identifies pre-conditions to organisational readiness for change as being change valence (valuing the change) and information appraisal (organisational members' assessment of task demands, resource availability and situational factors).

[2] NB: Although the statistical analysis plan stated rates of MBS consults, PBS prescriptions and hospital/emergency department use would be reported with 12-month follow-up data, we have reported 6-month follow-up data as the number of participants with data for >6 months is small (see Appendix 3.2 Table 3-2-4 for further details).

Ethical considerations

Approval was obtained from the University of Newcastle Human Research Ethics Committee (HREC) (H-2023-0035), the NSW Population and Health Services Research Ethics Committee (2024/ETH01457/2023.37) and the Services Australia Executive Committee (RMS3171). The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12623000882628).

Results

Participants

Pharmacy recruitment

Following a 2-month pilot, the main trial commenced on 31 July 2023, running for 10 months with recruitment closing on 31 May 2024. Of the 1,528 pharmacies who expressed initial interest, 1,320 (86.3%) pharmacies consented to trial participation (1,305 from NSW and 15 from the ACT). Of those consenting 1,028 (77.9%) recruited at least one participant with 69.2% located in metropolitan areas, 16.3% in major regional or large rural towns, 14.5% in small to medium rural towns, and one in a remote community (Figure 3.2). All 15 pharmacies in the ACT were in metropolitan areas.

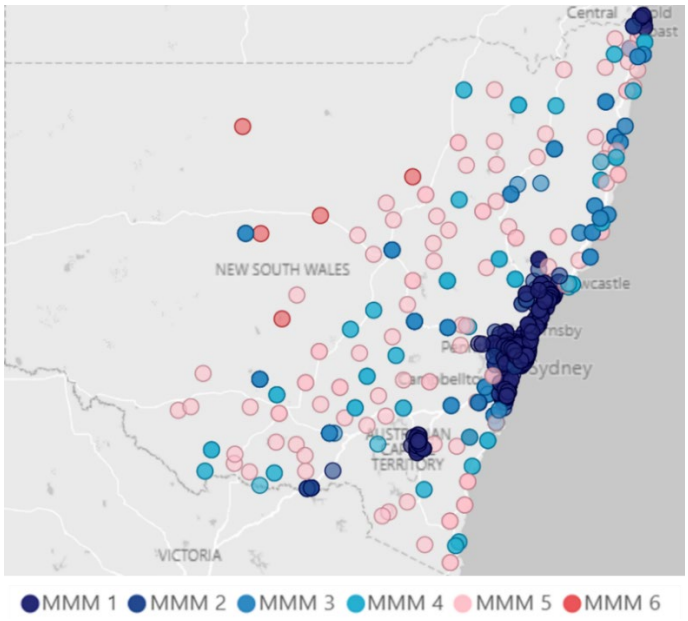


Figure 3.2: Geographic distribution of participating pharmacies

(MMM1=metropolitan, MMM2=regional centre, MMM3=large town, MMM4=medium town, MMM5=small town, MMM6=remote)

Participant Recruitment

A total of 20,308 self-consented forms were completed. Of these, 2,098 people (10.3%) did not proceed to receive the service for unknown reasons and are not included in this report. Of the 18,210 people who proceeded to meet with a study-registered pharmacist, a total of 17,380 (95.4%) were assessed as eligible for inclusion in the study. Of these, 830 (4.8%) used the service on more than one occasion. Sixty-seven eligible participants (0.4%) asked to be withdrawn from the study. Of the remaining 17,313 eligible participants, 18,143 care episodes were provided at a pharmacy. For these 18,143 care episodes, participants completed 14,671 (80.9%) surveys at 7-day follow-up and 3,472 (19.1%) surveys were not completed (Figure 3.3). In total, 16,453 (95.0%) and 15,453 (89.3%) participants provided consent for PBS and MBS data access, respectively (Figure 3.3). The CHeReL was used to link the 18,143 episodes of care to NSW Health datasets. After linkage, 17,219 unique participants contributed to 18,049 linkable care episodes. Recruitment rates were relatively consistent across the 10-month study period (Figure 3.4).

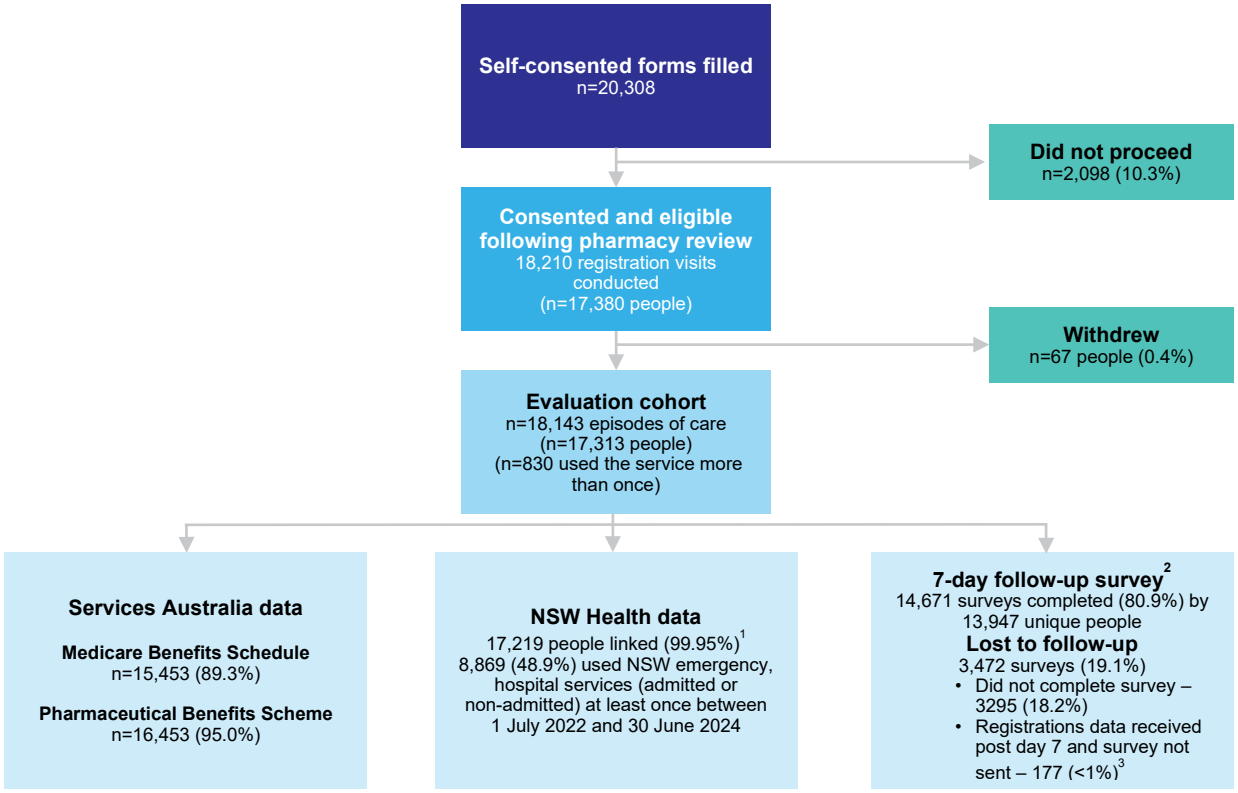


Figure 3.3: Participant flow in the study

Notes:

1. *CHeReL linkage false negative rate = 0.05%*
2. *Survey was distributed for each episode of care*
3. *These participants were not sent a survey form because the pharmacy data were sent to the research institute after day 7 of follow-up*

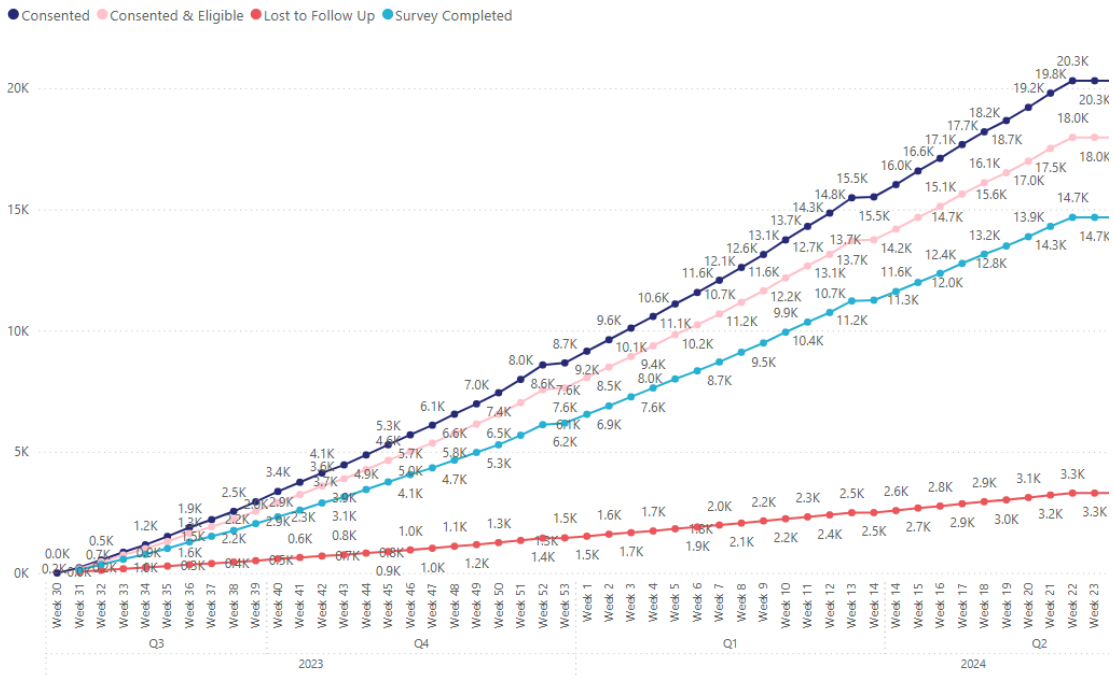


Figure 3.4: Cumulative recruitment and follow-up trends (Sep 2023 – May 2024)

Participant characteristics

Participant characteristics are provided for the 17,219 unique users identified in the linked dataset. The majority lived within MMM area 1 (Metropolitan; 72%). The most common participant age group was 46–65 years (39%). People with one or more red flags (6.3%) (see Appendix 2.1) were referred directly to a general practitioner. The most common presenting symptoms were urinary frequency (90%), urinary urgency (72%) and dysuria (72%) (Table 3-1). In the ACT, 787 people consented and were eligible to participate in the study. Appendix 3.3 Table 3-3-5 provides data on the participants by jurisdiction. There was a greater proportion of participants residing in the most advantaged areas, and higher proportions of participants with higher education and in full-time employment in the ACT compared to NSW.

Data on relative socio-economic data are not included in the linked dataset as postcode information is considered identifiable data. Based on participant-provided information at each care episode, we calculated the Index of Relative Socio-Economic Advantage and Disadvantage. The proportion of people in each quintile was as follows: 1st quintile, most disadvantaged, 8.8%; 2nd quintile, 16.1%; 3rd quintile, 21.2%; 4th quintile, 14.4%; and 5th quintile, most advantaged 38.4%; with a further 1.1% with missing postcode information.

Table 3-1: Participant characteristics (n=17,219)[1]

Characteristic	n=17,219
Age (years)	
18–25	3,275 (19.0%)
26–35	3,821 (22.2%)
36–45	3,473 (20.2%)
46–65	6,641 (38.6%)
>65[2]	9 (0.1%)
Remoteness category (Modified Monash Model)	
Metropolitan (MMM1)	12,327 (71.6%)
Regional centres (MMM2)	364 (2.1%)
Large rural town (MMM3)	2,471 (14.4%)
Medium rural town (MMM4)	1,320 (7.7%)
Small rural town (MMM5)	734 (4.3%)
Remote communities (MMM6)	3 (<0.1%)
Very remote communities (MMM7)	0 (0%)
Employment[3]	
Working full-time	7,555 (54.2%)
Working part-time	3,692 (26.5%)
Not in labour force/unemployed	1,407 (10.1%)
Other	1,293 (9.3%)
Education level[3]	
Year 10 or below	1,335 (9.6%)
Year 12	2,235 (16.0%)
Further education	8,128 (58.3%)
Prefer not to say	2,249 (16.1%)
Symptoms[4]	
Urinary frequency	15,471 (89.8%)
Urinary urgency	12,322 (71.6%)
Dysuria	12,318 (71.5%)
Suprapubic pain	6,292 (36.5%)
Systemic symptoms[5]	424 (2.5%)
Vaginal symptoms	273 (1.6%)
Number of UTI symptoms (excluding systemic and vaginal symptoms)	
0 to 1 symptom	167 (1.0%)
2 symptoms	7,352 (42.7%)
3 symptoms	7,160 (41.6%)
4 symptoms	2,540 (14.8%)
Participant history	
Hospitalised in the last 4 weeks	114 (0.7%)
History of UTI	303 (1.8%)
Increased sexually transmitted infection (STI) risk	111 (0.6%)
Travel to a low-to-middle income country in the last 3 months	279 (1.6%)
Referred to general practitioner for ongoing management	1,257 (7.3%)
Risk category[5]	
Red flag criteria (e.g., systemic symptoms, symptoms/signs of a complicated UTI)	1,086 (6.3%)

Characteristic	n=17,219
Orange flag criteria (symptoms suggestive of a cause other than UTI)	495 (2.9%)
Number of times the service was used by the participant through the trial*	
Once	16,440 (95.4%)
Twice	737 (4.3%)
Three times	33 (0.2%)
Four times	9 (<0.1%)
Antibiotic supplied	
Trimethoprim	15,232 (88.5%)
Cephalexin	427 (2.5%)
Nitrofurantoin	283 (1.6%)
None	1,277 (7.4%)

Notes:

1. *Unique participants were determined from the linked dataset generated by the CHeReL*
2. *Date of birth based on linked data – all participants self-reported a date of birth between 18–65 years (inclusive) at the registration visit*
3. *Employment status and level of education data were only available for the 13,947 people responding to the 7-day follow-up*
4. *Multiple responses allowed*
5. *Participants with systemic symptoms were in the red risk category and referred for ongoing medical care. Those with symptoms or signs suggestive of pyelonephritis or sepsis were recommended to go to emergency department and all others were recommended referral to a general practitioner*
6. *Based on the pharmacy management algorithms (see Appendix 2.1 for details)*

Primary and secondary outcomes

For 80.9% (n=14,671) of care episodes, participants completed a follow-up survey at day 7 post pharmacy consult. The main differences between responders and non-responders were that the latter were younger, had a greater rate of referral to general practitioners and had less use of antibiotics (see Appendix 3.3 Table 3-3-6).

Primary Outcome

Of those responding to the follow-up survey, participants for 79.4% (n=11,654) of care episodes reported that their symptoms were fully resolved at 7 days. For a further 17.9% (n=2,621) of care episodes, participants reported their symptoms had improved but were not fully resolved (Table 3-2).

Secondary outcomes

Implementation Outcomes

The proportions of pharmacies and pharmacists that provided consults and the proportion of patients that received the service are reported above (see 'Pharmacy recruitment' and 'Participant recruitment' sections). The proportion of patients meeting red flag criteria (see Appendix 2-1 for the clinical management protocol) and referred to another health professional was 6.3% (Table 3-1).

At follow-up, for most care episodes, participants reported taking trimethoprim (90.3%, n=13,251) with little variation in antibiotic used based on the number of presenting symptoms (Table 3-3). Similarly, for most care episodes (90.2%, n=13,235), participants reported that the prescribed antibiotic was taken as directed. Median symptom resolution time was 3 days and antibiotics were taken for a median of 3 days, with little variation by geographic location (Table 3-2).

In additional post hoc analyses, around one half of participants who responded to the follow-up survey reported using treatments other than antibiotics, with urinary alkalinisers, oral pain relief, and cranberry juice or capsules being the most common treatments (Table 3-2). Symptom resolution rates were broadly similar regardless of the antibiotic prescribed. For care episodes where participants reported not taking any antibiotics, there were higher rates of persistent or worsening symptoms (Table 3-3). Symptom resolution rates were higher in those presenting with two or more symptoms compared to those with zero or one symptom (Table 3-4) which is correlated with the higher rates of antibiotic use in those with more symptoms (Table 3-3).

Table 3-2: Self-reported 7-day symptom resolution rate by geographic region (n=14,671 care episodes)

	Total n=14,671	MMM1 n=10,482	MMM2 n=320	MMM3 n=2,100	MMM4 n=1,121	MMM5 n=645	MMM6 n=3
Symptom resolution rate (primary outcome)							
Complete resolution	11,654 (79.4%)	8,292 (79.1%)	255 (79.7%)	1,697 (80.8%)	897 (80.0%)	510 (79.1%)	3 (100.0%)
Improved but not resolved	2,621 (17.9%)	1,904 (18.2%)	59 (18.4%)	345 (16.4%)	193 (17.2%)	120 (18.6%)	0 (0.0%)
Not improved/worse	396 (2.7%)	286 (2.7%)	6 (1.9%)	58 (2.8%)	31 (2.8%)	15 (2.3%)	0 (0.0%)
Median resolution (days, interquartile range)	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	3 (2–4)	3 (3–3.5)
Antibiotic use							
Antibiotics taken for the recommended duration							
Yes	13,235 (90.2%)	9,424 (89.9%)	298 (93.1%)	1,883 (89.7%)	1,031 (92.0%)	596 (92.4%)	3 (100.0%)
No	605 (4.1%)	456 (4.4%)	10 (3.1%)	79 (3.8%)	43 (3.8%)	17 (2.6%)	0 (0.0%)
No response	831 (5.7%)	602 (5.7%)	12 (3.8%)	138 (6.6%)	47 (4.2%)	32 (5.0%)	0 (0.0%)
Median duration of use (days, interquartile range)	3 (3–3)	3 (3–3)	3 (3–3)	3 (3–3)	3 (3–3)	3 (3–3)	3 (3–3)
Use of other products for symptom control							
Overall	6,960 (47.4%)	4,951 (47.2%)	163 (50.9%)	1,007 (48.0%)	522 (46.6%)	317 (49.1%)	0 (0%)
Urinary alkaliniser	5,197 (35.4%)	3,656 (34.9%)	123 (38.4%)	763 (36.3%)	405 (36.1%)	250 (38.8%)	0 (0%)
Oral pain relief	2,671 (18.2%)	1,873 (17.9%)	74 (23.1%)	418 (19.9%)	200 (17.8%)	106 (16.4%)	0 (0%)
Cranberry juice or capsules	2,402 (16.4%)	1,728 (16.5%)	60 (18.8%)	326 (15.5%)	182 (16.2%)	106 (16.4%)	0 (0%)
Other product	736 (5.0%)	514 (4.9%)	19 (5.9%)	119 (5.7%)	53 (4.7%)	31 (4.8%)	0 (0%)
Vitamin C	480 (3.3%)	336 (3.2%)	18 (5.6%)	75 (3.6%)	28 (2.5%)	23 (3.6%)	0 (0%)

Table 3-3: Antibiotic prescribed by symptom number and symptom resolution (n=14,671 care episodes)

Characteristic	Trimethoprim (n=13,251)	Cephalexin (n=368)	Nitrofurantoin (n=256)	None (n=796)
Number of UTI symptoms				
0 to 1 symptom	17 (0.1%)	0 (0.0%)	0 (0.0%)	88 (11.1%)
2 symptoms	5,700 (43.0%)	156 (42.4%)	101 (39.5%)	285 (35.8%)
3 symptoms	5,629 (42.5%)	163 (44.3%)	121 (47.3%)	277 (34.8%)
4 symptoms	1,905 (14.4%)	49 (13.3%)	34 (13.3%)	146 (18.3%)
Symptom resolution				
Completely resolved	10,630 (80.2%)	302 (82.1%)	217 (84.8%)	505 (63.4%)
Improved but not completely resolved	2,292 (17.3%)	63 (17.1%)	34 (13.3%)	232 (29.1%)
Not improved or worsened	329 (2.5%)	3 (0.8%)	5 (2.0%)	59 (7.4%)
Median time taken to resolve (days, IQR*)	3 (2, 4)	3 (2, 5)	3 (2, 5)	4 (2, 5)
Median antibiotic duration (days, IQR*)	3 (3, 3)	5 (5, 5)	5 (5, 5)	5 (3, 7)

**Interquartile range*

Table 3-4: Symptom resolution by number of presenting symptoms (n=14,671 care episodes)

	Number of presenting symptoms			
	0–1 (n=105)	**2 (n=6,242)**	**3 (n=6,190)**	**4 (n=2,134)**
Completely resolved	69 (69.0%)	4,932 (79.5%)	4,917 (79.7%)	1,693 (79.3%)
Improved but not completely resolved	25 (25.0%)	1,097 (17.7%)	1,104 (17.9%)	375 (17.6%)
Not improved or worsened	6 (6.0%)	171 (2.8%)	148 (2.4%)	66 (3.1%)
Median days taken to resolve (interquartile range)	3 (2, 5)	3 (2, 4)	3 (2, 4)	3 (2, 4)

Participant Experience

Figure 3.5 and Appendix 3.3 Table 3-3-7 provide information on participant experience using a 7-point Likert scale and seven statements (1=strongly disagree with the statement, 7=strongly agree with the statement). Most participants across all seven statements agreed or strongly agreed, indicating a positive experience with the service. The median (IQR) self-reported cost for the service (inclusive of medication costs) was $20 ($13, $30). Overall, for 85.0% of care episodes, participants reported that cost would not be a barrier to using the service again; for 9.7% of care episodes, participants considered it may be a barrier and for 5.4% of care episodes, participants indicated it would be a barrier.

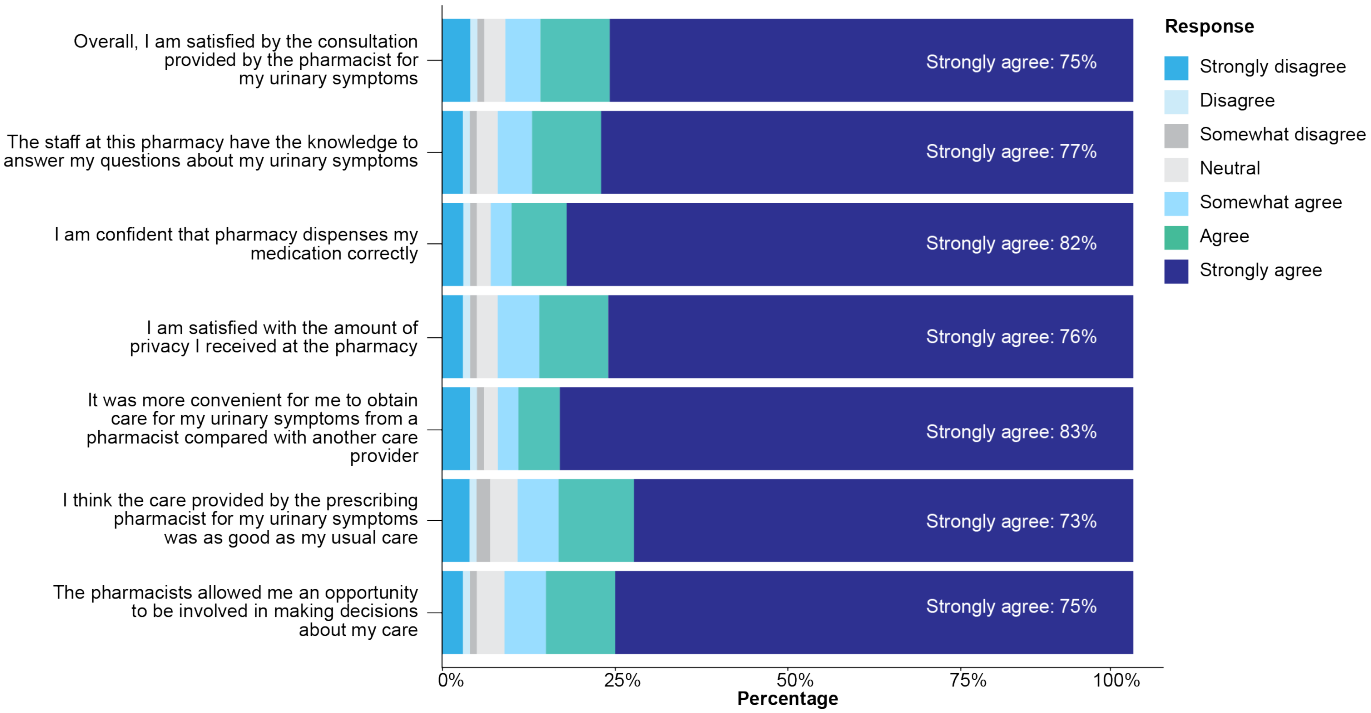


Figure 3.5: Participant experience (n=14,669 episodes of care)[1]

Note:

1. Data missing for two experience surveys

Primary Care Utilisation

For 2,402 care episodes (16.4% of those who responded to follow-up), participants reported seeing another healthcare professional – most commonly a general practitioner (14.1%) (Table 3-5).

Table 3-5: Self-reported use of another healthcare professional (n=14,671 care episodes)

	n=14,671
Another healthcare professional seen for the same symptoms in the last 7 days*	**2,402 (16.4%)**
A general practitioner	2,075 (14.1%)
A different pharmacy	91 (0.6%)
Same pharmacy	70 (0.5%)
Health information phone line	50 (0.3%)
Other professional	65 (0.4%)

**Multiple responses allowed*

Based on MBS data, the rates of seeing a general practitioner within 7 days were higher than in the self-reported in Table 3-5 – 11.1 and 13.7 per 100 people of those consenting to linkage saw a general practitioner within 2 days and within 3–6 days, respectively, following the initial pharmacy consultation (Table 3-6). Between 7–28 days, the rates of general practitioner encounters increased to 46.7 per 100 people. Over the 28 days post pharmacy consult, 6,668 unique people (43.2%) had a general practitioner consult – 25.1% had one consult, 11.6% had two consults, and 6.5% had more than two consults. The most frequently claimed MBS consult item was a standard (6–20 minutes) general practitioner attendance (53%), followed by a phone consult (19.9%) and a long general practitioner attendance (20–40 minutes) (12.3%) (see Appendix 3.3 Table 3-3-8 for more details).

Importantly, there were no data available on the reason for consultation. The rates of urine samples sent for pathology testing provide an indication of which encounters were related to a urinary condition, although this may be an under-estimate given not all UTI-related presentations may have resulted in a urine pathology specimen being sent. Within 0–2 days, 3–6 days and 7–28 days, the rates of urine testing were 5.4, 5.5 and 8.9 per 100 persons, respectively, and the proportions of general practitioner consults in which a urine test was ordered over these three time periods were 48.8% (836/1,712), 39.9% (854/2,119) and 19.0% (1,374/7,216), respectively. In a post-hoc analysis requested by NSW Health, we examined rates of pathology testing for STI. These are shown in Table 3-6 indicating a low rate of testing overall with an increase in testing between 7–28 days following the initial pharmacy consult.

Appendix 3.4 Table 3-4-1 provides the **proportions of participants** for each utilisation outcome rather than **rates of encounters** per 100 people. Rates may include more than one encounter per person and therefore are slightly higher than proportions.

Table 3-6: Health professional, antibiotic and hospital utilisation in the 28 days post pharmacy consult

	Number (rate per 100 people)[1]		
	0–2 days	**3–6 days**	**7–28 days**
General practitioner or specialist services provided (MBS data for 15,453 people)			
General practitioner consultation	1,712 (11.08)	2,119 (13.71)	7,216 (46.70)
Specialist consultation	95 (0.61)	165 (1.07)	888 (5.75)
Urine sample sent for pathology testing	836 (5.41)	854 (5.53)	1,374 (8.89)
STI test performed[2]	122 (0.79)	171 (1.11)	499 (3.23)
Antibiotics prescribed other than initial pharmacy prescription (PBS data for 16,453 people)[3]			
Any antibiotic prescribed	712 (4.33)	1,207 (7.34)	2,214 (13.46)
Antibiotic from clinical management protocol[4]	575 (3.49)	958 (5.82)	1,366 (8.30)

	Number (rate per 100 people)[1]		
New antibiotic and not supplied an antibiotic at pharmacist consult	186 (1.13)	90 (0.55)	124 (0.75)
Same antibiotic as supplied at pharmacist consult	113 (0.69)	215 (1.31)	332 (2.02)
Different antibiotic to that supplied at pharmacist consult	276 (1.68)	653 (3.97)	910 (5.53)
Antibiotic not from clinical management protocol	137 (0.83)	249 (1.51)	848 (5.15)
Hospital utilisation (NSW Health data for 16,479 people)[5]			
All-cause hospitalisations	36 (0.21)	50 (0.29)	131 (0.76)
Potentially preventable hospitalisations[6]	14 (0.08)	22 (0.13)	25 (0.15)
Potentially preventable hospitalisations related to genitourinary conditions[7]	14 (0.08)	21 (0.12)	20 (0.12)
Acute hospital admissions	36 (0.21)	50 (0.29)	128 (0.74)
Emergency department presentations[8]	238 (1.44)	171 (1.04)	418 (2.54)
Emergency department presentations for triage 3–5 conditions[9]	224 (1.36)	156 (0.95)	373 (2.26)
Emergency department presentations for genitourinary conditions[10]	107 (0.65)	63 (0.38)	68 (0.41)

Notes:

1. *Denominator varies depending on dataset used*
2. *Includes an MBS pathology billing code for any of the following: Chlamydia trachomatis nucleic acid amplification test; Neisseria gonorrhoea nucleic acid amplification test; HIV serology or RNA or genotype testing, syphilis serology, hepatitis B serology or DNA testing*
3. *Any medications recorded in PBS data on the same day as the pharmacy consult were excluded from the count*
4. *Trimethoprim, nitrofurantoin, cephalexin*
5. *Data were not available for ACT participants at the time of writing this report*
6. *Potentially preventable hospitalisations are defined as per NSW Health guidelines, https://www.healthstats.nsw.gov.au/page/potentially-preventable-hospitalisation-codes*
7. *Urinary tract infection, including pyelonephritis potentially preventable hospitalisations as defined by NSW Health*
8. *Includes multiple emergency department presentations per person*
9. *Triage category descriptions: 1: Immediate treatment needed; 2: Urgent treatment needed; 3: Serious condition; 4: Moderate condition; 5: Non-urgent condition*
10. *Defined in Appendix 3.3 Table 3-3-3 for ICD-10 and SNOMED codes*

Medication Utilisation

Based on PBS data, for those consenting to linkage, the rates of dispensing another antibiotic within 2 days and within 3–6 days following the initial pharmacy consultation were 4.3 and 7.3 per 100 people, respectively (Table 3-6). At days 7–28, the rate increased to 13.5 per 100 people. Across these three time periods (within 2 days, 3–6 days and 7–28 days), the proportions of antibiotic scripts that were for the same drug originally prescribed in the pharmacy consult were 80.1%, 79.4% and 61.7% respectively.

Hospital Utilisation

Hospital admissions and emergency department visits are also shown in Table 3-6 for the same time periods. All-cause hospitalisations were low in the 28 days following the pharmacy consult. For those admitted to hospital, the median lengths of stay (interquartile range) were 1.0 (1.0, 2.0), 1.0 (1.0, 3.0), 1.0 (1.0, 2.0) for days 0–2, 3–6 and 7–28, respectively. Within 0–2 days, 3–6 days and 7–28 days, the rates of emergency department visits were 1.4, 1.0 and 2.5 per 100 people, respectively. Over these same time periods, 45.0% (107/238), 36.8%

(63/171) and 16.2% (68/418), respectively, were related to genitourinary conditions.

Appendix 3.4 Tables 3-4-2 and 3-4-3 provide additional analyses related to Table 3-6 above. Appendix 3.4 Table 3-4-2 stratifies the utilisation outcomes by whether the participant was referred for ongoing care at the initial pharmacy consult. It shows that those referred by the pharmacist had greater use of general practitioner consults, antibiotics and hospital services (more details below in subgroup analyses). Appendix 3.4 Table 3-4-3 stratifies the utilisation outcomes by the self-reported symptom resolution status at day 7. It also shows greater use of general practitioner consults, antibiotics and hospital services for those with incomplete or unresolved symptoms.

Long-term Trends in General Practitioner, Antibiotic, Emergency Department and Hospital Utilisation

Figure 3.6 shows the utilisation trends over the 12 months pre and 6 months post pharmacy consultation. Although we initially intended to provide 12 months of follow-up data, the proportion of participants with >6 months of follow-up data was low (see Appendix 3.3 Table 3-3-4D). General practitioner and antibiotic prescriptions increased initially around the time of the pharmacy consult. These utilisation rates reduced after week 1 and then slowly increased thereafter. The mean weekly general practitioner consultation rate increased in the 6-month period post pharmacy consult compared to the 12 months pre consult (15.9 per 100 people vs 11.6 per 100 people, p<0.001). Mean weekly antibiotic prescription rates significantly increased over the same time period (4.3 per 100 people vs 2.2 per 100 people, p<0.001).

There was a rise in the mean weekly emergency department presentation rate in the 6 months post pharmacy consult vs the 12 months pre consult (0.8 per 100 people vs 0.6 per 100 people, p=0.01). This was mainly driven by an increase in the emergency department presentation rate in the first week post pharmacy consultation (2.4 per 100 people in week 1 vs 0.6 per 100 people in the 12 months pre intervention, p<0.001). This represents an absolute increase of 1.8 extra presentations per 100 persons. It is important to note that this includes all emergency department presentations, regardless of cause.

A total of 409 emergency department presentations were recorded after the first week of receiving the service, with 170 of these related to genitourinary conditions. Emergency department attendance was higher in patients referred by a pharmacist to a general practitioner compared to those non-referred (6.2% vs 1.0% at 0–2 days and 1.7% vs 0.9% at 3–6 days after the pharmacy consultation) (see Appendix 3.4 Table 3-4-4).

The mean weekly hospital admission rate reduced in the 6 months post pharmacy consult vs the 12 months pre consult (0.2 per 100 people vs 0.4 per 100 people, p<0.001). There were negligible differences in admission rates in the first week post pharmacy consult (0.5 per 100 people in week 1 vs 0.4 per 100 people in the 12 months pre intervention, p=0.38).

Appendix 3.4 Table 3-4-4 provides more details on the point estimates for the short- and long-term trends in general practitioner, antibiotic, emergency department and hospital utilisation.

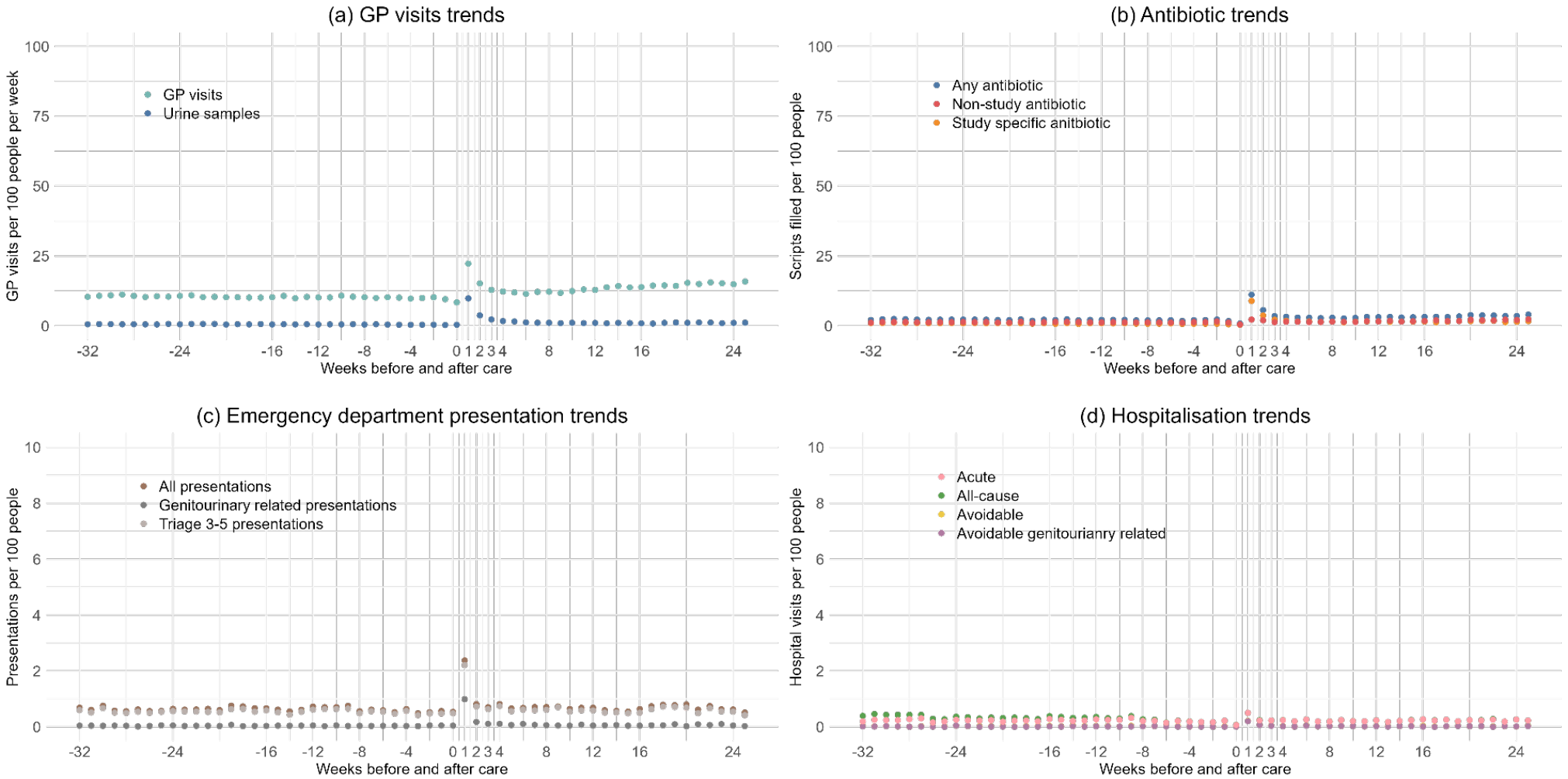


Figure 3.6: General practitioner, antibiotic, emergency department and hospital utilisation trends 12 months pre and 6 months post pharmacy consult[1]

Note

1. NB: different y-axis scales are used for emergency department presentation and hospitalisation compared to general practitioner and antibiotic utilisation rates

Sub-group analyses

Figure 3.7 highlights the pre-specified subgroup analyses for the primary outcome using a multivariate regression model. Additional analyses were conducted to look at the association of these variables with additional antibiotic prescribing and seeing a general practitioner following the initial pharmacy consult. For the primary outcome of complete symptom resolution, there were minimal differences for any of the subgroups. Increasing age and a pharmacist referral to a general practitioner were positively associated with both MBS-related general practitioner consults and increased antibiotic prescription rates.

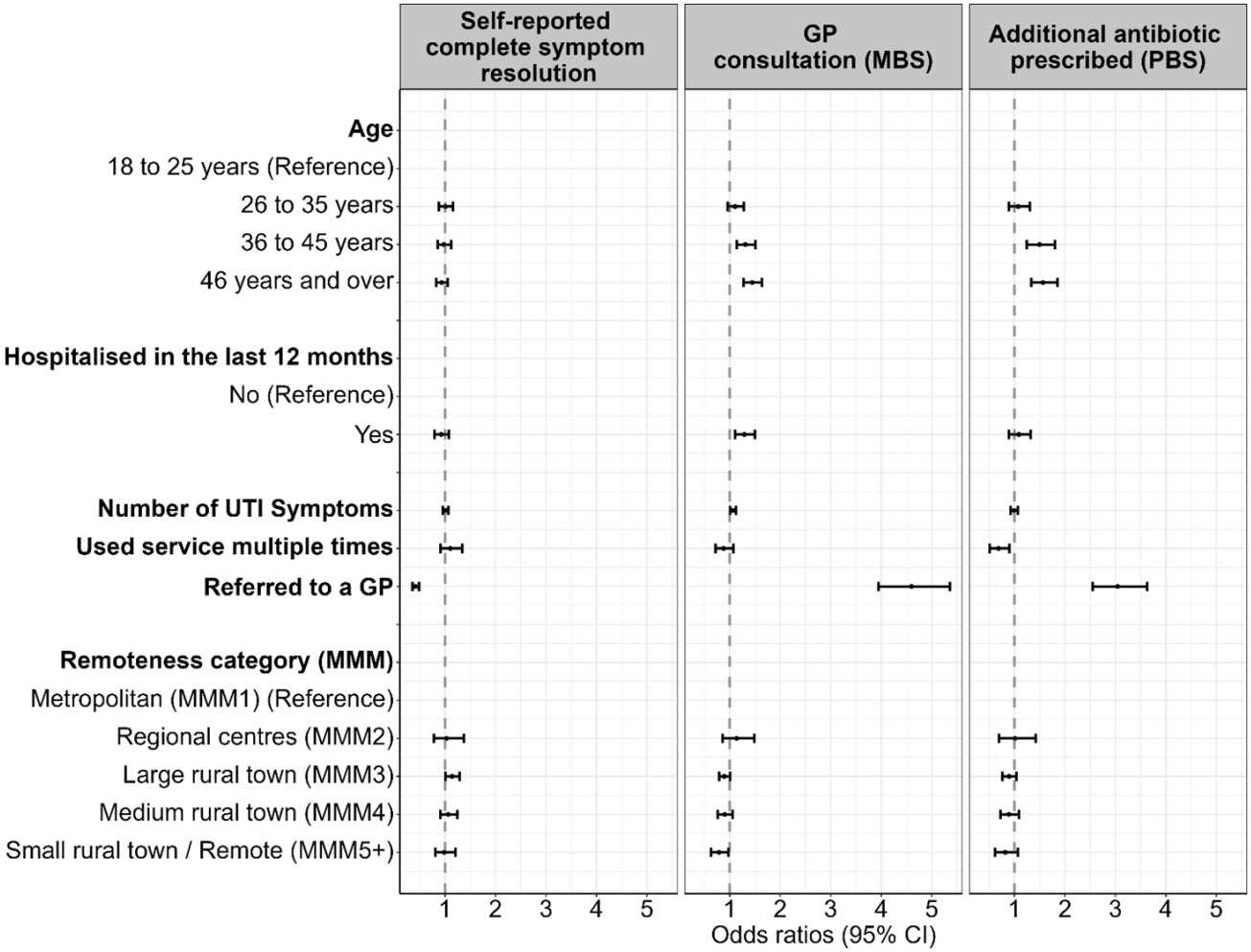


Figure 3.7: Subgroup associations for symptom resolution, general practitioner visits and additional antibiotics[1]

Note:

1. Odds ratios are adjusted for all other covariates in the model

As mentioned previously (see 'Quantitative data analysis' section in the Methods), we used the combined dataset with postcode information to look at associations by SEIFA wealth quintile and the primary outcome (complete symptom resolution) and there were no significant differences. For more details on subgroup analyses, see Appendix 3.4 Table 3-4-5.

Adverse events

The overall complication rate based on self-report data was 5.1%. The most common complication reported was gastrointestinal symptoms (Table 3-7). For 282 care episodes (1.9%), participants reported attending an emergency department and/or an urgent care clinic at the 7-day follow-up survey (Table 3-7). For these 282 care episodes, 12 (4.3%) were assessed to be in orange risk category and 62 (22.0%) were assessed to be in the red risk category based on the pharmacy consult data. There was little variation in self-reported adverse events by geographic region (see Appendix 3.4 Table 3-4-6). Self-reported adverse events occurred at a higher rate in the proportion of people who reported that their symptoms had not improved or worsened at the 7-day follow-up survey (see Appendix 3.4 Table 3-4-7).

Table 3-7: Self-reported adverse events based on survey responses (n=14,671 care episodes)

	n=14,671
Experience of adverse events or complications*	749 (5.1%)
Gastrointestinal complications	
Nausea	313 (2.1%)
Vomiting	41 (0.3%)
Diarrhoea/ loose stools	130 (0.9%)
Constipation	75 (0.5%)
Other complications	
Fatigue	136 (0.9%)
Skin rash	54 (0.4%)
Breathing difficulties	21 (0.1%)
Other complications not specified	346 (2.4%)
Attendance at an acute care facility*	
Presented at emergency	195 (1.3%)
Attended an urgent care clinic	80 (0.5%)
Attended an urgent care clinic and presented at emergency	7 (<0.1%)

**Multiple responses allowed*

The serious adverse events based on linked data analyses (emergency department visits, hospitalisation and specialist consults) are reported above in Table 3-7. A total of four deaths in the follow-up period were recorded, occurring between 25 and 91 days post care episode. None of these were related to genitourinary conditions and all were attributed to either a long-term illness or accident.

Qualitative data analysis

Participants Interviewed

Pharmacists

Interviews with pharmacists who participated in the trial were completed between January and April 2024. Eleven pharmacists were recruited from a sample of purposively selected pharmacies to represent a diverse range of experiences in implementation of the trial (Table 3-8).

There were ten high recruiting pharmacies, and one low recruiting pharmacy represented, with a uniform spread across geographical regions in MMM categories 1–5. Represented pharmacies had a variety of business models including extended hours and/or weekend trade and were located in the main streets or shopping centres across cities and small regional towns. Pharmacists interviewed held a variety of roles in the pharmacy ranging from general pharmacists, proprietors, and those with additional training in the provision of professional services, such as immunisations.

Table 3-8: Characteristics of pharmacists interviewed (n=11)

Characteristic	Number
Role in pharmacy	6 proprietors/ business owners 3 pharmacists 1 principal pharmacist 1 rotational pharmacist
Gender	7 men, 4 women
Pharmacy characteristics	3 retail focus 8 offering professional services 10 extended hours or weekends 5 main street 5 shopping centre locations
Remoteness category	3 metropolitan locations (MMM1) 2 regional centres (MMM2) 2 large rural towns (MMM3) 2 medium rural towns (MMM4) 2 small towns (MMM5)

Service users

Ten interviews were conducted between February and May 2024 with service users. Most participants interviewed were university educated and in full time employment. All had received an antibiotic following the consultation (Table 3-9). Service users who did not receive antibiotics were approached for interview, but all declined or did not respond to the invitation. Participant interview data were supplemented with additional service user experience data from feedback emails (n=61).

Table 3-9: Characteristics of service users participating in interviews (n=10)

Characteristic	Number
Age	3 × 18–25 years 4 × 26–50 years 2 × 51–65 years
Employment status	7 × full time work 1 × part time 1 × self employed 1 × not asked
Education	9 × university 1 × high school
Healthcare concession card eligible	2
Remoteness	3 × metropolitan 2 × regional 2 × large rural town 2 × medium rural town 1 × small rural town
Time seen for initial pharmacy consultation	2 × after business hours 4 × in business hours/ lunch break 2 × on holiday 2 × not asked
Antibiotic given	10 × yes
Symptom resolution at time survey completed	6 × symptoms completely resolved 4 × symptoms improved but not completely resolved

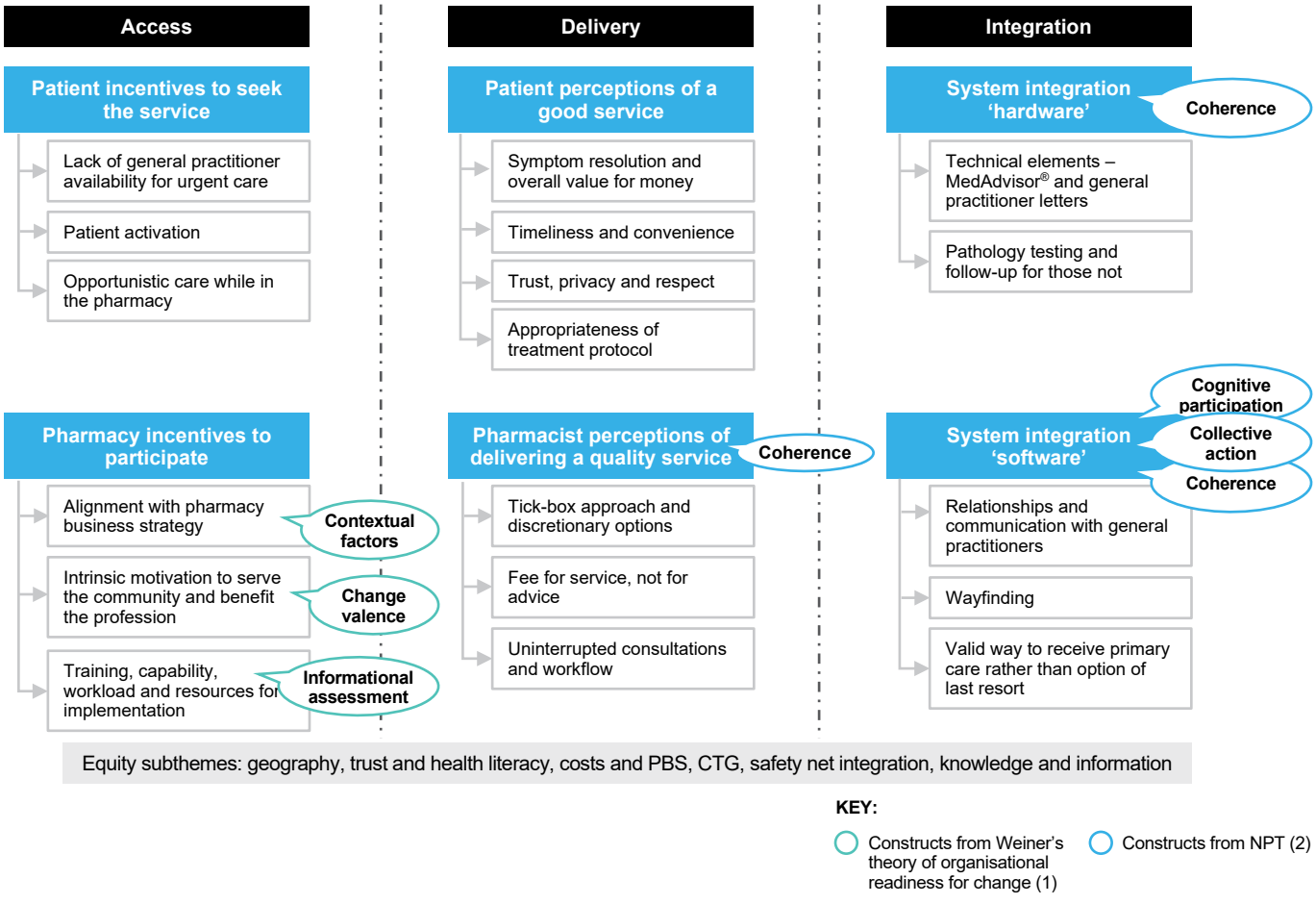
Key Themes – Factors Influencing Effective Uptake and Sustainment of the UTI Service

We identified six main themes influencing effective implementation of the service, categorised into three domains of access, delivery and integration (Figure 3.8).

1. **Participant incentives to use the service** included limited general practitioner availability, media promotion of the service, and opportunistic care while seeking symptom relief in the pharmacy.
2. **Pharmacist motivation to participate** included alignment with business models, intrinsic motivation to serve the community, and enhanced self-efficacy with a sense that service delivery was feasible and within their capability, and that there were adequate support and training.
3. **Participant perceptions of a 'good service'** included timely symptom resolution, value for money, and a service that prioritises trust, privacy and respect. Participants also expressed a desire for less restrictive eligibility criteria, improved integration with pathology services and more streamlined general practitioner referrals when needed.
4. **Pharmacist perspectives on service quality** included the importance of avoiding a tick-box approach to care and having quarantined time and workflow adjustments to conduct clinical consults.
5. **Integration with health system infrastructure and information systems** included better integration with health information systems and pathology services, and workforce capacity strengthening.
6. **Integration with health system values, culture and relationships;** this included nurturing positive working relationships with general practitioners, better care coordination with other healthcare professionals, and changing perceptions that the service is a 'last resort' option.

We also identified an additional theme related to equity that cuts across the three domains. While the wide geographic distribution of pharmacies and the provision and expectation of 'walk in' care is potentially a strong enabler of equity of access, most women participating in interviews were highly educated and came to the pharmacy with a clear sense of what they wanted from the service. The service did not provide access to PBS subsidised medications or benefits available for concession card holders or 'Closing the gap' (CTG) patients. This limitation, along with a lack of transparency around service costs, noted by some patients, may be disincentives for some to use the service.

We have mapped these themes to constructs from Weiner's theory of organisational readiness for change, and to the four Normalisation Process Theory (NPT) constructs of cognitive participation, coherence, collective action and reflexive monitoring.



References: (1) Weiner, B.J. A theory of organizational readiness for change. Implement Sci. 2009; 4: 67. doi: 10.1186/1748-5908-4-67; (2) May, C., & Finch, T. Implementing, embedding, and integrating practices: an outline of Normalization Process Theory. Sociology 2009; 43(3): 535-554. doi: 10.1177/0038038509103208.

Figure 3.8: Factors influencing effective uptake and maintenance of the UTI service – key themes

Theme 1: Participant Incentives to Seek the Service

Women who were health literate and engaged with their care sought out and accessed the pharmacy service through a considered process. A key driver of service uptake was perceived lack of availability of general practitioners for urgent care. This perception was shaped by experience seeking care from general practitioners for the current episode and past failed attempts at obtaining timely appointments. Women who had knowledge, confidence and skill to manage their overall health ('patient activation' [144]) found information on the NSW Health or ACT Health websites via internet searches and approached pharmacies to access the service. Opportunistic service provision through pharmacy staff promoting the service to women in the pharmacy seeking urinary alkalinisers or similar products appears to have also been an important entry point to accessing the service. This needs to be understood in the context of the majority of women accessing services coming from high SES, and the low uptake by pharmacies in rural, regional and remote areas.

Lack of general practitioner availability for urgent care

Perception of lack of general practitioner availability for urgent care and the relative ease of access to community pharmacies was a clear driver of participant demand for the UTI service. Women interviewed described having acute, uncomfortable symptoms that they knew required prompt treatment to avoid escalation, while at the same time knowing that it would be very challenging to obtain a timely general practitioner appointment. This situation of symptom intensity and escalation with limited access to timely general practitioner care was described as very stressful, and these women perceived the trial as addressing an important gap in service provision.

> *… when you have had it a few times YOU KNOW when it's coming on and can't get a booking at a general practitioner instantly. Sometimes you need to wait a week, which causes so much pain, disruption and a suboptimal existence. So, on the surface this service is great.*
>
> (Email 5)

Some women attempted obtaining a general practitioner appointment as first port of call, only reverting to the pharmacy service when unsuccessful.

> *So, one of the main reasons I looked up this service, I think I'd heard about it in a different jurisdiction, and I was like, that's a good idea … But at the time that I had the UTI symptoms, it was just after New Year's, so lots of doctors were, I assume on leave still and when I went to go book an appointment with my usual general practitioner, they're on leave … And when you have UTI symptoms, you know you have a UTI, and you want to get it treated and you don't want to wait 6 days, and you're not even meant to wait 6 days because it can progress into something more serious. So basically, there wasn't enough available general practitioners …*
>
> (P001)

One woman contrasted the challenge in getting care for one-off episodic health concerns such as UTIs, with the relative ease of obtaining planned care from general practitioners, for example to lock in appointments at regular intervals for obtaining repeat and routine prescriptions, including for oral contraceptives.

> *I think because you can get 3 months or whatever contraceptive pills; it's not as big of an issue for me. It's easier for me to just go to the general practitioner every 3 months. UTI is a bit more like a one-off kind of thing.*
>
> (P006)

The inability to obtain timely general practitioner appointments was particularly challenging for women in regional areas, and some women did not try to access general practitioners, resigning themselves to using emergency departments. Despite the long wait times at the emergency department, some women felt that prior to the trial this was their only option.

> *Well, I've got a general practitioner but it's hard to get an appointment. A lot of the time you sort of book into an appointment, there aren't any sort of walk-ins available for things like this*

because, basically, I think they're close to full. So, they're full staff and flat out ... And the emergency at the local hospital ... yeah, I've had to go there before for a UTI, and it took something like 5 hours at 1 o'clock in the morning.

(P005)

It's very, very difficult to get in to see a general practitioner if you have anything that is urgent but not necessarily serious. You basically still have to go to the hospital because the general practitioners won't see you ... usually, the best option to get any care is to go out to the hospital and utilise emergency services.

(P0010)

Perception of lack of availability of general practitioner appointments was compounded by the anticipation of out-of-pocket costs. One participant (P004) described calling around general practices prior to finding the pharmacy service and being told there were waiting times for an urgent appointment of around 24–36 hours, coupled with what she understood as new co-payment fees of around $240. This affordability concern created an access barrier for her. We note that this trial had a $20 consultation fee that, in NSW, was paid by NSW Health - transition to usual business will elicit patient being out of pocket for $20-75 as per other national pilots. Transition to business as usual will reduce the scale of the affordability advantage that the trial service had over a general practitioner visit.

Alternatives to emergency department services such as urgent care, telehealth and instant scripts for treatment of UTIs were mentioned by some women, but use of these services for UTIs was not predominant among women interviewed. One woman (P007) had specifically used the pharmacy in preference to a telehealth provider, as she believed that an in-person service, such as at a pharmacy, might include the usual care provided at her general practitioner – such as use of test strips. The use of such strips was not part of the trial protocol or standard pharmacy practice in offering the service.

I had booked in to the general practitioner, but they cancelled me because the general practitioner I booked in with at the practice had COVID. And they said I could do telehealth. And I thought, well, I don't want telehealth because I actually want to get a test. And then I was looking up just googling self-test for UTI. I wondered if you could just buy the indicator strips yourself. And then I came up on the trial. Just through the Google, it said there's this pharmacy trial. So, I thought that's a good idea. I'll give that a go.

(P007)

While none of the women interviewed had been referred to the community pharmacy UTI trial from general practices, instances of these referrals were mentioned by pharmacists interviewed. The instances of referral into the pharmacy service from general practitioners identified in interviews tended to be in regional areas – areas known to have several general practitioner shortages (and low trial uptake). Referrals from general practitioners into the pharmacy service was particularly evident in regional areas with severe general practitioner shortages (see 'Relationships and communication with general practitioners' section).

Participant activation

Women interviewed (most of whom were highly educated) demonstrated knowledge, confidence and skills to manage their own health. They related awareness of previous experience with UTI symptoms and an understanding of the risks of escalation without appropriate, timely management. The process of seeking care included internet searching for local participating pharmacies (following seeing an ABC News report about the trial, for example) and searching for alternatives to general practitioners when unable to access general practitioner appointments. Women who had searched the internet mentioned reputable sources such as the NSW Health and ACT Health websites.

I think just googled 'UTI pharmacy', I can't remember. 'UTI pharmacy something ACT'. I think a government page came up with information on it and then it had a link to the applicable pharmacies. And then I saw the pharmacy that I actually normally go to anyway was one of them.

(P001)

Other women used the HealthDirect phone line to guide them regarding whether hospital care was needed. One interviewee was referred to a participating pharmacy by HealthDirect – although this was only suggested to her by the triage nurse after the first recommendation (a scheduled general practitioner telehealth appointment) had failed to connect to her the previous day.

> *I called HealthDirect just to see if I should go up to the hospital or not and they said they would have a general practitioner call me in a script like a telehealth appointment. But then that was on Saturday evening, so I waited up until about 1 in the morning for a call and then they never called. So, then I rang back the next morning on Sunday ... And they said, 'well, why don't you go to the pharmacy?' That would've been helpful 8 hours ago. And so, then I went down to the pharmacy ...*
>
> (P010)

Most women interviewed had self-diagnosed their UTIs prior to seeking care at the pharmacy. Some women sought confirmation about the diagnosis from the pharmacy and had clear expectations about appropriate care and management for UTIs (e.g., antibiotic treatment of a certain type/duration and test strips). These expectations were shaped by past treatment from their general practitioners. As shown below in Theme 3 (see 'Appropriateness of treatment protocol' section), women's past experiences and expectations of the treatment pathway did not always concur with the trial protocol.

Opportunistic care while in the pharmacy

In some pharmacies, promotional materials approved for display during the trial were placed in the shop window, and on shelves next to common treatment products such as urinary alkalising agents (e.g., Ural®), with the intention that this would prompt participant enquiry and facilitate introduction of the trial to women seeking symptom relief. Among pharmacists interviewed, this opportunistic route to use of the service did not appear to be the key driver of service uptake in metropolitan areas, but it may have been more predominant in regional areas, where women had not necessarily heard of the trial but came seeking pharmacist assistance for symptoms suggestive of UTIs.

> *In terms of initiations in store, I don't think we've done a huge number of those ... in regard to how many have gone from (saying) 'I didn't know anything about it' to actually having the service ... is probably very small comparative to the people that came seeking it.*
>
> (Pharmacist, PH013)

One woman interviewed had accessed the service as she had a previous prescription for a UTI from a telehealth instant script provider a year earlier and had gone to the pharmacy to get the script filled as she believed there was a repeat on the script. However, the script was not on record, so the pharmacist suggested that she participate in the trial instead.

> *I've got instant scripts that I use on my phone. And I have actually done UTI that way before, as well. In fact, I thought I had a repeat on my instant script. And that's why I went to the chemist. And then the repeat is like when it was sort of worked out that the repeat wasn't there. That's when he suggested that I do this.*
>
> (P005)

None of the women interviewed suggested they had found out about the trial opportunistically. Opportunistic care as a motivator to seek the service may have been an entry point for women who are less health literate and engaged in their care (and consequently may have been less willing to be interviewed) – this is discussed in the 'Equity considerations' section.

Theme 2: Pharmacist Motivation to Participate

Pharmacists participating in the trial believed that the service is needed and worthwhile, is helping to solve an important community problem and an important health system issue and is of benefit to the development of their profession. A supportive context, including alignment with overall group strategy that promotes delivery of professional services or a targeted demographic, and alignment between business owner and pharmacists, was a key enabler for trial participation. Pharmacists interviewed considered that the service delivery was feasible and within their capability, and that there

were adequate support and training to provide the service effectively. They were motivated to provide the service as one of a suite of professional services. From a business perspective, they believed that expanded scope of practice, including the UTI service, would help drive retail sales. Training, systems and structures of support available to pharmacists as part of the trial were positively regarded by pharmacists, while costs and time for training, and challenges implementing consultations within workflow in the pharmacy were barriers.

Alignment with overall pharmacy business strategy

Where the pharmacy was part of a group that included a strong focus on professional services as a core part of their brand, pharmacists noted that the group had supported or promoted trial participation. The group provided guidance about how pharmacies could optimally use the scope of practice trials to build the professional services arm of the business. Business owners (who were often practising pharmacists themselves) believed that offering professional services, such as UTI services, would 'pay for themselves' by increasing foot traffic through the business and promoting sales of retail products.

> *So, we're part of the [name] group of pharmacies, and they have a professional services arm. They helped us with how to utilise this program to the best that's out there, it's ability. We all go together and are all ethically aligned. So, we are all interested in championing pharmacy services and pharmacy as a destination for health care. And don't get me wrong, I still want to sell heaps of product because we're a retail business, but we believe we can sell that really well by surfing off the services, and not the other way around.*
>
> (Pharmacist, PH007)

This pharmacist, whose pharmacy was in a large rural town (MMM3), described that their commitment to providing community health services was evident through employment of two registered nurses, and that staffing rosters were structured to ensure that nurse and pharmacist delivery of professional services were provided every day.

Another pharmacist, who was part of a group where the focus was not on professional services but on retail and price as part of the brand, noted that the interest and support for the trial among their peer group was driven by individual pharmacist interest, rather than centrally coordinated support. Peer support for implementation was provided through a general group chat forum that all pharmacists in the group could be part of.

> *It's like a big, long messenger thread … And there were certainly questions in there about, 'what if a patient this?' or 'how much can I charge on top of that?' or 'are we allowed to charge X?' There was just definitely that sort of question popping up …*
>
> (Pharmacist, PH002)

For retail-focused pharmacies, the alignment between their strategy and UTI service delivery was through the alignment with demographics they were targeting for retail sales (predominantly young women), rather than an explicit focus on developing a brand for trusted professional advice.

While business owners interviewed had made the initial decision to participate in the trial, participation by individual pharmacists in these businesses was not uniform. To effectively implement the service, pharmacists developed operational strategies whereby several staff were involved – for example, retail or dispensing staff were engaged to provide information to women about service availability, and for rapid pre-screening (e.g., checking age eligibility). Alignment of all staff members was seen to be a challenging aspect of the trial by some.

> *If anything, the hard part is getting our team on board, so getting all the staff to understand what it means. And getting all those restrictive things out in the open and clear so that people know exactly what they're going to be letting themselves in ...*
>
> (Pharmacist, PH007)

In some businesses, all pharmacists were strongly encouraged to complete the training and participate in UTI service delivery with support from the pharmacy, and in others, participation was left to the discretion of the individual pharmacists based on their interests.

... so, they weren't doing the training because the owner wasn't paying for it. They didn't want to pay out of their own pocket.

(PCF, S002)

Where all pharmacists were trained and able to deliver the service, this enhanced availability of the service. For some pharmacists, the cost of doing the training was a barrier to participation. In pharmacies where only one pharmacist on the staff was trained, the service was only available when this pharmacist was rostered- this meant instability of the service and that women couldn't always access care when they wanted or needed to.

Intrinsic motivation to service the community and health system, and benefit the profession

From interview data, pharmacists considered that the service was valuable and were motivated to participate because of perceptions that: (1) the service will help to solve an important community problem; (2) the service will help solve an important health system issue (perception of lack of timely access to general practitioner services and emergency departments); and (3) the expanded scope of service delivery will be of benefit to their profession.

In the context of limited access to general practitioners (e.g., in small towns), pharmacists saw participation in the service as helping them to provide a solution to a problem of limited access to timely primary care for UTIs. They cited complications that may arise because of treatment delays in explaining their motivation to provide the service.

I've found it rewarding personally to be able to provide a real solution rather than saying, 'here's some Ural® and off you go.'

(Pharmacist, PH002)

Nowadays it is a bit harder to get a general practitioner appointment. Sometimes you are waiting a few days. Given that it's like a time-sensitive thing, we want to get on top of therapy straight away if it is a UTI. So yeah, removing that barrier to having to wait to see a general practitioner because obviously if it's not treated, that can lead to complications.

(Pharmacist, PH001)

Motivation to address issues of access was particularly evident among those pharmacists from rural and regional areas, where general practitioner workforce shortages are perceived to be more pronounced. This needs to be interpreted in the context of the relatively few pharmacists who participated in the trial from such areas. A pharmacist from a medium-sized rural town (MMM4) said they put aside the financial viewpoint, explaining their participation as an opportunity to do the right thing for the community.

If you look at it purely at a financial standpoint, is this a service worth running for the money? Maybe, but we all jumped after it purely for the opportunity and it meant the right thing to do for patients in the community.

(Pharmacist, PH005)

While the perception that the service could help to solve a community problem was a motivator for pharmacy participation, some pharmacists, conversely, were demotivated by the limited discretionary options available in the protocol, since they felt at times frustrated in their attempts to serve the community. This is discussed in 'Tick-box approach and discretionary options' section.

The wider geographic distribution of pharmacies relative to general practitioners was seen as a relevant factor in addressing health system challenges. While there were few pharmacists participating from rural, regional, and remote areas, those interviewed who were from these contexts felt that the service provision role of pharmacists was greater in these areas. They attributed this to pharmacists' greater accessibility to the community than general practitioners, noting that pharmacists were regularly the first port of call for many people with a health concern in rural and regional areas. The UTI service through community pharmacy was seen as acknowledging this role, and providing another option for care needs to be met.

I think community pharmacists in regional and rural towns, I think, play a bigger role. Like we tend to be public figures, for better or worse. But I worked for a long time in Canberra and there's still really high levels of trust and things, as a pharmacist in a capital city. But, yeah, it's a little

bit next level in a country town. And I think largely because we are accessible ... People can walk in and just see you. Walk in and start having a conversation with you.

(Pharmacist, PH005)

Being a pharmacist for over a decade, the amount of people that come through our doors wanting advice on, 'I've got x, y and z symptom, what should I do?' It's good now that I have an option to help try and treat 70% of those people as opposed to having to refer 100% of them to the doctors.

(Pharmacist, PH006)

Noting that there was little or no monetary benefit to UTI service delivery for the participating pharmacists who were not business owners or profit sharers, one PCF explained the variation in participation by pharmacists as stemming from pharmacists having differing views of the future of the profession and aspirations for their current role.

… it comes down to what the pharmacist believes in terms of the trajectory of the profession. So if they believe that, you know, scope of practice and service-based pharmacy is the future of pharmacy, then they're definitely more likely to deliver consults … it's kind of like that internal incentive for them to have that professional satisfaction to go, 'look, I can do more. I can do more for my community. Why wouldn't I do it?'

... whereas others that are like, 'well, where's the benefit to me, because the money's going to the pharmacy owner, to the pharmacy? I don't see any remuneration. I'm not getting any commission for doing additional services … like I'm not getting paid more to do this, so why should I do it?' ... so, they weren't doing the training because the owner wasn't paying for it. They didn't want to pay out of their own pocket.

(PCF, S002)

Reputation in the community and among peers, was expressed as a motivator for pharmacist participation. Formal recognition included awards within their group and those of the peak body. Implicit to this view was the notion that delivering services to people who needed them was the right thing to do – and this was promoted as such by the profession.

If you're doing the right thing, people recognise you for that. They might talk about it around town. You could win pharmacy of the year, you know all of those kinds of things.

(Pharmacy Owner, PH013).

Training, capability, workload and resources for implementation

Training, systems and structures of support available to pharmacists as part of the trial were positively viewed, and pharmacists felt they had adequate technical and implementation capability to deliver the service.

I actually quite like the way that it's being delivered. All of the resources and everything that we've been given. I think we have all the resources we need to be able to do this successfully.

(Pharmacist, PH011)

The training was great. I was really impressed with the training I did through PSA, I believe. The actual process of conducting the interview and the questionnaires through MedAdvisor® again is fantastic. Having the patient being able to scan the QR and go through the consent form, that way again is brilliant. I guess the process itself, I can't fault.

(Pharmacist, PH005)

Lack of time and cost were cited as barriers for some pharmacists in completing the training for UTI service delivery. For some, training time and costs were sponsored by the pharmacy or peak body, whereas for others, training costs needed to be absorbed by the individual. This may have influenced the uptake of the training among some staff within participating pharmacies.

It all depends on how things are on the floor as to whether we can come up and do the training off the floor, because we're a very busy pharmacy. So, some people completed it straight away, some people even did it at home, but most of us had some allocated time at work to do it here. But watching all the videos and doing the training, it, it probably took a couple of hours total for each person.

(Pharmacist, PH001)

Business owners and pharmacists assessed UTI service requirements against their ability to deliver what was needed. Where the service requirements were found to be unfeasible, owners made modifications to the workflow or staffing to enable service requirements to be met.

A key constraint was the need for pharmacists to be 'off the floor' for the lengthy consultation required by the UTI service – this was a particular issue for small pharmacies with only one or two pharmacists, and during quieter periods (e.g., in the evenings), when only one pharmacist was typically rostered. Participating pharmacies found 'work arounds' to enable them to meet trial requirements – such as interrupting the UTI consults intermittently to attend to customers on the shop floor or meet dispensing requirements. Alternatively, some got support from retail or dispensing staff to perform rapid assessments on eligibility of potential participants prior to their starting a pharmacist consultation, helping to reduce the length of the consultation. Others rostered additional pharmacists to enable them to deliver the service after hours, when they felt it was most needed.

For the most part, we've been able to streamline it quite well where we've trained our dispensary techs to be able to help identify patients who will be worthy of the service. So that helps to minimise time wasted sitting down with a pharmacist for 10 or 15 minutes, only to realise that they're not eligible in the first place … they've already received their validation code, and we know for a fact that the patient will be eligible for the service.

(Pharmacist, PH006)

At the beginning of the trial, some pharmacies had to turn participants away if there were not enough pharmacists available during busy periods.

We didn't want to compromise our ability to deliver this program because that's one of our core values as an extended-trade pharmacy. So, it was a significant financial impost and work–life balance impost to have to change everybody's roster to roster a second registered pharmacist on … It hasn't been a financially viable decision for us, but it has been a community viable purpose success.

(Pharmacy Owner, PH011)

This pharmacist noted that the reason the UTI service was not a drain on resources (there was no access to PBS through the trial) was that they could charge for the medicines dispensed. Setting a higher cost for these medicines was seen by some as a useful way to help bridge the cost. Others saw the trial (and other professional service offerings) as a way to absorb residual spare workforce capacity following a reduction in need for other services such as for COVID-19 vaccinations.

We did have quite a lot of redundancy coming out of the COVID vaccination. So, we had had a lot of extra man-hours in pharmacies that were almost vaccinating back to back, which once that settled down a little bit, then we were thinking, well, this is great because we can redirect them into getting these programs up and running ...

(Pharmacist, PH002).

Pharmacists felt that the trial had provided a robust structure to enable them to deliver the UTI service. However, some contrasted the complexity of the MedAdvisor® IT forms for UTI with those needed for vaccinations, which they felt were much simpler. The underlying concern was the amount of time used to go through the process in the MedAdvisor® IT program.

I just feel that it doesn't roll too well to get from this menu to the other menu to put in the information. So, it's good if it could just flow through easier, it'll be less time-consuming … so the ones for vaccination are a lot simpler, ….
(Pharmacist, PH010)

Theme 3: Participant Perceptions of a Good Service

Women's perceptions of the service were shaped by whether they were able to access antibiotics and had resolution of their symptoms following the consultation. Treatment outcomes influenced perceptions of value for money. Other key factors driving positive perceptions of the service were its convenience, consistency in service providers (fostering trust) and being treated with empathy and understanding. Women compared the care experienced through the UTI service to the care received from general practitioners – favourably appraising the pharmacy service where treatment was considered equivalent to or consistent with what they would have received from general practitioners, and less favourably appraising the service where they felt care offered by pharmacists differed from what they had expected from general practitioners.

Symptom resolution and overall value for money

Where service users were eligible and received the treatment they expected, and treatment was successful, they felt that the costs they paid were acceptable. Women interviewed (who were predominantly university educated, and consistent with overall service usage skewed to socioeconomically advantaged groups) were generally accustomed to paying out-of-pocket for primary care and could afford the fee charged for medicines. Overall, these women felt the service offered value for money, although we note that transition to business as usual will entail a greater cost to patients as NSW Health will no longer be paying the consultation fee, and perceptions of value for money may change in the future. It is also relevant to note that among women interviewed, the perception of value for money of the service was less positive when they had not been eligible for treatment or their symptoms did not resolve. These women incurred additional costs seeking care for the same health concern and therefore felt the service was not worthwhile. For example, one woman (P004) related that she did not have her symptoms resolved by the 3-day course of antibiotics provided under the trial protocol. She required visits to two additional general practitioners and estimated spending over $100 in costs for this episode of UTI, in addition to the costs charged for the antibiotic under the trial.

Women interviewed highlighted the lack of transparency around the costs, noting that they were not informed of costs prior to initiating the assessment or service delivery.

The cost probably wasn't told to me until I got to the counter. I didn't think it was a cost; I wasn't concerned about the cost. You know, there wasn't a tag, or something stated where I got to the counter. So, you sort of had to agree to it on an unknown cost basis.
(P004)

… I was just happy to pay anything that was reasonable, and she didn't mention anything during it. She didn't say if the consult would be free. I assumed that I'd just be paying for the antibiotic, but I wasn't sure, I hadn't seen anything about it and I'm in a fortunate enough position that I would've just been happy to pay if it was $50. But it was only about like $15. Like I said, it was just for the little bottle with the medication in it. Like she didn't charge for anything else, but I only knew that when I got to the counter to pay.
(P002)

Regarding a consultation fee, women compared the out-of-pocket costs for pharmacy consults, plus medications, with out-of-pocket costs for general practitioners. They suggested that looking to the future, there should be greater control over what could be charged, such as introduction of capped fees since there was a perceived risk that fees would spiral out of control. We note that the out-of-pocket cost to the patient of the service in other national pilots range from $50–$75.

I think it's very reasonable to have it at that $20 or $30. The only trouble is that it starts off $20 or $30 and then, a few years' time, it's $50, $100. So, I think it would be good if that was capped. Or it's a bit like general practitioners,

there's the price that the Commonwealth pays, but the doctor can charge above that. So, I think it would be good to be controlled.
(P008)

Other women questioned whether first-line treatment for uUTIs warranted a consultation fee by either profession, considering that following a first-line treatment protocol was not complex nor did they believe that it required a great depth of knowledge.

Maybe it's just personal, but it would feel weird paying a pharmacist like $30 just to ask a couple of questions.
(P006)

Some felt that it was easier for them to justify paying general practitioners for the UTI service rather than pharmacists if other issues could be discussed in the same visit, whereas pharmacist scope of practice being more limited did not have that advantage.

In assessing value for money, women also factored in the convenience of obtaining treatment from a pharmacist who was perceived to be more accessible than general practitioners (discussed below).

From pharmacist interviews, it was reported that some women had turned down the service because of cost, instead seeking care at bulk-billed general practices or emergency departments. This is discussed in the 'Equity considerations' section.

Timeliness and convenience

Women interviewed appreciated the timeliness and convenience of the UTI service. An early-stage UTI was regarded as an urgent nuisance, not a 'real' health issue that required a general practitioner's help. They believed that through earlier intervention and immediate access to antibiotics, a general practitioner visit could be avoided.

It was much quicker, so that helps everyone because I'm not – not wasting, but like, it's not like I'm taking up time of a doctor or clinic for them to then just give me the same antibiotic that these pharmacists could give me over the counter. It was quicker so I could relieve my symptoms earlier.
(P002)

There was also a view that a community setting was more appropriate for care. One woman described her greater comfort in the more relaxed setting of the pharmacy.

Sometimes it's a bit of an uncomfortable setting to be in a doctor clinic like that. Where at this pharmacy, it's like a [retail pharmacy chain] and a pharmacy. So, it's kind of like, it's just much more relaxed and it was yeah, a bit nicer to be in and I was only in there for, I don't know, 15 minutes.

Convenience was described in terms of the ability to walk in rather than needing to lock in an appointment, to receive all necessary care at a single location rather than having to go from one place to another, and to access care outside of general practitioners' business hours. These factors together contributed to a favourable appraisal of value for money. We note that the ability to 'walk in' to the service cannot be always guaranteed in all places or times, especially in areas where there is low coverage and/or limited availability of trained staff.

No, for the convenience of being able to walk in and do the consult and get the prescription and then fill the prescription all in the same place versus having to go to multiple places, absolutely I would pay that. It's still cheaper than a general practitioner and you're not having to go to two separate locations, particularly for needing care on weekends when general practitioners aren't trading.
(P010)

Trust, privacy and respect

Having a consistent and knowledgeable care provider, having a private, uninterrupted consultation, and being met with empathy and understanding were key components in women's appraisal of a good service.

For some women, the pharmacist was their consistent provider and was viewed by them as being as good as, or equivalent to, general practitioners in relation to first-line treatment for UTIs. For others, their regular general practitioner was a consistent provider, and their encounters with pharmacists were more erratic.

> *I even trust the judgement of the general practitioner and I think as well, because I go to a regular general practitioner, I know the general practitioner. So, it's a trust basis. Whereas pharmacies, I tend to go [to] the ones that just happen to be nearby or that are convenient, which changes time to time … So, it's not that rapport or relationship built up in the same way.*
> (P004)

Women considered the educational level of general practitioners versus pharmacists and their relative skill in different areas when considering whether they trusted the service. The authority vested in pharmacists to prescribe for UTIs (i.e., what they were allowed to do) was a key factor in participant trust.

> *Pharmacists, to me, have a better understanding of drugs than doctors sometimes. But the question is whether they have the medical knowledge to know the drugs; you know, to prescribe. And so, if it's something that they [are able] to prescribe, I'd be happy to take it from them.*
> (P005)

Women's expectations about the kind of encounter to be provided at the pharmacy varied and shaped perceptions of the service. Some women expected a 'general practitioner-like' consultation and were disappointed in the instances where – despite it being a trial requirement – a private room was not used, where the pharmacist was attending to other things during the consult, where the pharmacist did not seem as confident as a doctor, where they deemed that the pharmacist was underprepared, or where the probable UTI diagnosis was not discussed with them. Other women had expectations that the UTI service was an extension for dispensing, and while they appreciated and desired privacy, did not see this as an essential component of the service, noting that dispensing and discussions about medications and treatment usually occurs at the counter and are not always private.

> *It would be good if they had private areas to interview patients. I wasn't that worried about people knowing if I had a urinary tract infection. There wasn't anyone around when I was there. But if it had been busy, depending on who it was, some people might not be comfortable speaking … It's the same as dispensing [at] any pharmacy, isn't it? It's not really private that they're giving you something.*
> (P008)

Some women were prepared to forgo privacy for the convenience of getting needed treatment.

> *I've got to say I felt a bit embarrassed, I was standing in a public place saying, 'I've got a urinary tract infection.' And having to describe my symptoms, sort of thing, and I would have appreciated if there had been a booth, or something a little bit more private, so that was my – but can I tell you, if you've got a UTI, it is extremely good you can get the antibiotics really quickly, and get it sorted rather than go through all the uncomfortableness.*
> (P005)

For others, lack of privacy, and concerns over the set-up and accuracy of the consultation eroded trust in the service. The value attached to privacy may have related to expectations that the pharmacist was offering a substitute general practitioner service – where expectations were high, women were disappointed.

> *And then they didn't come, and I had to get back to work. So, I popped my head out and said, 'Is there somebody coming?' And the pharmacist who was standing behind the public counter at his computer said, 'You have to come here. I have to do it on this computer …' So, I had to go and stand next to him at the public counter … So I was like, this is really weird being asked personal questions in a public*

space … he clearly wasn't well trained. So firstly, I could see the form, but he was skipping questions. So, on the question of 'are you Aboriginal?', he ticked no, but he didn't ask me the question ... And then there were other questions he skipped too ... he just ticked no. He didn't ask me ...

(P007)

While this woman was provided with the antibiotic, her symptoms did not resolve and, overall, she did not have a high regard for the service, considering that in future she would seek care from her general practitioner.

Where women found that pharmacists were able to relate to them and sensed their concern, they regarded the service as positive. Some women described pharmacists as being easier to relate to compared to general practitioners, since they had more time, were closer to community and had an appreciation of how important it was to access timely care.

She was younger. I felt like she just understood what was going on ... she would understand that other people would find that access a lot more helpful. So, I just think she was very understanding. It was all very quick ... I think she was just very understanding, and she wanted to do the best thing for me rather than this other, maybe older, lady doctor that was just doing her job as such.

(P002)

While not all women experienced empathy from the pharmacist, the benefits of access to the service were seen to outweigh this.

I think he thought he was quite clever, but he just had very little – he made me feel, he wanted me to be grateful to him, and I've got to say, and you can write this down, I just wanted to punch him in the nose, but I shut up because I wanted the antibiotics ... I tell you I would take that again, rather than go for 24 hours, go until the next day without antibiotics.

(P011)

Given the choice of no treatment because there are no doctors, and going to a pharmacist, I would be going to a pharmacist.

(P011)

Appropriateness of treatment protocol

Patients' perceptions of whether the treatment provided to them was appropriate influenced their perceptions of the service quality. Appropriateness of the eligibility criteria, of the dosage and duration of antibiotics, of the process for urine specimen collection and pathology testing, and of care integration with general practitioners were key factors in their determination of perceived appropriateness, and of service quality.

Disappointment about ineligibility for the service appeared to be related to an expectation that treatment would be provided following the consult, as is the expectation when seeing a doctor. Women who were ineligible for the service and who knew they would not be able to get a timely general practitioner appointment (e.g., women in regional areas), were frustrated at being referred to a general practitioner, when they (and the pharmacist) knew they would be unable to obtain a timely appointment.

Service eligibility criteria were not clear to women at the start, and women interviewed felt that this led to wasted time in the event they were ineligible – they asserted that they could make their own decisions about where to seek care and would have liked to have the information ahead of the consult.

I wasn't able to get the medication as I'd had a previous UTI. That question should have been asked at the beginning, so we don't get all the way through the process only to find out we don't qualify. That was disheartening as I was really needing that medication to ease my pain and discomfort.

(Email 62)

Sometimes pharmacists took on the role of helping to secure general practitioner appointments for ineligible women (although not a formal part of the model of care), and this contributed to positive perceptions of the service.

I found the pharmacy service very good and convenient; however, I could not access the antibiotics direct from the pharmacy as I take immunosuppressants for another condition. The pharmacist was very helpful and helped me to secure a general practitioner appointment that day and sent the initial screening information to the general practitioner. If there was an online self-screening before booking with the pharmacist, this would have informed me that I would need to see my general practitioner, and I would have not felt I wasted the pharmacist's time.

(Email 59)

When asked about the downsides of the UTI service, some women mentioned that the type and dosage of antibiotics received differed from what they previously received from their general practitioner. This raised concerns about the perceived effectiveness of a different treatment regimen to what they would have received through general practitioner care.

... when I got it prescribed at a general practitioner, I have like two or three a day for a week and they were big. And the ones that I got at the pharmacist were just three little ones that you have in the night before you go to sleep. So, it was obviously different. Because she did say, oh this would be the same thing that the doctor would give you. But the doctor did give me something different, well, last time I was there.

(P002)

... but I think I only got three tablets. Whereas if I've been to a general practitioner I've usually got like a week's treatment or something. So, I don't know if it was just a different antibiotic to what I've got in the past. But I noticed my symptoms didn't really go away as much as I thought they would.

(P006)

Generally, women whose symptoms resolved appeared to be satisfied with the antibiotics received, whereas those whose symptoms did not resolve did not typically appreciate that the first-line treatment with antibiotics was good practice – and had expectations that different or stronger antibiotics should have been given to them.

Although not a requirement of the trial procedures, some women believed that the service offered by pharmacies should have included results of a urine test prior to antibiotics being prescribed as they believed this was the standard used by general practitioners. Since pharmacists do not have access to MBS, the out-of-pocket costs to provide this would have been significant. However, for these women, when a urine test was not sent for testing, it undermined these women's perceptions of the quality of the service.

Always. They [the general practitioners] give you the specimen jar. You come back into the room. They stick the indicator strip in. They look at it. Sometimes it's obviously positive. Sometimes it's not sure. We'll send it off to the lab. Sometimes even if it's obviously positive, they still send it to the lab because they want to know what the bacteria is or the whatever that's lit up on the thing. I think if the protein lights up on the indicator strip, they'll send it off because they want to look at how much protein. Like do you have a kidney issue or whatever? So, the general practitioners tend to definitely do the strip and often send it off to the lab as well ... I've seen multiple general practitioners at the same practice over the many years. And they all do the same thing at that practice.

(P006)

In contrast, being able to receive antibiotics without testing and pathology was viewed as a positive aspect of the service by others. This may have been related to a priori expectations by participants of what the encounter should be. Where participants' expectations were simply for an antibiotic that they believed they needed, they considered that no testing and pathology was appropriate and advantageous as this was efficient and resulted in timely treatment.

Women who were ineligible for the service, or whose symptoms did not resolve with the first-line treatment, perceived that a good service would include better integration between pharmacy and local general practitioners. Care integration for them meant that

the pharmacist would be able to help them to access timely general practitioner appointments if ineligible or if symptoms did not resolve with the first-line treatment. They also saw care integration as being contingent on their general practitioners being well-informed about the UTI service treatment protocol and supportive of the pathway.

While some pharmacists obtained priority general practitioner appointments for ineligible women, the issue of facilitating follow-up by general practitioners when first-line treatment was ineffective seemed to be a harder ask. The role of the pharmacist in 'wayfinding' for follow-up care was limited.

> *... I thought it had initially gone away but now I have it back worse than ever with blood in my urine. All the medical centres have a 10 new patients a day policy or it now cost nearly $100 to see a doctor. What am I meant to do? I'm about to go to the emergency room.*
>
> (Email 52)

> *...I ended up with a kidney infection. Leading to stronger and different antibiotics after going to hospital then following up with my general practitioner.*
>
> (Email 50)

Most pharmacists interviewed related positive experiences of support from local general practitioners – see section 'Relationships and communication with general practitioners'. However, such support was not uniform-for example as explained in the quotation below, one of the patients interviewed believed that the general practitioner she saw after receiving the pharmacy service, appeared not to agree with the trial protocol.

> *So, I went to a general practitioner there; they prescribed the same medication. But their comment was that 3 days wasn't long enough course. That general practitioner ... gave me a 7-day dose of the same antibiotics as the pharmacist. And I took that for 7 days that didn't relieve my symptoms either, by which point I was in Sydney – at that time. And then I saw my local general practitioner … their comment was that the Newcastle general practitioner shouldn't have prescribed that same antibiotic if I hadn't noticed any changes in the symptoms … then I had to provide another sample ... the labs got sent through eventually to my Sydney general practitioner which was a long process because the Newcastle general practitioner wouldn't release their results … basically the antibiotics I had been taking for 10 days previously was ineffective against that strain. So, I had to take entirely different antibiotic.*
>
> (P004)

Theme 4: Pharmacist Perspectives on Service Quality

The treatment protocol was perceived by some pharmacists as enabling their delivery of a quality service through minimising risk, whereas for others, one or more elements of the protocol were believed to be constraining their delivery of patient-centred care that was responsive to patients' past history with medications, and to the local context.

As pharmacists typically do not charge community members for advice, some felt that charging for consults if they could not deliver a treatment was inappropriate. While pharmacists in NSW were renumerated by NSW Health for consultation, those in the ACT were not renumerated, but set their own fees. There seemed to be tension for some pharmacists between delivering a one-to-one uninterrupted consultation in clinic (expectations expressed by patients that there would be uninterrupted similar to a typical general practitioner consult) and competing demands of managing the shop floor and dispensing responsibilities. Pharmacists needed to prioritise delivery of professional services as a valid part of their role and felt that merited protected time.

Tick-box approach and discretionary options

In the context of limited availability of timely general practitioner appointments, some pharmacists expressed frustration that under the trial protocol they were unable to provide antibiotics to women whom they felt did not seek help sufficiently early and so were ineligible for the trial.

> *Quite often they don't go for help until they get to the end degree and then there's a person there say, 'Sorry, you have to go to the doctor.' 'My doctor can't see me for 2 weeks' … So then*

you are pushed to giving them the painkiller and the likes of Cranberry and Ural® … To open it up a bit more, they [the trial designers] have to trust our judgement. When they [the patients] go to the doctor they just state symptom. What difference does it make? They still have to wait to see the doctor. Meanwhile, at least they're getting a treatment.

(Pharmacist, PH010)

... the risk is obviously that there is a more serious thing that we don't see. So, someone has a medical misadventure or there's a more insidious cause for the symptoms. But I do look at that as being a very minimal risk because often the first port of call from the doctor is to treat with an antibiotic and investigate later. So, I don't see that as being a huge risk, but it still is there.

(Pharmacist, PH002)

Some pharmacists perceived that they were the main providers of continuity of care in the instances where women did not have regular general practitioners, or who used multiple general practitioners. A care provider's prior knowledge of the participant was, or should be, they felt, an important factor in treatment decisions, rather than being solely determined by their profession. This was reflected, for example, where a participant received a prescription for a drug previously ineffective for this person – and the pharmacist believed if they had the discretion to recommend a more effective drug, the care pathway would have been more efficient and effective.

So, with the UTI trial, you know how there's the first-line treatment and second and third, but then I remember there was one situation where a patient didn't meet that criteria because they had recurrent UTIs. And they previously were, because they had it too frequently. But trimethoprim usually worked with them. But then because they had it too frequently, we couldn't supply the antibiotic. So, then she just went to a normal general practitioner, like a random general practitioner, told them the exact same thing, but the doctor just prescribed cephalexin which is like the third-line treatment. And then they didn't even do a urine culture or anything like that. So, then it just made me feel very upset … a couple of days later she came back in for another script for trimethoprim. So, I just felt like if I had given her the first thing initially, but then we had that protocol, so I couldn't … it would have just saved her that visit and also taking a different antibiotic temporarily for no reason … And then she was just like, 'Yeah … I should have just been on that initially.'

(Pharmacist, PH012)

While the treatment protocol was felt to be too rigid by some, others, including business owners with oversight of a number of pharmacists in their team, felt that the strict criteria were useful to minimise risk, and to ensure that the pharmacy team kept within scope. A pharmacist from a large rural town (MMM3 category), who managed two pharmacies and employed nine pharmacists, perceived that the eligibility criteria specified in the protocol were appropriate.

The criteria are quite restrictive, and I see that as a good thing. So, anyone who has anything that could possibly be a complication – I mean it is uncomplicated UTIs and that's all we're treating. So no, we definitely ship people who have any of the more complex issues on to general practitioners…

(Pharmacist, PH007)

Fee for service – not for advice

Under the NSW trial, pharmacists were paid by NSW Health for delivering the consult regardless of the outcome. Following the trial, pharmacists could set their own consult fees as deemed appropriate by them. In the ACT, pharmacists did not receive a fee but were able to charge patients for the consultation.

A pharmacist from the ACT described the receipt of a consult fee regardless of treatment provision as an 'industry shift' and felt that a consult charge without direct service provision went against the usual 'for free' triage service that has traditionally been provided by community pharmacists. They perceived an issue that community members traditionally did not expect to pay for advice from a pharmacist. The pharmacist's solution, also described by others, was not to charge women seeking care for UTI symptoms, unless they were treatment eligible.

Pharmacists provide triage and tell people where to go when they need to go anyway for free. So, there is a workplace shift, an industry shift here. And maybe you come in historically with an uncomplicated early stage UTI and I'm just going to give you lifestyle advice anyway, we don't charge for that. So, the ACT data that goes through MedAdvisor® really, we're only charging for the people we're going to give the antibiotics to.

(Pharmacist, PH006)

Charging patients for consults who did not receive a treatment was considered by some pharmacists to be inappropriate. This applied to the ACT pharmacies only.

Several pharmacists provided examples of disgruntled patients who spent 20 minutes completing trial paperwork and initiating the consultation to then be told they were ineligible and would need to see a doctor to receive treatment. Experiences of a similar nature were also sent by patients to the UTI trial support email. Pharmacists recognised that these patients would likely face further costs at the next stage in seeking care and so felt there was an implicit ethical issue here.

Someone might be upset because I charged them for 30 minutes and I just gave them a referral where they're going to have to pay another $120 to see someone else.

(Pharmacist, PH013)

From interviews some pharmacies initiated a system of pre-screening by retail or other staff, only sending those likely to be eligible for a formal pharmacist consultation. It is only those who were seen by the pharmacist who were entered into the MedAdvisor® IT program and for whom a consult fee was received from NSW Health, in the case of NSW participating pharmacies. Pharmacists felt the main financial incentive to provide the service was charging for the medications and from any additional retail sales – the consult fee was not deemed worth the risk of annoying their regular clientele.

I find she's not happy to do all that paperwork and then by the end of it she won't be taking any antibiotics. So, I find that just it's linked with that service that you have to provide that antibiotic.

(Principal Pharmacist, PH009)

Uninterrupted consults and workflow

Pharmacists needed to prioritise delivery of professional services as a valid part of their role, and that merited protected time. One pharmacist initially believed that patients would be happy to wait with an expectation of getting a treatment, but found in practice that neither they, nor the women undergoing the consultation, appreciated the back and forth and interruptions due to the competing demands of dispensing, shop floor management and professional service consults.

So, first consult took me maybe half an hour going back and forth because I always tell my staff that if I'm in a clinic room and there's someone waiting on a script, just to knock on the door, and then if I can be interrupted, that'll be fine to go up and check the scripts and then I get back in. Because usually [the] patient who you [are] consulting is more than happy to wait for you because you're doing them a service and then they know that you might eventually get a treatment and they're happy to wait for you. And I didn't like it. I felt like I'm going back and forth too much.

(Pharmacist, P007)

Delivering a quality service thus required re-organising pharmacy workflow. In practice, pharmacy-led strategies entailed upskilling retail staff to pre-screen using the most common reasons for ineligibility, then directing women to the QR code, with the pharmacist only engaging with the participant once she had completed the QR code forms, thus streamlining the use of pharmacist time on the consultation itself.

We had a couple of cranky customers, and we thought the whole point of this was to make them happy. So yeah, we thought, 'how can we make it less … to screen them?' So we have

staff screening them obviously, because often there's non-pharmacists for that initial port of call … Then we had the QR code thing, I started having a process in place, which is, I found, very very effective where people while they're waiting, like the patient waiting for the UTI consult, they can scan the QR code on their phone, fill up the consent and read it and everything. When they're done, they let me know and then I take them to the room, go through the questionnaire from the PlusOne app on MedAdvisor® and then go from there.

(Pharmacist, PH007)

Theme 5: Integration with Health System Infrastructure and Information Systems

Technical elements – MedAdvisor® and general practitioner letters

Pharmacists interviewed appreciated the integration of the UTI service eligibility considerations and workflow into the MedAdvisor® IT program, a commonly used digital platform provider already used for other categories of professional service delivery, such as vaccinations. Most pharmacists interviewed believed it was not necessary to change anything about the MedAdvisor® UTI component and found it helpful in guiding the service delivery decisions.

I believe the framework through PlusOne on MedAdvisor® works well. It's a good little checklist to make sure that pharmacists aren't missing any important questions, as they're going through their differential diagnosis and product recommendation.

(Principal Pharmacist, PH006)

The MedAdvisor® IT program included a pro-forma general practitioner notification letter that could be sent to general practitioners. However, pharmacists relayed that it was at times challenging to know where to send the letter since some women – particularly younger women using the service – did not always have a regular general practitioner or did not know their names (e.g., they may attend a general practice, but would see any general practitioner who was available, or not have a regular general practitioner or general practice). Some pharmacists printed out the letters and provided them to patients to take to whichever general practitioner they would see next, with some inaccurately believing that telehealth doctors could not provide MBS pathology to patients for UTI.

I give her a printout of the general practitioner letter. I said to her just to keep it at her medical file at home … A lot of patients don't know the name of their doctors sometimes, so we have to google search and then search the surgery and then try to find out, because a lot of, especially young female, I find they don't have a particular doctor they go to especially if they don't have, like, health conditions ... Sometimes I do write 'dear doctor's team' at blah, blah, blah surgery. And then that patient can take that with her and then next consult with a doctor. And, with that lady as well today, for example, the urine testing. So, she won't be able to take that urine sample before she starts the antibiotic because ... she won't be finding any doctor to write her a referral [to the pathology laboratory] She says she need[s] to go to hospital then. So, I said to her like, 'don't worry about it, just start the antibiotic so you can have some sort of relief and then go to hospital in 2 days if symptoms not improved' so then she can do it there. Sometimes you just need to think outside the box a little bit.

(Pharmacist, PH009)

Some women interviewed who required follow-up care with a general practitioner indicated that the general practitioner did not seem to know what the trial was about or did not appear to agree with it. Some also perceived that the general practitioner did not appear interested in reading the letter.

INTERVIEWER: And did you get a letter from the pharmacy to take to your general practitioner as well?
P001: Yeah, yeah, I gave it [the letter] to him but he didn't really read it.

(P001)

Pharmacists expressed a desire for two-way communication about patient care, feeling that this should be supported by a technical solution. One

cited a previous example of a communication pathway that had worked well in another setting.

> *I don't know how long ... ago this was probably like 15 years ago. We used to use like a messaging service between. I used to work in a rural pharmacy, and we had a private messaging service between us and the general practitioners, and we used to send things backwards and forwards like all the ... I do think that on a broader scale, something along that line would be beneficial for patient care and whether that is so we provide a service, and it's uploaded to My Health Record so everyone can see it, or we provide the service and it's sent by, you know, private messaging to the general practice. But the general practice has to acknowledge that, it can't just sit there.*
>
> (Pharmacist, PH013)

Pathology testing and follow-up for those not improving

Patients whose symptoms did not improve or worsened had varied understandings of the process they needed to follow, particularly in regard to pathology testing. Conversely, the pharmacists interviewed believed that their explanations of the process were clear.

Patients' misunderstandings about the pathology testing process appeared to be related to unclear expectations by women regarding the role of the pharmacist in the trial, whether as a 'general practitioner substitute' or as 'extended dispensing'. Some women wanted the ability to take a specimen directly to the local pathology centre, or have it sent directly to the laboratory, as this is the process they would expect from the general practitioner. There were also barriers for women seeking follow-up. Barriers arose when women took their pre-treatment urine sample to the general practitioner, as per the trial protocol, seeking a referral to pathology, but found that general practitioners were not receptive to providing one, appearing unaware of or not in support of this aspect of the trial protocol.

> *I tried to explain that I was meant to bring it [the pre-treatment urine sample] in if I needed to go see the general practitioner again. Like that was what I was instructed to do by the pharmacy. He didn't seem to be aware of that, and he was like, no, no, no, you need to do another sample or something. So that was the downside.*
>
> (P001)

Training resources

Pharmacists felt that post trial, ongoing UTI service delivery could be adequately supported through existing systems (i.e., support provided by professional associations) and that they do not require separate ongoing support for this particular program. Pharmacists' perceptions of the training are discussed in the 'Training, capability, workload and resources for implementation' section.

Theme 6: Integration with Health System Values, Culture and Relationships

Relationships and communication with general practitioners

There was a perception by some pharmacists that the general practitioners in their area simply could not provide timely appointments to all who needed them, even patients who were regular at the practice, and this situation led to the local practice managers and general practitioners being in support of the trial.

> *When a patient calls up the doctor for an appointment – it might be a week, or a 2-week wait to see someone – the doctors appreciate that's far too long for an infection that needs prompt treatment. So, they're happy with the service.*
>
> (Principal Pharmacist, PH006)

Several pharmacists from regional and rural towns noted they had received participant referrals from general practices for the UTI service. One of these pharmacies noted that as a matter of courtesy, he always let the general practitioners know when a new service started (e.g., COVID-19 and flu vaccines), and that most patients coming to the pharmacy for the UTI service had been referred from the practice staff. These suggestions, that patients try the pharmacy, were typically made by the reception or booking staff.

Probably 75% of our people who've come in for the trial have been sent there by the general practitioner surgery because they go to the doctor, say, 'Oh, I've got UTI, I need to see a doctor.' They say, 'We haven't got any appointments, but have you tried the pharmacy? They're running a trial.' So, while I haven't heard anything directly from the general practitioners, I think it's been largely positive from them.

(Pharmacist, PH005)

So, they usually have to call the practice to get in the … And they usually ask the person just to see whether, if there is the emergency, and they can arrange the quicker appointment, or they're just going to be worked within their books. So, they usually just say, 'Look, for this one, you can just go to the pharmacy and see the pharmacist, they can help.' So … yeah, the general practitioners, they are sending us a few people as well.

(Pharmacist, PH008)

Support for the trial was also evident in metropolitan areas. One pharmacist in a metropolitan area, in which there were four to five general practices in the local area, had anticipated there would be resistance from the local general practitioners but had not experienced this.

I actually thought there would be a lot of backlash from the local general practitioners, but not one of them has.

(Pharmacist, PH010)

Other pharmacists expressed that they had feared participating in the trial as they did not want to spoil relationships with their general practitioner colleagues. While most had received no feedback or only positive feedback from their general practitioner colleagues, one pharmacist received a complaint from a local general practice at the initiation of the trial.

There's a doctor in town who complained about it first and he said, 'Oh, you're going to start taking my patients off me, or you're going to prescribe UTI antibiotics and stuff.' And then his receptionist basically when his patient calling to book an appointment and then tell the receptionist, 'I think I have a UTI infection, can you please book us for the doctor?' And he's fully booked. So, she and reception started preparing his patients to see me.

(Principal Pharmacist, PH009)

Although not a trial requirement, some pharmacies have established relationships with local general practices to facilitate urgent appointments for ineligible women.

So, we've made sort of an agreement that if we have anyone that needs immediate attention, that we can't provide the service for in the pharmacy, if we can send them straight over there [to the general practice] and they'll look after them.

(Pharmacist, PH001)

Challenges in the relationship and communication between pharmacists and general practitioners were most evident in relation to women whose symptoms did not resolve with the first-line treatment. As described earlier, other patients who presented to general practitioners with continuing symptoms following first line treatment had found general practitioners to be unreceptive to the urine sample, or critical of the duration of antibiotics dispensed under the trial protocol.

One participant interviewed suggested there needed to be a means to fast-track general practitioner appointments (and have a seamless care experience) in cases where first-line treatment was ineffective.

If the trial gets administered now into the ACT Health system, like doctors being fully aware of it and even if there's like, I don't know, certain general practitioners around that are connected to certain pharmacies in some way. If you need to go, if you need to have an appointment because the drugs haven't worked, and you need to make an appointment quite soon. If there are certain partner general practitioners that can make sure they have availabilities ...

(P001)

Wayfinding

Pharmacists went beyond trial requirements by playing a wayfinding role in relation to accessing the required level of care for ineligible patients. A pharmacist from a small coastal town described helping regular clients and women visiting the town on holidays to access local general practitioners.

> *I have a 94 [-year-old] lady the other day, like, she's my patient and she said, 'I heard you can prescribe me something.' I said, 'Yeah, I wish, but it's just a trial and I'm restricted for the number of patients I can serve.' So, I just have to explain to her like that, so she doesn't feel like she's old … She didn't understand that online [general practitioner telehealth] thing. So, I said to her, come to the pharmacy, see me, she sat down, I asked my assistant to give the free general practitioner service a call. She booked her an appointment within 10 minutes and then she did the consult while she's in the pharmacy. I ensured that she got something …*
>
> (Pharmacist, PH009)

Other pharmacists related phoning several clinics on behalf of ineligible patients, to help them to secure same-day or next-day appointments or directing them to other services such as HealthDirect or Mid North Coast Virtual Care.

Valid way to deliver and receive primary care, rather than option of last resort

There is some evidence of changed perceptions about professional service delivery by pharmacy from being an option of last resort to a valid way to receive primary care. This was apparent from how pharmacists viewed their role and was also expressed by some patients interviewed. The experience of service delivery by pharmacists during the COVID-19 response has enabled this shift, instilling confidence and changing norms about how pharmacists viewed their role and how the public perceived pharmacists' capabilities.

> *Certainly, I think, like, individual pharmacists' [now] have a bit more confidence that they can deliver stuff like this … Pre-COVID, I'd personally given probably 20 or 30 flu vaccines over the preceding 2 or 3 years. During 2021, I gave a couple of hundred flu vaccines, and most pharmacists will be in the same boat. And so, I think that probably changed a lot of our viewpoints that we just dispense and check scripts to 'we can do lots of other things as well'.*
>
> (Pharmacist, PH005)

> *It starts the potential for the general public to see pharmacists as primary healthcare providers. I do think that there's a little bit of a mystery about what pharmacists can and can't do in a broader sense. So, I know that there are patients who really rely on their pharmacies, and they get a lot out of their pharmacies, but for a lot of the public, not to point a phrase, but we are a little ticket clipping. I think what it's done is when you can provide a real proper therapeutic intervention, particularly with respect to the UTIs, then that does give us a little bit more of that public perspective of being expertly trained and being able to handle these kinds of things. So, I think it hasn't been specifically towards the UTI, but I think that opens the door for future things.*
>
> (Pharmacist, PH002)

Pharmacists felt that accessibility, a key goal of primary health care, was something they could offer.

Cross-cutting Theme: Equity Considerations

Geography, trust and health literacy

The wide geographic distribution of pharmacies, and the provision and expectation of 'walk-in' care is potentially a strong enabler of equity of access. However, as indicated earlier, pharmacist participation in the trial tended to be mostly in the metropolitan areas. One pharmacy in a regional town noted the large geographic area that their clients travel from, alongside the participation of their pharmacy in outreach services (e.g., vaccinations) and felt increased scope of practice would benefit women whose access to care was limited by geographical location.

> *[We participate in] plug-in community services, which we usually do once a year or two ... Yeah, we go out of the pharmacy, again depending on the legislation, and we provide the services to the community because these communities are actually widespread, so sometimes a patient will be coming say, 30 kilometres. We will be the*

only pharmacy in their 30-kilometre radius ... Increased scope of the practice. Yes, that would definitely help then those people.

(Pharmacist, P008)

This pharmacist, whose pharmacy was located at the end of the shopping strip near a large Aboriginal community, felt that the utilisation of the UTI service in their pharmacy was representative of the population in the area. They described that their patients often did not seek help or information ahead of time via internet sources, and most had not heard about the trial. This experience differed from reports by women interviewed and by pharmacies in some other areas and may have been due to differences in health literacy, or other factors.

In some pharmacies, pharmacists perceived that women who were less well educated were not generally well represented among those seeking the UTI service. In seeking to explain why the majority of women using their service were, they felt, from a higher socio-economic status in their rural town, one pharmacist was of the view that women who are less health literate may be less inclined to trust the pharmacist for UTI consultation and care, preferring to see a general practitioner.

… we have another cohort that are poorly health literate, they have poor health outcomes. To get them across the line would be a little bit more difficult, they would have more trust in the general practitioner, and they would be happy to wait and go and see the general practitioner. Whereas a health-literate, educated woman who's busy, these are the types of things that really appeal to them.

(Pharmacist, PH007)

I mean for us, like the ones that we've probably done, are probably people who are organised enough to do it. They knew what they're after … They've already read somewhere about it because that's why they came here.

(Pharmacist, PH013)

Costs, PBS and subsidy integration, knowledge, and information

Under the trial and an important consideration for subsequent routine service delivery, pharmacists could not provide access to MBS investigations and pathology, and pharmacists could not provide concession rate PBS drug access. All drugs were private scripts. The NSW trial covered a consultation fee paid by NSW Health for NSW pharmacies. There was no cap placed on medication cost, and this continues at present in usual practice. If pharmacists charge a consultation fee, this will be an additional out-of-pocket for the patient. During the trial there was not a requirement for pharmacies to display cost information or have it publicly available. As indicated earlier, even the relatively well-educated and empowered service users raised concerns in interviews about lack of transparency of out-of-pocket costs, often not being aware of costs until payment at the till. It could be anticipated that women from equity groups – such as women of low socio-economic status, Aboriginal or Torres Strait Islander women, and women, for example, with intellectual disabilities or mental health concerns – may lack confidence to obtain information about costs, and either be put off future service use by the costs incurred or decline the service at the point when costs became apparent. Some pharmacists reported that, occasionally, women had declined the service because of costs, however, this was 'a small proportion' of patients.

Discussion

Summary of key findings

This trial of a pharmacy-delivered care model for women with suspected uUTI involved 17,313 eligible participants, comprising 18,143 care episodes. A total of 1,058 pharmacies participated in the trial with a high representation in metropolitan, large regional and small to medium town and few pharmacies participating in remote and very remote regions The most common age group was 46–65 years (38.2%).The majority of participants (71.8%) lived in metropolitan areas which is slightly lower than the NSW Census 2023–2024 estimate of 76.0%. Over half of all participants (52.8%) resided in areas in the top two quintiles of relative socio-economic advantage. For a total of 14,671 (81.6%) care episodes, participants completed the 7-day follow-up survey. For 79.4% of these care episodes, participants reported complete symptom resolution at day 7. For a further 17.9% of care episodes,

participants reported improved but not fully resolved symptoms. This symptom improvement rate is similar to that reported in the international literature, summarised in the introduction to this report [124, 125]. A similar 7-day symptom relief rate (87.6%) was also reported in the Queensland Urinary Tract Infection Pharmacy Pilot (UTIPP-Q), although follow-up rates were low in that study, and there is a high risk of reporting bias [85]. These symptom improvement rates are also similar to those reported in the wider primary care literature based on retrospective cohort studies. A retrospective cohort study in Singapore of 4,253 women (18–50 years) with uUTI found 75.1% were resolved [45]. Another retrospective cohort study of 865 adults attending an emergency department in Saudia Arabia reported symptom improvement rates of 89.5% [46].

Most participants indicated a positive experience with the service, reporting that they agreed or strongly agreed with seven statements related to service quality. The median cost estimated by participants for the whole service, inclusive of medication costs, was $20 (exclusive of pharmacy consult costs covered by NSW Health). For 85.0% of care episodes, participants reported that cost would not be a barrier to using the service again; for 9.7% of care episodes, participants considered it may be a barrier and for 5.4% of care episodes, participants indicated it would be a barrier.

In total, 7.3% of participants were recommended by pharmacists to see a general practitioner. Based on self-reported data, 14% of participants said they saw a general practitioner. Based on MBS data, the proportion seeing a general practitioner was higher than in the self-reported data – 10.5% and 12.4% saw a general practitioner within 2 days and within 3–6 days, respectively, following the initial pharmacy consult. Over the 28 days post pharmacy consult, 43.2% had a general practitioner consult – 25.1% had one consult, 11.6% had two consults, and 6.5% had more than two consults. Although the reasons for visits are not available, 48.8% and 39.9% of these encounters within 2 days and within 3–6 days of the initial pharmacy consult, respectively, were accompanied by a urine test sent to pathology, which suggests they were UTI related. This may be an under-estimate given not all UTI-related presentations may have resulted in a urine pathology specimen being sent. Overall, the level of general practitioner utilisation suggests reasonable continuity of care was available for people requiring further care when needed. However, the lack of a comparator group precludes making any comment on how these general practitioner utilisation rates compare with usual care following a UTI.

Based on PBS data, for those consenting to linkage, the proportions prescribed another antibiotic within 2 days and within 3–6 days following the initial pharmacy consultation were 4.3% and 7.1%, respectively. At days 7–28, the proportion increased to 11.8%. The majority of these prescriptions were for one of the same three antibiotics used in the trial (trimethoprim, nitrofurantoin and cephalexin). This level of additional antibiotic use appears consistent with the literature. A large US study using electronic medical records for 376,004 women (aged ≥12 years) with uUTIs found a treatment failure rate of 16.7% (defined as needing a new antibiotic prescription within 28 days) [47]. Another US retrospective observational cohort study, of 95,322 adult patients with incident complicated UTIs, found a treatment failure rate of 23% for outpatients <65 years of age. An older UK study of 75,045 women with UTIs treated initially with trimethoprim found that 14% needed a second antibiotic within 28 days [48].

From month 1 to month 6, both MBS general practitioner consults and PBS prescriptions for antibiotics slowly rose. The recurrence rate for UTIs in adult women within the first 6–12 months after an initial infection varies significantly across different studies, ranging from 15% to as high as 70% [49-52]. The American Urogynecologic Society reports approximately 30% to 44% of women will experience a recurrent UTI within 6 months of an initial infection [53]. These high recurrence rates may explain the increase in antibiotic use and general practitioner visits in the 6 months following the pharmacy consultation.

The self-reported rate of adverse events was 5.1%, with gastrointestinal symptoms reported as the most common complication. The University of Newcastle researchers conducted additional analyses which compared the incidence of self-reported adverse events in PATH-UTI to rates of adverse events in national and international databases, which are sourced from consumer, provider and industry reports. The self-reported adverse events rates in PATH-UTI were similar to those reported in these databases (see Appendix 3.5). The serious adverse event rate was low. When compared with the pre-trial period, emergency department attendance rates did rise, primarily in the first week after the pharmacy consult, and around 40% of presentations in week 1

were related to genitourinary conditions. There was little variation in complication rates or follow-up care patterns by geographic region. The low overall admission and emergency department utilisation rates suggest there were minimal serious adverse events observed in the trial period. However, the lack of a control group precludes making any inference on whether the rates observed are different to those for usual care.

Interviews with participants and pharmacists revealed six key themes that influenced implementation of the service: (1) community incentives to participate (general practitioner service unavailability, effective media promotion, opportunistic pharmacy delivery); (2) pharmacist motivations (business alignment, a duty to service the community, adequate support and training); (3) participant perceptions of a good service (timely symptom resolution, trust, privacy, value for money, integration with pathology services); (4) pharmacist perceptions of quality care (avoiding tick-box care, dedicated consultation time); (5) integration with health system infrastructure and information systems; and (6) integration with health system values, relationships and culture.

Considerations for ongoing implementation

Combining the quantitative and qualitative findings, four overarching domains related to service access, service delivery, health system integration and equity were identified. These are core priorities in driving the uptake, quality and sustainability of this service. As the service transitions to usual practice, key considerations within each of these domains are summarised here.

Service access

1. **Enhance health literacy and engagement:** Recognise the importance of health literacy in relation to UTIs and support service users to recognise the purpose and value of the service and how to navigate further care if symptoms persist.
2. **Leverage a wide variety of information sources:** Combine promotion of the service via social media and reputable websites like NSW Health with targeted pharmacy-led promotion in local communities.
3. **Build capacity in the pharmacy sector:** Ensure ongoing pharmacist support by aligning the service with business models, capitalise on pharmacists' intrinsic motivation to address community health priorities, and provide professional development opportunities.

Service delivery

1. **Focus on service user perceptions of value:** Implement monitoring mechanisms to assess whether effective, convenient, consistent and empathetic care is being delivered.
2. **Manage service expectations:** Clearly communicate service scope and treatment limitations (including eligibility and types of treatment available in pharmacy) and provide clear follow-up instructions on what consumers should do if no improvement, to enhance service user experience.
3. **Prioritise service quality:** Allow flexibility in management protocols to accommodate user circumstances and recognise competing pharmacist responsibilities (e.g., dispensing duties) that may impact consumer expectations and perceptions of the service.

Health system integration

1. **Improve software integration with other systems:** Implement secure two-way messaging systems that are integrated with pharmacy software systems to ensure timely communication between pharmacists and general practitioners and enhanced service coordination.
2. **Facilitate access to pathology services:** Incorporate mechanisms for better access to pathology testing for patients with persistent or worsening symptoms to ensure continuous care.
3. **Strengthen relationships with general practitioners:** Prioritise integrated care approaches to delivery of comprehensive primary care, fostering strong relationships and effective communication channels with general practitioners. This will enhance community perceptions of the service as a component of primary care that complements rather than competes with general practice.

Equity

Proactive monitoring of equity impacts is warranted as the service transitions to usual practice. There was a disproportionately high number of participants

from the least disadvantage socioeconomic quintiles which suggests a risk of inequitable uptake. This may include consideration of: (1) whether people who are less 'activated' to engage in their health care are accessing the service; and (2) whether the user-pay model without access to PBS concessional benefits for medications or integration with Medicare-rebated services leads to inequitable uptake of the service. Further, in the NSW component of the trial, the costs of the consultation were borne by NSW Health (as stipulated by the ethics committee). As the model transitions to being a part of routine service delivery, these costs will be borne by the consumer which may exacerbate inequity.

Study strengths and limitations

There are four main strengths to this study: (1) a large number of people and pharmacists participated with diverse geographic representation, making this the largest such trial reported in the literature to date; (2) high follow-up rates – 80.9% participated in the 7-day follow-up survey, which is 2.8 times higher than the follow-up rate observed in the 2022 Queensland UTIPP-Q (28.9%); (3) linkage of records to NSW administrative data and federal Medicare data provided robust information to examine service utilisation in the hospital and primary care sector; and (4) a detailed qualitative evaluation of implementation barriers and enablers.

As stated above, the key study limitation is the lack of a comparison group to assess outcomes relative to usual care. Although the gold standard would be a randomised controlled trial, there are many logistical and feasibility challenges with such a design. Because participants are self-nominated in a pharmacy setting, it was considered a major risk to engagement and follow-up if people were randomly allocated to a control group that would be advised to seek usual care from a general practitioner. Similarly, a quasi-experimental design with a matched comparison group derived from routinely collected data was considered, but there is a high risk of confounding bias with such an approach because of participant self-selection. The symptom resolution rates are similar to those reported in other expanded scope of practice community pharmacy trials, both in Australia and internationally. While this provides some reassurance, we do not recommend making any inferences around the effectiveness of this model of care relative to current care practices.

An additional study limitation is the relatively small sample of interview participants from rural areas, particularly remote and very remote areas and those with lower educational levels. The qualitative research was designed to provide an in-depth understanding of the implementation model, however the themes generated may be of varying relevance in particular geographic settings.

At the time of writing, the ACT hospital data were not available. Given the relatively small number of people from the ACT enrolled in the trial, and the low rates of emergency department and hospital use observed in NSW, we do not expect the findings to change appreciably when the ACT hospital data are added. We will update findings once these data are analysed.

Conclusions

This 10-month trial of a pharmacy care delivery model for women with uUTIs achieved a high level of both pharmacist and participant uptake and is the largest such trial reported in the literature to date. The complete symptom resolution rates align with findings reported in the literature which are generally around 80–90%. Participant satisfaction with the service was high. The service was disproportionately used by women with higher levels of education and for those residing in wealthier areas. A minority of people reported cost as a potential barrier to future use of the service.

The trial has contributed a greater understanding of care utilisation practices using linked data analyses. Around 1 in 14 people were referred by the pharmacist to see a general practitioner, 1 in 4 people actually saw a general practitioner within 1 week of the initial consult, and a urine pathology test was ordered in 1 in 10 consults. Around 1 in 8 people were prescribed an additional or alternative antibiotic within 1 week, which is consistent with international literature. The rates of follow-up care suggest there was continuity of care for those that needed ongoing support. The serious adverse event rates (emergency department presentations and hospital admissions) were low. There was a slight rise in emergency department presentations in the first week post pharmacy consult, but minimal differences in overall utilisation rates in the 12 months pre and 6 months post consult.

As the service transitions to usual practice in NSW and the ACT, several key factors related to

sustaining access, supporting quality service delivery, promoting equity and enhancing health system integration should be considered in the translation of this service from trial conditions to part of usual practice in NSW and the ACT.

04

ECONOMIC EVALUATION OF PATH-UTI: ASSESSING VALUE AND RELATIVE COST DISTRIBUTION

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 4: Economic Evaluation of PATH-UTI: Assessing value and relative cost distribution

Introduction

This chapter presents the economic evaluation of pharmacist-led management of uncomplicated urinary tract infections (uUTIs), conducted by the Health Economics group at the Hunter Medical Research Institute.

In recent years, community pharmacy has emerged as a setting for managing uUTIs, offering patients timely, accessible and potentially cost-effective care. While numerous international jurisdictions have implemented and piloted pharmacist management of uUTIs, the global literature evaluating both the costs and clinical outcomes of pharmacist-led urinary tract infection (UTI) management remains limited. A literature review identified only two studies that assessed both cost and effectiveness of community pharmacist prescribing as a first-line treatment, compared to general practitioner or emergency department services [127, 145]. Of these, only one study, conducted by Sanyal *et al*., reported on the cost-effectiveness of pharmacy-led prescribing using an incremental cost-effectiveness ratio (ICER) and quality-adjusted life months (QALMs) as key outcomes [145].

The Canadian study by Sanyal *et al*. demonstrated that pharmacist-led management of uUTIs was clinically comparable to general practitioner and emergency department care, while incurring significantly lower costs [145]. From a healthcare system perspective, the average cost per consultation was CAD$72.47 (Canadian dollars) in pharmacy, compared with CAD$141.53 in general practice and CAD$368.16 in emergency departments. QALMs and cure rates were comparable across the three care models, suggesting that the lower cost pharmacist care was likely good value for money. Furthermore, a budget impact analysis estimated that public funding for pharmacist-led care accessed by 25% of eligible Canadian women could exceed over CAD$51 million in net savings over 5 years [145].

A pilot study by Thornley *et al*. in the United Kingdom examined treatment pathways for patients presenting to community pharmacies with UTI symptoms [127]. The study found that combining pharmacist consultation with smartphone apps enhanced first-line treatment for uUTIs. Among participating women, 71.1% indicated they would have otherwise sought care from a general practitioner, and 38.5% reported that they would have also considered self-treatment. However, the study did not include an economic model or comparative cost-effectiveness analysis (CEA) [127].

Beyond UTI-specific evaluations, several international studies have investigated the economic impact of community pharmacist management of minor ailments more broadly [146-149]. In the United Kingdom, Watson *et al*. conducted a prospective cohort study to estimate the cost of pharmacy-based care compared with general practice and emergency department care [146]. They reported that pharmacy-based care cost £29.30 per consultation, significantly lower than general practitioner care (£82.34) and emergency department care (£147.09), with equivalent rates of symptom resolution. Similar conclusions were drawn in Canadian and Spanish studies [147, 150], where pharmacist-led minor ailment schemes consistently demonstrated reductions in health care resource use, improved patient outcomes, and cost savings from both public payer and societal perspectives.

The RxEACH trial in Canada demonstrated that pharmacist-led prescribing and care resulted in a 21% reduction in cardiovascular events, with a projected saving of CAD$4.4 billion over 30 years if implemented for just 15% of the eligible population [151, 152]. In Saskatchewan, a pharmacist-led minor ailment prescribing program yielded an estimated cost saving of approximately CAD$546,832 in its first year, with a return on investment of 2.53 over 5 years [147]. In Ontario, a cost-minimisation analysis using decision-analytic modelling evaluated the economic impact of implementing a remunerated pharmacist prescribing program for minor ailments [153]. It reported per-patient cost savings of CAD$7.51 for upper respiratory tract infections, CAD$4.08 for cold sores, and CAD$5.15 for conjunctivitis. When extrapolated to a cohort of 30,000 patients, the program estimated significant reductions in healthcare service use, including 799 fewer

emergency department visits, 3,677 fewer family physician visits, and 5,090 fewer walk-in clinic consultations. Across all simulated scenarios, pharmacist prescribing for minor ailments consistently resulted in cost savings [153].

Within the Australian context, evidence also suggests that pharmacist-led care may be cost-effective. Findings from a cost utility analysis, that used data from a cluster randomised controlled trial evaluating a pharmacy-based minor ailment scheme, indicated an ICER of AUD$2,277 (95% confidence interval (CI): 681.49–3,811.22) per quality-adjusted life years (QALY) gained [154]. The authors suggested that implementation of a pharmacy-based minor ailment scheme in Australian pharmacies provides good value for money. However, despite the growing momentum to expand health services delivered through community pharmacies, economic evaluations specific to expanded scope of practice in community pharmacy for management of uUTIs in Australia are virtually non-existent.

To address this evidence gap, the large-scale implementation and evaluation study (PATH-UTI) aimed to assess the economic impact of pharmacist-led management of uUTIs in the Australian setting.

Objectives

The aim of this economic evaluation was to assess the value of the addition of PATH-UTI as a service option and to assess any associated redistribution of costs across sectors, providers and patients. PATH-UTI, a community pharmacist-led service to manage uUTIs in women aged between 18–65 years in New South Wales (NSW) and the Australian Capital Territory (ACT), was compared to a base case of usual care prior to the introduction of PATH-UTI intervention (pre-PATH-UTI), comprising other clinical pathways including general practitioners, urgent care clinics, emergency departments, and self-care (conservative management).

Methods

Study design

The trial was conducted in NSW and the ACT, Australia. Both jurisdictions operate under a universal health coverage system that provides publicly funded healthcare services, with hospital care primarily free of charge at the point of use, and primary health care delivered through a nationally subsidised fee-for-service model.

The economic analysis to assess value consisted of a CEA calculating the mean incremental cost per additional person with uUTI symptom resolution in 7 days, between a model with PATH-UTI (w/PATH-UTI) and a pre-PATH-UTI model.

An assessment of cost distribution changes was also undertaken, to evaluate any changes to costs for various payers with the introduction of the PATH-UTI model.

Using the simulated datasets, three scenarios were evaluated in the CEA:

- **Scenario 1 –** One presentation to a healthcare provider to seek treatment for an uUTI, including one consult and subsequent treatment costs.
- **Scenario 2 –** Initial presentation plus a set cost to represent the additional costs of re-presentation to a healthcare provider within the follow-up period and subsequent costs.
- **Scenario 3 –** Data from linked administrative datasets to model the additional costs incurred by women re-presenting to healthcare services during the 7-day follow-up period.

To inform the costs in the model, a cost analysis via decision modelling was piloted to compare the cost of the intervention pathway (PATH-UTI) with the costs of the current care pathways (general practitioner, general practitioner online, emergency department, and urgent care clinic; pre-PATH-UTI). The analysis, using the piloted decision model, was performed using summarised patient-level data derived from the statistical analyses conducted by statisticians from The George Institute for Global Health. A decision analytic framework was then constructed and populated by the trial data and the evidence from the literature where trial data were unavailable for parameters. Components of the economic evaluation are summarised in Table 4-1.

Table 4-1: Components of the economic evaluation

Component	Detail
Types of analysis	(1) Cost-effectiveness and (2) cost distribution
Intervention	Model including management of uUTIs by community pharmacists
Comparator	Model including conservative management, general practitioners, online general practitioners, emergency departments, urgent care clinics
Outcome	Self-reported 7-day symptom-free rate
Perspective	Health service only (value) and partial societal (cost distribution)
Population	Simulated dataset of women aged 18–65 years living in NSW
Time horizon	7 days
Method used to generate results	Decision analytic modelling
Software	SAS Software v9.4 [155]

This economic evaluation was primarily conducted from a health service perspective to assess whether the community pharmacy management intervention represented value for government-funded health systems. This perspective is appropriate, as any ongoing investment in the intervention falls on government-funded public health systems at a national and jurisdictional level. Moreover, the economic evaluation aimed to assess whether the community pharmacy management trial was effective and had the potential to reduce the current burden on general practitioners, emergency departments and health system costs. In addition, a supplementary cost distribution analysis was undertaken from a partial societal perspective to describe how costs were borne by governments and patients. This dual approach enabled assessment of both system-level value and the financial impact on health consumers while remaining aligned with the short trial time horizon.

A time horizon of 7 days was applied to align with the primary outcome of the trial: patient self-reported 7-day symptom-free rate. The trial follow-up period for all patient self-reported data was 7 days, with no further self-reported data collected. The short time horizon meant discounting was not required.

Analyses were performed following the Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) [156].

For the cost distribution assessment, the analysis was conducted from a partial societal perspective, incorporating costs incurred by the State and Commonwealth governments and by patients (out-of-pocket [OOP]), excluding broader societal costs such as productivity losses.

All trial data cleaning was conducted as part of the statistical analysis by The George Institute for Global Health statisticians. Details are available in the Trial Statistical Analysis Plan (SAP) version 2.5 (8 July 2024). There were no missing data for the purposes of the economic evaluation. The Health Economic Analysis Plan (HEAP) is available in Appendix 4.1.

Population

A simulated dataset was created to represent each of the comparison arms for our models. The number of observations to be simulated was determined by calculating the proportion of women aged 18–65 years living in NSW in 2023 [157], multiplied by the proportion diagnosed with an uUTI each year [158]. This resulted in a sample population of 275,000 women.

To understand the true extent of the introduction of pharmacy-led treatment, costs were presented for the estimated number of women likely to access health care for uUTIs in a calendar year. Approximately 50% of the 275,000 women were allocated to each arm (w/PATH-UTI and pre-PATH-UTI). Using SAS, trial arms were created to replicate the decision tree based on the pathway probabilities assigned to each arm, with and without the pharmacy care pathway. Due to randomisation and subsequent rounding, it was not guaranteed that each arm would contain 137,500 participants.

Decision model

Decision trees were developed to model patient movement through the healthcare pathways and in alignment with the Clinical Management Protocol for pharmacies (Appendix 2.1 – Clinical management protocol), and were constructed in SAS software version 9.4 [155]. Conceptual diagrams of the pathways are illustrated in Figure 4.1 to Figure 4.4. The decision trees used in the 2-month feasibility study were updated with information from the final trial statistical analysis conducted by The George

Institute for Global Health. The model required several parameters, which were derived from the statistical analysis report provided by The George Institute for Global Health, including linked administrative data for Scenario 3 for the CEA (Scenario 2 in the cost distribution analysis); and available published literature.

The decision-analytic structure used to compare management of women presenting with symptoms of uUTI before and after the introduction of community pharmacy as an initial care pathway is shown in Figure 4.1 and Figure 4.2. Figure 4.1 represents the pre-PATH-UTI model, in which patients are assumed to seek care through existing pathways only, including general practice, online general practitioner services, emergency departments, urgent care clinics, or self-management. Figure 4.2 shows the PATH□UTI model, in which community pharmacy is available as an additional option for initial consultation and treatment.

In both models, patients entering a formal healthcare setting undergo consultation and assessment, after which, management is assumed to involve either prescription of antibiotics by a medical practitioner or self-care using over-the-counter treatments. In the PATH-UTI model only, patients may also receive antibiotics supplied directly by a community pharmacist. Patients who self-manage are assumed not to incur consultation costs and to use over-the-counter products only.

Following initial management, patients transition to a short-term outcome state at 7-day follow-up, classified as self-reported symptom-free or not symptom-free. In Scenario 1, the model assumes that costs are incurred only for the initial episode of care, and no subsequent healthcare utilisation is modelled beyond this outcome point.

The decision-analytic structure used in scenarios which include the costs of re-presentations for the same symptoms within 7 days, modelled as re-presentation to healthcare providers other than pharmacies (general practitioner, online general practitioner, emergency department, urgent care) (see description of scenario analyses below). The pre-PATH-UTI model can be seen in Figure 4.3 showing the counterfactual in which patients can seek initial care through existing pathways only (general practitioner, online general practitioner, emergency department, urgent care clinic, or self-management). The structure seen in Figure 4.4 (PATH-UTI) retains the same pathways and assumptions but includes community pharmacy as an additional initial point of care, enabling pharmacist consultation and, where permitted, direct supply of antibiotics. Patients remain assigned to the initial management pathway, with re-presentation modelled as an additional event occurring within the 7-day follow-up period and resulting in costs attributed to the initial pathway.

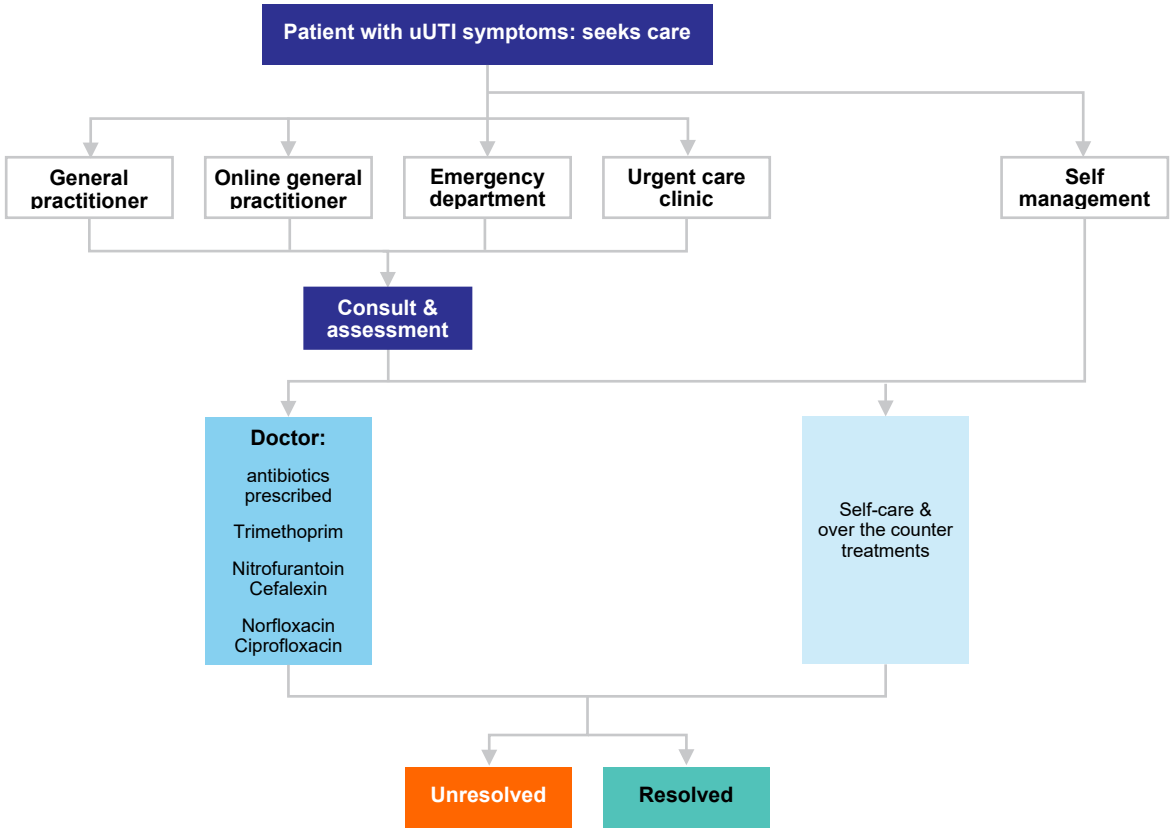


Figure 4.1: Decision-analytic structure for management of uUTI before the introduction of community pharmacy as an initial care pathway (Pre-PATH-UTI)

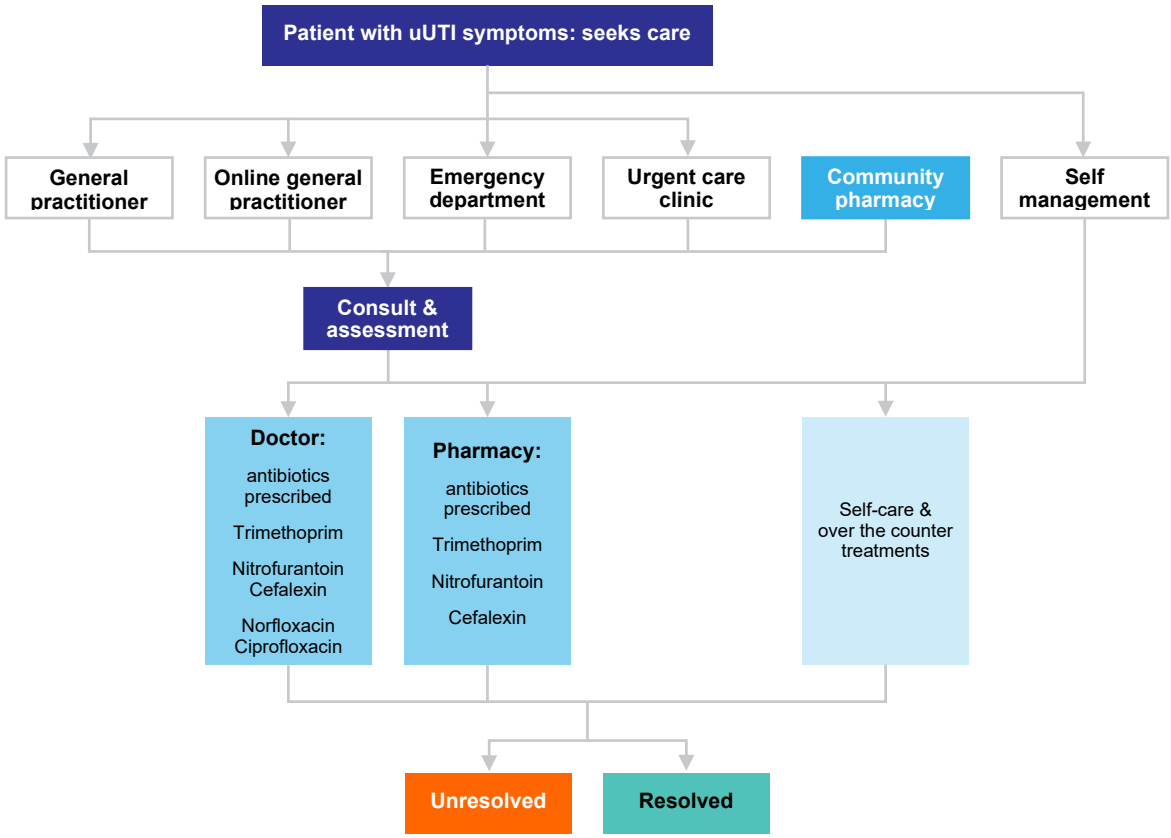


Figure 4.2: Decision-analytic structure for management of uUTI after the introduction of community pharmacy as an initial care pathway (PATH-UTI)

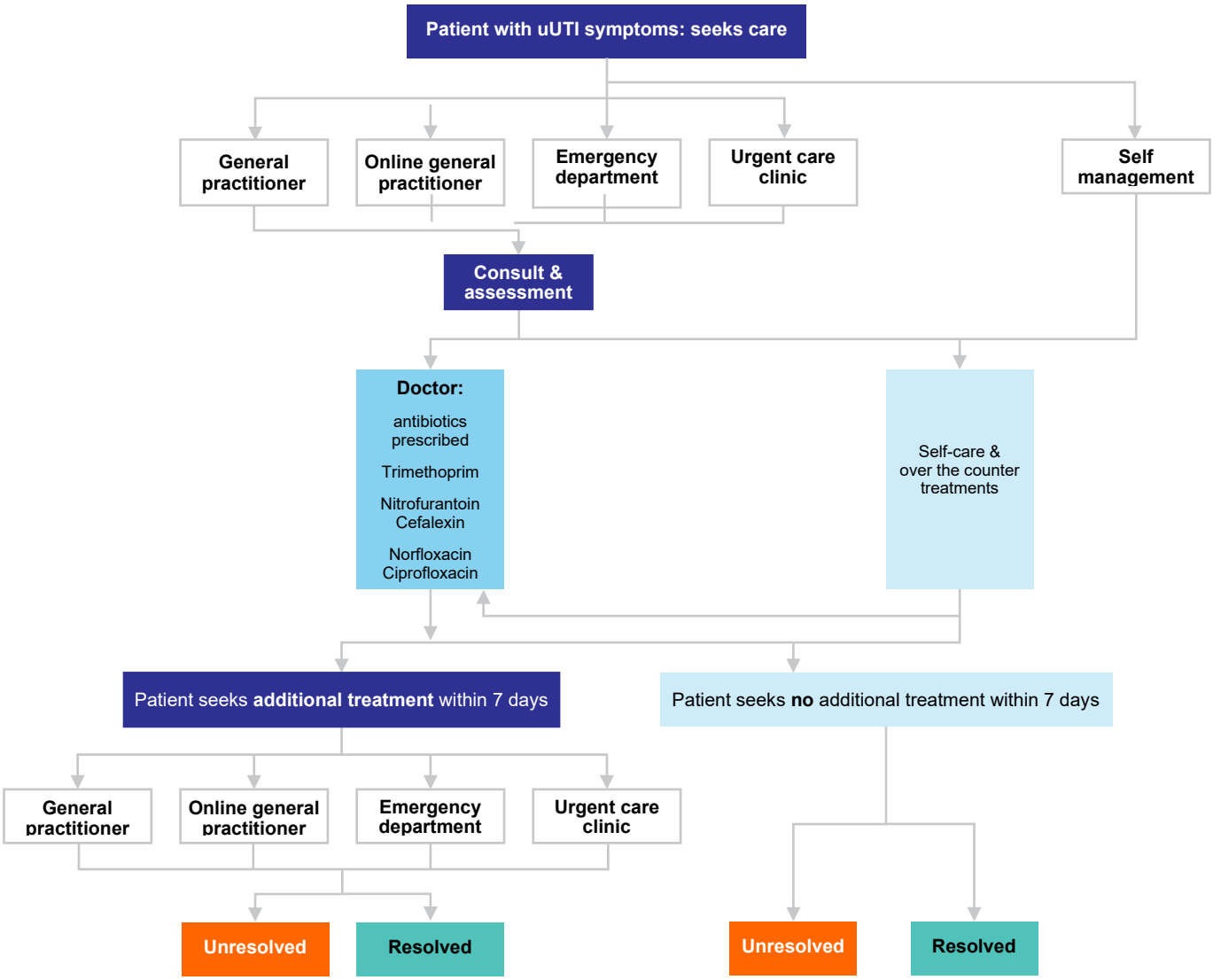


Figure 4.3: Decision-analytic structure for management of uUTI before the introduction of community pharmacy as an initial care pathway (Pre-PATH-UTI) with re-presentation to healthcare providers other than pharmacies

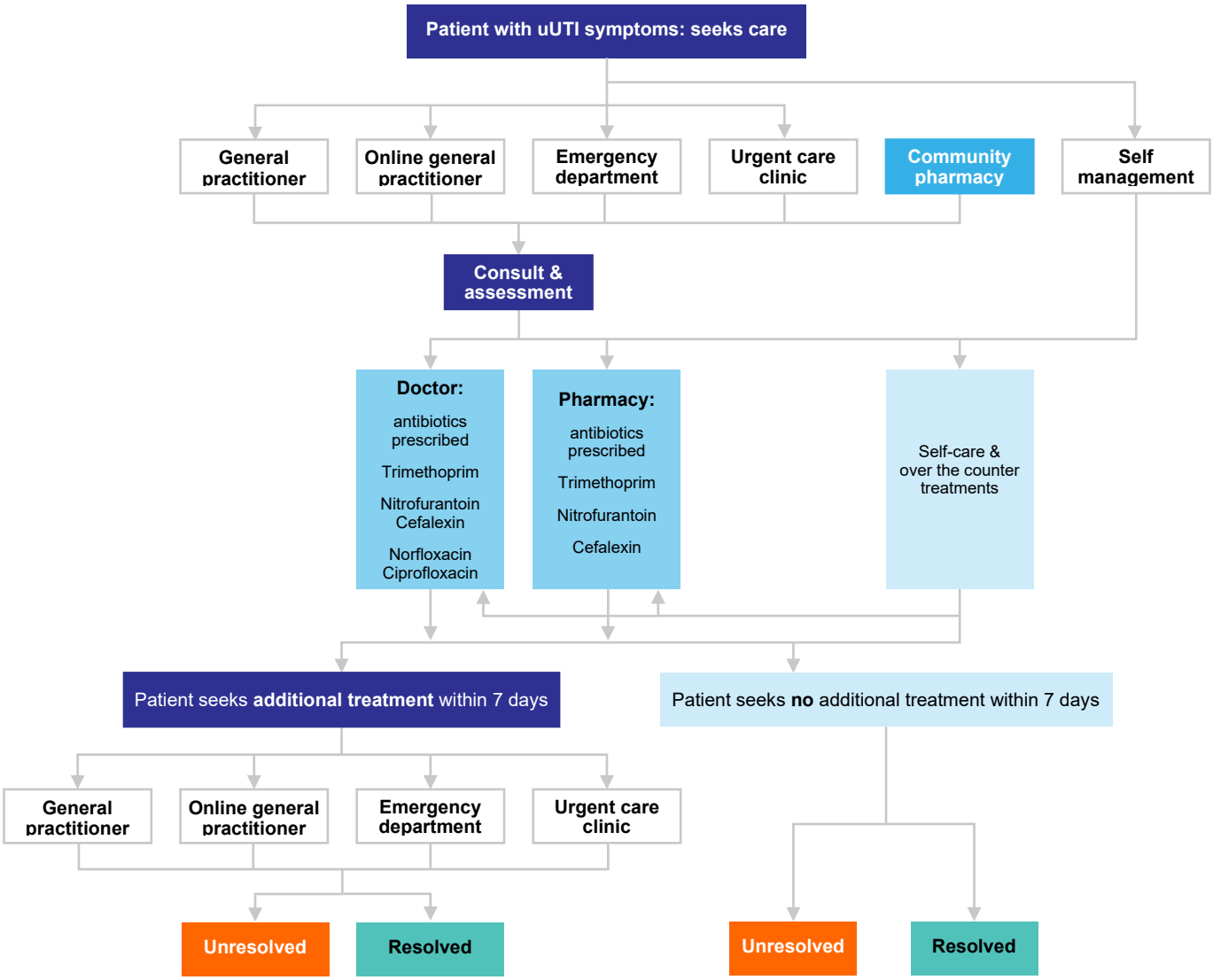


Figure 4.4: Decision-analytic structure for management of uUTI after the introduction of community pharmacy as an initial care pathway (PATH-UTI) with re-presentation to healthcare providers other than pharmacies

Model parameters

The economic evaluation assessing value included direct delivery costs of the consultation and costs associated with treating the condition. The effectiveness outcome for the economic evaluation was patient self-reported 7-day symptom-free rate, defined as the complete absence of UTI symptoms.

Pathway Utilisation

Models assumed that 13% of women would access the pharmacist-led care instead of standard pathways. Pathway probabilities were sourced from Butler *et al.* [159] and adjusted to account for the addition of the pharmacy pathway (see Appendix 4.3 – Probability tables for further details).

Table 4-2 shows the probabilities of pathway utilisation used in the evaluation. The same probabilities were used in each of the scenarios presented. (see Appendix 4.3 – Probability tables for further details)

Table 4-2: Pathway utilisation per patient

Clinical pathway	pre-PATH-UTI %	w/PATH-UTI %
Pharmacy	0	13.15
Conservative management	5.20	4.54
General practitioner	76.60	66.80
Online general practitioner	2.20	1.90
Emergency department	12.20	10.22
Urgent care clinic	3.80	3.40
Overall	100	100

Identification, Measurement and Valuation of Resources

The economic evaluation includes direct costs to the health system likely to be incurred by the healthcare providers in each pathway. Out-of-pocket costs to the patient for any relevant prescription and non-prescription treatments that may be purchased were also included in the cost distribution analysis only. Broader societal costs, such as productivity losses, time off paid or unpaid work, and other non–healthcare impacts, were not included. The short follow-up period further limits the feasibility of estimating productivity impacts in a robust and interpretable manner. Information on the types of resources used in uUTI symptom resolution were drawn from the Australian Therapeutic Guidelines [99], consultation with clinicians (including general practitioners, urologists and pharmacists), and published literature. Details of the approach to valuation for the CEA are summarised in Table 4-3. See Appendix 4.2 for the approach to valuation and sources for the cost distribution evaluation. Note that the allocation of pharmacy consultation costs differed by analytic perspective: in the value assessment models these costs were attributed to the state government, while in the cost distribution assessment they were assigned to patients.

The cost analysis via decision modelling was conducted to compare the cost of the intervention pathway (w/PATH-UTI) to the costs associated with each of the base case pathways (general practitioner, general practitioner online, emergency department, and urgent care clinic; pre-PATH-UTI). For the CEA, at each stage of the model, activities were costed by applying the unit costs as shown in Table 4-4 to the specific item associated with the pathway.

Table 4-3: Approach to valuation for the CEA

Category	Item	Approach to valuation/costing
Health professional costs	Community pharmacist consultation*	Reimbursement rates for pharmacist consultations used in the PATH-UTI trial
	General practitioner consultation	Medical Benefits Schedule (MBS) website [160]
	Online general practitioner consultation	Market rates found online via web searches
	Emergency department presentation	Independent Health and Aged Care Pricing Authority (IHACPA) website [161]
	Urgent care clinic presentation	Market rates found online via web searches
Medication costs (subsequent treatment)	Antibiotics	Pharmaceutical Benefits Scheme (PBS) website [162]
	Over-the-counter medication	Market rates for example from the Chemist Warehouse website [163]

** Pharmacy consultation costs are allocated to the state government in the value assessment, and to patients in the cost-distribution assessment*

Table 4-4: Model input parameters for CEA (AUD 2023)

Parameter	Value	Sources
Health professional costs		
Community pharmacist consultation*	$20.00	PATH-UTI research trial
General practitioner consultation	$61.40	MBS website (Item: 23) [160]
Online general practitioner consultation	$50.00	https://www.instantconsult.com.au/pricing/
Emergency department presentation	$593.31	Independent Health and Aged Care Pricing Authority (IHACPA) website [161]
Urgent care clinic presentation	$350.00	https://www.healurgentcare.com.au/fees/
Medication costs (subsequent treatment)		
Prescription antibiotics	$21.59 to $36.42†	PBS website [162]
Over-the-counter medication	$5.99 to $21.50	Chemist Warehouse website [163]
Cure rates		
Antibiotics	83.3%	Parekh *et al*. [164]
Conservative management	65.0%	Daumeyer *et al*. [165]

** Pharmacy consultation costs are allocated to the state government in the value assessment, and to patients in the cost-distribution assessment*
† Private scripts not considered

Frequency and cost of resource use were determined by generating a simulated dataset using inputs from The George Institute for Global Health statistical analysis, the previous feasibility study conducted by the research team, and published literature. For CEA Scenario 3 and cost distribution Scenario 2, proportional instances of re-presentation to healthcare providers within the 7-day follow-up period were included. The information was from the primary outcomes analysis conducted by The George Institute for Global Health. Output from the linked data analysis provided by The George Institute for Global Health is presented in Appendix 4.4 – Statistical analysis of linked data. Specifically, CEA Scenario 3 and cost distribution Scenario 2 include general practitioner visits (including costs for urine sample pathology and additional antibiotics for UTIs) and avoidable genitourinary hospitalisations (including emergency presentation for genitourinary-related problems) during the 7 days following a pharmacy consultation for uUTIs.

Due to the timing of the two economic analyses, different cost years are used. For the cost-effectiveness analysis, all resource use was valued in monetary terms using appropriate Australian unit costs at the time of data collection (2023–2024). Costs were adjusted for inflation using the appropriate Consumer Price Index (CPI) [166] and are reported in 2023 Australian dollars, unless otherwise specified. The cost of prescription medication was sourced from the PBS website [162], and general practitioner services were sourced from the MBS website [160]. Online general practitioner and urgent care clinic fee schedules were based on market rates found via online searches of NSW providers. Pharmacist reimbursement costs for the consultation were drawn from the NSW Health reimbursement rates used in the trial. Costs for emergency department visits were taken from the IHACPA website (2022–2023 pricing) [161]. Over-the-counter medication costs were assigned retail market value.

For the cost distribution analysis, all resource use was valued in monetary terms using Australian unit costs of 2024–2025. All costs are reported in 2025 Australian Dollars. The cost of prescription medication was sourced from the PBS website [162] and general practitioner services were sourced from the MBS website [160]. Online general practitioner and urgent care clinic fee schedules use market rates found via online search of NSW providers. Pharmacist reimbursement costs for the consultation are drawn from the NSW Health reimbursement rates considered in the trial. Cost for emergency department visits are taken from the Independent Aged Care and Hospital Pricing Authority (IHACPA) 2024–2025 [161]. Over the counter medication costs are assigned retail market value. See Appendix 4.2 for cost sources.

Identification, Measurement and Valuation of Outcomes

The effectiveness outcome for the CEA was defined as the rate of patient-reported uUTI symptom-free at the 7-day follow-up. The economic evaluation used results from the trial statistical analysis conducted by statisticians at The George Institute for Global Health for the pharmacy pathway, while data for the other pathways were drawn from the published literature.

The outcome was valued in its ‘natural’ unit; that is, it was reported as measured. The three response options presented in the trial patient follow-up survey were transformed into a binary value. Responses were classified as ‘resolved’ if patients reported ‘symptoms completely resolved’ at follow-up, and as ‘not resolved’ if they reported either ‘symptoms improved but not completely resolved’ or ‘symptoms not improved or worsened’ at follow-up. This reflected a conservative approach, meaning there were some patients with partial resolution who thereby received some symptom relief and benefits from the trial; those benefits were not accounted for in the analysis.

The trial outcomes were not considered in the cost distribution analysis. This analysis was designed to examine how healthcare costs may be redistributed across care settings and payers following implementation of the intervention, rather than to assess cost-effectiveness or overall value for money.

Cost-effectiveness analysis

To enable decision-makers to understand the additional investment needed, an ICER was presented, showing the cost-effectiveness of the models. The current analysis reported the mean incremental cost per unit change in uUTI symptom resolution between the w/PATH-UTI and pre-PATH-UTI models.

In the context of the current trial, the ICER was defined as the incremental cost per additional patient achieving symptom resolution for an uUTI. The ICER calculation compared an environment in which

pharmacy-led care was not available (pre-PATH-UTI) with an environment where it is an option (w/PATH-UTI). The incremental cost per additional patient reporting symptom resolution in 7 days was calculated.

Mean differences in costs and benefits between w/PATH-UTI and pre-PATH-UTI models were estimated with associated 95% confidence intervals (CIs). Differences in the use of services between the pathways are described but not compared statistically. All descriptive analyses showing the mean, standard deviation, median, minimum and maximum costs per treatment path considered are reported.

ICER plane graphs were produced with 80% and 95% prediction ellipses to identify variation in the sample data, providing a visual indication of skewness and outliers in the estimates.

Scenario Analyses

Ideally, women who seek management from a pharmacist achieve resolution of symptoms during the 7-day follow-up period; however, it is likely that a proportion of women do not experience symptom resolution and will re-present to healthcare services. In the current evaluation, two additional scenarios were tested, serving as sensitivity analyses to assess the robustness of the results found in the primary model (Scenario 1).

Scenario 1: Initial presentation

This scenario includes only the initial care costs, which comprised the first contact with a healthcare provider to seek treatment for uUTI and associated expenses such as those for pathology and antibiotics.

Scenario 2: Initial presentation and re-presentation

This scenario assumes additional costs are incurred due to a proportion of women seeking further health care during the 7-day follow-up period to a place other than a pharmacy. It incorporates the parameters from Scenario 1 as well as an estimated average cost for women who seek additional care for the same symptoms during the 7-day follow-up period. Patients remain assigned to the initial management pathway, with re-presentation modelled as an additional event occurring within the 7-day follow-up period and resulting in costs attributed to the initial pathway. The average cost for accessing another healthcare professional in the 7-day period (re-presentation) was adapted from the trial data. The responses to the self-report survey question 'Another healthcare professional seen for the same symptoms in the last 7 days' was used as a guide to calculate the average cost of re-presentation ($104.27) per patient (see Appendix 4.4 for details). The value for the proportion of women re-presenting included in the model was informed by findings from the feasibility study.

Scenario 3: Initial presentation and re-presentation – linked data

Scenario 3 utilises trial information from the linked administrative datasets to determine any additional costs incurred due to women re-presenting to healthcare services other than a pharmacy during the 7-day follow-up period (see Appendix 4.3 for the data provided by The George Institute for Global Health). The analysis includes all parameters from Scenario 1 including any additional cost of treatment for women who reported having re-presented to a healthcare provider for the same symptoms during the 7-day follow-up period.

Cost distribution analysis

The analysis aimed to assess changes in patterns of health service use, associated with the option for patients to seek care and treatment for uUTI by community pharmacists using a partial societal perspective. Patient costs were included, notably pharmacy consultation costs were allocated to the patient and variation in medication costs to the patient due to prescriber/supplier. Mean differences in costs and benefits between PATH-UTI and Pre-PATH-UTI models were estimated with associated CIs. Differences in the use of services between the pathways are described but not compared statistically. Descriptive analyses showing the mean, standard deviation, median, minimum and maximum costs for each treatment pathway are provided.

Bulk billing for general practitioner consultations

To account for the fact that most general practitioner consultations would be bulk billed, the costs of general practitioner consultations were modelled using probability of bulk billed p = 0.69 and not bulk billed p = 0.31, using the Australian Institute of Health and Welfare (AIHW) report on general practitioner attendances and costs [167].

Scenario Analyses

Scenario 1 (base case)

Scenario 1 (Initial presentation) includes the costs of the initial instance of care, only, that is, the initial contact with a healthcare provider to seek treatment for uUTI and associated treatment costs, such as pathology and antibiotics.

Scenario 2 (Initial and re-presentation to healthcare other than pharmacy - linked data)

Scenario 2 uses information from the linked administrative datasets to determine any additional costs incurred due to women re-presenting to healthcare services during the 7-day follow-up period (See Appendix 4.4 for the data provided by The George Institute for Global Health). The analysis includes the parameters in Scenario 1 plus any additional cost of treatment for women who reported having re-presented to a healthcare provider for the same symptoms during the 7-day follow-up period. Patients remain assigned to the initial management pathway, with re-presentation modelled as an additional event occurring within the 7–day follow-up period and resulting in costs attributed to the initial pathway.

Additional Sensitivity Analyses

In the base case analysis, a single average patient consultation cost was assumed for all patients. However, in practice, pharmacy consultation fees may vary across sites and patients, reflecting differences in pricing policies and fee waivers. A deterministic sensitivity analysis was undertaken to assess the impact of uncertainty in the patient cost for the community pharmacy consultation on the cost-shifting results.

To explore the implications of this variability, two alternative fee distribution scenarios were evaluated. Rather than varying a single unit cost, these scenarios varied the proportion of patients incurring different consultation fees, while holding all other model inputs constant. Specific proportions and consult costs used in the sensitivity analyses are shown in Table 4-5. Values were sources from Queensland Community Pharmacy Chronic Conditions Management Pilot Handbook [168]. These settings were selected to reflect plausible variation in patient charges in practice and to test the robustness of the cost-shifting findings to alternative assumptions about pharmacy consultation pricing.

Table 4-5: Sensitivity analysis on pharmacy consultation fees, model inputs (AUD 2025)

Pharmacy consult fee	Sensitivity analysis 1	Sensitivity analysis 2
	% of patients	% of patients
No charge	0	10
$19.50	20	20
$36.70	75	65
$70.50	5	5

Uncertainty analyses

Non-parametric bootstrapping was used to generate uncertainty intervals around the costs and the outcomes for each scenario. Parameter uncertainty was assessed using probabilistic sensitivity analysis via bootstrapping methods producing 5,000 samples. 95% CIs were calculated to provide upper and lower estimates for the trial mean cost estimates by clinical pathway. Non-parametric bootstrap 95% CIs indicating the uncertainty of the respective estimate of the patient costs were determined. No statistical assumptions on the distribution of the data or the desired cost estimate were required due to the nature of the generated dataset. A total of 5,000 independent samples were produced with replacement from the generated dummy distribution of patient data. The weighted average cost estimates were calculated for each of the replicate samples by the relevant subgroups for reporting. The overall mean costs and respective 95% CIs by subgroup and overall totals were calculated by the weighted average of the bootstrapped samples. While the bootstrap sample size was set to generate 10,000 datasets, this was reduced to 5,000 due to the large number of records and insufficient computation power. Small differences between the base case and sensitivity analyses are expected due to stochastic variation introduced by the bootstrap resampling process.

Model validation

Validity testing (conceptual model, input data, assumptions, model outcomes) was carried out iteratively as part of the development of the model throughout the project, with pharmacy and health economics experts on the research team, and through feasibility testing. This was carried out as review of model structure, inputs and outcomes.

Results

Assessment of value (CEA)

Costs in CEA Scenario 1: Initial Presentation

The costs associated with the initial presentation to healthcare providers for uUTIs are presented in Table 4-6. The costs included for the initial presentation informed the model parameters for Scenario 1. Table 4-6 provides a summary of the estimated mean costs per patient for each pathway and cost category. The primary difference in cost arose from the consultation fee cost. The cost of an emergency department presentation was nearly double that of the next highest fee, which was for urgent care consultations. Conservative management (self-management) was assigned no dollar value as no consultation was undertaken in that instance. The mean cost per patient for the pharmacy pathway was $48, compared with $82 per patient for a general practitioner consultation, and $672 for an emergency department presentation. Costs related to prescription and non-prescription medications varied across the pathways.

Non-prescription treatment costs were not included in the modelled analysis as these were outside the health service perspective. However, they are reported in Table 4-6. The cost for non-prescription medicine was the highest in the conservative pathway. Pharmacy had the lowest mean non-prescription cost ($1.19), but the costliest prescription at $27.42 (Table 4-6). While there was variation in costs for prescription medication between pathways, the consultation fee remained the primary contributor to costs, with emergency department being the most expensive ($654.59), followed by urgent care ($296.37).

Table 4-6: Estimated mean cost of patient pathways: initial presentation (AUD 2023)

Cost item	Mean cost per patient (standard deviation)					
	Pharmacy	**Conservative management**	**General practitioner**	**General practitioner online**	**Emergency department**	**Urgent care clinic**
Consultation	20.00 (0)	0 (0)	70.66 (0.03)	46.19 (0)	654.59 (0.22)	296.37 (0.01)
Prescription medicine	27.42 (0.04)	0 (0)	11.68 (0.03)	15.30 (0.17)	17.70 (0.07)	17.19 (0.11)
Total	48.60 (0.04)	0 (0)	82.30 (0.40)	61.30 (0.20)	672.30 (0.300)	313.60 (0.10)
Non-Prescription medicine*	1.19 (0.03)	21.97 (0)	8.13 (0.02)	8.12 (0.15)	5.72 (0.06)	5.72 (0.1)

**Not included in the models*

Costs in CEA Scenario 2: Initial Presentation and Re-presentation

A proportion of women in the trial reported accessing another healthcare provider for the same reason (uUTI) within the 7-day follow-up period. To estimate the impact of re-presentation on costs for w/PATH-UTI, further modelling was conducted. Scenario 2 incorporated both initial presentation and a proportion of women who sought additional treatment during the follow-up period, defined in the analysis as a re-presentation. Table 4-7 shows the mean cost per patient for the pharmacy pathway was $49.90, compared with $94.40 per patient for the general practitioner pathway and $678.40 per patient for an emergency department presentation.

Table 4-7: Mean cost per patient by pathway: Scenario 2 initial presentation costs plus re-presentation costs (AUD 2023)

Clinical pathway	Mean cost (standard deviation)
Pharmacy	49.90 (0.00)
Conservative management	23.30 (0.00)
General practitioner	94.40 (0.00)
General practitioner online pathway	70.10 (0.10)
Emergency department	678.40 (0.30)
Urgent care clinic	319.60 (0.00)
Overall	157.30 (0.40)

For this scenario, emergency department visits remained the most expensive pathway, and accounted for 12.2% of presentations in the pre-PATH-UTI model (Table 4-2). The w/PATH-UTI model showed just over 10% of women used the emergency department, indicating a 2.2% reduction in emergency department utilisation when pharmacy treatment was available. A reduction of 10% in general practitioner service use was also achieved, resulting in approximately 21,000 women per calendar year diverted away from general practitioners to pharmacies for the management of uUTIs.

All pathways experienced increased costs. The greatest increases in costs were observed in the conservative management pathway ($23) and general practitioner pathway ($12).

Costs in CEA Scenario 3 and Cost Distribution Scenario 2: Initial Presentation and Re-presentation – linked data

These Scenarios used linked data from trial participants to establish instances of re-presentation, including for those with and without symptom resolution (see Appendix 4.3 for the data provided by The George Institute for Global Health). Table 4-8 presents the proportions of participants accessing additional services in the linked data and stratified by resolution status. Results indicate that women who reported their symptoms unresolved at the 7-day follow-up sought additional treatment. Note: individual participants may have accessed multiple services and therefore could be included in multiple categories in Table 4-8.

Table 4-8: Re-presentations in the 7-day follow-up period – linked data*

Presentation	Resolved %	Unresolved %
General practitioner visit	16.4	43.0
Pathology – urine sample	6.3	26.1
Additional antibiotics for UTI	5.9	30.3
Emergency presentations genitourinary related	0.52	2.6
Avoidable genitourinary hospitalisations†	0.08	0.32

**Note that percentages do not sum to 100% as some patients received multiple additional services, and others sought no additional health care*
†While percentages have been provided for the entire sample, hospitalisations needed an emergency department visit first

Table 4-9 presents a summary of the estimated mean re-presentation costs per patient, grouped by initial treatment pathway. The descriptive results showed the primary difference in cost arises from re-presentation (including general practitioner visits, pathology and medication) costs. The mean total re-presentation cost per patient during follow-up was $89 for the pharmacy pathway, $153 for general practitioner pathway and $52 for conservative management (Table 4-10). The cost of additional treatment via the emergency department and hospital

presentations was higher for women who initially used conservative management, as they had a lower likelihood of 7-day symptom resolution and therefore required further care.

Table 4-9: Estimated mean cost (standard deviation) per patient of re-presentation at general practice, emergency department and hospital by pathway – linked data (unadjusted costs) (AUD 2023)

Clinical pathway	Additional general practitioner costs	Additional emergency department costs	Mean total cost of re-presentation*
Pharmacy	22.94 (0.23)	6.25 (0.34)	39.94 (1.75)
Conservative management	29.05 (0.44)	8.89 (0.69)	52.12 (3.48)
General practitioner	24.66 (0.11)	6.99 (0.16)	43.27 (0.82)
General practitioner (online)	23.12 (0.61)	6.31 (0.90)	39.17 (4.41)
Emergency department	22.62 (0.26)	6.11 (0.39)	38.97 (1.96)
Urgent care clinic	22.55 (0.45)	6.11 (0.67)	38.63 (3.34)

**Re-presentation total cost includes hospitalisation costs*

Table 4-10 shows the total of the initial treatment costs plus the re-presentation treatment costs reported in the linked data.

Table 4-10: Pathway utilisation and costs per patient: Scenarios with initial presentation and re-presentation – linked costs (AUD 2023)

Clinical pathway	Mean cost (standard deviation)
Pharmacy	88.60 (1.80)
Conservative management	52.10 (3.50)
General practitioner	152.60 (0.80)
General practitioner online	100.40 (4.40)
Emergency department	711.30 (2.00)
Urgent care clinic	352.20 (3.30)
Overall	184.40 (0.70)

Scenario 1: Initial Presentation

A CEA was conducted using modelled data produced from the decision analytic model. The analysis estimated the mean incremental cost per unit change in uUTI symptom resolution between the w/PATH-UTI and pre-PATH-UTI models, assuming one healthcare presentation with associated treatment costs.

Table 4-11 presents the results for Scenario 1 (initial presentation). The addition of the pharmacy pathway costs over $850,000 per year; however, this additional cost was offset by the cost savings by reducing burden of the alternative pathways. The number of presentations to other healthcare providers decreased when pharmacy was included as an option. In the model, pharmacy access potentially reduced the annual cost burden by over $2.2 million. Note, the analysis divided the potential patient population between the two models. Therefore, if implemented to the entire eligible population in NSW (women aged 18–65 years with symptoms), the total saving would equate to $4.4 million.

Table 4-11: Results of Scenario 1 – initial presentation (AUD 2023)

		pre-PATH-UTI (N=137,480)		w/PATH-UTI (N=137,520)		
Clinical pathway	**Mean cost ($1,000s)**	**N (1,000s)**	**Total cost ($1,000s)**	**N (1,000s)**	**Total cost ($1,000s)**	**Cost difference ($1,000s)**
Pharmacy	440	-	-	18	880	880
Conservative management	-	7	-	6	-	-
Emergency department	10,352	17	11,265	14	9,438	-1,826
General practitioner online	173	3	185	3	160	-25
General practitioner	8,118	105	8,637	92	7,653	-1,109
Urgent care clinic	1,551	5	1,637	5	1,464	-172
Total	20,633	137	21,761	138	19,506	-
Total difference						**-2,255**

Table 4-12 shows the results of the CEA for Scenario 1. The model incorporating the PATH-UTI intervention was dominant relative to the base case (pre-PATH-UTI), indicating that it was both more effective and less costly. The total cost for w/PATH-UTI was $19.5 million compared to $21.7 million for pre-PATH-UTI. The intervention also resulted in 850 additional women achieving symptom resolution at 7-day follow-up.

Table 4-12: Cost-effectiveness in Scenario 1: initial presentation (AUD 2023)

	pre-PATH-UTI	w/ PATH-UTI	Difference
Cost ($1,000s)	21,761	19,506	-2,255
n Resolution (1,000s)	105	106	0.85
Incremental cost per resolution			**Dominant**

Uncertainty analyses

Parameter uncertainty was assessed using probabilistic sensitivity analysis via bootstrapping methods producing 5,000 samples. The results are visually presented on a cost-effectiveness plane (Figure 4.5), where each of the 5,000 points represents the difference in cost and effect per bootstrapped sample, using pre-PATH-UTI as the reference. All 5,000 samples were grouped in the bottom-right quadrant where the comparator intervention (w/PATH-UTI in this case) was both cheaper and more effective, indicating the intervention was cost-effective. Note the scale of the x-axis, which shows that there was minimal difference in uUTI symptom resolution rate between the two groups. The red colour in the heatmap represents where a greater proportion of bootstrapped samples lie, suggesting greater certainty in that area. The ellipses show where 80% and 95% of the bootstrapped estimates land, indicating minimal variation across the bootstrapped estimates. All points fell within the bottom-right quadrant, indicating a 100% probability that inclusion of the pharmacy option resulted in lower costs and similar or improved health outcomes in Scenario 1.

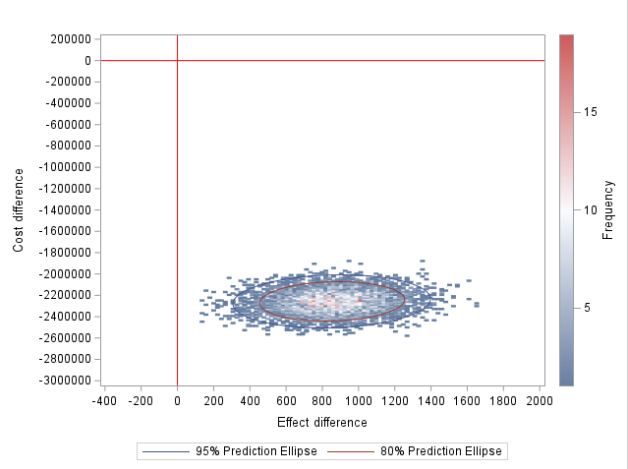


Figure 4.5: Cost-effectiveness plane for Scenario 1: initial presentation – incremental costs and symptom-free days for pharmacy-led management of uUTI compared with usual care (health service perspective, 7-day horizon) (AUD 2023)

Scenario 2: Initial Presentation and Re-presentation

Table 4-13 shows the results for Scenario 2 of the analysis with and without PATH-UTI, inclusive of re-presentation costs. In Scenario 2, w/PATH-UTI total cost per year exceeded $20 million but still achieved a cost saving of more than $2 million compared to the pre-PATH-UTI model.

Table 4-13: Results of Scenario 2 – initial presentation and representation (AUD 2023)

		Pre-PATH-UTI (N=137,487)		w/PATH-UTI (N=137,515)		
Clinical pathway	**Mean cost ($1000s)**	**N (1,000s)**	**Total cost ($1000s)**	**N (1,000s)**	**Total cost ($1000s)**	**Cost difference ($1000s)**
Pharmacy	451	-	-	18	1,056	1,056
Conservative management	156	7	71	6	62	-9
Emergency department	10,445	17	11,385	14	9,537	-1,848
General practitioner online	198	3	207	3	179	-28
General practitioner	9,308	105	9,401	92	8,198	-1,203
Urgent care clinic	1,581	5	1,674	5	1,497	-177
Total	21,633	137	22,738	138	20,529	-
Total difference						**-2,209**

The results of the CEA for Scenario 2 are presented in Table 4-14 and show that the w/PATH-UTI model remained dominant compared with the base case (pre-PATH-UTI), meaning it was both more effective and less costly. The total cost was $20.5 million for w/PATH-UTI compared to $22.7 million for pre-PATH-UTI. w/PATH-UTI was also more effective, with approximately 840 more women reporting symptom resolution at 7-day follow-up than in pre-PATH-UTI.

Table 4-14: Cost-effectiveness in Scenario 2 – initial presentation and re-presentation (AUD 2023)

	pre-PATH-UTI	w/ PATH-UTI	Difference
Cost ($1,000s)	22,738	20,529	-2,209
n Resolution (1,000s)	105.2	106.1	0.84
Incremental cost per resolution			**Dominant**

These results indicate that even when the costs of additional care for unresolved symptoms were included, providing the option of pharmacy-led care could have reduced overall costs by more than $4.4 million per year in NSW.

Uncertainty analyses

The cost-effectiveness plane (Figure 4.6) for Scenario 2 shows the uncertainty analysis results. The majority of simulations fell in the bottom-right quadrant, indicating that including pharmacy-managed treatment of uUTIs (w/PATH-UTI) was cost-effective when compared to pre-PATH-UTI. The scale of the x-axis reflects minimal differences in the symptom resolution rate between the two groups. The ellipses indicate where 80% and 95% of the bootstrapped estimates landed, indicating minimal variation and a greater than 95% probability that inclusion of the pharmacy option resulted in lower costs and similar or improved health outcomes.

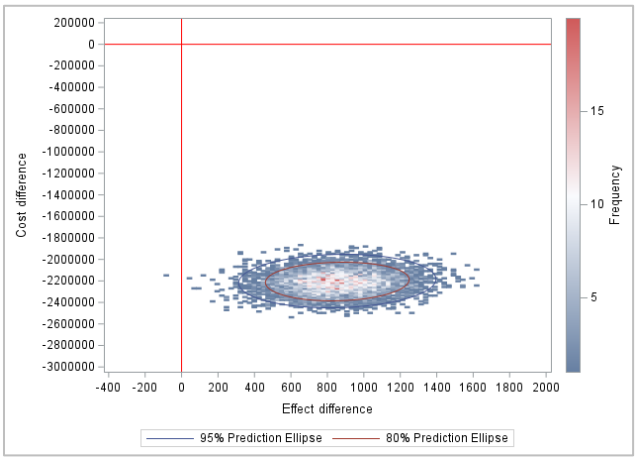


Figure 4.6: Cost-effectiveness plane for Scenario 2 – initial presentation and re-presentation: incremental costs and symptom-free days for pharmacy-led management of uUTI compared with usual care (health service perspective, 7-day horizon) (AUD 2023)

Scenario 3: Initial presentation and re-presentation – linked data

Table 4-15 shows the total costs from the simulated dataset for Scenario 3, which includes re-presentation costs derived from the linked administrative data. These costs added nearly $5 million per year to both the w/PATH-UTI and pre-PATH-UTI arms, compared to just $19 million and $21 million when only an initial consultation was included (Scenario 1). Including re-presentation treatment costs derived from the linked administrative data demonstrated a slight increase in cost savings overall of approximately $2.3 million per year, compared to Scenario 2 approximately $2.2 million in savings (Table 4-15). The total cost saving for Scenario 3, scaling the results up to the entire eligible NSW population, was estimated at $4.6 million per year.

Table 4-15: Results of Scenario 3 – initial presentation and re-presentation – linked data (AUD 2023)

		pre-PATH-UTI (N=137,480)		w/PATH-UTI (N=137,520)		
Clinical pathway	**Mean cost ($1,000s)**	**N (1,000s)**	**Total cost ($1,000s)**	**N (1,000s)**	**Total cost ($1,000s)**	**Cost difference ($1,000s)**
Pharmacy	1,490	0	-	18	1,490	1,490
Conservative management	288	7	309	6	267	-43
Emergency department	10,861	17	11,824	14	9,899	-1,925
General practitioner online	272	3	289	3	255	-35
General practitioner	11,692	105	12,490	92	10,894	-1,596
Urgent care clinic	1,713	5	1,806	5	1,620	-185
Total	25,571	137	26,718	138	24,424	-
Total difference						**-2,295**

Table 4-16 presents the results of the CEA for Scenario 3. The model with PATH-UTI was dominant when compared with the base case (pre-PATH-UTI), with a total cost of $24.4 million compared to $26.7 million for the base case (pre-PATH-UTI). The PATH-UTI model was also more effective, with at least 850 more women achieving symptom resolution at 7 days.

Table 4-16: Cost-effectiveness in Scenario 3 – initial presentation and re-presentation – linked data (AUD 2023)

	pre-PATH-UTI	w/ PATH-UTI	Difference
Cost ($1,000s)	26,718	24,424	-2,295
n Resolution (1,000s)	105.2	106.1	0.85
Incremental cost per resolution			**Dominant**

Uncertainty analyses

Parameter uncertainty was assessed using probabilistic sensitivity analysis via bootstrapping methods, producing 5,000 samples. The results are visually presented on a cost-effectiveness plane (Figure 4.7) for the 5,000 samples, where each point represented the cost and effect differences per bootstrapped sample, using pre-PATH-UTI as the reference. All samples fell within the bottom-right quadrant, where the comparator intervention (w/PATH-UTI) was both less costly and more effective. This indicated that the intervention was cost-saving and improved health outcomes and was therefore cost-effective across all simulations. The scale of the x-axis reflected minimal differences in the symptom resolution rate between the two groups. The red colour in the heatmap represents where there is a greater density of points on the graph. Additionally, Figure 4.7 shows the extent of variation across the 5,000 samples. The ellipses show where 80% and 95% of the bootstrapped estimates landed. There was slightly more variation in the distribution of the points compared with Scenarios 1 and 2 due to some outliers with high emergency department or hospitalisation costs from the administrative data.

However, all points fell within the bottom-right quadrant, indicating a 100% probability that inclusion of the pharmacy option resulted in lower costs and similar or improved health outcomes in Scenario 3.

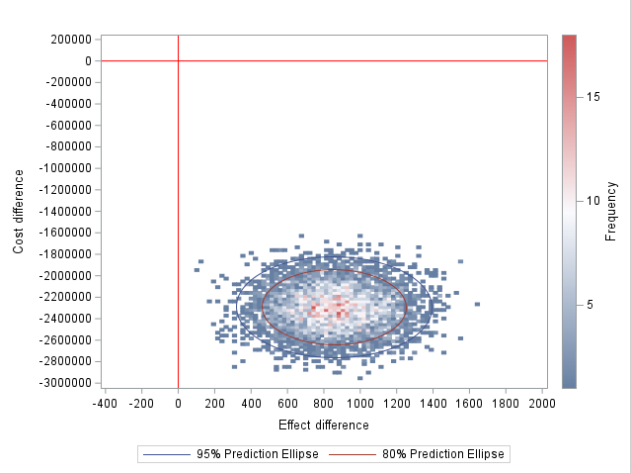


Figure 4.7: Cost-effectiveness plane for Scenario 3: Initial presentation and re-presentation – linked data: incremental costs and symptom-free days for pharmacy-led management of uUTI compared with usual care (health service perspective, 7-day horizon) (AUD 2023)

Summary of the Assessment of Value

Across all scenarios tested, the current economic evaluation showed that including pharmacy-led care as an option for initial treatment of uUTIs was highly likely to result in substantial cost savings, while achieving similar health outcomes. The modelling indicated that an upfront investment in pharmacy-led care could reduce the burden on other parts of the healthcare system by diverting uUTI patients away from more costly providers, thereby freeing them up for other patients.

Table 4-17 is a summary of the results for the three scenarios tested in this economic evaluation. The total mean costs across all clinical pathways increased from $21 million in Scenario 1 to $25.5 million in Scenario 3 when re-presentation costs were included.

Table 4-17: Summary of mean cost differences between pre-PATH-UTI and w/PATH-UTI models for all scenarios (AUD 2023, 1,000s)

	Scenario 1 Initial presentation		Scenario 2 Initial presentation + re-presentation		Scenario 3 Initial presentation + re-presentation (linked data)	
Clinical pathway	**Mean cost**	**Cost difference**	**Mean cost**	**Cost difference**	**Mean cost**	**Cost difference**
Pharmacy	440	880	451	1,056	1,490	1,490
Conservative management	-	-	156	-9	288	-43
Emergency department	10,352	-1,826	10,445	-1,848	10,861	-1,925
General practitioner online	173	-25	198	-28	272	-35
General practitioner	8,118	-1,109	9,308	-1,203	11,692	-1,596
Urgent care clinic	1,551	-172	1,581	-177	1,713	-185
Total	20,633		21,633		25,571	
Total difference		**-2,255**		**-2,210**		**-2,295**

Across all scenarios, pharmacy care pathway costs ranged from $880,000 in Scenario 1 (initial presentation costs only) to $1.5 million in Scenario 3 (including linked data for re-presentations). This evaluation used a health service perspective; therefore, conservative management incurred no cost to the health service in Scenario 1. Over-the-counter medication costs were considered out-of-pocket expenses borne by the patient. However, when re-presentation costs were evaluated in Scenarios 2 and 3, the mean cost to the health service was estimated to be $156,000 in Scenario 2 and increased markedly to $288,000 in Scenario 3. This suggests a greater proportion of women required additional treatment or more extensive additional treatment on re-presentation.

Across the various clinical pathways for managing uUTIs, the mean overall total costs were highest when either an emergency department or a general practitioner was the initial source of treatment. After accounting for re-presentation costs, the total emergency department costs were marginally higher in Scenario 3 (using administrative linked datasets to derive costs), totalling approximately $11 million. For the general practitioner pathway, including the linked administrative data increased costs by $2 million, making it the costliest pathway in Scenario 3 at over $11 million. However, it is important to note that the general practitioner pathway was also the most frequently used pathway in all scenarios, and therefore these costs were distributed across a much larger number of patients than the emergency department costs.

Figure 4.8 presents the mean costs of each initial pathway by scenario. The emergency department and general practitioner pathways consistently remained the costliest. Conservative management and general practitioner online remained the least costly. While pharmacy costs do increase when using linked data to estimate the costs of re-presentation within the 7-day follow-up period, the CEAs showed that a model including the pharmacy pathway remained consistently less costly than one without it. The impact of a model including the pharmacy pathway is evident when looking at the cost differences between the scenarios. Figure 4.8 shows that a model including the pharmacy pathway results in cost savings to other pathways consistently across every scenario evaluated.

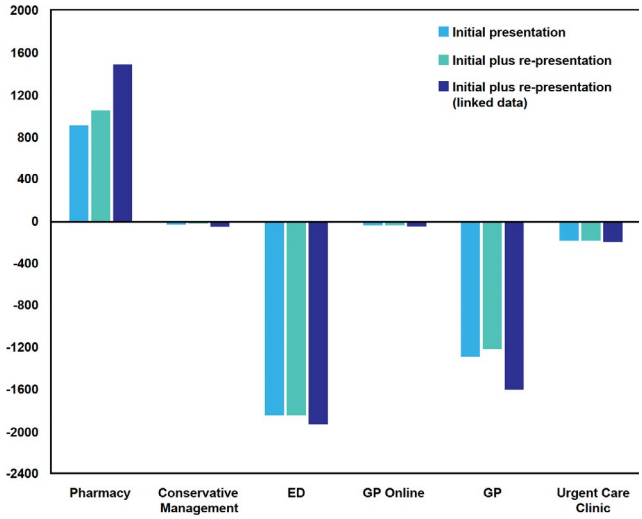


Figure 4.8: Mean cost difference in initial pathway by scenario – pharmacy-led management of uUTI compared with usual care (health service perspective, 7-day horizon) (AUD 2023)

Assessment of cost distribution changes

Scenario 1: Initial Presentation

Costs

Table 4-18 summarises the unit costs applied in the analysis for antibiotics, consultations (including diagnostics), and conservative management treatments, disaggregated by care pathway and payer. Antibiotic costs were borne entirely by patients across all non-emergency department pathways, with similar average costs for pharmacy and general practitioner-based pathways, reflecting the use of comparable first-line therapies.

For emergency department presentations, antibiotic costs were assumed to be included within the State-funded episode of care, on the assumption that treatment is dispensed on site and patients do not receive a prescription to be filled at a community pharmacy.

Consultation costs varied substantially by pathway and payer. Pharmacy consultations were associated with patient out-of-pocket costs only, with a wide range reflecting variation in fees across sites.

In contrast, general practitioner consultations incurred costs to both the Commonwealth and patients, while online general practitioner and urgent

care consultations were funded entirely through patient out-of-pocket payments.

Emergency department presentations represented the highest consultation cost and were borne entirely by the State government. For conservative management, all costs were incurred by patients and reflected the use of over-the-counter products, with cranberry products contributing the largest share of self-care costs.

Table 4-18: Costs (AUD 2025) included in the model for each pathway by payer

		Cost (min, max)		
Cost item	**Pathway**	**State**	**Commonwealth**	**Patient**
Antibiotics				
	Pharmacy	—	—	23.85 (19.22, 27.78)
	General practitioner* Online general practitioner†, Urgent care†	—	2.78	20.94 (17.77, 25.00)
Consult (including diagnostics)				
	Pharmacy	—	—	37.65 (20.40, 71.49)
	General practitioner*	—	74.53 (53.70, 105.45)	43.00 (30.16, 60.80)
	Online general practitioner†	—	—	56.59 (39.00, 99.95)
	Urgent care†	—	—	273.75 (115.00, 350.00)
	Emergency department	644.60	—	—
Conservative management treatments				
Analgesia[a]	Self-care	—	—	6.82 (0.59, 18.99)
Cranberry[b]	Self-care	—	—	25.20 (7.99, 56.99)
Urinary alkaliniser	Self-care	—	—	14.78 (7.30, 32.99)

** Including MBS subsidy eligible telehealth*
† Consult not eligible for MBS subsidy
[a] Paracetamol, ibuprofen, naproxen aggregated cost
[b] Juice and supplements/capsule

Table 4-19 shows the average cost per uUTI episode by initial care pathway, disaggregated by payer. The emergency department pathway had the highest average cost per episode, with costs borne entirely by the State government. Urgent care and general practitioner pathways were also associated with relatively high total costs, reflecting a combination of consultation and treatment expenses, with costs distributed between government and patients.

In contrast, pharmacy and conservative management pathways had substantially lower total costs per episode, with costs incurred entirely by patients as out-of-pocket payments.

Online general practitioner services fell between these extremes, with total costs driven primarily by patient out-of-pocket consultation fees and minimal government expenditure.

Overall, the results highlight marked variation in the average cost per episode across care pathways and clear differences in how costs are distributed between government and patients depending on the setting of care.

Table 4-19: Average cost per uUTI episode by initial care pathway and payer: initial presentation (AUD 2025)

Pathway	Common-wealth	State	Patient	Total
Pharmacy	—	—	61.50	61.50
General practitioner*	77.31	—	63.94†	141.25
Online general practitioner‡	0.56	—	77.53	78.09
Urgent care‡	2.78	—	273.75	276.53
Emergency department	—	644.60	—	644.60
Conservative management only	—	—	46.80	46.80

** Including MBS subsidy eligible telehealth*
† Value for fee paying patients. Bulk billed patient cost was $0
‡ Consult not eligible for MBS subsidy

Cost-shifting

Using a simulated population to estimate annual system-level impacts, the introduction of PATH-UTI was associated with lower government-funded and patient out-of-pocket costs across general practitioner, online general practitioner, urgent care clinic and emergency department pathways, reflecting reduced utilisation of these services when pharmacy management was available.

The largest absolute reduction in government expenditure occurred for emergency department presentations, with lower State costs under PATH-UTI compared with the pre-PATH scenario. Reductions were also observed in Commonwealth-funded general practitioner services and patient out-of-pocket costs for general practitioner and urgent care pathways. In contrast, patient out-of-pocket costs increased for the pharmacy pathway, reflecting the introduction of pharmacy consultations as a new point of care rather than increased costs within existing pathways.

Conservative management pathways showed modest reductions in patient costs. As shown in Table 4-20, the net effect across all pathways was a reduction in State and Commonwealth government costs, but with an increase in patient expenditure, indicating a redistribution of costs between payers rather than a uniform change in total expenditure.

Table 4-20: Total health care costs for initial presentation by payer (AUD 2025, 1,000s)

	Pre-PATH			PATH-UTI			Difference		
	State	Common-wealth	Patient	State	Common-wealth	Patient	State	Common-wealth	Patient
Pharmacy	—	—	—	—	—	1,197.79	—	—	1,197.79
General practitioner*	—	6,436.60	3,921.43	—	5,613.72	3,419.98	—	-822.88	-501.46
Online general practitioner†	—	0.13	260.04	—	0.12	224.83	—	-0.02	-35.23
Urgent care clinic†	—	0.22	1,562.71	—	0.19	1,398.61	—	-0.02	-164.10
Emergency department	10,802.46	—	204.16	9,049.48	—	170.98	-1,752.99	—	-33.18
Conservative management only	—	—	334.68	—	—	292.11	—	—	-42.57
					Total difference		**-1,752.99**	**-822.92**	**421.28**

** Including MBS subsidy eligible telehealth and value accounts for 69% of patients being bulk billed*
† Consult not eligible for MBS subsidy
Note: Cell shading is used to assist visual interpretation only and indicates the direction of the cost amount. Blue shading denotes a value below zero; red shading denotes a value over zero. Density of shading increases as the values move further from zero
Note: Totals may not sum exactly due to rounding of individual values

Sensitivity: Initial presentation

Sensitivity Analysis 1 examined the impact of alternative pharmacy consultation fee distributions on cost-shifting outcomes, while holding all other model inputs constant at base case values. Under this scenario, patient costs for pharmacy consultations were allocated such that 20% of patients incurred a low fee ($19.50), 75% incurred the base case fee ($36.70), and 5% incurred a higher fee ($70.50).

When applied to the simulated annual population, the overall pattern of cost redistribution remained consistent with the base case analysis. As with the base case, the PATH-UTI model was associated with reductions in State and Commonwealth government costs across general practitioner, online general practitioner, urgent care clinic and emergency department pathways, reflecting reduced utilisation of these services when pharmacy management was available.

There was an increase in patient costs, due to pharmacy consultations being a new point of care, although the magnitude of this increase was lower due to the assumed distribution of consultation fees. The results are shown in Table 4-21.

Table 4-21: Sensitivity Analysis 1 – total health care costs for initial presentation by payer, various pharmacy consultation fees (AUD 2025, 1,000s)

	Pre-PATH			PATH-UTI			Difference		
	State	Common-wealth	Patient	State	Common-wealth	Patient	State	Common-wealth	Patient
Pharmacy	—	—	—	—	—	1,166.11	—	—	1,166.11
General practitioner*	—	6,436.60	3,921.43	—	5,613.72	3,419.98	—	-822.88	-501.46
Online general practitioner†	—	0.13	260.04	—	0.12	224.83	—	-0.02	-35.21
Urgent care clinic†	—	0.22	1,562.71	—	0.19	1,398.61	—	-0.02	-164.10
Emergency department	10,802.46	—	204.16	9,049.48	—	170.98	-1,752.99	—	-33.18
Conservative management only	—	—	334.68	—	—	292.11	—	—	-42.57
						Total difference	**-1,752.99**	**-822.92**	**389.60**

** Including MBS subsidy eligible telehealth and value accounts for 69% of patients being bulk billed*
† Consult not eligible for MBS subsidy
Note: Cell shading is used to assist visual interpretation only and indicates the direction of the cost amount. Blue shading denotes a value below zero; red shading denotes a value over zero. Density of shading increases as the values move further from zero
Note: Totals may not sum exactly due to rounding of individual values

In Sensitivity Analysis 2, a proportion of pharmacy consultations were assumed to incur no patient fee, while all other model inputs were held constant at base case values. Under this scenario, 10% of patients were assumed to incur no consultation fee, with the remaining patients distributed across low, base case and high pharmacy consultation fees (Table 4-2).

When applied to the simulated annual population, the overall pattern of cost-shifting remained consistent with the base case analysis. Inclusion of a zero-fee subgroup resulted in a slightly smaller increase in patient out-of-pocket costs for pharmacy consultations. Note, minor differences in mean costs and uncertain intervals between the base case and this sensitivity analysis were observed, this is consistent with sampling variation introduced by bootstrap resampling, and do not materially alter the direction or interpretation of the results. The findings from the base case analysis and both sensitivity analyses indicate a consistent redistribution of costs following the introduction of PATH-UTI. Detailed results can be seen in Table 4-22.

Table 4-22: Sensitivity Analysis 2 – total health care costs for initial presentation by payer, various pharmacy consultation fees including $0 no fee (AUD 2025, 1,000s)

	Pre-PATH			PATH-UTI			Difference		
	State	Common-wealth	Patient	State	Common-wealth	Patient	State	Common-wealth	Patient
Pharmacy	—	—	—	—	—	1,099.68	—	—	1,099.68
General practitioner*	—	6,437.20	3,921.77	—	5,613.22	3,419.70	—	-823.97	-502.07
Online general practitioner†	—	0.13	260.06	—	0.12	224.81	—	-0.02	-35.25
Urgent care clinic†	—	0.22	1,562.89	—	0.20	1,398.39	—	-0.02	-164.50
Emergency department	10,803.13	—	204.14	9,048.81	—	170.97	-1,754.32	—	-33.18
Conservative management only	—	—	334.65	—	—	292.13	—	—	-42.52
						Total difference	**-1,754.32**	**-824.01**	**322.16**

* *Including MBS subsidy eligible telehealth and value accounts for 69% of patients being bulk billed*
† *Consult not eligible for MBS subsidy*
Note: Cell shading is used to assist visual interpretation only and indicates the direction of the cost amount. Blue shading denotes a value below zero; red shading denotes a value over zero. Density of shading increases as the values move further from zero
Note: Totals may not sum exactly due to rounding of individual values

Scenario 2 Initial and Re-presentation – Linked data

Costs

Scenario 2 used linked administrative data from trial participants to identify instances of re-presentation within the 7-day follow-up period, stratified by whether uUTI symptoms were reported as resolved or unresolved (see Appendix 4.4 for data provided by The George Institute for Global Health). Table 4-23 summarises the proportion of participants accessing additional healthcare services during follow-up.

Participants who reported unresolved symptoms at 7 days were more likely to seek additional care across all service types, including general practitioner visits, pathology testing, additional antibiotic treatment, emergency presentations, and avoidable genitourinary hospitalisations.

Cost-shifting

The second scenario modelled in the analysis evaluated the base case with the addition of costs associated with re-presentation to healthcare providers other than pharmacies within the 7-day follow-up period. Linked trial data was used to capture additional service use following the initial consultation.

When both initial presentation and subsequent re-presentation were considered, PATH-UTI was associated with lower total costs across all non-pharmacy pathways compared with the pre-PATH scenario (Table 4-24). Reductions were observed for general practice, online general practitioner, urgent care clinic, emergency department and conservative management pathways, with decreases evident across State and Commonwealth cost components.

Emergency department presentations accounted for the largest absolute reduction in State-funded costs when pharmacy management was available, consistent with lower reliance on higher-cost acute care following initial treatment. In contrast, costs attributed to the pharmacy pathway increased under PATH-UTI, reflecting both initial pharmacy

consultations and subsequent re-presentations to other providers captured in this scenario.

When aggregated across all pathways, the inclusion of re-presentation costs resulted in a net reduction in State and Commonwealth government expenditure as well as for patient costs, indicating that savings (although smaller than Scenario 1) remain when short-term follow-up care is taken into account.

Table 4-23: Re-presentations in the 7-day follow-up period – linked data*

UTI Symptoms	General practitioner visit %	Pathology – Urine Sample %	Additional antibiotics for UTI %	Emergency presentations GU related %	Avoidable GU hospitalisations %†
Resolved	16.4	6.3	5.9	0.52	0.08
Unresolved	43.0	26.1	30.3	2.6	0.32

** Note that percentages do not sum to 100% as some patients received multiple additional services, and others sought no additional healthcare*

† While percentages have been provided for the entire sample, hospitalisations needed an emergency department visit first

Table 4-24: Total health care costs for initial presentation plus re-presentation at health care providers other than pharmacies by payer (AUD 2025, 1,000s)

	Pre-PATH			PATH-UTI			Difference		
	State	Common-wealth	Patient	State	Common-wealth	Patient	State	Common-wealth	Patient
Pharmacy				300.55	209.12	1,330.99	300.55	209.12	1,330.99
General practitioner*	1,910.48	7,730.78	4,754.89	1,669.10	7,344.45	4,154.49	-241.38	-386.33	-600.40
Online general practitioner†	51.61	35.31	283.49	48.62	30.56	244.66	-3.00	-4.75	-38.82
Urgent care clinic†	80.04	59.64	1,601.71	77.21	53.38	1,432.45	-2.83	-6.26	-169.26
Emergency department	11,075.25	191.24	326.56	9,273.58	160.27	274.10	-1,801.67	-30.97	-52.46
Conservative management only	160.35	101.30	401.77	136.20	88.49	349.85	-24.15	-12.81	-51.92
						Total	**-1,772.48**	**-231.99**	**418.13**

** Including MBS subsidy eligible telehealth and value accounts for 69% of patients being bulk billed*

† Consult not eligible for MBS subsidy

Note: Cell shading is used to assist visual interpretation only and indicates the direction of the cost amount. Blue shading denotes a value below zero; red shading denotes a value over zero. Density of shading increases as the values move further from zero

Note: Totals may not sum exactly due to rounding of individual values

Discussion

Assessment of value

Community pharmacy management as an effective avenue for the treatment of minor ailments has already been shown to be clinically effective compared to usual practice in Australia [169], and there is growing evidence for its cost-effectiveness [170]. However, previous evaluations have grouped several minor ailments together, and the variety of treatments and ailment characteristics in previous trials make it difficult to determine the value of pharmacy-led care for an individual condition. This evaluation assessed the cost-effectiveness of including community pharmacy as an option for uUTI management.

Cost-effectiveness was evaluated by comparing modelled datasets consisting of costs and outcomes of a treatment arm including pharmacy (w/PATH-UTI) and a control arm without pharmacy (pre-PATH-UTI). Across all evaluated scenarios, the model including pharmacy was found to be cost saving while improving outcomes, and therefore cost-effective. This finding was robust, with the w/PATH-UTI model remaining dominant even when the costs of re-presentation for additional treatment were included. Uncertainty analyses also demonstrated high confidence in the cost-effectiveness results.

A key limitation in the modelling is that the synthesised sample dataset assumes women will present to a healthcare professional with an uUTI only once in the designated year. It has been reported that 27% of women will have a recurrent UTI within 6 months of the first episode, and up to 2.7% will have a third instance of uUTI in that timeframe [158]. The clinical management protocol classifies two or more UTIs within 6 months as requiring an immediate referral to a general practitioner; however, in practice, women could present to pharmacies for uUTI treatment more than once in a 12-month period. This could mean a proportion of the population requiring treatment for uUTIs over a 12-month period and associated healthcare system savings may have been underestimated. Similarly, the total cost savings may increase as more people become aware of the pharmacy-led service and choose that treatment pathway. The current analysis estimated that 13% of women with an uUTI would present to a pharmacy, whereas other studies in Canada have used 38% [153] or up to 50% [145] and found substantial cost savings.

Another limitation of the current analysis is the exclusion of implementation costs (e.g., training for pharmacies) or costs incurred by the pharmacies to provide the service (e.g., provision of consult rooms). This appears to be a significant gap in the published literature; namely, Sanyal *et al.* [145] also do not include implementation costs. Given the potential impost of uUTI management to individual pharmacies, future economic evaluations should consider costing those resources.

Assessment of cost distribution changes

The current evaluation assessed potential cost-shifting effects of including community pharmacy as a healthcare option for uUTI management.

Across all scenarios evaluated, the introduction of PATH-UTI was associated with a redistribution of healthcare costs across care settings and payers. In Scenario 1, PATH-UTI was associated with lower State and Commonwealth government costs across general practice, online general practitioner, urgent care clinic and emergency department pathways, alongside an increase in patient out-of-pocket costs reflecting uptake of pharmacy consultations as a new point of care. The sensitivity analyses, which tested alternative distributions of pharmacy consultation fees (including a zero-fee subgroup), demonstrated only modest changes in the magnitude of patient costs and no change in the direction of cost-shifting. When costs associated with re-presentation to healthcare providers other than pharmacies were included in Scenario 2, reductions in government-funded costs across non-pharmacy pathways persisted, particularly for emergency department presentations, while costs attributed to the pharmacy pathway increased to reflect both initial and follow-up care. Taken together, these findings indicate that, when applied to a simulated annual population, PATH-UTI consistently shifts activity away from higher-cost settings and redistributes costs between government and patients.

At present, pharmacies have freedom to set fees for their consultations. The values used for pharmacy consult fees in the current analysis was based on the recommendations in the handbook for Queensland pharmacies [168]. There are no publicly available data about the fees charged by pharmacists for these services in NSW or ACT. Without evidence of real-world consult fees and utilisation, the impact of variations in pharmacy consult fees on uptake of the

services could not be evaluated. Pharmacy consultation fees have the potential to greatly impact the affordability and accessibility of pharmacy management compared to other health care pathways and therefore should be evaluated if/when data become available.

The evaluation was limited to a partial societal perspective because available data supported inclusion of out-of-pocket medication costs, but not broader societal impacts such as productivity gains from reduced time off work. It is likely that increased and timely access to services (via PATH-UTI) would result in reduced time off work for some patients. As a result, the societal benefits of PATH-UTI are likely underestimated.

Conclusion

The economic evaluations presented indicate that a model with community pharmacy management of uUTIs has the potential to bring about substantial cost savings to the health system for both State and Commonwealth payers. In doing so, some costs may be shifted to patients.

The CEA, which tested three different scenarios, indicates that a model with community pharmacy management is cost-effective compared to one without and has the potential to bring about substantial cost savings to the healthcare system. Patient out-of-pocket costs were not included in the CEA model, which took a health service perspective. However, patient costs were included in the cost distribution analysis. This showed some increase in patient costs, shifting costs away from the government payers, when patients chose the pharmacy option.

Enabling community pharmacists to manage uUTIs could potentially save money and reduce the workforce burden on general practitioners and emergency departments for treatment of this condition. The analyses presented provide evidence to inform policy-making decisions regarding the support of community pharmacy-led care for uUTIs.

05

AN EVALUATION OF IMPLEMENTATION FIDELITY AND EFFECTIVENESS

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 5: An Evaluation of Implementation Fidelity and Effectiveness

Introduction

This chapter presents findings from research undertaken by the University of Newcastle and the University of Technology Sydney. Additional implementation research was undertaken by The George Institute for Global Health (see Chapter 3).

Translation of research evidence into routine healthcare practice is often delayed [24]. A literature review examining time lags in translating health research into practice found that, on average, it takes approximately 17 years for evidence-based practices (EBPs) to become part of standard health care, with approximately 50% implementation success rate [24]. This gap in applying research findings exists across all settings, disciplines and countries [25]. Therefore, to optimise the public health impact of innovations and EBPs, implementation programs with Practice Change Facilitators (PCFs), ongoing performance feedback and targeted strategies are needed to support their integration into practice. Addressing this challenge is the core focus of implementation science [26, 27].

PCFs are individuals with subject matter expertise who assist, mentor, coach or support implementation through working with organisations (community pharmacies) and with the service providers (community pharmacists) [28] to implement new services (pharmacist management of uncomplicated UTIs (uUTIs)).

The Consolidated Framework for Implementation Research (CFIR) [29] is a framework used to classify implementation determinants which includes five domains related to:

- innovation (pharmacy service);
- individuals (pharmacy staff or patients);
- the inner setting (pharmacy);
- the outer setting (general practice or clinics, other pharmacies); and
- the implementation process.

Implementation determinants are contextual factors that affect an implementation effort. Determinants that negatively affect implementation are known as barriers; facilitators are contextual factors that positively affect implementation. Moullin *et al.* promulgated the importance of the evaluation of the implementation determinants, how they changed over time, and the strategies used to overcome them [171]. Implementation strategies are defined as methods or techniques used to enhance the adoption, implementation and sustainability of a clinical program or practice [172]. The Expert Recommendations for Implementing Change (ERIC) framework classifies 73 different strategies.

Implementation outcomes are defined as 'the effects of deliberate and purposive actions to implement new treatments, practices, and services' and are distinct from service and client (patient) outcomes [173]. Proctor *et al*. defined eight different implementation outcomes: acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability. Implementation outcomes have also been divided into two levels: level of service provision (e.g., reach, fidelity) and level as a service provider (e.g., feasibility) [171].

Most implementation determinants for pharmacist prescribing services reported in the literature have been barriers related to the outer setting (i.e., negative perception of pharmacist prescribing by general medical practitioners), the inner setting (i.e. lack of pharmacists' time) and innovation (i.e. lack of reimbursement) [174-177]. Additionally, a 2019 scoping review [178] of pharmacist prescribing suggested inadequate training in diagnostic knowledge and skills as a key barrier to implementation. Dale *et al.* highlighted the expansion of pharmacist prescriptive authority and a culture of support for clinical pharmacists as important facilitators. Other major facilitators identified [179] were competence, self-confidence and the potential for positive impact on patient care.

Objectives

The objectives were to:

- assess implementation uptake of the intervention, including reach, fidelity and adoption of the intervention in community pharmacies, participant characteristics, and variation in uptake by geographic region; and
- identify contextual enablers and constraints which influence access, adoption, fidelity, impact, sustainability and generalisability of the intervention.

To meet these objectives, the PATH-UTI study included a feasibility study of 2 months and a main trial of 10 months. During the final 8 months of the main trial, both the implementation of PATH-UTI and PATH-OC (trial for the re-supply of the oral contraceptive pill in community pharmacy) were active. The University of Newcastle team, in association with the University of Technology Sydney, undertook the study while The George Institute for Global Health undertook stakeholder interviews (see Chapter 3).

Methods

A holistic approach was adopted to evaluate the implementation of the PATH-UTI trial, aligned with study outcomes, theoretical frameworks and databases described in Figure 5.1.

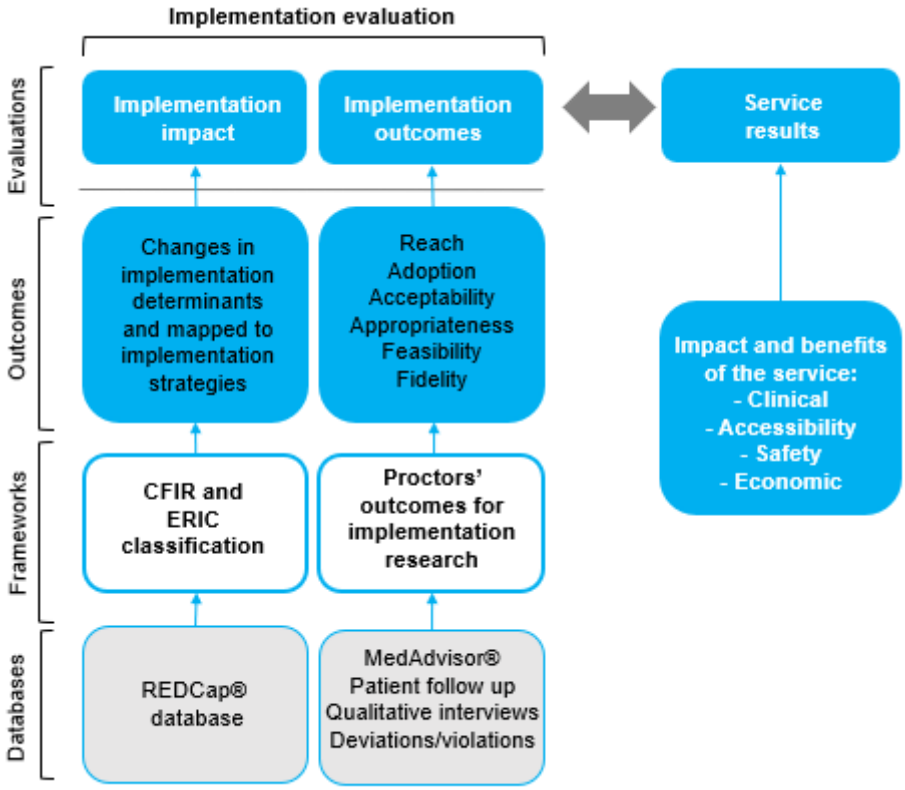


Figure 5.1: Implementation evaluation aligned with study outcomes, theoretical frameworks and databases

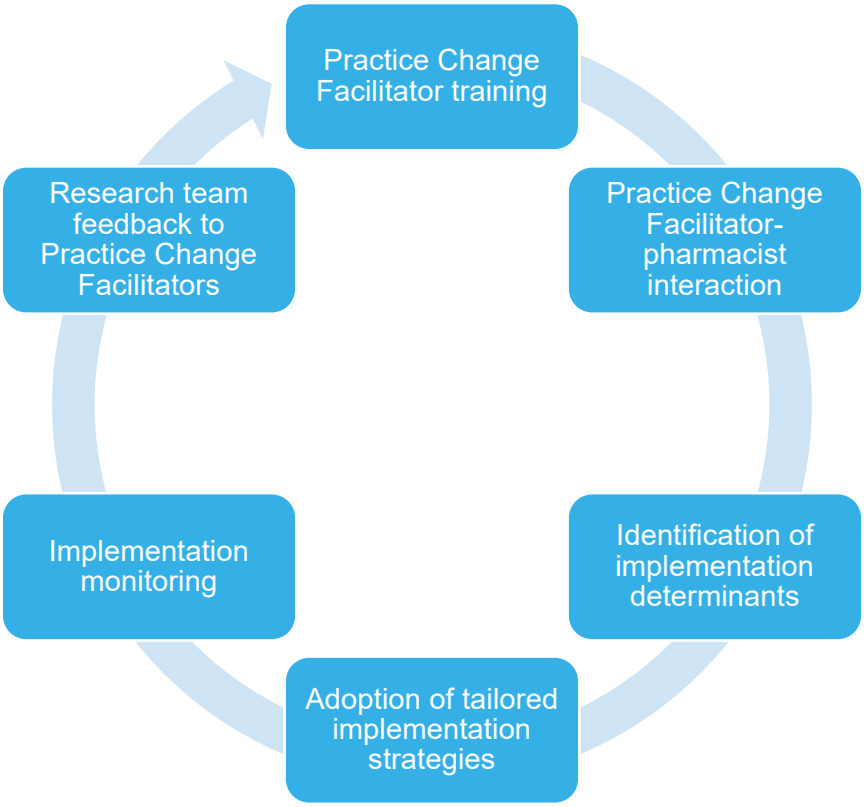


Figure 5.2: PCF–pharmacist intervention process

Facilitation process, implementation determinants and strategies

The key components of the facilitation process used in this study are described in Figure 5.2.

Training for PCFs

Training was delivered by the research team to four PCFs prior to trial commencement and reinforced fortnightly throughout the study period. The training consisted of:

- the uUTI pharmacist management service. PCFs also completed the training required for participant pharmacists (online clinical training);
- the classification of the implementation determinants following the CFIR [29];
- the classification of the implementation strategies using the ERIC framework [30];
- data collection systems (detailed below) including the implementation database for PCFs using a predesigned REDCap® IT form [180]. REDCap® is a secure web application for building and managing online databases. PCFs used this database to detail encounters with pharmacists, the information discussed, and the strategies provided;
- key priorities when supporting pharmacists and triage of requests; and
- feedback reports on their performance and performance of the pharmacies.

PCF–Pharmacist Interaction

As part of the support provided for pharmacists, PCFs were in contact with pharmacists face-to-face or through video calls, phone calls and/or emails to respond to queries and ensure quality of patient data. The rates of these contacts were determined by:

- date of trial commencement for each pharmacy;
- pharmacist-initiated requests due to doubts with any aspect of the service (i.e., use of the MedAdvisor® IT program, UTI protocol, required training, materials used, etc);
- data analysis of pharmacist–patient consultations carried out by the research team. Pharmacies were classified based on the number of

consultations: low-performing pharmacies had 0 consultations, medium-performing pharmacies had 1–5 consultations, and high-performing pharmacies had more than 5 consultations; and

- strategic decisions made by the research team depending on the needs and progress of the overall study.

Identification of Implementation Determinants

PCFs identified and evaluated implementation determinants (barriers and facilitators), using a checklist developed through consensus by the research team (Appendix 5.1), as part of their contact with participants. The CFIR [29] was used to classify these implementation determinants.

Tailored Implementation Strategies and Monitoring

After the identification and prioritisation of implementation barriers and facilitators, PCFs selected and executed strategies by matching to determinants according to perceived feasibility and impact of strategies. The ERIC [30] system was used to classify these strategies. The follow-up and prioritisation of contacts were based on pharmacy performance in terms of number of consultations, appropriate use of the clinical protocol and the use of the MedAdvisor® IT program. Follow-up allowed monitoring of the strategies and the pharmacists' engagement with the provision of the service.

PCFs Audit and Feedback

Pharmacy performance was monitored by the research team through the community pharmacy data received daily from the MedAdvisor® IT platform and patient follow-up data provided by The George Institute for Global Health. Continuous feedback to PCFs, delivered at weekly meetings by the research team and through three types of formal reports, was used to prioritise the selection of face-to-face visits. The three different formal reports were:

1. weekly activity report to monitor contacts (in situ visits, phone calls, emails) with pharmacies;
2. monthly clinical implementation report to provide pharmacy performance data and implementation report to monitor the implementation determinants and strategies recorded by PCFs in REDCap®; and
3. a report with Sankey diagrams (both at the study level and individually for each PCF) to link implementation determinants and strategies, providing a visual analysis of the strategies' success (Appendix 5.2).

Implementation outcomes

Acceptability

Acceptability is defined as the perception among implementation stakeholders and patients that the service is agreeable, palatable or satisfactory [173]. Acceptability was measured in two different ways: patients received a follow-up survey from The George Institute for Global Health via their preferred method (SMS and/or email) selected during the consent process. Follow-up occurred 7 days after the pharmacist-patient consultation to elicit acceptability of the service, with up to three reminders at the second, fourth and sixth day after the initial email. For this outcome, seven questions, each scored on a 7-point Likert scale, were posed (see Chapter 3). Patients were asked questions about their experiences with the service, including its advantages and disadvantages, and whether they would recommend it to others.

Appropriateness

Appropriateness refers to the perceived fit, relevance or compatibility of the service for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue or problem [171]. It was measured during the qualitative interviews by The George Institute for Global Health. Patients were asked about their perception of the usefulness of the service and any downsides when using it, while community pharmacists were asked three questions focusing on their reflection about the service (see Chapter 3).

Feasibility

Feasibility is defined as the extent to which the service can be successfully used or carried out within a given agency or setting [171]. Feasibility was evaluated during the qualitative interviews; pharmacists were asked questions focusing on the impact of the service on the practice and workflow (see Chapter 3). A combination of data was taken from the PCFs' reports and from The George Institute for Global Health's data (from patient follow-up surveys, and from interviews with patients and pharmacists). For further information, refer to Chapter 3.

Accessibility

To explore geographical accessibility for patients, a heatmap of the participating pharmacies and population of pharmacies derived from the Pharmacy Council of New South Wales list of registered pharmacies (up to January 2024) was generated.

Adoption and Reach

Adoption is the 'intention, initial decision, or action to try or employ' the service [173]. It was measured as the absolute number, proportion and representativeness of pharmacies and pharmacists that were willing to initiate the service. Reach of a service is defined as the representativeness of individuals who are willing to participate in each initiative, intervention, or program [181]. Reach was measured using:

- the number of consultations per pharmacy (data source was the MedAdvisor® IT program); and
- the number of pharmacies and pharmacists involved in the trial (data sourced from the University of Newcastle training and pharmacist consent database).

Fidelity

Fidelity is the degree to which the service is implemented as it was defined in the protocol or as it was intended by the program developers [173]. Fidelity was evaluated through pharmacists' compliance to the clinical protocols. All pharmacy consultations and patient follow-up surveys were reviewed every 48 hours, including clinical assessments, pharmacist recommendations, and patient outcomes and responses.

The process for data validation, as well as for identifying and classifying any potential adverse events arising from lack of fidelity (protocol violations), was sent to and approved by the committees in charge of monitoring the trial safety, including the University of Newcastle Human Research Ethics Committee (HREC), the Data Safety Monitoring Board (DSMB) and the Safety and Stewardship Working Group (SSWG). Breaches to the clinical management protocol and to the research protocol were identified as protocol violations, which were defined as 'any departure from the requirements of Good Clinical Practice, the approved clinical trial protocol, trial documents, or any other information relating to the conduct of the study which has the potential to significantly impact the safety or rights of trial participants or the reliability and integrity of the study data and the study outcomes'.

The databases used were PCFs' data (REDCap® IT platform) – this database included PCFs' checklists, identified implementation determinants and tailored implementation strategies – and consultation data (MedAdvisor® IT platform).

Data analysis

A mixed methods analytic approach was applied. Descriptive statistics were produced for the quantitative implementation outcomes (reach, fidelity, acceptability and adoption), implementation determinants (using the CFIR) and implementation strategies (using the ERIC framework). Sub analyses were conducted to differentiate implementation determinants and strategies according to timing (i.e., PATH-UTI only and phase 2 including PATH-UTI and PATH-OC simultaneously). A majority of pharmacists participating in the PATH-UTI trial were also providing the oral contraceptive service, with PCFs supporting both services concurrently.

Results

Facilitation process, implementation determinants and strategies

In total, 69.3% of pharmacies (n=915) were visited in situ at least once by PCFs; 97.6% of participating pharmacies (n=1,288) had some form of contact with a PCF (Table 5-1).

Implementation Determinants

PCFs identified implementation barriers for a total of 854 pharmacies (64.6%), with a mean of 2.2 barriers per pharmacy (Table 5-2). A mean of 5.2 facilitators was identified per pharmacy in 68.0% of the pharmacies (n=898).

The six most common barriers accounted for 73.8% of all barriers for the trial (Table 5-3). These barriers were attributed to the pharmacists' capability when delivering the service, the equipment available in the pharmacy for the provision of the service, the workflow and infrastructure of the pharmacy and/or the engagement of patients to be included in the service. Barriers accounted for 39.4% of the total implementation determinants during the first 2 months and decreased to 27.1% during the last

8 months. Examples of the most common barriers are included in Table 5-3.

The five most common facilitators accounted for 91.2% of all facilitators for the trial (Table 5-4). Most facilitators were attributed to pharmacists' knowledge and skills, infrastructure and equipment available in the pharmacy, and patient engagement. Facilitators accounted for 60.6% of the total implementation determinants during the first 2 months and increased to 72.9% of the total implementation determinants during the final 8 months. Examples of the most common facilitators are included in Table 5-4.

Table 5-1: Overview of urinary tract infections (UTI) pharmacies, in-situ visits and other contacts

	Overall study	Study during PATH-UTI only (2-month period)	Study during PATH-UTI & PATH-OC (8-month period)
Pharmacies visited in situ, n (%)	915 (69.3%)	162 (12.3%)	753 (57.0%)
Pharmacies contacted by any method*, n (%)	1,288 (97.6%)	410 (31.1%)	878 (66.5%)

**Apart from the in situ visits, additional contacts were made through emails, phone calls, video calls or messaging.*

Table 5-2: Implementation determinants

	Barriers	Facilitators
Total number	1,874	4,648
Mean per pharmacy, X ± standard deviation (SD)	2.2 ± 1.39	5.2 ± 3.25

Table 5-3: Common implementation barriers according to the CFIR [29], identified through any type of contact with pharmacists/pharmacies

Barriers	Overall study		Study during PATH-UTI only		Study during PATH-UTI & PATH-OC		Common examples*
	n	%	n	%	n	%	
Pharmacists' capability	413	22.0	76	21.8	337	22.1	Some pharmacists have not completed the training
							Lack of understanding the MedAdvisor® IT program or QR process
Available resources (equipment)	312	16.6	63	18.1	249	16.3	Lack of availability of computers in the consultation room
							Pharmacy has not received the promotional material or QR code
Work infrastructure	217	11.6	33	9.5	184	12.1	Pharmacy workflow needs adjusting (e.g., solo pharmacists at times)
							Trained pharmacists' leave periods
Engaging patients	180	9.6	23	6.6	157	10.3	Lack of service promotion
							Lack of coverage for service provision at all opening hours
Physical infrastructure	167	8.9	27	7.7	140	9.2	Consultation room did not meet all the NSW trial Authority requirements
IT infrastructure	96	5.1	29	8.3	67	4.4	Software issues associated with the MedAdvisor® IT program (e.g., connection issues, software frozen)
							Lack of software availability on the computer located in the consultation room
Total	**1,874**	**100**	**349**	**100**	**1,525**	**100**	

**To find common examples of each barrier, key terms were used in their 'open-ended' descriptions, e.g., training, computer, consultation room*

Table 5-4: Most common implementation facilitators according to the CFIR [29], identified through any type of contact with pharmacists/pharmacies

Facilitators	Overall study		Study during PATH-UTI only		Study during PATH-UTI & PATH-OC		Common examples*
	n	%	n	%	n	%	
Pharmacists' capability	1,612	34.7	145	27.1	1,467	35.7	Pharmacists' knowledge or skills
IT infrastructure	695	15.0	76	14.2	619	15.1	MedAdvisor® IT program was operating on all computers in the pharmacy
Physical infrastructure	695	15.0	101	18.8	594	14.4	Consultation room met all the trial requirements
Available resources (equipment)	669	14.4	75	14.0	594	14.4	Availability of promotional material and/or updated QR code
Engaging patients	562	12.1	39	7.3	523	12.7	Service delivered at all opening hours
							Display of promotional material
Total	**4,648**	**100**	**535**	**100**	**4,123**	**100**	

**To find common examples of each facilitator, key terms were used in their 'open-ended' descriptions, e.g., training, computer, consultation room*

Once PCFs identified implementation determinants (either barriers or facilitators), strategies were planned and executed to solve barriers or maintain facilitators. A total of 770 pharmacies had strategies in place (58.0%), with a mean of 2.9 ± 2.3 strategies per pharmacy, and an average of 5.3 ± 34.4 days to resolution (Figure 5.3).

As expected, a higher number of barriers than facilitators had strategies in place. Of all barriers identified, 59.9% (n=1,122) had a strategy planned; 70.1% (n=787) of those strategies were applied by the end of the study, of which 69.9% (n=550) successfully addressed the implementation barrier (Figure 5.3).

The majority of strategies implemented related to the facilitation process, development of an implementation blueprint, distribution of materials, and provision of audit/feedback to pharmacies and pharmacists. These common strategies accounted for 71.4% of all strategies implemented by PCFs (Table 5-5).

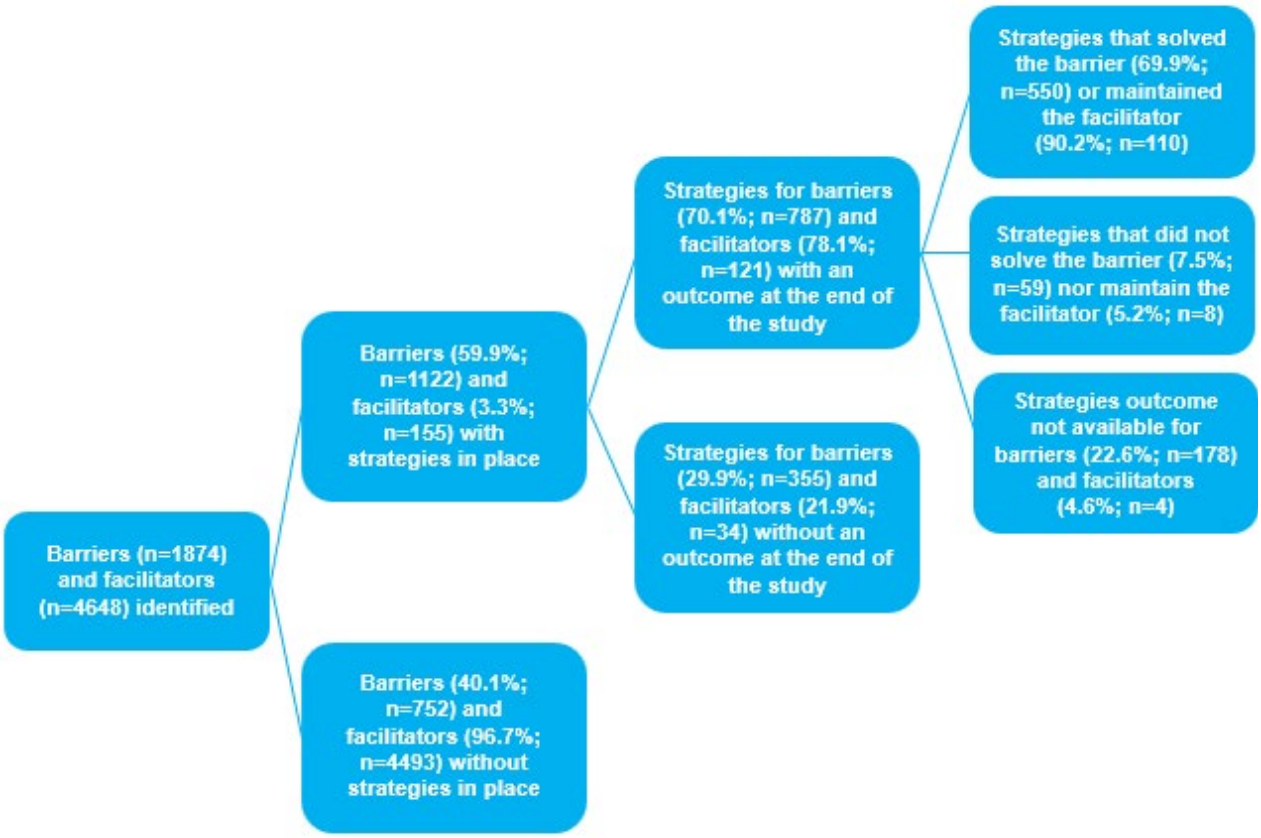


Figure 5.3: Planning and progress of the implementation strategies to solve identified barriers or to maintain facilitators during the trial

Table 5-5: Strategies used during the study that either solved the barrier or maintained the facilitator

Strategies	Overall study		Strategies that solved the barriers		Study during PATH-UTI only		Study during PATH-UTI & PATH-OC	
	n	%	n	%	n	%	n	%
Facilitation, defined as 'a process of interactive problem-solving and support that occurs in a context of a recognised need for improvement and a supportive interpersonal relationship'	387	30.3	199	36.2	103	33.9	284	29.2
Develop a formal implementation blueprint, defined as 'use and update an implementation plan to guide the implementation effort over time. The blueprint should include the aim/purpose of the implementation; scope of the change; timeframe and milestones; and appropriate performance/progress measures'	179	14.0	44	8.0	39	12.8	140	14.4
Distribute materials, defined as 'distribute educational materials (including guidelines, manuals and toolkits) in person, by mail, and/or electronically'	142	11.1	98	17.8	42	13.8	100	10.3
Audit and provide feedback, defined as 'collect and summarise clinical performance data over a specified time period and give it to pharmacists to monitor, evaluate and modify behaviours'	108	8.4	76	13.8	21	6.9	87	8.9
Conduct local needs assessments, defined as 'collect and analyse data related to the need for the service'	98	7.6	15	2.7	19	6.2	79	8.1

Implementation outcomes

Acceptability, Appropriateness and Feasibility

Over 80% (n=14,671) of patients responded to the follow-up survey 7 days after the pharmacist-patient consultation (see Chapter 3). During the qualitative interviews, patients were also asked about the perceived usefulness of the service, any downsides they experienced and their perceptions of a 'good service'. Key terms observed included: timely symptom resolution; value for money; a service that prioritises trust, privacy and respect; a service with less stringent eligibility criteria; improved integration with pathology services and streamlined referrals to general practitioners when needed (see Chapter 3). Community pharmacists expressed their perceived feasibility of the service for their setting. The results obtained highlighted the need for integration with health system 'hardware' such as health information systems, pathology services and training curricula, and integration with health system 'software' elements including nurturing relationships with general practitioners, supporting care navigation with other professionals, and changing perceptions of this being a service of last resort (see Chapter 3).

Accessibility

The distribution of participating pharmacies by the Modified Monash Model (MMM) categories shows that there were similar participation percentages for pharmacies in MMM1 to MMM5. However, although there were only 17 total pharmacies in MMM6 to MMM7 in NSW, only three MMM6 pharmacies participated in the trial, with none included for MMM7 (Table 5-6). Even in those participating, only one consult was delivered.

Table 5-6: Number of pharmacies by MMM

MMM	Number of pharmacies per MMM in New South Wales (NSW)*	% pharmacies per MMM in NSW	Pharmacies at the end of the trial	% consented pharmacies from all NSW pharmacies	Active pharmacies at the end of the trial	% active pharmacies from MMM NSW pharmacies
1	1,455	72.3	759	52.2	672	88.5
2	42	2.1	25	59.5	22	88.0
3	215	10.7	148	68.8	132	89.2
4	118	5.9	82	69.5	77	93.9
5	165	8.2	82	49.7	71	86.6
6	12	0.6	3	25.0	1	33.3
7	5	0.2	0	0	0	0
Total	**2,012**	**100%**	**1,099***	**Average 54%**	**975****	**Average 80%**

**This table uses the MMM 2019 classification for pharmacies as they were invited to the trial between April and June 2023*
***These numbers refer to pharmacies consented and active at the end of the trial and, therefore, exclude withdrawn pharmacies.*

The heatmap (Figure 5.4) shows potential patient access across the state to the service. Access was defined as being within a 1 km radius of a consented pharmacy.

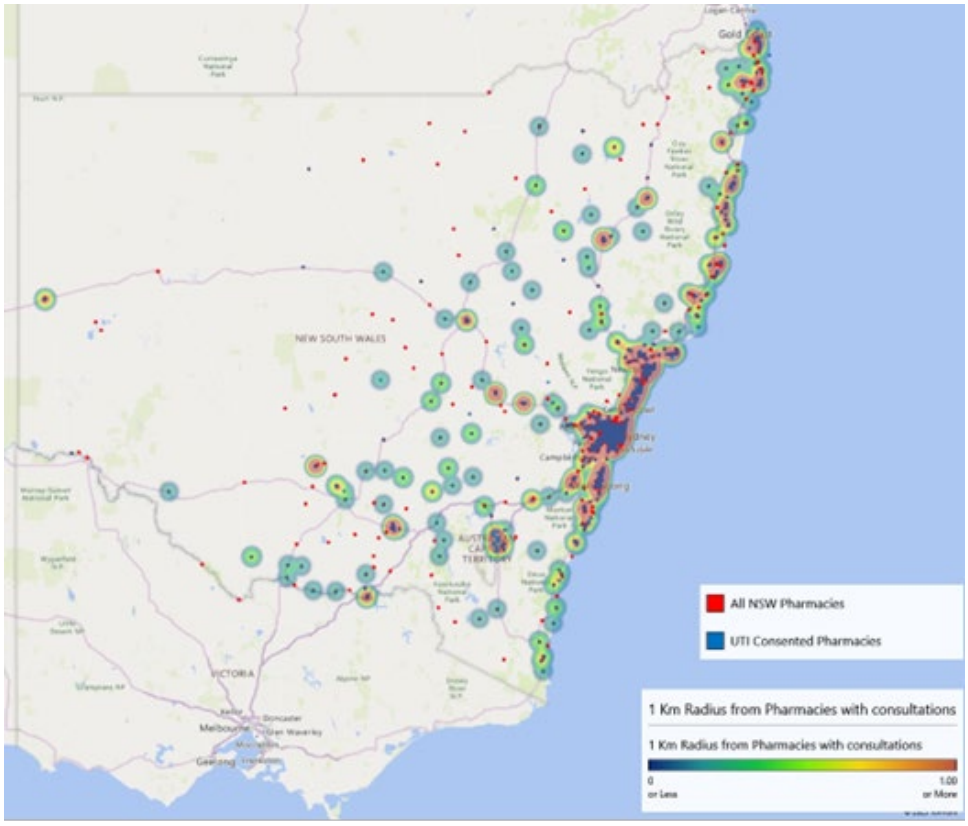


Figure 5.4: Heatmap for the accessibility of the service by total pharmacies in NSW versus pharmacies participating in the UTI trial at the end of the study

Adoption and Reach

The number of consultations per pharmacy shows that nearly a quarter of the pharmacies provided 20 or more consultations (Figure 5.5), with a mean of 15.7±15.5 consultations.

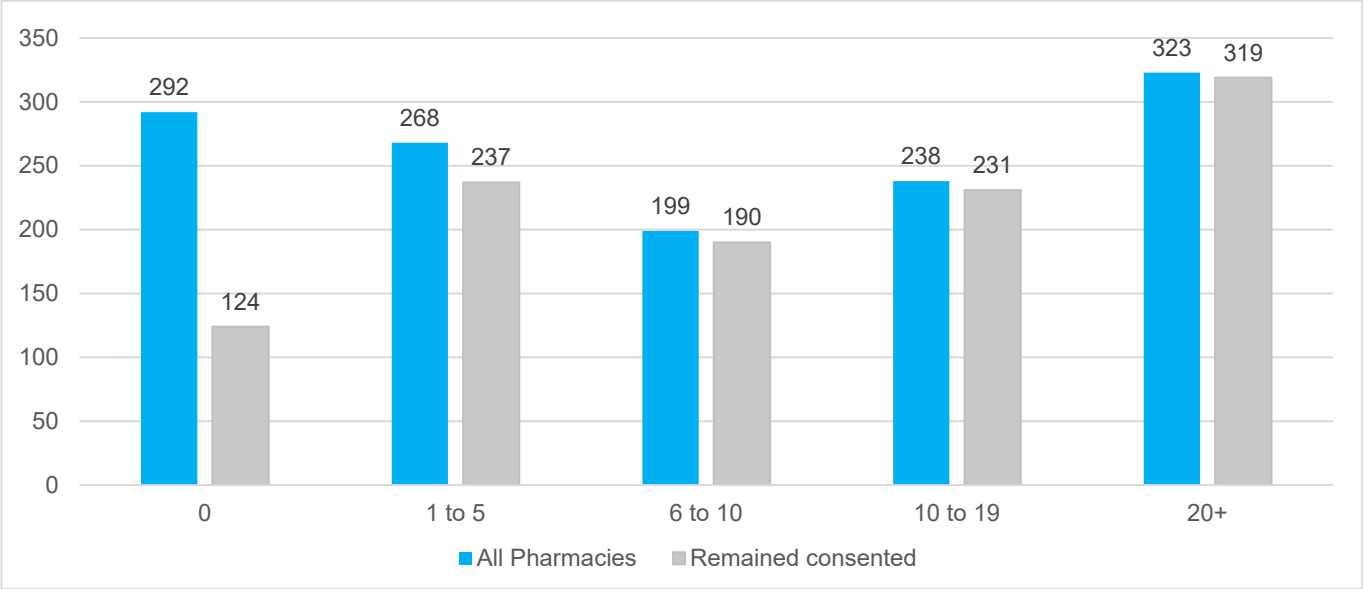


Figure 5.5: Distribution of consented pharmacies by the number of consultations

A total of 1,320 pharmacies and 3,484 pharmacists consented to the trial. Of these, 1,028 pharmacies (77.9%) and 3,049 pharmacists (87.5%) provided at least one consultation (Figure 5.6).

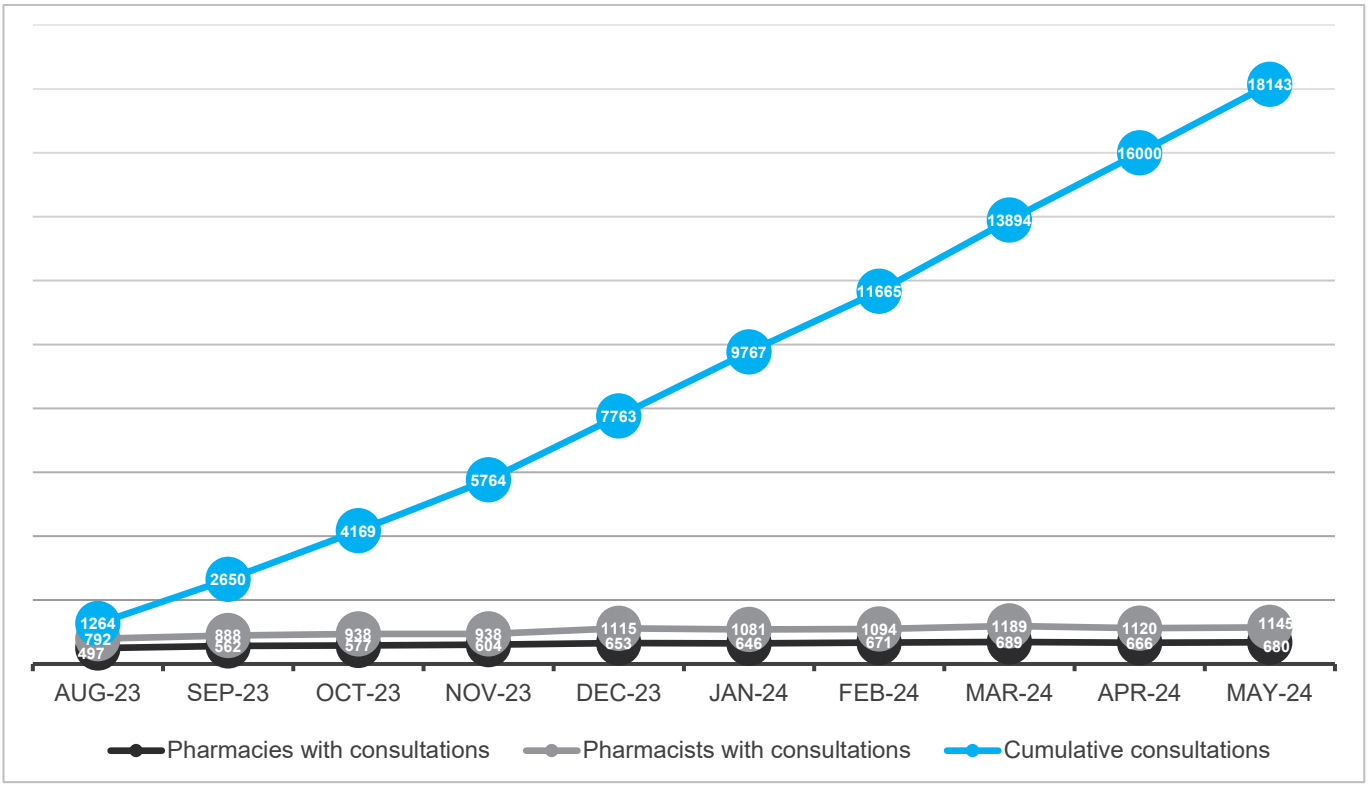


Figure 5.6: Number of consultations and consented pharmacies that have provided at least one consultation

Fidelity

In over 99% the of total consultations (n=17,963/18,143), pharmacists appropriately followed the clinical management protocols, referring over 7% of patients to a general practitioner or the emergency department when complications or risk factors were identified. When an antibiotic could be prescribed, pharmacists primarily used the suggested first-line antibiotic, trimethoprim (96%, 16,046/16,806), as indicated by the protocol. Fourteen protocol violations were identified during the trial (0.08%, 14/18,143). These violations were almost completely related to a patient presenting with a high-risk factor, most commonly with a previous UTI in the last 7 days (64%, 9/14) (Table 5-7). Note that nine of these 14 were classified as protocol violations, although the pharmacist did not provide any pharmacological treatment. This might have been due to a lack of documentation of the referral at the time of the consult.

All pharmacists involved in protocol violations were contacted by the trial team as part of the process approved by the University of Newcastle HREC, the DSMB, the SSWG and NSW Health. Attitude from pharmacists to these reports was positive. Five of the nine pharmacists indicated that patients were referred to a general practitioner, though this was not registered in the platform. If those protocol violations were not to be considered, the rate of protocol violation would be 0.05% (9/18,143).

Table 5-7: Protocol violations at close of validated database for 18,143 UTI consultations

Description of the issue	Number of patients	Main reasons to be considered a violation
Not referred with a high-risk factor	9	Although the pharmacists did not document a referral, they did not provide any antibiotic treatment for these patients. Since there were no patient follow-up data, this was classified, in a conservative manner, as a protocol violation
Prescribed with a high-risk factor after referring them to a general practitioner	3	Although these patients were prescribed antibiotics, they were also referred to a general practitioner. For two patients there was no follow-up information, and one patient visited an urgent care clinic
Allergy to the medication prescribed	1	The documentation for this patient shows that the pharmacist ticked 'Yes' for an allergy to the medication; however, the pharmacist supplied the medication. No patient follow-up information was available, so it is not known if there were negative outcomes or not
Pharmacist did not document the consultation in the MedAdvisor® IT program yet undertook a number of consultations	Not known, assigned 1	A PCF reported this incident following a visit to the pharmacy. The trial did not have any information on the patients. It is not known if there were negative outcomes or not. The pharmacist and pharmacy were withdrawn from the trial
Total	**14**	

Discussion

Over 18,000 consultations were provided in 10 months, with nearly 90% of the consented pharmacists providing at least one consultation. Over a quarter of the pharmacies provided over 20 consultations to patients. Populations in high-density areas, including MMM1 to MMM5, were appropriately covered by the service, ensuring that women presenting with symptoms of UTIs had increased accessibility to health care across NSW. This is particularly beneficial for women experiencing UTI symptoms, who often require timely medical attention to prevent complications. However, in rural and remote sites (MMM6 to MMM7), services were limited, and those participating provided limited services. Future research should focus on evaluating potential barriers and strategies, particularly ensuring coverage in remote areas to improve access and equity and adjusting the service model.

Fidelity to protocols was found in over 99% of the consultations. Additionally, for those patients who were not appropriately referred due to a high-risk factor, no treatments were recommended by the pharmacist. There were no protocol violations in terms of the order of choosing the pharmacological treatments, with trimethoprim being used as first-line treatment. These fidelity results provide evidence that the pharmacist-led service is safe with respect to protocol adherence.

PCFs played a crucial role in supporting pharmacists in the facilitation process for the implementation of the service. During their regular contacts with pharmacies, PCFs identified barriers for the implementation and provision of the service. These barriers were recurrent among providers and were mainly attributed to understanding the IT program, availability of computers in counselling rooms, the workflow and infrastructure of the pharmacy and/or the engagement of patients to be included in the service. Nearly one-third of the total barriers encountered by pharmacists when providing the service were resolved by strategies applied by PCFs, highlighting the key role of PCFs supporting new and existing providers. When comparing the two phases of the study (PATH-UTI only vs PATH-UTI/PATH-OC simultaneously), a decrease in the number of identified barriers was observed, likely attributable to overcoming initial barriers.

Additionally, about three-quarters of the pharmacies had facilitators that assisted in the provision of services. These facilitators were related to the pharmacists' skills in providing the service, a consultation room that complied with the requirements and was available for sole use, readiness and understanding of the software used for consultations, and promotional materials available to inform patients about the service. Increasing the prevalence and maintenance of these facilitators improved service provision and accessibility for patients.

Five different strategies accounted for over 70% of the strategies used. Two of these strategies, facilitation and distribution of materials, resolved approximately a quarter of the barriers. Implementing practice changes in an already busy and stressful environment is challenging. Therefore, offering appropriate support through interpersonal relationships and problem-solving is key during the implementation process. This was demonstrated by the percentage of barriers to service provision resolved and the high number of consultations and the high fidelity to clinical and research protocols.

The George Institute for Global Health was responsible for patients' follow-up 7 days after the consultation in community pharmacies, with a total of 14,671 participants (81.6%) completing the follow-up survey. Most participants indicated a positive experience with the service, reporting that they agreed or strongly agreed with seven statements related to service quality. Interviews with patients revealed two key themes: **(1)** community incentives to participate, including general practitioner unavailability, effective media promotion, and opportunistic pharmacy delivery; and **(2)** participant perceptions of a good service – i.e., timely symptom resolution, trust, privacy, and value for money (see Chapter 3).

Interviews with pharmacists revealed four key themes related to service implementation:

1. Pharmacist incentives, including business alignment, a duty to service the community, and adequate support and training.
2. Pharmacist perceptions of quality care, including avoiding tick-box care and dedicated consultation time.
3. Integration with health system 'hardware' such as information systems, pathology services and training curricula.

4. Integration with health system ‘software’ such as improved relationships with general practitioners, care navigation and changing service perceptions (See Chapter 3).

Conclusions

The implementation of a pharmacist service for the management of uUTIs in community pharmacies demonstrated uptake, protocol fidelity, and patient satisfaction, particularly in metropolitan and regional areas. However, the limited reach in remote settings highlights a pressing need to be addressed. The critical role of PCFs in identifying and resolving implementation barriers emphasises the value of tailored support and facilitation during service rollout. Furthermore, both pharmacists and patients expressed positive experiences with the service. The service is relevant and potentially sustainable within the broader health system. More work needs to be done to integrate these services into existing healthcare infrastructure, especially in under-served areas. Strategic workforce and systems support will be key to enhancing accessibility and equity in community-based care.

06

EVALUATING PATTERNS AND DRIVERS OF ANTIMICROBIAL RESISTANCE

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 6: Evaluating Patterns and Drivers of Antimicrobial Resistance

Introduction

This study was designed to analyse any potential impact on antimicrobial resistance attributable to the *NSW Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists.* It used government measures of success: enhanced antimicrobial stewardship and minimised risk of antimicrobial resistance (AMR). The study was undertaken by a team from Westmead Hospital and the Sydney Children's Hospitals Network, with statistical advice from the University of Technology Sydney and support from the University of Newcastle research team.

AMR is a global concern, with organisations such as the World Health Organization (WHO) calling it one of the top 10 global public health threats facing humanity [182]. Within New South Wales (NSW), systems for AMR monitoring primarily utilise available laboratory data in small local catchment areas to identify and report on resistance trends. Separately, Pharmaceutical Benefits Scheme (PBS) prescribing and dispensing data are used to report on antimicrobial usage rates. While reports such as the Australian Report on Antimicrobial Use and Resistance in Human Health (AURA) are useful in identifying prescribing patterns, they do not yet effectively report on community-based AMR trends in NSW, particularly for infections such as an uncomplicated urinary tract infection (uUTI) [183].

Antimicrobial stewardship interventions such as guidelines, protocols and educational programs, developed in conjunction with AMR experts, are essential in promoting the appropriate use of antibiotics, optimising patient outcomes, and preventing the development of antibiotic resistance [184]. Previous national and international pharmacist-led prescribing trials have not monitored AMR trends via pre- and post-implementation surveillance. Instead, they have primarily focused on expanding the scope of pharmacist prescribing, without researching the potential impact on antibiotic resistance [15, 185, 186]. Monitoring and surveillance of AMR are crucial in interventional trials, as they provide valuable data on the possible impact of pharmacist prescribing on antibiotic use patterns and resistance rates.

Pre-implementation surveillance provides baseline data on antibiotic utilisation and resistance patterns in a given population, providing a reference point for the comparison of trends during the trial. Post-implementation surveillance allows for monitoring of changes in antibiotic prescribing practices and evaluation of the impact on AMR trends. By capturing data on prescription rates, appropriateness of prescribing and resistance patterns, surveillance can provide valuable insights into the effectiveness of pharmacist prescribing programs in mitigating the emergence of antibiotic resistance [187-189].

A trend analysis of de-identified NSW community data on disease-causing bacteria that infect the urinary tract (uropathogens) and cause a clinical urinary tract infection (UTI) will be used as an indirect measure of 'antibiotic pressure' on AMR in the community before and after the pharmacist trial for the clinical management of uUTI. In order for this study to assess the impact on AMR broadly, this study did not use the same exclusion criteria in terms of patient characteristics or antimicrobials that were used in the main UTI trial. This is essential in attempting to thoroughly evaluate AMR within NSW, recognising that resistance development is a complex entity and not necessarily directly related to an individual's antimicrobial-uropathogen resistance relationship.

This is a preliminary report, as data collection is still ongoing, namely the collection of comparator and 12 months post-trial surveillance data. Due to data availability, only 12 months of pre-intervention statistical analysis has currently been included in the regression model. Further analysis will extend and quantify any statistically significant changes and outliers, attempting to identify if any of these changes can be linked to the introduction of the UTI trial. Detailed analysis, specifically geo-spatial analysis, inclusion of trial prescribing rates and comparator prescribing, has not been completed at this stage.

Objectives

The overall aim was to describe AMR rates before and during the *NSW Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists* and to assess whether there was evidence that the program impacted AMR rates. The primary objectives of this research update were to:

a. Quantify the prevalence of AMR rates for uropathogens within NSW before and during the *NSW Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists*, according to drug and pathogen; and

b. Estimate differences in AMR rates immediately before and after commencement of the trial, and between trial phase and a counterfactual estimate based on existing trends.

Methods

Ethics approval (H-2023-0173) was obtained from the University of Newcastle Human Research Ethics Committee (HREC).

Study design

This study was conducted as a population-based study using routinely collected health data from private pathology providers and data from the PATH-UTI trial.

Data sources

The datasets used were:

- retrospective and prospective de-identified de-duplicated data on community uropathogens from patients/residents in NSW from Laverty Pathology and Australian Clinical Labs (Douglass Hanly Moir, the largest pathology provider, declined to participate in this study); and
- de-identified data from the PATH-UTI trial that geolocates the areas in NSW with a pharmacy participating in the pilot.

From these datasets, the variables shown in Table 6-1 were collected.

Table 6-1: Data variables

Data source	Variable group	Variable
Private pathology data and Data from PATH-UTI	Harmonised pathology data	Age Gender Postal area (postcode) Organism Susceptibility Susceptibility testing method Date of collection
Data from PATH-UTI	Study sites	Postal area (postcode) for study sites

Outcomes

The primary outcome was the rate of AMR among uropathogens (urine cultures resistant to selected antibiotics/number of bacterial positive urine cultures).

Data analysis

Data were summarised using visualisations to describe the rates of AMR over time (on a weekly basis). Retrospective data (1/1/2018 – 31/3/2023) and data during the trial period (1/4/2023 – 31/3/2024) were used. These data were annualised to align with yearly periods (e.g., 1/4/2022 – 31/3/2023 forms one annual period, immediately before the pilot). Annualised trends were presented overall by drug, and by drug within the five most prevalent organisms.

Confidence intervals (CIs) for each annualised period were estimated using the Wilson score method confidence interval (CI) [190]. The difference between the rate of the trial annualised phase and the preceding 12-month period was tested with a Poisson regression model. A projection of the rate during the pilot phase was estimated from all preceding periods, using a generalised linear model (GLM), with Poisson distribution, and time in a log-linear form. This provided a simple counterfactual of what could have occurred had the trial had not taken place.

Analyses were completed on urinary isolates to describe overall resistance rates to standard

antimicrobial therapy, in accordance with the Australian Commission on Safety and Quality in Health Care specification for an antibiogram. Resistance categories are:

- amoxicillin non-susceptible;
- amoxicillin-clavulanic acid non-susceptible;
- cefalexin non-susceptible;
- trimethoprim non-susceptible;
- norfloxacin or ciprofloxacin non-susceptible; and
- nitrofurantoin non-susceptible.

Data presented in this report consist of uropathogen data from Laverty Pathology and Australian Clinical Labs collected retrospectively from the pre-intervention period (1/1/2018 – 14/5/2023) and data from the trial period (15/5/2023 – 31/5/2024).

Specific uropathogens reviewed include *Enterococcus faecalis, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis* and *Staphylococcus saprophyticus,* which are the most common organisms causing UTIs. The selected antimicrobials – amoxicillin, amoxicillin–clavulanate, cefalexin, ciprofloxacin, norfloxacin, nitrofurantoin and trimethoprim – represent standard first-line testing in pathology laboratories. Results from children <18 years of age were excluded from this analysis; however, a protocol amendment has been submitted to include them in the full analysis. Additionally, data from patients with postal areas listed outside of NSW were excluded as this study focuses on NSW only.

Results

A total of 165,466 samples were analysed from the Australian Clinical Labs dataset, and 433,580 samples were included from the Laverty Pathology dataset. The median age of patients was 55 years (range: 18–107) in the Australian Clinical Labs cohort and 58 years (range: 18–108) in the Laverty Pathology cohort (Table 6-2). Full details on exclusions of records and tests are provided in Appendix 6.1.

The number of samples varied across study years. In the Australian Clinical Labs dataset, the highest number of samples was recorded in 2023 (21%), followed by 2022 (18%) and 2019–2021 (each at 13%). The lowest number of samples was in 2024 (10%). Similarly, in the Laverty Pathology dataset, the highest proportion of samples was observed in 2018 and 2019 (both 18%), with a gradual decline in subsequent years, reaching 6.4% in 2024 (Table 6-2).

A majority of samples in both datasets were from female patients. In the Australian Clinical Labs dataset, 88% of isolates originated from female patients, compared to 87% in the Laverty Pathology dataset. Males accounted for 12–13% in each dataset.

Escherichia coli was the most frequently identified organism in both datasets, representing 79% of isolates in Australian Clinical Labs samples and 80% in Laverty Pathology samples. *Klebsiella pneumoniae* was the second most common pathogen, detected in 7.2% and 8.1% of samples in Australian Clinical Labs and Laverty Pathology datasets, respectively. *Enterococcus faecalis* was isolated in 4.8% of Australian Clinical Labs samples and 4.0% of Laverty Pathology samples. *Proteus mirabilis* was identified in 4.4% of Australian Clinical Labs samples and 4.1% of Laverty Pathology samples. Lastly, *Staphylococcus saprophyticus* was detected in 5.0% of Australian Clinical Labs samples and 3.7% of Laverty Pathology samples (Table 6-2).

Overall, both datasets exhibited similar trends in organism distribution and sex-based sample representation, with *Escherichia coli* being the predominant pathogen.

Table 6-2: Summary information on the study sample

Characteristic	Australian Clinical Labs N=165,466[1]	Laverty N=433,580[1]
Age (years)	55 (18–107)	58 (18–108)
Year		
2018	19,826 (12%)	76,154 (18%)
2019	21,831 (13%)	78,027 (18%)
2020	21,964 (13%)	66,911 (15%)
2021	21,427 (13%)	63,949 (15%)
2022	29,001 (18%)	60,358 (14%)
2023	34,652 (21%)	60,334 (14%)
2024	16,765 (10%)	27,847 (6.4%)
Sex		
Females	145,215 (88%)	378,842 (87%)
Males	20,110 (12%)	54,662 (13%)
Other	141 (<0.1%)	76 (<0.1%)
Organism		
Escherichia coli	129,902 (79%)	347,069 (80%)
Klebsiella pneumoniae	11,953 (7.2%)	35,078 (8.1%)
Staphylococcus saprophyticus	8,344 (5.0%)	15,934 (3.7%)
Enterococcus faecalis	7,972 (4.8%)	17,520 (4.0%)
Proteus mirabilis	7,295 (4.4%)	17,979 (4.1%)

Note:
1. *n (%); Mean (Min – Max); n/N (%)*

Figure 6.1 presents the combined yearly rates of AMR for all included uropathogens. The solid vertical lines intersecting after 2023 separate the pre-intervention data (left) and the intervention data (right). The dotted lines represent a predicted rate of resistance for the intervention period based on the pre-intervention trend. Figure 6.2 shows the same data, but with only postcodes that contained pharmacies registered in the UTI trial included. Visual representation of the rates of resistance by specific organism are included in Appendix 6.2 and Appendix 6.3.

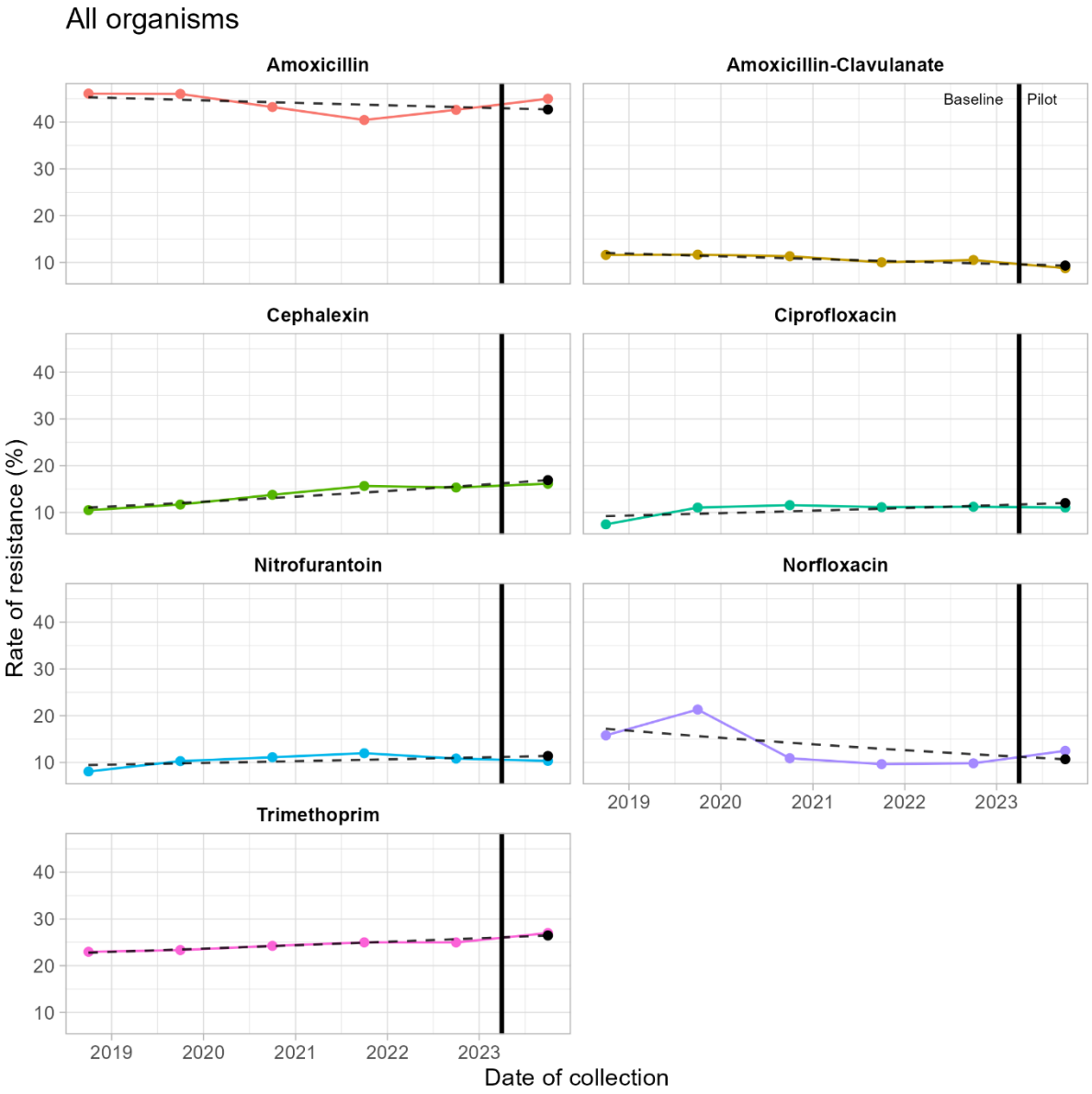


Figure 6.1: Rates of resistance across all organisms by drug

Coloured solid lines and dots represent observed AMR rates (with whiskers showing 95% CIs, which are small and difficult to visualise on this scale). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot). The 2023 and 2024 CIs can be found in Table 6-3.

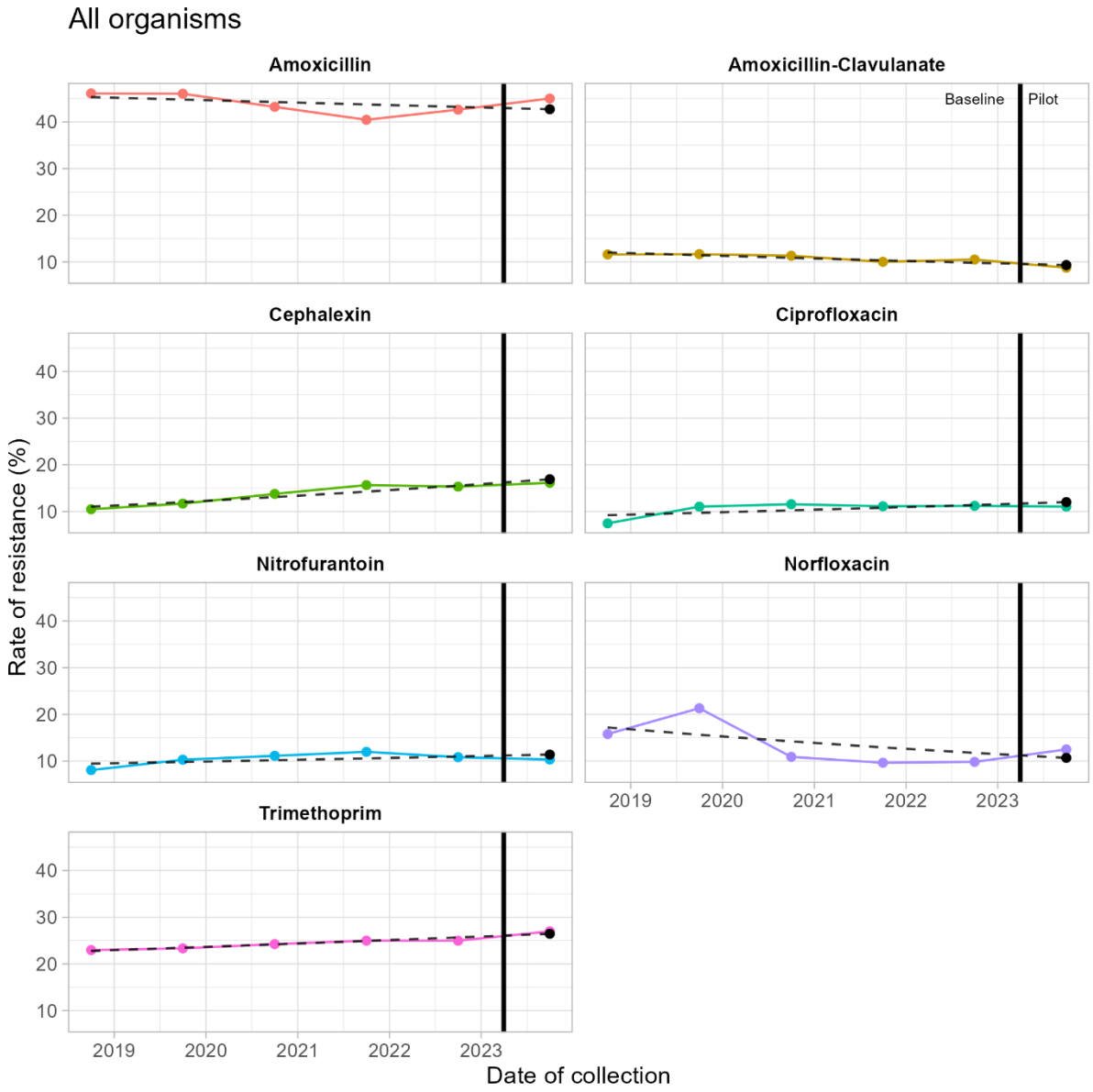


Figure 6.2: Rates of resistance across all organisms by drug in areas with pharmacies participating in the pharmacy trial

Coloured solid lines and dots represent observed AMR rates (with whiskers showing 95% CIs, which are small and difficult to visualise on this scale). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot).

Table 6-3: Rates of AMR in the 12-month period prior to and during the pilot pharmacy trial, with rate ratio, rate difference, and test of rates

Drug name	Pre-intervention period (12 months)	Pre-intervention period (12 months) rate (95% CI)	Intervention period	Intervention period rate (95% CI)	Rate ratio (95% CI)	Rate difference (95% CI)	GLM intervention period projected rate[1]
Amoxicillin	39,753/93,267	42.6% (42.3%; 42.9%)	43,070/95,704	45.0% (44.7%; 45.3%)	1.06 (1.05; 1.06)	2.38% (1.93%; 2.83%)	42.71% (42.41%; 43.01%)
Amoxicillin–clavulanate	89,66/85,260	10.5% (10.3%; 10.7%)	7,922/90,409	8.8% (8.6%; 8.9%)	0.83 (0.81; 0.85)	-1.75% (-2.03%; -1.48%)	9.33% (9.19%; 9.48%)
Cefalexin	14,301/93,320	15.3% (15.1%; 15.6%)	15,460/95,769	16.1% (15.9%; 16.4%)	1.05 (1.04; 1.07)	0.82% (0.49%; 1.15%)	16.91% (16.71%; 17.1%)
Ciprofloxacin	6,807/60,697	11.2% (11.0%; 11.5%)	6,715/60,809	11.0% (10.8%; 11.3%)	0.98 (0.96; 1.01)	-0.17% (-0.53%; 0.18%)	12.01% (11.81%; 12.21%)
Nitrofurantoin	10,096/93,261	10.8% (10.6%; 11%)	9,891/95,787	10.3% (10.1%; 10.5%)	0.95 (0.93; 0.98)	-0.50% (-0.78%; -0.22%)	11.39% (11.23%; 11.55%)
Norfloxacin	24,17/24,617	9.8% (9.5%; 10.2%)	4,293/34,398	12.5% (12.1%; 12.8%)	1.27 (1.22; 1.32)	2.66% (2.15%; 3.17%)	10.68% (10.41%; 10.95%)
Trimethoprim	23,290/93,257	25.0% (24.7%; 25.3%)	25,839/95,780	27.0% (26.7%; 27.3%)	1.08 (1.07; 1.09)	2.00% (1.61%; 2.40%)	26.46% (26.22%; 26.70%)

Note:
1. Projected rate is from a GLM (Poisson distribution) using all available study data before the 2023 annualised period

A comparison of AMR rates before and during the intervention period revealed significant differences across multiple antibiotics (Table 6-3).

Resistance to amoxicillin increased from 42.6% (95% CI: 42.3%–42.9%) in the pre-intervention period to 45.0% (95% CI: 44.7%–45.3%) during the intervention period, with a rate ratio of 1.06 (95% CI: 1.05–1.06) and a statistically significant rate difference of 2.38% (95% CI: 1.93%–2.83%). The predicted resistance for amoxicillin during the intervention period was 42.71% (95% CI: 42.41%–43.01%), closely aligning with the observed increase.

Similarly, resistance to cefalexin rose slightly, from 15.3% (95% CI: 15.1%–15.6%) to 16.1% (95% CI: 15.9%–16.4%). The predicted resistance was16.91% (95% CI: 16.71%–17.1%), consistent with the observed trend. Trimethoprim resistance increased from 25.0% (95% CI: 24.7%–25.3%) to 27.0% (95% CI: 26.7%–27.3%).

The largest relative increase was observed for norfloxacin, with resistance rising from 9.8% (95% CI: 9.5%–10.2%) to 12.5% (95% CI: 12.1%–12.8%), with a rate ratio of 1.27 (95% CI: 1.22–1.32), though predictive values were not specified.

Conversely, resistance to amoxicillin-clavulanate significantly decreased from 10.5% (95% CI: 10.3%–10.7%) to 8.8% (95% CI: 8.6%–8.9%), with a rate ratio of 0.83 (95% CI: 0.81–0.85) and a rate difference of -1.75% (95% CI: -2.03% to -1.48%). The predicted resistance was 9.33% (95% CI: 9.19%–9.48%), which aligns with the observed decrease.

A small but statistically significant reduction was also observed for nitrofurantoin, with resistance decreasing from 10.8% (95% CI: 10.6%–11.0%) to 10.3% (95% CI: 10.1%–10.5%). The predicted resistance was slightly higher at 11.39% (95% CI: 11.23%–11.55%), though the observed trend remained consistent with expectations.

Ciprofloxacin resistance remained stable at 11.2% (95% CI: 11.0%–11.5%) in the pre-intervention period and 11.0% (95% CI: 10.8%–11.3%) during the intervention period, with no significant change reported and no predictive values given.

Overall, the GLM predictions closely matched the observed resistance rates, reinforcing the reliability of the trends identified. The intervention period was associated with statistically significant changes in AMR rates, with increases in resistance observed for amoxicillin, cefalexin, trimethoprim and norfloxacin, while reductions were seen for amoxicillin-clavulanate and nitrofurantoin. Ciprofloxacin resistance remained stable.

Discussion

This study evaluated the impact of a pilot pharmacy intervention on AMR. Although some changes in AMR trends were observed, the relationship between these changes and the intervention remains complex and cannot be fully explained in this preliminary analysis.

Of the antimicrobials prescribed by pharmacists in the UTI trial, trimethoprim resistance was one of the most prominent findings in this study. Trimethoprim is the first-line antimicrobial in the UTI study as well as the first-line antimicrobial in national prescribing guidelines for the management of UTIs. Resistance to trimethoprim increased from 25.0% (95% CI: 24.7%–25.3%) in the pre-intervention period to 27.0% (95% CI: 26.7%–27.3%) during the intervention period. This 2% absolute increase was statistically significant; however, the GLM-predicted resistance for trimethoprim during the intervention period (26.46%, 95% CI: 26.22%–26.7%) closely aligned with the observed rate (27.0%), suggesting that the pre-existing trend of increasing resistance continued mostly as expected.

Nitrofurantoin, the second-line antimicrobial based on the UTI study, showed a slight but statistically significant decrease in resistance from 10.8% (95% CI: 10.6%–11.0%) to 10.3% (95% CI: 10.1%–10.5%) during the intervention period. The GLM-predicted resistance for nitrofurantoin (11.39%, 95% CI: 11.23%–11.55%) was higher than the observed decrease. Nitrofurantoin usage in the study was extremely low, and it is unlikely that the study directly influenced resistance rates. It is possible that with strict adherence to first-line antimicrobials by pharmacists, there may have been a reduction in total nitrofurantoin usage for community-based UTI treatment across both pharmacists and doctors.

Resistance to cefalexin, the third-line antimicrobial in the UTI study, increased marginally from 15.3% (95% CI: 15.1%–15.6%) in the pre-intervention period to 16.1% (95% CI: 15.9%–16.4%) during the intervention period. While this change is statistically significant, the increase in resistance is relatively small and may reflect broader trends in AMR, including the natural evolution of resistance due to the increasing usage of cephalosporins broadly. The GLM-predicted resistance for cefalexin (16.91%, 95% CI: 16.71%–17.1%) aligned closely with the observed resistance, suggesting that the intervention did not have a substantial effect on cefalexin resistance.

The observed resistance trends for the study drugs (trimethoprim, nitrofurantoin and cefalexin) align with expected AMR trends, suggesting that the changes seen during the trial period are likely a continuation of pre-existing trends rather than a direct result of the UTI trial. While trimethoprim and cefalexin resistance showed statistically significant increases between 2023 and 2024, the GLM-predicted values closely matched observed rates, reinforcing the idea that these shifts were expected based on historical data. Conversely, nitrofurantoin resistance decreased slightly; however, due to its low usage in the study, no conclusions can be made about its correlation to the trial. These findings indicate that while resistance patterns continue to evolve, it is unlikely that the UTI trial alone is the primary driver of these changes.

One of the most notable non-study drug findings was the increase in resistance to amoxicillin, which rose from 42.6% in the pre-intervention period to 45.0% during the intervention period. While this increase was statistically significant, the GLM-predicted resistance for amoxicillin (42.71%, 95% CI: 42.41%–43.01%) was similar to the observed resistance rate. In contrast, resistance to amoxicillin-clavulanate decreased significantly, from 10.5% to 8.8%. Amoxicillin-clavulanate is a commonly used antimicrobial for the management of UTIs in the

community but was not utilised by pharmacist prescribers in this study.

The most significant relative increase in resistance was observed for norfloxacin, where resistance rose from 9.8% to 12.5%. Norfloxacin is a fluoroquinolone, which has long been associated with rising resistance rates globally. This change was not reflected in ciprofloxacin, a similar antimicrobial, where we would have expected to see matching resistance trends. From an antimicrobial susceptibility testing perspective, these antimicrobials are often considered equivalent, though there are some caveats in more complex clinical situations.

The resistance trends observed in non-study drugs, such as amoxicillin and norfloxacin, further support the view that the increases observed in the trial antimicrobials are unlikely to be directly attributable to the UTI trial. The statistically significant increase in amoxicillin and norfloxacin resistance between 2023 and 2024 occurred despite neither being used by pharmacist prescribers in the study. This suggests that external factors, rather than the trial itself, are likely driving these increases. The fact that similar resistance increases were observed in both trial and non-trial drugs reinforces the idea that the UTI trial did not singularly contribute to rising resistance rates, but rather that these shifts reflect ongoing and expected AMR trends within the community.

Several limitations must be considered when interpreting the results of this study. The observational nature of the data means that causal inferences cannot be drawn, as multiple factors may have contributed to the changes in AMR rates. The inability to obtain a complete dataset to reflect community AMR rates due to the non-participation of the largest private pathology provider in NSW has also limited the analysis. Across the datasets, there may be subtle differences in susceptibility testing methods as well as incomplete geographic coverage, which may also impact the reliability of the final conclusions.

There are limitations in the analyses presented. In the analyses limited to postal areas with a pharmacy participating in the pilot, the data will not be particularly specific to the ‘catchment population’ that could be affected by the introduction of pharmacy management of uUTI. In a large postal area, residents may have other pharmacies available or seek services outside their home area and may not visit the pilot pharmacy. There is currently no way to directly connect outcomes from individuals using pharmacy management of uUTI or to match them at an individual level to suitable controls.

A second limitation is that a change from one annual period to the next, or what is projected from assuming a log-linear effect of time, is unlikely to create a perfect counterfactual of what AMR rates would be without the introduction of some pharmacist prescribing. There are a wide range of environmental and social factors that are considered to change rates of AMR, and the initial analyses presented in the report do not attempt to account for these [191]. This will be addressed comprehensively once further testing data are available and a more sophisticated model that can properly account for these factors is able to be specified and estimated.

With large sample sizes, as seen in this dataset, the CIs for most rate estimates are relatively narrow, indicating precise estimates of the true effect (rate differences and rate ratios). For example, the 95% CI for amoxicillin resistance change (1.93%–2.83%) is narrow, meaning the observed difference of 2.38% is precise, but this also suggests that even small changes in AMR may be detected as statistically significant due to the power of the large sample size.

It is important to note that GLM predictions are based on historical data trends and may not capture the full complexity of the intervention’s effects, especially if other concurrent factors influenced resistance during the intervention period.

Several observed changes in AMR rates deviated from predicted trends and could not be directly attributed to the pharmacist trial for the management of uUTI, suggesting the influence of external factors beyond the study’s control. Notably, resistance increases were observed not only in trial antibiotics but also in non-study antibiotics, such as amoxicillin and cefalexin, making it implausible that the trial alone drove these changes. An explanation for this may be a post-COVID-19 pandemic rebound effect. Based on the Antimicrobial Use and Resistance in Australia (AURA) report *Antimicrobial use in the community: 2023* and other literature, community-based prescribing of antimicrobials decreased substantially during the pandemic [192-195]. This decrease in antimicrobial prescribing was also seen internationally [196]. This U-shaped trend in antimicrobial use may have contributed to shifts in resistance patterns observed in this study [192-195].

Further detailed statistical analysis, including geo-spatial analysis, and inclusion of trial prescribing rates and comparator prescribing are required before clearer connections to the pharmacist prescribing and general conclusions can be drawn.

Conclusions

This study provides an initial analysis of AMR trends before and during the *NSW Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists*. While some statistically significant changes in AMR rates were observed, the relationship between these trends and the pharmacist management of uUTI intervention remains complex and requires further investigation.

Key findings indicate that resistance to trimethoprim, the primary antibiotic prescribed in the trial, continued to rise in line with predicted trends. These findings highlight the need for more comprehensive data analysis, including geo-spatial and prescribing pattern assessments, to better understand the impact of pharmacist-led prescribing on AMR. Some observed changes in AMR rates were unlikely to be explained by the pharmacist management of uUTI and were therefore likely influenced by external factors beyond the study, including a well-documented post-COVID-19 rebound in antimicrobial prescribing. This U-shaped trend may be contributing to resistance shifts seen in both trial and non-trial antibiotics, suggesting more complex resistance-prescribing relationships at play.

Despite its limitations, this study underscores the importance of ongoing surveillance and rigorous AMS strategies in pharmacist management of uUTI. Further detailed statistical analysis, incorporating prescribing data and additional comparator groups, is essential to determine whether pharmacist prescribing has a direct or indirect impact on the AMR of uropathogens in NSW.

This study is still ongoing and at the time of this report the following are outstanding:

- Collection and integration of the full 2-year post-implementation data (2023–2025) as specified in the protocol. This dataset goes up to and includes May 2025. Once this date has passed, the trial team will request the data from the providers and undertake final analysis.
- Final, in-depth analysis of the uropathogen data. Due to data availability, only 12-month pre-intervention statistical analysis has currently been included in the regression model. Further analysis will work to extend this out and quantify any statistically significant changes and outliers, attempting to identify if any of these changes can be linked to the introduction of the UTI study.
- Finalisation of the spatio-temporal model incorporating PBS dispensing data and trial prescription rates.

This study, including collecting the remaining data and full data analysis, is expected to be completed by Quarter 4, 2025.

07

A QUALITATIVE EVALUATION WITH ABORIGINAL AND TORRES STRAIT ISLANDER COMMUNITIES

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Chapter 7: A Qualitative Evaluation with Aboriginal and Torres Strait Islander Communities

Introduction

This chapter outlines the methods and rationale for exploring the perspectives of Indigenous peoples, the Aboriginal Community Controlled Health Organisation (ACCHO) staff and community pharmacists in relation to pharmacist-led management of uncomplicated urinary tract infection (uUTI). This research was conducted by the Co-Design Health Research and Innovation team at the University of New South Wales (UNSW).

Indigenous Australians experience significant health disparities compared to the broader population, including dying from avoidable causes at three times the rate of other Australians [2, 11, 31-35]. These disparities are influenced by multiple systemic factors, including health programs that lack cultural safety [197], ineffective health communication [198] and limited access to healthcare services [197]. These challenges are exacerbated for Indigenous people living in regional, rural and remote locations. Community priorities have traditionally not informed the direction of health research, resulting in programs that do not meet the needs of Indigenous people or achieve sustainable outcomes [199]. Compounding these challenges, Indigenous Australians access the PBS (Pharmaceutical Benefits Scheme) at lower rates despite experiencing higher morbidity [200]. Likewise, while general practitioner use among Indigenous Australians is slightly higher (1.2 times) compared to non-Indigenous Australians, the burden of disease suggests that their needs for such services is considerably greater (2.3 times that of non-Indigenous Australians) [201]. Moreover, Indigenous people living in more remote locations experience poorer access to healthcare services [202].

Pharmacist management of uUTI is widely seen as a potential solution to improve medicine accessibility. However, limited evidence exists on how Indigenous communities perceive this practice and its implications [16, 36]. For example, pharmacists in New South Wales (NSW) were previously asked for their views on how to assist with the healthcare needs of Aboriginal and Torres Strait Islander people [198]. All but one of the pharmacists interviewed felt that Aboriginal and Torres Strait Islander people were comfortable seeking care in their pharmacies. In stark contrast, this view was not shared by Aboriginal health workers, many of whom felt that Aboriginal people were uncomfortable when seeking care in pharmacies and embarrassed to ask a pharmacist for clarification or advice [198, 203]. This disconnect highlights the importance of understanding and incorporating Indigenous perspectives, knowledges and priorities to ensure pharmacist prescribing initiatives are culturally appropriate and effective. Without this integration, pharmacist prescribing may not fully address the needs of these communities.

International models, such as those in New Zealand, where Indigenous healthcare frameworks are integrated into pharmacist prescribing programs, may offer insights into best practices for implementation in Australia [204].

As part of the *NSW Community Pharmacy Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists,* it is important that the unique perspectives of Indigenous people are sought and incorporated into best practice to enable fair access for all people in NSW, particularly those who have experienced inequity within the health system. This study aimed to examine perspectives of Indigenous community members, ACCHO staff who serve these communities and community pharmacists.

Objectives

The key objectives of this study were to:

a. Better understand the perspectives of Indigenous community members, health organisations and community pharmacists regarding the trial for an expanded scope of practice for community pharmacists in NSW; and

b. Identify any specific risks in a broader rollout of community pharmacists managing urinary tract infections (UTIs) for Indigenous peoples across NSW and provide mitigation strategies for these risks.

Methods

Co-design

To ensure local context and culture were prioritised in this study, a co-design model validated for health research involving Indigenous people, including oral health [205, 206], vocational health education [207] and atrial fibrillation [208], was applied. The Co-design Health Research Model [209] (Figure 7.1) is measurable and structured and requires the sharing of power and resources. It focuses on the collective rather than the individual, privileges the perspectives of the people affected by the research, and recognises community contributions in ways that communities experience as valuable, including for example compensation for time and co-authorship on papers. The model aligns with the National Health and Medical Research Council guidelines for conducting ethical research with Aboriginal and Torres Strait Islander people [210]. A study protocol for this project has been published [211].

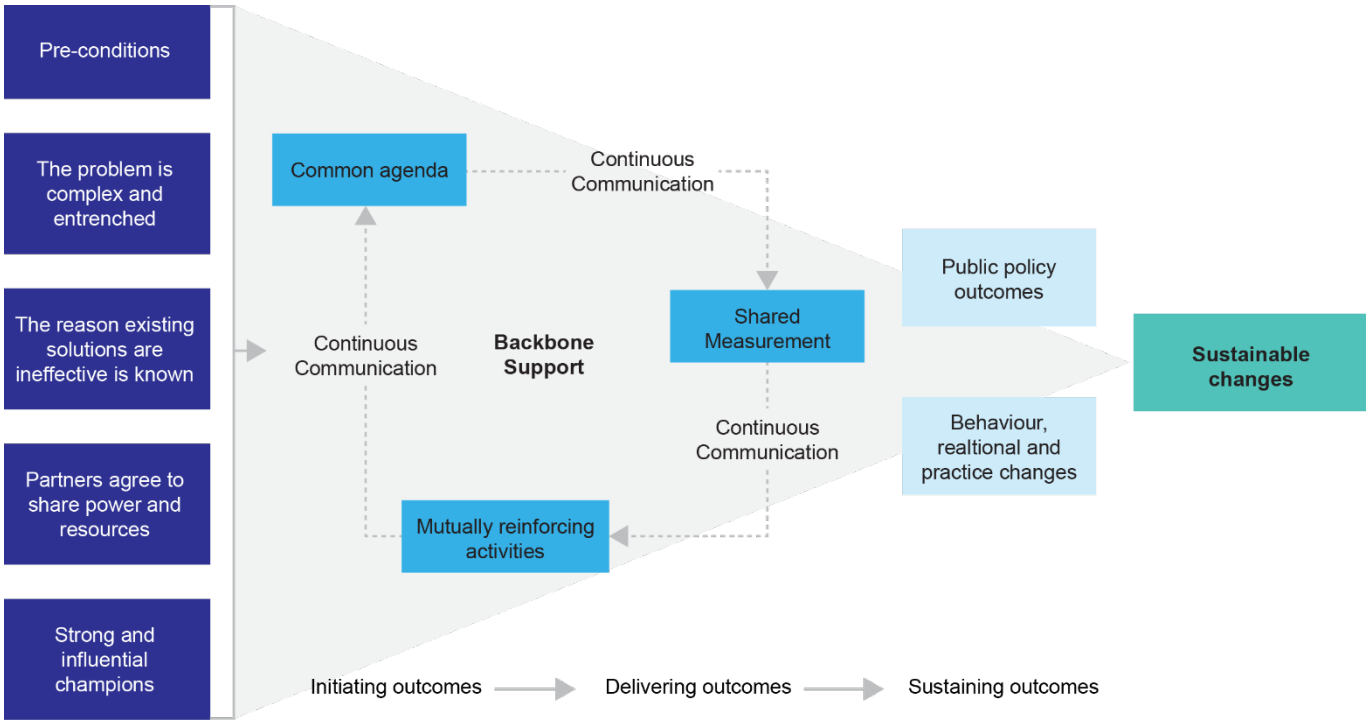

Figure 7.1: Model of co-design [209, 212]

Yarning is an Indigenous research tool and a key technique to co-create knowledge, including collecting, analysing and interpreting research data. Yarning is an Indigenous communication style that ensures participants feel safe, comfortable and confident enough to participate by providing their opinions and perspectives [213, 214]. A yarning circle comprises group discussion, whereby facilitators pose open questions and invite participants to use the questions as a catalyst for discussion. Similarly, individual yarns are semi-structured and begin with questions to stimulate thinking and discussion on a particular topic of interest. In the individual and group-based yarns, participants are encouraged to re-frame and re-interpret the questions, and the format includes ample time for non-structured discussion [213, 214].

Recruitment of communities and consent

Three ACCHOs and four sites in NSW were invited to collaborate as partners, with their participation and leadership being pivotal to the success of the project. The research team has established longstanding partnerships with the ACCHOs involved in this study. To classify the study locations, the Modified Monash Model (MMM) was applied [37]. The research sites included a very remote site (MMM7), a rural site (MMM4), a regional site (MMM3), and an urban site (MMM2).

Following the establishment of research partnerships for this project with ACCHOs, support was sought in recruiting Aboriginal and Torres Strait Islander adults

from the clinic, clinicians working with Aboriginal and Torres Strait Islander peoples, and community members, including Elders. Recruitment numbers were guided by the ACCHOs, with an estimated range of three to 12 participants per yarning circle and between 15 and 30 participants per community. The study was fully explained to those expressing interest in participation, with a detailed participant information sheet and consent form provided. Participants received a $25 voucher for each half hour of participation in recognition of their time and contributions.

Data collection

Six investigators, in pairs, conducted yarns. The yarning groups were homogeneous regarding cohort; for example, no ACCHO staff or pharmacists were included in yarns with Indigenous community members. The yarns began by briefly describing the sub study aims and conducting a knowledge check regarding potential changes in pharmacists' management of uUTI and the potential supply of certain medicines. Investigators commenced the yarns by asking the group to discuss their perspectives on the potentially changed scope of practice for pharmacists. Participants were prompted to describe the positives (benefits) and the negatives (risks) they envisioned for Indigenous people. Participants were also asked to discuss any recommendations to make the practice safe and acceptable for Indigenous people. In keeping with the yarning methodology, participants were free to take the discussion in any direction that suited them, thus ensuring that issues not anticipated by the research team but important to the participants were also included in the data collection (see Box 1). Data collection continued until saturation was reached.

Box 1: Yarning prompts

There were three prompts to facilitate discussion in the yarns:

1. *What positives/benefits do you see for Indigenous people related to this change in practice?*
2. *What negatives/risks do you see for Indigenous people related to this change in practice?*
3. *Do you have any recommendations to make the service safer or more accessible for Indigenous people?*

Data analysis

Yarns were audio recorded and transcribed. Qualitative data were intuitively analysed, creating composite descriptions of participants' experiences and perspectives related to each area of interest: positive perceptions, including potential benefits; negative perceptions, including risks; and recommendations to improve equity or access for Indigenous people. The responses also suggested a fourth theme: challenges experienced by participants in accessing medicines when they needed them.

Data-checking sessions were conducted to ensure findings and conclusions resonated with participants. These were conducted by pairs of investigators. We described our findings regarding the four areas of interest and asked participants if these resonated with their experiences. The sessions were conducted both online and in person for participants and included Indigenous community members who had not participated but expressed an interest in learning about the findings.

Ethical considerations

This qualitative research adhered to the guidelines for ethical research in Aboriginal and Torres Strait Islander populations and relevant ethics committee approvals. Ethics approval was obtained through the Aboriginal Health and Medical Research Council of NSW, Reference 2096/23: KG00193.

Results

A total of 63 adults participated in this study. ACCHO staff included both Indigenous and non-Indigenous employees. Pharmacists were registered professionals and practising within the communities identified through ACCHO staff or Indigenous investigators as likely service providers for Indigenous people. Community members were residents and self-identified as Indigenous. To ensure privacy of people living in these small communities, no demographic data were collected, and only high-level descriptors of cohort sizes are reported.

Table 7-1: Participants in the yarning groups

Location/ participant	Community member	ACCHO staff	Pharmacist
Remote	17	6	0
Rural/ regional	7	3	1
Urban	17	9	4
Total	**41**	**18**	**5**

This study was marked by strong community engagement, such that all community members invited to participate agreed, and many recommended friends and family. Engagement among ACCHO staff was also high, with only a few declining due to scheduling conflicts. Participants provided thoughtful and considered responses and engaged in respectful discussions. Key themes and risk mitigation suggestions were uniformly endorsed in the data-checking sessions.

Finding 1: Many benefits and concerns identified were not specific to Indigenous people

Participants identified convenience and rapid access to medications to relieve pain and discomfort as the primary benefits of the pharmacist-led service. For some participants, location was a more important variable than Indigeneity. For example, community members, particularly in smaller locations, highlighted its potential benefits for areas with infrequent doctor access, especially where pharmacists are integral to the community. Community members also highlighted that pharmacies provided walk-in opportunities to speak with a pharmacist rather than requiring an appointment. Urban pharmacists similarly noted greater value for smaller communities without regular doctor access.

Table 7-2: Key benefits

Convenience	
Easier and faster access to prescriptions compared to waiting for a doctor's appointment	*I think it saves the stress of running out of meds, people going without, you know, blood pressure meds* **--Indigenous community member – Rural**
Easy to access medications at the last minute	*It's hard to get in to a doctor… Especially on a Saturday* **--Indigenous community member – Remote**
Older people reliant on others for transportation will have more flexibility	*They'll either come in and get it done again and it's a lot of hassle. It's hard to get in to the doctor. And it saves a lot of time* **--Indigenous community member – Rural**
Working parents can more easily access medications outside of work hours	*My daughter has, like, bad skin conditions and like there's been times we've gone days waiting for the doctor to get a script. So, like, even if it was $20 like that would benefit her being able to just walk into the chemist, tell them that we've ran out of this and can't get in to the doctor. So, something like that would really benefit, because some days she gets, like, has to miss out on school for stuff. She could have went to school the next day if it was treated* **--Indigenous community member – Urban**
Pharmacies do not require an appointment, enabling clients to drop in at their convenience	

	Urine infections are everyday thing. There's always someone with a urine. You need that tablet on the weekend **--Indigenous community member – Remote**
Rapid access to medications to relieve pain and discomfort	
Prompt relief from the discomfort of UTIs and skin conditions which may worsen while waiting for an appointment with a general practitioner	*As a support worker, we're always trying to get clients in to see the general practitioners, for scripts. But a lot of times they're not available – the doctors. So, by doing this here, seeing the pharmacist, see if they can do a script for them, it'd be good. That'll save a lot of time too, because with an appointment it could take up to 2 weeks* **--ACCHO staff – Rural**

Some participants expressed enthusiasm for the service to expand to other medications or conditions. Community members discussed medicines that were not currently part of the service. A person cited changes implemented during the COVID-19 pandemic that allowed pharmacists to dispense certain asthma medicines without a prescription, which they felt improved the system. They were pleased this change had continued after the pandemic. Others spoke about repeat prescriptions related to chronic conditions, including some that are not part of the current trial.

> *My partner had the start of type 2 diabetes, so he has to come regularly for diabetes medication. It's not going to change for him. So, like, it's hard for him because all he wants to do is go to bed of an afternoon. So, he'll go home, sleep, get up for tea and then go back to sleep. But, if he has to have a doctor's appointment to get his script, then it's hard because it's not planned. Sometimes he doesn't realise his medication's running out so he has to make an appointment, but then he might be 2 or 3 days without meds because he didn't realise.*
>
> Indigenous community member, Regional

Likewise, some participants felt that it was burdensome to return to the clinic for routine medicines and preferred to access long-term repeat medicines for chronic conditions directly from the pharmacist, including medicines currently not on the service.

> *Their repeats run out. They'll either come in and get it done again and it's a lot of hassle. It's hard to get in to the doctor.*
>
> Indigenous community member, Rural

Many community members indicated that they and their families would use the service if the service became a reality.

> *If they say, well, look, you've got to go and see the doctor to get this, well then, I'd have to go and see the doctor. But, if I was able to buy it over the counter, yeah, it'd be …*
>
> *And, you would use that service?*
> *Yeah. Yeah.*
>
> *And, would there be anything that would worry you about that?*
> *No. No. I don't – yeah. I don't think so.*
>
> Indigenous community member, Remote

Overall, Indigenous community members and pharmacists viewed the service more positively than the ACCHO staff. ACCHO staff tended to be more conservative regarding the benefits they perceived for their clients. Nevertheless, the ACCHO staff did see benefits, and many indicated they would use the service themselves. A similar discrepancy between ACCHO staff and community members was apparent in perceptions about how Indigenous people might be at a more significant disadvantage compared to non-Indigenous people, with ACCHO staff voicing concerns particularly around cultural safety, continuity and holistic health care and community

members not so. Importantly, ACCHO staff acknowledged the benefits of overcoming existing barriers, such as transportation and wait times for community members to access appointments within the ACCHO.

> *My thought process is community orientated. So, I'm thinking about, you know, my grandmother, for instance. I know how difficult it is for her to get in to the general practitioner or get herself up to come to it.*
>
> ACCHO staff, Urban

> *Yeah. I think it's – yeah. I don't – like, when we look at – especially within our AMSs, we're pretty equipped when it comes to, like, ensuring cultural safety and stuff, but how can we ensure that that will take place within the chemists? Because you're not used to having consults at a chemist.*
>
> ACCHO staff, Remote

> *One of the things that mainly worries me about it is the fragmentation of care.*
>
> ACCHO staff, Urban

Finding 2: Concerns about quality and continuity of care were amplified for Indigenous people and potentially other priority populations, such as people living with complex medical conditions

Participants identified two main concerns associated with the potential expansion of pharmacists' scope of practice: (1) quality and continuity of care; and (2) privacy. ACCHO staff were particularly concerned about the quality and continuity of clinical care between the primary health clinic and the pharmacist. Community members also identified concerns associated with privacy for pharmacy consultations.

Table 7-3: Concerns and risks

Quality and continuity of care	
Specific concerns	**Quotes from participants**
ACCHO staff were concerned that incidental care that occurs when clients attend the clinic for routine check-ups or script renewals would be lost if clients are not required to attend the clinic for prescriptions	*That people wouldn't be actually getting their health checks done, they wouldn't be getting their care plans done, because they're not really going to see the doctor. So, if you're not accessing a medical service to get your scripts, then you're missing what I call opportunistic education and interventions* **--ACCHO staff – Remote**
ACCHOs tend to have deeper knowledge of patients' family history, which may assist with more specific diagnosis and treatment	*Clinic is very relationship-focused, more …* *And, it's not just about the patient, it's about their family too*
Healthcare workers at the urban data collection site raised concerns about misdiagnosing UTIs. These workers stated that the practice at their clinic was compulsory urine testing before diagnosis and treatment. This concern was not echoed in rural or remote clinics	*You know, you know what's going on at home most times and you …* *… you know, you may – you know that there's a reason why, you know, someone's really pushed for time …*

Quality and continuity of care	
Specific concerns	**Quotes from participants**
Healthcare workers more broadly noted the value of having double-checks built into the current prescribing and dispensing system	*… and – and hasn't been taking their blood pressure medication. It's not necessarily about the fact that they just haven't wanted to take it, it's about the fact that …* *… you know, they're – they're looking after their grannies or …* *… you know, so …* *It's that very holistic care* **--ACCHO staff – Remote** *A lot of people think they've got a UTI and they don't. So, they're having unnecessary antibiotics. So, we automatically do a dipstick straight away, as soon as they come in here, and, if nothing shows up on that dipstick, they're not getting antibiotics, until that urine has been sent away to pathology* **--ACCHO staff – Urban** *On a more, I guess, philosophical level, I don't think that there should be the same people prescribing and dispensing. I think there's a very good reason why that is separate. As a doctor, I don't want to be – you know, there's a reason when we are giving someone a medicine, in a doctor's surgery, we get someone else to check it to make sure it's correct. And, the pharmacy – pharmacist provides such an important second pair of eyes, second assessment, you know, that – that double-looking is such an important thing* **--ACCHO staff – Rural** *We know their clinical history. So – and, that's something that if they're seeing a pharmacist who's may not going to have that sort of knowledge, and – and so then there's the possibility for something to get missed.* **--ACCHO staff – Regional**

Finding 3: Two key factors to ensure equitable and safe access for Indigenous people

Participants identified two critical factors necessary to ensure equitable and safe access to the service for Indigenous people: (1) aligning the service with the Close the Gap (CTG) program; and (2) providing pharmacist training in cultural competence.

Table 7-4: Necessary factors for equity and safety

Align the service with the CTG payment scheme	
Specific concerns	**Quotes from participants**
Consultation and medication costs were identified as key issues that could impact equity by many participants Some participants indicated they would pay the additional cost under some	*A lot of our elders can't afford to pay extra money for their medication, you know – and that will become a barrier* **--Indigenous community member – Rural** *That will definitely bugger people up if there's no Closing the Gap*

Align the service with the CTG payment scheme	
Specific concerns	**Quotes from participants**
circumstances, but for some this was not an option	**--Indigenous community member – Remote** *It all depends on how long you'd have to wait for the doctor, see. Like, if some people have got the money there and they haven't got to wait a week, well, they'd pay* **--Indigenous community member – Remote**
Cultural competence	
Community members and healthcare workers emphasised the importance of trusting relationships in Indigenous health, including a holistic concept that stretches beyond diagnosing or prescribing and relies heavily on relationships ACCHO staff raised that Aboriginal women may hesitate to approach a male pharmacist about medications for sensitive issues such as UTI, the contraceptive pill and even skin conditions Pharmacists also recognised the need for additional training	*When people come in here dealing with their contraception, they see the nurse first and they document everything and they make a little note, so the doctor's fully aware and can treat them very culturally appropriately, sort of thing. And, especially with the younger girls, we always say, 'Now, if you need us to come in with you'* **--ACCHO staff – Remote** *We are getting better at it. We are taught a little bit about Aboriginal health, but it's experiencing it, and not treating patients different, but understanding that their barriers to health is different* **--Pharmacist – Rural** *I think enabling us to develop a stronger relationship with our patients is great. Enabling that level of trust. A lot of Aboriginal people are very wary of the health system due to historical issues Myself as well as other pharmacists, are understanding more that it's not as easy as we think it is, if that makes sense.* **--Pharmacist – Rural**

Participants also identified three other factors that would benefit all community members: public education about the service, a framework for ensuring continuity of care, and longer opening hours for pharmacies in smaller communities.

Participants thought it was essential to educate the public about the service. Most felt that understanding how the service worked, including which medicines were included and the associated costs, would facilitate better uptake and quality of care. We also noted that some misinformation and misunderstanding about the service had contributed to concerns that were not warranted, such as the belief that pharmacists would prescribe addictive medications or there would not be a private consultation space provided in the pharmacy.

To mitigate concerns associated with continuity of care, participants suggested establishing clear protocols for communication between pharmacists and primary health professionals. This suggestion was particularly common in small locations where pharmacists and doctors were known to each other.

> *I think that would have to be mandatory that they report once a week or once a month or something to the doctor to say, look, such and such has had this amount, I think she's either had too much or too many or whatever.*
>
> Indigenous community member, Remote

> *I would be positive about it. Only in the provision that there is the correct framework around how we do it. There are always bad eggs in the pharmacist side, prescriber side. We don't want anybody exploiting the system, but we also want our patients looked after well, and ensuring that high level of care occurs is important.*
>
> Pharmacist, Rural

Participants in smaller communities suggested that if pharmacists opt in to the service, they should be required to stay open for longer hours, thus providing better service to the community.

> *In the smaller location, you find that pharmacists will close, you don't have that 7-day-a-week access. You go to Sydney, and you've got a chemist open pretty much 7 days, maybe even to 11 o'clock at night you can access a pharmacist. Here they'll close at 5:00, 5:30, and they'll close at 12:00 on a Saturday. So … And won't be open on a Sunday. That's right. And, it's – so, if they're going to take on this role, it can't be, 'Well, I'll do it in my normal hours'. They have to be aware of, well if we're offering a service, we have to make sure we're offering that complete service.*
>
> ACCHO staff, Regional

Discussion

This co-designed qualitative study is the first to capture the perspectives of Indigenous people, healthcare providers and local pharmacists regarding the proposed expansion in pharmacists' scope of practice and the potential benefits and risks for Indigenous people in NSW. Understanding the perceived risks and benefits from those directly affected is critical to ensure culturally safe and efficacious implementation.

While Indigenous community members saw greater benefits and fewer risks than ACCHO staff, most participants in this study articulated similar benefits and concerns. Participants in this study are best described as cautiously optimistic about the new service. Benefits, including greater convenience and speed in accessing medication for pain relief, were perceived as valuable changes, and a common suggestion was for expansion of the service to include repeat prescriptions for chronic illnesses. Concurrently, participants expressed the need for careful consideration and evaluation of any changes to the health system that impact Indigenous people. The ACCHO staff were aware that the same treatment provided in the same way was not as effective for Indigenous people, when compared to non-Indigenous people. The need to ensure cultural safety for Indigenous people was emphasised, and it highlighted the demonstratable value of holistic care.

Concerns expressed by ACCHO staff and Indigenous participants were to ensure continuity of care between the pharmacists and the primary care clinic, and to ensure privacy for consultations within the pharmacy.

Two key factors in respect to this service were identified. Firstly, pharmacists have limited training in healthcare and cultural responsiveness in working with Indigenous people. This gap is evident in this study. If pharmacists are to have a greater role in managing the healthcare of Indigenous people, they must enhance their knowledge and experience in culturally safe care. This will be increasingly important as the expansion in pharmacists' scope of practice becomes routine in NSW for some medications. Secondly, the costs of medications under this service are not currently eligible for CTG payments. Addressing this gap is important to avoid cost becoming a barrier for those not covered by CTG. While these policy changes should not delay roll-out of the service, they are important for the long-term efficacy and access for Indigenous people.

This study had several limitations. A primary limitation of this study was that community members were recruited through ACCHOs and were therefore likely to be active clients who may differ from the broader community. In addition, the study was conducted after the service was designed and thus did not allow for Indigenous input into its design. This study was strengthened by the co-design approach, which included local partners who shaped the study by refining the study's aims and remained active co-design partners throughout the study. This partnership ensured that the co-created knowledge is relevant to the people it impacts.

Conclusions

An expanded scope of practice for pharmacists is supported by Indigenous people in NSW and the clinicians who care for them. Like the broader population, the new service offers potential benefits and raises some concerns for Indigenous people. This study captured the perspectives of a small number of Indigenous people, and further examination of access to and impact of the service for Indigenous people as it becomes part of routine care in NSW will be important. Given that two subsequent trials will follow the UTI trial, additional research will be undertaken to investigate Indigenous needs, perspectives and contextual factors, to

determine whether an alternative service delivery model would be more appropriate and effective for Indigenous populations.

08

QUALITATIVE INSIGHTS FROM HEALTH PROFESSIONALS IN REGIONAL AND RURAL COMMUNITIES

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 8: Qualitative Insights from Health Professionals in Regional and Rural Communities

Introduction

This research was conducted by Charles Sturt University and the Rural Doctors Network.

Approximately seven million Australians, representing 28% of the population, live in rural and remote areas, encompassing many diverse locations and communities [215]. *The Rural Health in Australia Snapshot 2025* report highlights that people living outside our major cities, as a percentage of the population, tend to be older in regional areas and younger in very remote areas. Additionally, a greater percentage of Aboriginal and Torres Strait Islander people live outside our major cities [216].

Australians living in rural, remote and very remote communities generally have poorer access to health care compared to people living in regional centres and metropolitan areas. This is primarily due to restricted access to local health services, with people travelling longer distances to locate or attend health services or receive specialised treatment [38]. These barriers are caused by several factors, including a lack of healthcare professionals in these communities as well as the dispersion of these communities, resulting in lower population densities and long distances to be travelled between towns [217]. Relative to population size, small rural towns have the lowest number of health professionals, except for pharmacists [215].

Rural areas face challenges which are exacerbated by workforce shortages [216]. This has contributed to higher rates of potentially preventable hospitalisations (PPHs) [216]. These are hospitalisations that could have potentially been prevented through the provision of appropriate individualised preventative health interventions and early disease management, typically delivered in primary care or community settings. The rate of PPH increases with remoteness and is highest in very remote and rural areas. When compared with major cities, the rate of PPH is two to three times as high for people living in remote and very remote areas [218].

The Modified Monash Model (MMM) defines whether a location is metropolitan, rural, remote or very remote based on the distance to the nearest significantly more populated town. The model measures remoteness and population size on a scale of MMM categories: MMM1 (major cities) to MMM7 (very remote) [219]. Areas classified MMM2 to MMM7 are considered regional, rural or remote. People living in these areas can find it difficult to acquire medical assistance, and accessing health professionals can be time consuming and costly [219].

Pharmacists are often the only health professional in these regional and remote communities, providing vital access to health care and medicines and for acutely unwell patients [220]. A recent evaluation of Australian rural community pharmacists' perspectives of expanded services indicates that health professionals are supportive of the delivery of expanded services, describing improved health outcomes and increased access to health services as potential benefits [221].

In primary care, interprofessional collaboration has been shown to improve patient pathways, healthcare efficiency and cost-effectiveness [222]. Collaborative and integrated working between general practitioners and community pharmacists can lead to effective and equitable solutions, while increasing the efficiency of services and reducing health inequalities [223]. A systematic review of factors influencing interprofessional collaboration between general practitioners and community pharmacists indicated that co-location, co-education to understand professional capabilities, and using compatible technologies to facilitate communication between the professions all positively influence collaboration [224]. This is underpinned by mutual trust, as well as interdependence, perceptions and expectations about professional skills, role definition, and communication [225]. This study aims to further explore interprofessional collaboration between community pharmacists and general practitioners and its relevance to healthcare delivery in regional and remote areas.

Trust is widely acknowledged as a critical element in successful interprofessional collaboration between healthcare professionals [225-229], and interprofessional collaboration has been found to have a positive impact on patient outcomes [230-232]. The literature emphasises that trust is also a key driver in initiating, sustaining and optimising collaborative relationships between pharmacists and general practitioners. Zeffane *et al.* (2011) conceptualise trust as involving mutual commitment, competence, reciprocity and power balance – qualities that are essential in establishing functional partnerships [233]. Yet, trust is not automatic; it often needs to be facilitated, particularly in emerging practices like pharmacist prescribing [234]. Previous research has identified a gap in understanding the mechanisms that foster trust in pharmacist–general practitioner collaboration, particularly in rural environments [17, 235]. This study addresses an urgent need by exploring trust as both an enabler of interdisciplinary care and a necessary foundation for developing innovative healthcare models that respond to Australia's evolving workforce and health service needs.

Objectives

This study contributed to the following project objective:

- Identification of key drivers of collaboration and trusting relationships between pharmacists and general practitioners which might influence the service model in regional or rural areas.

Methods

Twenty-one semi-structured, online interviews were conducted between October and December 2023 with pharmacists (n=10) and general practitioners (n=11) who had experience working in, or were currently working in, regional or rural settings in Australia. To gain an in-depth understanding of factors that influence general practitioner-pharmacist collaboration and trust, an interview guide consisting of open-ended questions was developed. These questions were informed by current literature and the trials.

Participant recruitment

A brief overview of the study and its aims was advertised online through the Rural Health Pro newsletter (a popular digital platform that connects health professionals and organisations interested in rural health) and the Consultant Pharmacists Australia Facebook page (a private, moderated group consisting of over 3,200 pharmacists from across Australia). Both platforms maximised the visibility of the study. Interested participants were provided with detailed written information about the study and a consent form. Additionally, a snowball sampling strategy was employed, where participants were asked to refer other medical practitioners or pharmacists who met the eligibility criteria (i.e., those who were currently practising in, or had experience working in, a rural or regional setting in Australia). Suitable times were then arranged for the interviews, which were conducted online via Microsoft Teams. Prior to the interviews, participants were requested to give verbal consent for the recording and transcribing of the conversation. All interviews were conducted by three researchers. One participant, a general practitioner, submitted their response via email since a suitable time for an interview could not be arranged. This response was included in the study and was coded and themed in the same manner as the other transcripts.

Data collection

Interviews lasted between 45–60 minutes, were recorded, and then automatically transcribed through Microsoft Teams. All transcripts were checked against the original audio recordings to ensure accuracy. The interviews were concluded upon reaching data saturation, where no substantially new information or insights were obtained, and the data collected proved sufficient to address the research question.

Data analysis

Three verified transcripts were initially coded by two researchers using descriptive codes and presented to the research team to identify and resolve inconsistencies. Three researchers then completed the assessment of the agreed codes to complete the remaining transcripts. ChatGPT Version 4.0 was used to condense the codes and establish early relationships between the codes. Recognising that this tool should not be a substitute for human judgement, the researchers carefully checked the codes, and the remaining transcripts were subsequently coded [236, 237]. Following manual checking and refining of the AI-generated codes, the remaining transcripts were coded and, once fully

coded, the identified themes were validated by manually sourcing supporting quotes in the raw data.

The research proposal was approved by Charles Sturt University Human Research Ethics Committee (HREC) (H23761) on 26/7/2023.

Results

Four themes emerged from the analysis of the transcripts, and these and their subthemes are included in Table 8-1.

Table 8-1: Final themes arising from the analysis of 21 transcripts

Themes	Subthemes
Dynamics of collaboration	• Direct interaction facilitates collaboration • Enhanced collaboration in regional settings • Sustainable collaboration is achieved through value-driven interactions and mutual respect • Pharmacists are vital collaborators in interdisciplinary health systems
Dynamics of communication	• Open communication involving multiple forms of communication is important • Discrepancies in communication methods and extent
Dynamics of leadership	• Understanding each other's roles and capabilities in patient care is essential • Need to acknowledge general practitioners as leaders in multidisciplinary teams and custodians of patients
Dynamics of patient-centred care	• Patient-centred and service-orientated care facilitates collaboration • Collaborative care optimises patient care • Patient feedback can foster general practitioner–pharmacist collaboration

The themes – collaboration, communication, leadership and patient-centred care – along with their intersections, offer a comprehensive and practical framework for assessing, monitoring and enhancing trust between pharmacists and general practitioners.

Theme 1: Dynamics of collaboration

This theme refers to the factors that enable or hinder interprofessional collaborative practice. This includes open communication and interaction across disciplines, such as between physicians and pharmacists, to improve patient care [238].

Participants recognised that any opportunity facilitating direct interaction between general practitioners and pharmacists aids in building collaboration. Co-location was identified as an *'untapped resource' (Respondent 6)* that facilitates respectful general practitioner-pharmacist interaction. The integration of pharmacists in general practitioner clinics was cited as a successful example of co-location that enhanced collaboration between both professions. One participant expressed optimism about this:

> *I also look forward to potentially future collaboration if we can one day devise a model to either have a pharmacist in practice or a pharmacist potentially alongside our practice. If we do expand our clinic and have a pharmacist co-located.*
>
> Respondent 7

Although co-location is frequently regarded as a straightforward facilitator of collaboration, any forms of routine interactions, whether formal or informal, have been identified as critical contributors to collaborative dynamics. Similarly, joint training opportunities, which were more common before COVID-19, were noted as not only providing networking opportunities that fostered relationships between the two professions, but also providing opportunities to address concerns. Furthermore, the close-knit nature and strong sense of community in many small towns fostered collaboration more effectively in regional and rural areas than in metropolitan regions. As reported by Respondent 14, '*that trust, that community spirit and togetherness*' which are fundamental for effective collaboration are already present in regional towns. Similarly, the close-knit nature of regional and rural towns allows

individuals to get to know each other beyond their professional roles, which may also facilitate collaboration.

Enhanced collaboration in rural and regional settings is further assisted by the reduced availability of health services, requiring pharmacists and general medical practitioners to rely on each other for survival:

> *I, like many rural doctors, have a really close abiding and I think mutually respectful relationship with our pharmacist. So, in terms of collaboration, we collaborate very closely on ensuring certainly that patients receive not just their medications appropriately but also very safely.*
>
> Respondent 7

> *I'm a general practitioner's biggest ally as far as I'm concerned. I will refer people to general practitioners like I said probably 10 times a day.*
>
> Respondent 5

Collaboration was prioritised when there was an emphasis on demonstrating its value, providing timely services, and ensuring interactions were not burdensome for either profession. One participant emphasised the importance of bringing high-value issues to general practitioners.

Dynamics of collaboration align with aspects of both relational trust and social exchange theory, particularly with regards to mutual respect and consideration of each other's time and professional pressures. Overall, collaborative interactions between general practitioners and pharmacists are primarily human interactions and are most effective when face-to-face in rural settings.

Theme 2: Dynamics of communication

The dynamics of communication theme refers to the complex and interactive processes through which individuals exchange information, ideas and meaning, influenced by factors such as context, relationships, cultural norms and modes of communication. In healthcare, these dynamics play a crucial role in fostering collaboration and trust, and improving patient outcomes, through open, transparent and respectful dialogue between professionals.

Participants acknowledged the importance of communication in general practitioner-pharmacist collaboration, and recognised that, '*trust* [between the profession] *is built on communication' (Respondent 3).* While some participants were satisfied with the current state of communication in their practice, others recognised it as the *'biggest challenge' (Respondent 9).* The current modes of communication used by most participants included phone calls, emails, faxes and letters. However, these methods were only effective if they reached the intended recipient. Many pharmacists expressed frustration with gaining access to the general practitioner, while many general practitioners reported a similar frustration regarding access to senior pharmacists. Multiple lost emails also added to frustrations:

'So I'll email them, but I never get a reply, so I don't know whether that changes happened or not' (Respondent 9). Respondent 8 suggested that communication *'can be definitely improved if there is a way of direct messaging between the two'*, which then allows them to bypass receptionists and pharmacy assistants.

Interestingly, for some participants, who they communicated with was just as important as the method of communication. Previous positive interactions and demonstrated value in collaboration made communication much easier for these participants.

Open communication, including face-to-face interactions, is essential for building trust and fostering effective collaboration. Respondent 3 emphasised the value of *'hallway conversations'* in creating a community of practice between the two professions. While *'face-to-face interaction has been one of the biggest drivers of that collaboration' (Respondent 6),* opportunities for such interactions are often limited for many general practitioners and pharmacists in the community unless they are co-located.

Although effective communication is crucial for establishing collaborative relationships, once collaboration is in place, communication remains an integral part of it, creating a reciprocal relationship where each continues to reinforce the other. This then makes the initial conversation the biggest barrier to overcome.

> *I'm always glad when I speak to the owner because then I know them and have known them for some years. I know there is mutual respect and I know they will try and get things done.*
>
> Respondent 1

Furthermore, the extent of communication was recognised as a key component in effective collaboration. In the context of NSW pharmacy trials, most general practitioner participants highlighted the importance of communicating prescribing and consultation outcomes with patients' general practitioners. However, they also stressed that such a high volume of communication can hinder daily practice.

Participant 10 noted that, although the increased communication resulting from the trials can be overwhelming for the already busy schedules of both professions, remunerating time allocated for such communication could help mitigate the potential disruption.

> *I suppose that if you've got a pharmacist that is really proactive and does want to have a discussion, that's 10 minutes out of my day that I can't bill and, you know, it's actually me giving clinical care that I can't get paid for. So if there was a Medicare item number that facilitated that, there's a trust builder right there, because I, you know, it could actually be built into the system rather than just depending on everyone's goodwill.*
>
> Respondent 10

Similarly to theme 1 (dynamics of collaboration), the dynamics of communication theme identified in the data provides strong evidence that both professions seek strategies to engage with each other at a personal level, using non-cognitive tools that are part of their professional training. Similarly to collaboration as well, direct communication between the professionals is positively associated with the establishment and maintenance of trust, while communications via third parties (e.g., administrators) or excessive volumes of communication are perceived negatively.

Theme 3: Dynamics of leadership

The dynamics of leadership theme refers to the evolving and interactive processes that shape leadership roles within interprofessional teams, especially in healthcare. It involves navigating traditional hierarchies, fostering collaboration and balancing power relations between professions to create an environment of trust, respect and collective learning.

Understanding and accepting each other's roles and capabilities in interdisciplinary care is essential for trust building. The role of pharmacists in medication management and as providers of medicine information was acknowledged widely and utilised regularly in practice, thus reinforcing their positions as an integral part of the multidisciplinary team. However, the capability of pharmacists beyond identification of medication-related issues was not collectively agreed upon. Concerns were expressed about the level of training pharmacists have in diagnostics and clinical reasoning, while others felt the current level of training is sufficient.

Many participants emphasised the importance of recognising general practitioners as leaders within the multidisciplinary team and as custodians of patient wellbeing. Several pharmacist participants expressed the need for assuring *'[general practitioners] to be in control' (Respondent 5)*, *'not wanting to waste time' (Respondent 3)* or the need for ensuring that all interactions are *'demonstrating some value' (Respondent 12)*. These views highlight a desire for respect and acknowledgement from general practitioners. They also reflect an acceptance of the existing medical hierarchy, which reinforces the general practitioner's dominant role and the expectation that other healthcare professionals align with their leadership to maintain effective collaboration. This hierarchical nature of the medical profession and the subsequent power imbalance can hinder effective collaboration and development of trust and respect for other professions.

> *When we consistently bow down to other professions and diminish what it is that we're doing, we're never gonna get anywhere as a profession, and we're never going to mature and grow and get the respect that we need from the rest of the health system.*
>
> Respondent 17

Dynamics of leadership include behaviours that bridge cognitive and non-cognitive behaviours and skills. The purpose of leadership considering the change process is to establish a new balance between 'Who leads who?' and 'Who leads what?' It is a behaviour that is associated with key issues that are perceived as important by one or both professions, such as patient safety, clinical and non-clinical education, and expert knowledge (e.g. medication management) as a response to claims of 'lack of clinical knowledge'. Leadership also sees a natural recognition of general practitioners as health leaders and integrators, with no significant evidence of a desire to completely challenge this hierarchy, but rather to take a more 'rightful' place as a member of the multidisciplinary health team.

Theme 4: Dynamics of patient-centred care

This theme refers to the complex interactions and collaborative processes among healthcare providers that prioritise the needs, preferences and values of the patient. It involves teamwork, effective leadership, patient input and navigation of organisational and interpersonal factors to improve care outcomes. The collaborative approach leads to more holistic care, where the contributions of both general practitioners and pharmacists are valued and integrated into the patient's treatment plan:

> *That relationship is so important, and over the years, I really feel like the relationship I have with a particular general practitioner really impacts the outcomes we can achieve for the patient. There's definitely some variability, and I think a direct relationship between what we can do for patients when we have a general practitioner who's willing to have those conversations with us.*
>
> Respondent 6

When healthcare providers prioritise the needs and preferences of patients, it not only improves patient outcomes but also strengthens the collaborative relationship between pharmacists and general practitioners. Pharmacies that are locally owned or managed tended to have stronger personal relationships with patients, which fostered better opportunities for collaboration. In contrast, corporate pharmacies with business models that are less service-driven were perceived as less considerate, which can lead to breakdowns in relationships compared to local, family-owned pharmacies. In a study by Bradley *et al*. (2012), general practitioners were found to adopt demarcation strategies toward community pharmacies and pharmacists, with independent pharmacies being favoured over multiple chains, and regular pharmacists favoured over locum/sessional pharmacists [275]. This differentiation was repeatedly highlighted by general practitioners and found to affect their ability or willingness to collaborate.

Patients can sometimes act as either initiators or disruptors of trust between the two professions. As Respondent 9 pointed out, *'patient feedback determines a lot of it [trust].'* Previous personal negative experiences as a consumer and/or negative feedback from patients played a significant role in shaping trust toward a health professional.

> *So whenever I have an engagement with another health practitioner, part of me is going through the mental chess checklist of 'oh would this patient, would this person be safe? Would I trust them with my patients?' And so if I've had a good engagement as a patient, I'm much more likely to then go.*
>
> Respondent 19

The dynamics of patient-centred care are mostly non-cognitive, offering general practitioners and pharmacists a space for clinical activities and discussions. The patient is able to provide a judgement of the overall integrated care they receive in their community. Patients still recognise a hierarchy; however, they are primarily interested in the integrated approach to their healthcare rather than to blame one profession. They provide a de-escalation pathway from the professional and/or personal tensions by focusing on a third party. Most importantly, the quality of their health experience (measured using patient-reported measures) may be the most significant outcome measure of the change process studied here.

Discussion

Characterisation of the behavioural components of trust in the relationship between rural general practitioners and pharmacists.

Interviews with 21 rural general practitioners and pharmacists suggest that trust between these

professions is grounded in collaboration, communication, leadership and patient-centred care. These findings are consistent with findings from previous studies exploring the nature of interprofessional relationships between health professions [239, 240], although these studies were conducted in 'business as usual' contexts and were not specifically set in a rural context.

This study is grounded in a context of rapid change in the scope of practice of pharmacists, with a background of pre-established relationships between general practitioners and pharmacists. The process of change is therefore a source of heightened behaviours between the professions.

Approaches to change management in the health sector follow frameworks that have been developed in broad professional settings and applied in diverse contexts. Frameworks of change such as Kotter's 8 steps [241], Lewin's 3 stages [242] and the Awareness, Desire, Knowledge, Ability, and Reinforcement (ADKAR) framework [243] are widely used and are grounded in intense communication between stakeholders.

Such frameworks are most useful when designing a process of change affecting relatively large population groups, such as an organisation. However, they are less suitable to explain the behaviour observed once the implementation has started or for evaluative purposes. In this study, we chose to interpret our findings in the context of the Theoretical Domains Framework version 2 (TDF) of change behaviours [244] because of its relevance to applications in health studies. This framework is the outcome of the integration of 128 theoretical constructs drawn from 33 behavioural change and implementation science theories by a group of international specialists. The TDF identified 14 domains and 85 component constructs, organised in three broad behaviour categories (opportunity, motivation and capability). In general, the practical applications of the TDF have been to align observed behaviours with the TDF domains and constructs, for the purpose of designing behavioural interventions that aim to modify behavioural barriers to achieving the program goal. Although there has been a significant amount of literature published using the TDF; to date we have not identified peer-reviewed literature that documents the trust relationship between general practitioners and pharmacists during a scope-of-practice change process using the TDF.

When mapping our data against the TDF (see Table 8-2), we note that the four previously discussed themes align with eight of the 14 domains of the TDF, spanning all three sources of behaviour categories (opportunity, motivation and capability). The behavioural domains identified in our study align with the previous literature focusing on trust, integrated care, interprofessional relationships and general practitioner–pharmacist relations.

Table 8-2: Characterisation of the behavioural components of the trust relationship between rural general practitioners and pharmacists using the theoretical domain framework (TDF) [244]. Data arising from the analysis of 21 transcripts

Factor contributing to trust	Behavioural TDF domains and associated source of behaviour (in brackets)
Dynamics of collaboration	3. Social/professional role and identity (Motivation) 4. Beliefs about capabilities (Motivation) 11. Environmental context and resources (Opportunity)
Dynamics of communication	1. Knowledge (Capability) 2. Skills (Capability) 13. Emotion (Motivation) 14. Behavioural regulation (Capability)
Dynamics of leadership	3. Social/professional role and identity (Motivation) 4. Beliefs about capabilities (Motivation)
Dynamics of patient-centred care	3. Social/professional role and identity (Motivation) 4. Beliefs about capabilities (Motivation) 12. Social influences (Opportunity)

The dynamics of collaboration and dynamics of leadership were the most complex themes with regards to the behaviours displayed by the respondents. By contrast, dynamics of communication and dynamics of patient-centred care were more restricted in the scope of the behaviours displayed by the respondents. Given the small sample size, further work is required to validate these findings, particularly to clarify which behavioural constructs within the TDF domains are most suitable for interventions, and at what stage of the program

implementation. Nonetheless, combination of our pilot results and the TDF provide a strong structure for the creation of robust interventions informed by the TDF constructs identified in this study.

Using the TDF in making sense of the change behaviours observed in our study was useful in identifying which behaviours displayed during this change process were suitable candidates for interventions. These interventions may be targeted at improving the current trust relationships between general practitioners and pharmacists in rural areas for the purpose of improving patient outcomes or health access through workforce incentive programs or practice incentive programs, or for the purpose of increased engagement with the increased scope of pharmacy practice in remote areas. Alternatively, these behaviours may also be the subject of interventions to support the implementation or extension of future interprofessional programs such as novel scope-of-practice change programs. Our results are now examined in the context of the timing of such interventions to support future change programs.

Towards a trust framework for future programs focusing on trust in the relationship between rural general practitioners and pharmacists

Health services responding to population demand and in pursuit of high-quality care, often through interprofessional models, rely on trust between professional groups at both organisational and interpersonal levels. This trust cannot be assumed or considered static because staff flow (e.g., locum workforce movements), policy changes (e.g., changes in scope of practice), resource availability (e.g., scarcity of staff in remote areas), service demand (e.g., low or high service demand for general practitioners or pharmacists in rural and remote settings) and other changes can challenge and disrupt interprofessional relationships. Service or program development efforts may be required to maintain and strengthen this trust. Based on our analysis, the trust framework (Table 8-3) offers a way of assessing, monitoring and strengthening trust between pharmacists and general practitioners, particularly in rural and remote areas.

Leadership plays a crucial role in fostering collaboration and trust between pharmacists and general practitioners. In the early stages of a collaboration, leadership can offset conflict [245] and help create safe opportunities for understanding each other's roles and capabilities in patient care, where mutual understanding is crucial for the seamless delivery of healthcare services. If necessary, experienced leaders can bridge professional divides, promote mutual respect, and facilitate more open communication channels. According to Bollen *et al*. (2019), leadership that emphasises shared goals and collective responsibility can significantly enhance interprofessional collaboration. Leaders can support this further and advocate for a culture of trust and transparency, mitigate hierarchical barriers, and empower both pharmacists and general practitioners to contribute meaningfully to patient care [246]. Power differentials, however, can impede this. Coburn (2006) helps contextualise this and bring into focus power and medical dominance by placing it within a broader context [247]. That is, like trust, power changes as the actors change. Respect and engagement of all disciplines are fundamental to successful healthcare delivery, and developing strategies to balance power relations between pharmacists and general practitioners can make true collaboration and trusting relationships easier to achieve.

Communication is another critical component. Studies have shown that structured communication strategies, such as regular interdisciplinary meetings and shared electronic health records, can improve the quality of information exchange and foster a collaborative environment [248]. Good communication can assist pharmacists and general practitioners in aligning their understanding of patient needs and treatment plans, enhancing care and enabling trust and cooperation. Of course, miscommunication or even the absence of communication can lead to harm and, in the clinical domain, mortality [249]. Addressing communication needs early is vital, and seeking and acting on patient feedback is fundamental to achieving safe, effective and person-centred care [250].

Collaboration between pharmacists and general practitioners is most effective when it is centred around the patient, and this approach not only improves patient satisfaction but more easily enhances the therapeutic alliance between healthcare providers. Kwint *et al*. (2013) highlight that collaborative care models which include pharmacists in the decision-making process lead to better medication management and patient outcomes, and this can be strengthened by co-design, shared spaces or co-location of intersecting and shared processes, especially for clinical trials [251].

Focusing on patient-centred care as a common purpose aligns the goals of different healthcare providers, fostering a unified effort towards improving patient health and encouraging collaboration to ultimately improve health and health equity [251]. This approach ensures that all collaborative efforts are directed towards optimising positive patient outcomes [252]. By keeping the patient at the centre of care, healthcare teams can provide more personalised and effective treatment. In the delivery phase, facilitating discussions about legislative and practice-based responsibilities for multidisciplinary teams, record-keeping and continuity of care is vital.

The same approach proposed for building trust between pharmacists and general practitioners in their day-to-day practice can – and arguably should – be applied to clinical trials and evaluations. The trust framework can be considered a valuable resource in the initial stages of project management, especially as a method for assessing readiness for participation by pharmacists and general practitioners.

Table 8-3: The rural general practitioner-pharmacist trust framework for the delivery of change programs based on the transcripts of 21 rural general practitioners and pharmacists

	Leadership	Communication	Collaboration	Patient-centred care
Planning	Create safe opportunities for understanding each other's roles and capabilities in patient care	Facilitate open and direct discussion about effective communication methods and extent, as might occur due to different clinical and business pressures of pharmacists and general practitioners	Consider the co-design of intersecting and shared processes, and where possible co-locate services	Focus on patient-centred care as a common purpose and consider how collaborative care can optimise positive patient outcomes
Delivery	Facilitate discussion about legislative and practice-based responsibilities for multidisciplinary teams, record-keeping and continuity of care, and consider the notion of being 'custodians of patients'	Use open and multiple forms of communication without becoming excessive. Facilitate sustainable communication that is value driven and shows mutual respect	Build on existing working relationships and facilitate direct interaction. Seek patient feedback to inform collaboration	Regularly seek patient feedback and formally feed this information into agreed communication arrangements
Respect and engage	Develop strategies to balance power relations between general practitioners and pharmacists, which could foster true collaboration	Set and agree on expectations for respectful, honest and transparent communication	Consider sociological theory for understanding how to work together productively. Adopt a strength-based mindset and celebrate value-driven interactions and examples of mutual respect	Highlight and seek agreement on the primacy of patient care
Clinical trials	Address any concerns about scope of practice, medico-legal responsibilities and potential conflicts of interest	Make evidence-informed trial protocols available and facilitate opportunities for discussion about these	Use illustrations of how collaborative approaches optimise patient outcomes	Highlight that shared experiences and collaborative efforts during trials can foster a deeper understanding and mutual respect across disciplines

Conclusions

This study set out to identify the key factors/enablers that contribute to building trust between rural pharmacists and general practitioners in the context of PATH-UTI in NSW. In close-knit rural and regional communities, where healthcare options are limited, trust is the foundation of effective collaboration between pharmacists and general practitioners. Without the flexibility to easily seek new professional partnerships, a breach of trust could significantly undermine the interprofessional care we know to achieve improved patient outcomes. Therefore, our study focused on exploring the key features of trust in this evolving professional landscape.

Collaboration, communication, leadership and patient-centred care are key components of the trust construct between the two professions. Each of these components are associated with identifiable behaviours that may be used for the purpose of facilitating future change programs, or to maintain strong relationships through workforce support programs.

The trust framework, which draws from our thematic analysis and can be placed within the context of clinical trials and service development, provides early evidence towards a comprehensive approach to assessing and strengthening trust in general practitioner-pharmacist healthcare settings. This framework may be particularly valuable when designing or implementing programs whereby trust is a key enabler of success.

Our findings highlight that trust is not a static construct but one that requires continuous effort and development, particularly in dynamic healthcare environments. Leadership is pivotal in creating opportunities for mutual understanding and respect, while structured communication strategies and patient-centred approaches are essential for aligning the goals of different healthcare providers.

The framework's applicability extends beyond day-to-day practice to include clinical trials and evaluations, emphasising the importance of clear roles, responsibilities and open communication in these contexts. Ultimately, the framework aims to enhance the overall quality of patient care by fostering a trusting and collaborative environment. While this study focuses on pharmacists and general practitioners, the principles and strategies outlined can be applied to various health professional groups and geographical settings where trust is considered important, if not critical, in interprofessional relationships.

09

OVERALL DISCUSSION

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT

Chapter 9: Overall Discussion and Conclusion

The key measures of success from the New South Wales (NSW) Government were to:

- provide timely access to care for patients presenting with symptoms;
- ensure patient safety by appropriately referring those who do not meet criteria for pharmacy-only management to a general practitioner or hospital;
- foster stronger relationships between pharmacists and general practitioners, particularly in regional and rural areas;
- demonstrate that the initiative does not contribute to antimicrobial resistance (AMR); and
- ensure the model does not negatively impact lower socio-economic patients in terms of out-of-pocket costs.

This chapter will assimilate and integrate the analysis of the results from the seven individual studies addressing these key measures of success under five main pillars: Access and equity, Economic sustainability, Safety and efficacy, Implementation, and Practice. The overall discussion was prepared by the University of Newcastle research team.

Access and Equity

Accessibility to primary care services is one of the primary drivers for policy change related to pharmacy prescribing. During the urinary tract infection (UTI) trial, over 17,000 women in more than 1,000 pharmacies accessed the service in a 10-month period, presenting with symptoms indicative of uUTIs.

The overall incidence of uUTIs in women is challenging to estimate accurately due to many factors, including self-treatment by women along with treatment by pharmacies, general practitioners and emergency departments. Some studies estimate all age annual incidence for uUTIs in women at approximately 7%, with higher estimates for those aged 20–24 and over 65 years [39]. Applying this estimate to the 2023 Australian Bureau of Statistics population data suggests that approximately 175,000 women in NSW and 10,000 women in the ACT would have developed an uUTI in 2023 [40]. The PATH-UTI trial, having included 17,219 women in NSW and 787 in the ACT in the 10-month study, may have covered up to 9.5% and 7.8% of all uUTI cases in this population for NSW and the ACT, respectively. Accessibility to the pharmacy service could thus further improve access to health care for a higher proportion of women in these states. Increased consumer awareness may be a significant driver of the potential increased usage, considering high satisfaction rates by users of the pharmacy service.

Most consultations (71%) were delivered by pharmacies located in Modified Monash Model (MMM) category 1 areas, which represented 72% of pharmacies in NSW (with similar trends for MMM2). For metropolitan pharmacies, key barriers to service provision appear to relate to pharmacists' capabilities, including the need for additional training and challenges associated with using the IT solution. Other barriers include limited resources (such as the absence of a computer in the consultation room), the need to adapt existing pharmacy workflows, and low levels of patient engagement.

Fourteen percent of patient consultations occurred in pharmacies in larger rural towns (MMM3), which account for approximately 11% of all pharmacies registered in NSW [41]. A broadly similar distribution was observed across MMM1 to MMM5, with heatmaps providing visual analysis. However, no pharmacies in MMM7 areas consented to participate in the trial, and of the MMM6 pharmacies participating, only three delivered at least one consultation. Anecdotal evidence from PCF interactions with participating pharmacies, together with findings from the rural qualitative research conducted by Charles Sturt University and the Rural Doctors Network, indicates that certain NSW Health Authority requirements were challenging to meet in these settings. Ongoing workforce shortages were reported, with locum pharmacists typically providing coverage only 1–2 days a week. Additional concerns included the inability to conduct consultations in a separate room, as the sole pharmacist on duty could not leave the dispensary unsupervised for the 10–20 minutes required for each consultation. Privacy, considerations further compounded these challenges. These barriers should be taken into consideration, as remote communities are usually the most affected by lack of access to healthcare

services, with a higher risk of clinical complications if UTIs remain untreated [253].

Further consideration needs to be given to the service model and associated legislation for remote pharmacies. Additionally, research with Aboriginal and Torres Strait Islander communities highlighted strong interest and support for pharmacist management of uUTIs to improve access in remote areas, while also emphasising the importance of involving these communities in designing a culturally respectful and appropriate model of care.

Equitable outcomes

Accessibility is also affected by equity. Ensuring positive health outcomes for socio-economically disadvantaged populations, particularly Indigenous communities, while maintaining quality and continuity of care is of paramount importance. Findings from this study highlight that community members, including Indigenous participants, valued the convenience and rapid access to care and medications provided by pharmacies, particularly in rural and remote areas where doctor availability was limited. The qualitative studies suggest that while potential financial barriers exist, participants generally do not see them as outweighing their use of the service.

Health inequities continue to disproportionately affect Aboriginal and Torres Strait Islander communities, contributing to poorer health outcomes and lower life expectancy [33]. The integration of the pharmacy UTI service into Indigenous healthcare models could provide an accessible and culturally appropriate option of care. However, affordability remains a key concern, as out-of-pocket costs may deter Aboriginal and Torres Strait Islander patients from utilising pharmacy services. Additionally, government subsidies or targeted funding initiatives could support greater access to pharmacy-based care for Aboriginal and Torres Strait Islander patients, reducing financial barriers and promoting health equity. The Closing the Gap (CTG) scheme was suggested as a potential strategy to address the issue. The CTG initiative was implemented to address healthcare inequities, yet concerns were raised about potential financial barriers if pharmacy services were not integrated into CTG payment schemes. Without such financial support, Indigenous patients, especially elders and those with chronic conditions, may struggle to afford necessary medications, exacerbating existing health disparities.

Furthermore, ensuring cultural safety in pharmacist consultations was identified as critical, as Indigenous community members emphasised the importance of trust and relational healthcare, consistent with the holistic approach advocated in Indigenous health models. A culturally responsive approach was identified as essential to avoid unintended negative consequences, such as fragmented care or reduced engagement with Aboriginal Community Controlled Health Organisation (ACCHO) services.

For the trial population, consisting mostly of high SES patients, out-of-pocket expenses and cost barriers for accessing the service did not appear to be a major issue. During follow-up, most patients (>85%) replied that the service cost was not a limitation for access. However, the service was disproportionately accessed by higher income populations and/or Socio-Economic Indexes for Area (SEIFA) groups. The service was generally positively viewed.

Unlike general practitioner and emergency department visits, which are often at least partly subsidised under the Medicare and state departments, pharmacy consultations and non-Pharmaceutical Benefits Scheme (PBS) medications require full direct patient payment. In comparison, the United Kingdom has integrated pharmacist-led UTI services into the National Health Service, where government funding helps to reduce cost barriers and promote more equitable access [254]. This financial barrier may disproportionately affect low-income populations, leading to disparities in access to timely treatment. A potential solution for improving access and equity in Australia would be the inclusion of pharmacy UTI consultations under Medicare or a subsidy for non-PBS antibiotics. Addressing these inequities requires policy interventions, such as expanding subsidies or implementing tiered pricing models, to ensure that cost does not become a barrier to necessary pharmaceutical care. Without such measures, the financial burden associated with private prescriptions will continue to exacerbate health disparities and limit equitable access to essential medications. Policymakers should consider these implications when evaluating the long-term sustainability of pharmacy-led UTI management.

Economic Viability and Cost-Shifting

To date, while numerous international jurisdictions have implemented and piloted pharmacist

management of uUTIs, the global evidence base evaluating both the costs and clinical outcomes of pharmacist-led UTI management remains limited.

The economic analysis for the UTI trial was conducted independently by the Hunter Medical Research Institute health economics group. This was the largest trial conducted to date, allowing for the inclusion of these probabilities into the economic modelling process. Across all three modelled scenarios in the cost-effectiveness analysis, pharmacy-based care consistently demonstrated substantial cost savings when compared to existing treatment pathways. The inclusion of pharmacy care resulted in total healthcare system savings ranging from $2.2 million to $2.3 million across scenarios, even when re-presentation costs were accounted for through administrative linked datasets in Scenario 3. This scenario provided the most comprehensive and conservative estimate by capturing actual healthcare utilisation patterns. The cost-effectiveness analysis presented provides strong economic evidence to inform policy-making decisions regarding the support of community pharmacy-led care for uUTIs.

Uncertainty analyses for all three scenarios, visualised through cost-effectiveness planes, consistently showed that 100% of probabilistic simulations fell in the bottom-right quadrant, confirming that pharmacy-led care is cost-saving and improves outcomes with high certainty. Minimal variation in effect size (symptom resolution) across models suggests the pharmacy pathway delivers similar clinical effectiveness to other care settings, but at a reduced cost.

These findings were similar to the findings of previous pharmacist prescribing UTI interventions in Canada [145] and the United Kingdom [255]. In other countries, studies have found substantial cost savings. In one study, the budget analysis projected that if 25% of eligible Canadian women accessed the service via public health funding, the net savings could exceed CAD$51 million over 5 years [145].

The cost distribution analysis showed that across all modelled scenarios, PATH-UTI produced a redistribution of spending between care settings and payers. In Scenario 1, government costs fell across general practice, online general practitioner, urgent care and emergency department pathways, while patients paid more out-of-pocket due to choosing pharmacy consultations. Sensitivity analyses, including scenarios with no pharmacy fee, showed similar patterns. Scenario 2, which included re-presentations, maintained a similar pattern across all payers, with a slightly lower reduction Commonwealth government cost due to re-presentations largely being general practitioner follow-up visits.

A major limitation across all analyses was the assumption that women present only once per year, despite recurrence rates of 27% and 2.7% for second and third infections within six months [256]. This likely underestimates the total number of presentations and potential government savings. Uptake was also modelled at 13% whereas international benchmarks suggest that with greater awareness and policy support, this could rise to 38–50% [145, 153], potentially amplifying system-wide cost saving.

The analyses also excluded productivity benefits and pharmacy implementation costs, such as pharmacist training, private consultation room setup, or system integration, meaning societal benefits and true service costs remain underestimated.

Safety and Efficacy

Safety and efficacy parameters of the pharmacy service were analysed through data linkage, with the final analysis independently conducted by The George Institute for Global Health (Chapter 3). In parallel, the University of Newcastle research team continuously evaluated patient consultation outcomes throughout the trial period, enabling ongoing monitoring of the service. Data linkage has been described as a powerful tool for improving healthcare service delivery and patient outcomes exploration, allowing for longer follow-up periods and for estimating costs and implications of health interventions [257]. For PATH-UTI, patients were asked for additional consent to access these data, which included MBS and PBS data from Services Australia records, and emergency department presentations and hospital admissions data from NSW Health and ACT Health records. The criteria to assess the trial safety and efficacy were:

- rate of symptom resolution;
- referral rate to general practice or emergency departments;
- re-consultation rates;
- emergency department visits;

- hospitalisations;
- deaths;
- adverse events reported by patients;
- antibiotic prescribing rates; and
- AMR impact and levels.

Of the 17,313 individual patients in NSW who consented to the trial, MBS and PBS data were received for 89.3% and 95%, respectively, and 17,219 patients were successfully linked to NSW Health data related to emergency department presentations and hospital admissions (99%). These numbers show a high level of coverage for the data linkage process and a low risk of missing information from the total sample. This allowed for in-depth analysis and high confidence for the outcomes observed. Due to administrative limitations and time constraints, ACT Health data for the 787 consented patients (4.3%) were not available by the time of writing of this report.

Rate of symptom resolution

The primary outcome, defined as the self-reported total absence of symptoms (or total symptom resolution) at 7 days after receiving the service, was achieved in 79.4% of the patients that completed the follow-up survey (11,654/14,671), with another 17.9% (2,621/14,671) reporting partial resolution of their symptoms. These findings are in line with similar studies that have explored pharmacy prescribing for uUTIs (75–91%) [45-54].

Clinical effectiveness has previously been examined in several studies in pharmacy [42-44]. Beahm *et al.* in Canada reported a clinical cure rate of 88.9% of patients (n=750 patients enrolled in the study). In the same study, of those that did not have sustained symptom resolution, most (5.5% overall) had symptom recurrence after completion of therapy. Stampfli *et al.* [44] in Switzerland reported on consultation outcomes for minor health disorders including cystitis, resulting in a resolution rate of 84.7% (n=1,629). In 8.7% (n=168) of cases, the symptoms were not yet resolved, and in 6.6% (n=126), an appointment with a physician or an emergency department had been made in between netCare consultation and follow-up call [44]. In Australia, the Queensland Urinary Tract Infection Pharmacy Pilot-Queensland (UTIPP-Q) reported a 87.6% symptom resolution rate, with a 28.9% patient follow-up rate [258]. Importantly, the literature demonstrates similar symptom resolution rates for physician-led uUTI interventions, ranging from 67% to 95% when using the antibiotics included in the trial and other alternatives not available to pharmacists during the trial [45-54].

Interestingly, previous literature reports spontaneous resolution of symptoms associated with uUTIs in approximately 27–42% of patients who consulted their general practitioner [45-54]. In the PATH-UTI study, among the 796 patients who completed follow-up without receiving an antibiotic from the pharmacist, 505 (63.4%) reported complete symptom resolution by day 7. Notably, 54% of these patients (272/505) indicated that they subsequently visited a general practitioner (n=243) and/or presented to an emergency department (n=29) following their consultation with the pharmacist, which may account for the higher-than-expected symptom resolution rate.

Referral rate to general practice or emergency departments

Referral rates to general practitioners and other healthcare providers are often used as an indicator for pharmacists applying treatment protocols in an appropriate manner [259]. Pharmacists referred nearly 7% of all patients to a general practitioner or emergency department, based on the complexity of their condition. The most common high-risk factor prompting referral was the presence of systemic symptoms, such as fever. Based on MBS data, the rates of seeing a general practitioner within 7 days of the initial pharmacy visit were slightly higher than self-reported rates – 11.1 and 13.7 per 100 patients who consented to data linkage saw a general practitioner within 2 days and 3–6 days, respectively. In comparison, 14% of patients self-reported visiting a general practitioner during patient follow-up. Of those with linked data, 10.9 per 100 people had a urine sample collected for testing, and 11.7 per 100 people received an antibiotic prescription in the first week following the pharmacy consultation. Analysis of MBS records showed that patients referred by pharmacists had significantly higher odds of visiting a general practitioner within 7 days, suggesting pharmacists effectively identified patients requiring more complex care. Notably, 1,690 of 3,097 general practitioner visits were likely related to UTIs, as indicated by urine samples being sent for testing. Pharmacists referred 1,257 of these patients.

Protocol adherence by pharmacists was generally high. Only nine protocol violations related to missed referrals were recorded (0.05% of consultations). In five of these cases, pharmacists reported that referrals had been made but were not documented in the MedAdvisor® system, indicating strong understanding of clinical and protocol requirements among pharmacists. Referral rates varied by region. The ACT had a lower referral rate (4%) compared to NSW (7%). As a result, the researchers explored the potential reasons by consulting with PCFs and ACT Health. Anecdotal evidence suggests that, because consultations in the ACT were not government-funded and patients had to pay for each visit, pharmacists were conducting pre-screenings to ensure they only provided the service to patients who were likely eligible for antibiotics. There was a perception that registering consultations that led to referrals was 'not worth it' for both pharmacies and patients due to the associated out-of-pocket costs.

Re-consultation rates

The overall re-consultation rate, defined as the percentage of patients who consulted a general practitioner after the pharmacy service (indicated by registering an MBS episode), showed that over the 28 days post pharmacy consult, 6,668 participants (43.2%) had a general practitioner consult – 25.1% had one consult, 11.6% had two consults, and 6.5% had more than two consults. Among all patients in PATH-UTI who had an MBS episode registered within 7 days after the intervention, approximately 44% had a urine sample sent for pathology testing, suggesting that most general practitioner visits may not have been related to UTIs. These rates are similar to those previously reported in pharmacy-led and physician-led UTI interventions (15–42%) [45-54]. Similarly, studies have shown that nearly 40% of women aged 18–65 years who receive treatment for uUTIs will return to a general practitioner for similar symptoms within the 6 months following their initial visit, with this figure rising to 60% after 12 months [45-54]. For PATH-UTI, the re-consultation rate was significantly higher in patients that were older, and in patients that were referred to a general practitioner by the pharmacist during the service. As a result, the evidence suggests that PATH-UTI demonstrated expected re-consultation rates for patients with uUTIs.

Emergency department visits

The need for emergency department visits after initial pharmacy care for patients with uUTIs is difficult to assess individually, as most studies in this area have focused on initial presentations. One study in the United States followed a large cohort of 374,171 women with an initial diagnosis of an uUTI between 2016 and 2020, from whom 313,007 were between 18 and 67 years old (83.7% of the total sample) [54]. During the 4-year period, 13.9% of women visited the emergency department at least once, and 5.9% two or more times.

In the PATH-UTI trial, there were minimal differences in hospitalisation rates or visits to emergency departments and urgent care clinics for genitourinary-related consultations before and after the trial among patients who received the service. During the first week, 409 emergency department presentations were recorded, though 170 of these presentations were related to genitourinary conditions (41.6%).

As part of the clinical management protocol, pharmacists could directly refer to the emergency department when a high-risk factor was observed. The proportion of patients that visited an emergency department was between 2–6 times greater for patients that were referred by the pharmacists versus non-referred patients (6.15% versus 1.01% at 0–2 days, and 1.66% vs 0.93% at 3–6 days after the pharmacy consultation) (see Appendix 3.4 Table 3-4-4). Follow-up data indicated that 147 patients had been referred either directly by a pharmacist or indirectly through a general practitioner, although no direct linkage was possible between these two groups. This suggests that the pharmacist is supporting continuity of care by appropriately referring patients to the relevant level of care.

Total emergency department presentations in NSW for the period 2023–2024 was approximately nine million. Among females aged 15–64 years, presentation rates ranged from 296 to 400 per 1,000 people. Of these, 4.4% to 8.7% were due to genitourinary conditions [260], including UTIs. When comparing this with our study data and broader trends in genitourinary presentations to emergency departments, it appears the PATH-UTI trial demonstrated patterns similar to other established models of care for uUTIs.

Hospitalisations

In the PATH-UTI trial, 86 patients (0.52%) were hospitalised for any cause within 7 days of receiving the service, with 35 of these admissions related to genitourinary conditions. Importantly, the mean weekly hospital admission rate remained stable when comparing the 12 months prior to the pharmacy consultation (0.4 per 100 people) and 6 months post pharmacy consultation (0.2 per 100 people). In the first week after the pharmacy consultation, the admission rate was 0.5 per 100 people, indicating no significant increase in hospitalisations post intervention compared with the 12 months pre intervention.

In comparison, a trial in the United States reported that 6.1% of patients were hospitalised at least once for UTI complications over a 4-year follow-up period, with 1.4% experiencing multiple hospitalisations after receiving care through general practice or hospital/emergency services [54]. Additionally, data from the Australian Commission on Safety and Quality in Health Care showed that there were more than 21,000 potentially preventable hospitalisations related to UTIs and kidney infections for all sex and age groups, or 0.27 per 100, in 2017–2018 [261]. The hospitalisation rate observed in the PATH-UTI trial after 7 days of the intervention (0.20 per 100 people) was lower than the national rate for potentially preventable hospitalisations due to UTIs and kidney infections (0.27 per 100 people, according to 2017–2018 data [261]).

Deaths

During the PATH-UTI trial period, no deaths related to the UTI service were identified through data linkage.

Adverse events reported by patients

To monitor adverse events, patients were given multiple opportunities to report any complications experienced following their consultation, including through the follow-up survey, by returning to the pharmacy, or by directly contacting NSW Health or the research team. With a patient follow-up rate for the trial exceeding 80%, the reported rate of adverse events was low (5.1%), with the majority of cases involving gastrointestinal adverse events related to the antibiotics prescribed.

This rate is consistent with those observed in previous studies and is expected, as gastrointestinal adverse events are common when antimicrobials are prescribed [55]. One study by Beahm *et al*. reported that 7.2% (n=54) of patients experienced adverse events during their treatment, with gastrointestinal adverse events (59.3%), secondary vaginal infections (14.8%), other (14.8%) and headache (11.1%) being reported [42]. In the same study, a total of five (0.7%) reported adverse events resulted in a general practitioner or emergency department visit. The study revealed no statistically significant differences in adverse event rates between patients treated by pharmacists and those managed by general practitioners, as evidenced by p values greater than 0.1079 across all comparisons [42].

In the Queensland UTIPP-Q, a total of 10,270 instances of service provision were analysed. These services were recorded by 588 pharmacies that delivered at least one service [262]. Follow-up data were available for 28.9% of services (2,973/10,270). For 85 follow-up consultations (2.9%), patients indicated experiencing adverse events from antibiotic treatment.

The researchers performed a literature and clinical database review for the incidence of the reported adverse events for the three antibiotics included in the trial, and no important differences were found for patients that received trimethoprim, the most common antibiotic prescribed (95%). As for nitrofurantoin and cefalexin, no significant conclusions could be made due to much lower percentages of patients being prescribed these agents during the trial, although no serious adverse events were reported.

Antibiotic prescribing rates

Approximately 88.5% (n=15,232) of patients in the PATH-UTI trial were prescribed trimethoprim by the pharmacist, in line with the clinical management protocol, demonstrating high adherence to the guidelines. Only 2.5% and 1.6% of patients were prescribed cephalexin and nitrofurantoin, respectively, while 7.4% did not receive an antibiotic. Overall, pharmacists prescribed antibiotics in 92.6% of patient encounters, with trimethoprim being the primary agent (95%), aligning with first-line treatment recommendations in both the therapeutic guidelines and the trial's management protocol. For the small proportion of patients receiving nitrofurantoin (2%), the most common reasons for not prescribing trimethoprim were prior treatment failure or allergy to the medication. For those prescribed cephalexin

(3%), reasons cited included previous adverse events from nitrofurantoin, the inconvenience of its dosing schedule (four times daily), and prior success with cephalexin.

In comparison, the AURA 2023 report, which examined a sample of general practices, found a 90.8% prescribing rate for UTIs, with only 42% using trimethoprim as the first-line treatment [56]. Furthermore, previous pharmacy studies present prescribing rates between 80% and 97%, and physician-driven trials have usually reported between 80% and 97% of antibiotic prescribing [45-54]. This percentage seems to be higher when empirical treatment is used, in contrast to when laboratory testing or point-of-care testing is involved [127].

In the PATH-UTI trial, there were 712 PBS prescriptions issued for antibiotics dispensed within 0–2 days after the pharmacy service (4.3 per 100 people), and another 1,207 prescriptions issued on days 3–6 after the pharmacy service (7.3 per 100 people). Repeated antibiotic prescriptions and additional visits to general practitioners are common for uUTIs. Some studies have reported that between 10% and 18% of patients revisit a general practitioner within 7 days of receiving their first antibiotic course for further treatment [263].

Pharmacists were only authorised to provide a 3-day supply of trimethoprim in the clinical management protocol, which was in line with the Australian Therapeutic Guidelines at the time, but 5–7 days is a common treatment duration provided by healthcare providers [264]. Anecdotal evidence from PCFs and follow-up surveys revealed that some patients and pharmacists felt the 3-day treatment was ‘too short’, perceiving it as insufficient, which may have led to additional visits to general practitioners for extended treatment courses. Despite the evidence being similar for the use of 3 days versus 5 or 7 days of trimethoprim, some trends have shown higher symptom resolution rates with longer treatments, especially in populations where trimethoprim resistance is high, and when bacteriological cure is needed [265]. As most clinical guidelines no longer recommend trimethoprim due to increased resistance, patients may benefit more from receiving other medications such as nitrofurantoin as the first treatment instead of increasing trimethoprim duration in the service.

Antimicrobial impact and levels

AMR is one of the key emerging threats to global health, with its importance in Australia underlined by publication of the Australian Commission on Safety and Quality in Health Care’s AURA 2023 report [56]. AMR data was defined by NSW Health as one of the key safety criteria for the trial due to the increased risk of complications that it could generate in the population. In monitoring AMR trends before, during and after the trial, the research aimed to assess whether the introduction of pharmacist-led UTI treatment could influence resistance patterns in a way that might raise concerns for patient safety or public health.

The resistance levels observed for the antibiotics prescribed during the trial were consistent with the expected trends based on both previous and current laboratory data, with trimethoprim resistance at 27% (see Chapter 6). Given these results, it is unlikely that the antibiotics prescribed by pharmacists for UTIs had a significant impact on AMR, especially considering that fewer than 17,000 patients received prescriptions out of an estimated total antibiotic prescribing rate of 827 per 1,000 people per year in NSW [57]. The observed resistance trend in this trial likely thus reflects ongoing developments in AMR, rather than any major deviation linked to the trial’s interventions [56]. More detailed analysis of AMR data is presented in Chapter 6.

Several national and international guidelines recommend that trimethoprim should not be used as first-line treatment when resistance to this medication is larger than 20%, unless treatment sensitivity is detected by urinalysis, as clinical cure reports could decrease from 85–95% in sensitive organisms to 70–80% on resistant strains [58, 266-268]. As a result, several international and local clinical guidelines, including those from Western Australia and previous pharmacy-led interventions for uUTIs, have recommended and/or used nitrofurantoin and/or fosfomycin as first-line empirical treatments [269-271].

Primary outcome analyses for the PATH-UTI trial showed a trend towards higher rates of symptom resolution for patients prescribed nitrofurantoin or cefalexin by the pharmacist (84% and 82%, respectively) compared to trimethoprim (80%). However, as nitrofurantoin and cefalexin were second- and third-line therapies in the PATH-UTI clinical management protocol, they were much less

frequently prescribed than trimethoprim (2–3% vs 95%). Further research is needed to explore if modifying the first-line antibiotic for pharmacist prescribing increases the efficacy of the intervention. Given the current high levels of trimethoprim resistance in Australia, the therapeutic guidelines for UTI were updated at the end of March 2025 (post-trial) and as this report was being written. Trimethoprim has now been replaced with nitrofurantoin as first-line treatment, with fosfomycin as a second-line agent, and trimethoprim moved to a third-line option [58]. Cefalexin was also moved to a second option, to be used when first-line treatments are unavailable or ineffective.

A study by Saha *et al*. [272] highlights the important role of general practitioners and community pharmacists as antimicrobial stewards in primary care. In this regard, effective collaboration between general practitioners and community pharmacists is needed for the professions to firmly engage in antimicrobial stewardship activities. A 2019 systematic review and meta-analysis reported that antimicrobial stewardship strategies involving pharmacists can reduce antibiotic prescribing and improve guideline adherence of prescribing by general practitioners [273]. Effective interventions identified in the review included group meetings between general practitioners and pharmacists, pharmacist-facilitated academic detailing, educational training, and audit and feedback [273].

The consistency with expected resistance patterns emphasises the importance of continued surveillance and adaptation of treatment guidelines to mitigate the growing risk of AMR. It also highlights the need for ongoing discussions regarding alternative treatment strategies, including the potential role of second- and third-line antibiotics, as well as broader antimicrobial stewardship efforts to reduce the impact of resistance on public health. As the analysis was restricted up to the end of the PATH-UTI trial, additional analyses 12 months post-trial will provide further insights when published in the future.

In summary, although the researchers initially proposed a randomised controlled trial (RCT), due to challenges related to healthcare access, ethical considerations, and the desire for the service to be applicable in real-world settings, this design was not utilised. Although an RCT – the gold standard for evaluating service models – was not conducted, the cohort study design, utilising mixed methods (quantitative and qualitative research), combined with existing literature on alternative treatments for uUTIs (such as general practice consultations, emergency department visits, and other pharmacy-led studies for the management of minor ailments), provided valuable insights. The PATH-UTI trial has provided evidence on nine key outcomes related to safety and efficacy, supporting the recommendation that pharmacy-led management for uUTIs is as safe and effective as other forms of care. Additionally, the data-linkage process, which reflects the utilisation of other healthcare providers, demonstrates that appropriate continuity of care was achieved throughout the trial.

Implementation

Eligibility to participate in the trial was determined by the NSW Health Authority, and in the ACT by a licence issued by ACT Health, which defined both pharmacy and pharmacist criteria (Appendix 3.1). The most critical requirement for pharmacies was the availability of a consultation room with characteristics different of those of the Quality Care Pharmacy Program (QCPP), which created challenges for pharmacies. There is a need for consideration of aligning NSW, QCPP and individual legislative requirements post-trial.

The need for additional training for pharmacists for the UTI program was facilitated by both the Pharmaceutical Society of Australia (PSA) and the Australasian College of Pharmacy (ACP) providing free substantive training for the clinical component of the program. This training was augmented by the University of Newcastle researchers' online learning modules. Approved pharmacists could only provide UTI services from consented pharmacies who met all the requirements.

The University of Newcastle team developed an implementation program to support pharmacies and pharmacists in the trial. The advice from NSW Health was to open the trial to all registered pharmacies and pharmacists in NSW. For ACT, the sample was initially randomised by ACT Health per region. The implementation program was based on the Consolidated Framework for Implementation Research (CFIR) and evaluated using the Expert Recommendations for Implementing Change (ERIC) classification. Four PCFs contacted pharmacies in various ways, including face-to-face visits and phone and video calls, among others. Overall, 97% (1,288/1,320) of pharmacies that consented to the

trial were contacted to provide support, and 69% received at least one face-to-face visit (915/1,320). In total, 4,984 contacts were made, with 1,038 total face-to-face visits. The four PCFs recorded data based on their contacts with pharmacies using the REDCap® IT program. They were employed, trained and managed by the University of Newcastle researchers in association with the University of Technology Sydney and the University of New England. In addition, The George Institute for Global Health undertook qualitative research using interviews with stakeholders, including patients, pharmacists, health authorities and professional organisations.

One of the challenges faced during the period of the PATH-UTI trial was that the PATH-OC trial commenced. Therefore, some of the implementation determinants were applicable to both trials.

For PATH-UTI, the outcomes used to evaluate the implementation program were:

- identification of implementation determinants and strategies;
- acceptability and appropriateness;
- feasibility;
- accessibility;
- adoption and reach; and
- fidelity.

Identification of implementation determinants and strategies

The PCFs identified 1,874 barriers and 4,648 facilitators during contact with pharmacies, with a mean of 2.0 ± 1.39 barriers and 5.2 ± 3.25 facilitators per pharmacy. The most common barriers found were related to the pharmacist's capability when delivering the service, particularly when there was limited familiarity with the MedAdvisor® IT program or training had not yet been completed. In most cases, training was incomplete due to time constraints. Supporting pharmacy owners to allocate dedicated time during work hours for staff to complete training could help address this challenge. Encouragingly, issues related to the use of the MedAdvisor® IT program were often resolved through collaborative interactions between the PCFs and pharmacists. Additionally, pharmacists expressed interest in having access to a dummy patient or practice scenario within the MedAdvisor® IT program, which would allow them to build confidence in the consultation process prior to delivering the service.

It should be noted that some pharmacies were withdrawn from the trial by the research team for not meeting NSW Health Authority requirements for consultation rooms (Appendix 3.1). From the pharmacy perspective, a common barrier, despite having a consultation room, was the absence of a computer within the room. To support service provision in these cases, the researchers, through the PCFs, supplied hard copies of the consultation form. While this enabled pharmacists to continue delivering the service, it was not ideal, as it introduced the risk of consultations not being subsequently entered into the MedAdvisor® IT program. A consideration could be making access to a computer in the consultation room a mandatory component of the consultation room criteria. Another barrier identified was the need for workflow adjustments due to the requirement that consultations be conducted in a private consultation room. While appropriate and justified, this requirement effectively excludes single-pharmacist pharmacies from participating in the trial, as pharmacists cannot legally leave the dispensary unattended.

In pharmacies with multiple pharmacists, two additional challenges were observed. First, meeting the criteria required significant adjustments to existing workflows. It is recommended that national-level guidance be developed for consultation workflows, analogous to the established workflows for dispensing. Second, the expectation that a pharmacist be available to deliver the service during all pharmacy opening hours proved challenging. To address this, two potential solutions are suggested: allow pharmacies to define and communicate specific service hours to patients or ensure that all pharmacists within a pharmacy are trained to provide the service.

Pharmacies also reported a general lack of consumer awareness about the new service, despite the final number of consultations exceeding initial expectations. Promotional materials provided by NSW Health were reported to be highly effective in raising awareness. However, there was interest, particularly from pharmacy banner groups, in developing tailored promotional materials aligning to their branding and customer base during the trial. Therefore, outside of trial conditions, pharmacies

could be permitted to create their own promotional materials, provided they comply with relevant advertising regulations.

Conversely, the implementation facilitators included pharmacists who had knowledge and skills related to the service, as well as pharmacies that had the MedAdvisor® IT program available on all relevant computers and had consultation rooms that met all NSW Health requirements.

The PCFs implemented strategies to address 60% of the identified barriers during pharmacy contacts, successfully resolving nearly half. Effective strategies included conducting role-plays with pharmacists during visits, providing hands-on support with the MedAdvisor® IT program, and clarifying the clinical management protocol. These challenges were predominantly addressed through face-to-face visits to the pharmacy. Based on this experience, pharmacists and pharmacies seeking to deliver expanded scope-of-practice services could receive similar support during the initial implementation phase. The financial investment required for this support could be considered a shared responsibility, by pharmacy businesses seeking to expand their services, by professional organisations supporting the evolution of the profession, and/or by governments aiming to implement policies that improve healthcare access.

Acceptability and appropriateness from patients and pharmacists

Acceptability and appropriateness were measured in two different ways: patients received a follow-up survey from The George Institute for Global Health via their preferred method (SMS and/or email) selected during the consent process which contained questions related to patient satisfaction; and during qualitative research conducted using interviews by the same team. In addition, there was other qualitative research specifically focused on the perspectives of Indigenous community members, health organisations and community pharmacists for an expanded scope of practice for community pharmacists.

Overall, patient satisfaction with the service was high. More than 80% of follow-up survey respondents reported positive experiences, a sentiment echoed in individual interviews. Patients reported high levels of engagement and emphasised that the service was highly convenient, and were confident on the level of care received from the pharmacist. Interviews revealed that key incentives for seeking the service included limited availability of usual care and the feeling of being actively involved in their care. Many patients felt the service offered good value for money, and cost was generally not seen as a barrier to access. However, it is important to note that patients from higher socioeconomic backgrounds were overrepresented in the trial. Among Indigenous participants, similarly positive feedback was received. Concerns were raised about the affordability of the service, despite cost not preventing access, and about the importance of culturally sensitive engagement. These findings suggest the need for tailored strategies to support equitable access and culturally appropriate care.

Based on interviews with 11 pharmacists, several key themes emerged regarding their motivation to participate in the trial. These included alignment with their business model, a strong intrinsic motivation to better serve their community, and a sense of enhanced self-efficacy, driven by the belief that delivering the service was both feasible and within their professional capability. Pharmacists also felt well supported through training and ongoing assistance. As noted previously, this was reflected in the high level of participation throughout the trial.

In summary, the service was well received by both patients and pharmacists, demonstrating high levels of acceptance and perceived appropriateness for the service being provided in community pharmacies. However, further research is needed to explore cost-related barriers, particularly for individuals from lower socio-economic backgrounds and Aboriginal and Torres Strait Islander communities, to ensure equitable access to the service.

Feasibility

The feasibility of the trial was closely linked to the NSW Health Authority criteria and the behavioural changes associated with the new service. Key requirements, such as documenting consultations and transferring information to a patient's regular general practitioner, represented novel changes to practice. While informal communication systems between pharmacists and general practitioners already exist, the extended scope of practice requires formalised communication channels. Furthermore, the results highlighted the need for integration with health system 'hardware' such as health information systems and pathology services. The behavioural

components require changes in clinical decision-making and workflow systems. In participating pharmacies, this adaptation was undertaken on an individual pharmacy basis rather than through recommended professional standard processes. Despite this, participating pharmacists successfully navigated these changes and demonstrated feasibility of the service. However, there is a clear need to establish professional standards to guide the implementation of new services.

Accessibility

The heatmaps developed reflect the extensive accessibility of community pharmacies. Metropolitan areas up to rural towns (MMM1 to MMM5) were well served in service provision, with most of the general population residing within 1 kilometre of pharmacies that were providing the service. However, there was a lack of participation for pharmacies in remote communities (MMM6 and MMM7), reflecting the inability to meet the NSW Health Authority requirements (Appendix 3.1) – for instance, not having a consultation room or pharmacists not willing to undertake further training. Consideration should be given to investigating and co-designing service models that meet the needs of both pharmacies and the population in these areas. There is a need for further research to qualitatively and quantitatively have a deeper understanding of the barriers for pharmacies in MMM6 and MMM7 areas.

Adoption and reach

Overall, 1,320 pharmacies and 3,484 pharmacists participated in the trial, with 984 pharmacies performing at least one consultation. The total number of pharmacies registered by 2023–2024 in NSW was 2,014, which represented approximately 60% of community pharmacists in NSW [274]. In comparison, in the Queensland UTIPP-Q, with 1,215 registered pharmacies in Queensland, approximately 67% of total pharmacies participated. 74.5% of NSW pharmacies delivered a mean of 18.4 consultations per pharmacy in the trial, compared to 72% in Queensland who delivered a mean of 17.5 services [85]. It is important to note that the Queensland pilot lasted for 12 months, in contrast to 10 months for the NSW trial.

The service was provided to over 17,500 women across NSW and ACT. As mentioned earlier, this could represent up to 10% of the annual number of women presenting with uUTIs. This means a significant opportunity to expand the population, particularly outside the high SES patients. However, consideration is to be given to the lower SES participation and accessibility to the service.

Fidelity

Fidelity was evaluated based on pharmacists' adherence to the clinical management protocol. The low level of protocol violations (0.05%) provides evidence of a high level of service fidelity. Almost all antibiotics prescribed (95%) were for first-line treatment as defined by the clinical management protocol. For context, the AURA 2023 report indicated that 48% of general practitioners adhered to this same parameter [56]. The fidelity of patients following pharmacist advice was explored using patient adherence to treatment recommendations including referrals made by pharmacists to other healthcare providers. Of those patients who completed the follow-up survey, 90% reported using the prescribed antibiotic for the full treatment cycle of 3–5 days. Regarding referrals, 68% of patients who were referred to a general practitioner and/or emergency departments by pharmacists appeared to have visited these settings within the following 7 days, as confirmed through linked MBS and NSW Health data.

Practice

The evolution of pharmacists' extended scope of practice has the potential to significantly impact primary healthcare systems. This trial has emphasised the need for greater integration between community pharmacy and general practice. Several challenges encountered during the PATH-UTI trial have highlighted the necessity for formal, bi-directional communication pathways between pharmacies and general practitioners. Collaborative practice must be further developed to ensure an integrated approach to patient care, particularly in establishing clear parameters to define the boundaries between professions.

For sustainability of the service more broadly, fundamental system changes are required. These include improved accessibility to the patient's My Health Record, combined clinical meetings, revised remuneration systems, and direct communication between pharmacists and general practitioners.

The rural and remote qualitative study identified methods for strengthening the relationships between pharmacists and general practitioners, particularly in

rural areas, using a trust framework. This approach is based on four key pillars: collaboration, communication, leadership, and patient-centred care. It is suggested that this trust framework could be equally effective in metropolitan areas as well.

The trial has provided evidence that community pharmacists are confident in determining when to prescribe and when not to prescribe antibiotics for uUTIs, with the data aligning closely with other pharmacy-led and physician-led trials. The observed referral rate to general practices and emergency departments (nearly 7% of all patients), the low frequency of protocol violations, and the linked data on emergency presentations and hospitalisations suggests appropriate delivery of the service by pharmacists.

Strengths and Limitations

To our knowledge, PATH-UTI represents the largest trial for pharmacy management of uUTI, including prescribing, to date. There were more than 18,000 consultations provided to 17,500+ patients in both NSW and the ACT during a 10-month period, with 80% follow-up of patients. More than 1,300 pharmacies and 3,000 pharmacists consented to the study, representing over half of all pharmacies in NSW, with at least 80% of them delivering at least one service. These numbers demonstrate a high adoption rate for the service and allow for in-depth analyses of real-world applicability, effectiveness and safety of the UTI pharmacist service. Additionally, to assess longer-term outcomes of the intervention and patient follow-up within the healthcare system, data linkage was achieved for over 85% of the total sample, with linkage reaching 99% for emergency department visits and hospitalisations.

Other analyses were also included in the study, such as exploration of the adoption of the service in rural and remote communities, Aboriginal voices and experiences, qualitative research including patient satisfaction and evaluation, stakeholders' (including policymakers') views, and analysis of AMR patterns before and during the implementation of the service. Furthermore, an implementation program was developed by the researchers to explore the adoption, reach and other relevant parameters for health service integration, with PCFs supporting the implementation of the UTI service, and delivering additional training and/or follow-up to pharmacists when needed. All analyses conducted by the research team and independent evaluators make PATH-UTI the most comprehensive evaluation of pharmacist management of uUTI, including prescribing, to date.

There are several limitations to the trial, as discussed by each external and independent aspect of the report. The main limitation is related to the lack of control group for the intervention; this limits the capacity to compare the findings and individualise the effect of the intervention, and increases the risk of internal and external bias. To mitigate the internal validity concerns arising from the lack of a control group, literature comparators are often cited as a suggested method to reduce these risks [275]. As discussed above, study outcomes were compared to those previously reported for pharmacist-led interventions for uUTIs, including accessibility, clinical and economic results. The findings were also consistent with those reported for physician-led interventions and usual practice for this condition, including rates of antibiotic prescribing, symptom resolution and re-consultation (including emergency department presentations and hospitalisations). These results reassure the researchers that the intervention appears to yield outcomes similar to those of usual practice, which could not be directly tested in a controlled trial due to the real-world nature of the community pharmacy setting.

Several trial elements were implemented:

- The study protocol was designed in conjunction with external researchers and stakeholders using a co-design process. This approach ensured that the clinical management protocol for the intervention was locally assessed and adapted, and included views from external stakeholders such as general practitioners and health authorities.
- The study protocol was registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) to make all aspects of the research accessible to the public after the research elements were defined during the co-design process, to address the risk of selective data analysis or statistical manipulation.
- Eligibility criteria for the intervention were established during the co-design process and were not modified during the trial. These criteria were clear and transparent to avoid the risk of selection bias for the intervention.

- Statistical analyses were planned at the start of the trial and made publicly available to increase the transparency of the findings. Several sensitivity analyses were conducted to decrease the effect of potential cofounders related to the open nature of the trial, such as the age and economic backgrounds of the participants.
- Independent researchers developed external data collection and analysis to explore all aspects of the service. These external teams developed several processes and/or platforms covering patient consent, consultations records, patient follow-up, data linkage and outcomes exploration and analyses. The University of Newcastle research team provided feedback, though decisions related to their research methods, results and conclusions were made independently.
- Data monitoring processes were established to ensure that data collection was consistent and accurate for the service. This included pharmacy and pharmacists' data, patient consultations and patient follow-ups, and ended with data validation procedures to account for participant withdrawals and any potential data errors found by internal and external researchers.
- Regular preliminary data reports were provided to the trial sponsor and to the governance groups in the trial monitoring for safety aspects, to address any potential patient risk that could appear. These included the report of serious adverse events and protocol violations to the University of Newcastle Human Research Ethics Committee.

Interpretation of the trial's findings is limited by the subsidisation of consultation fees throughout the trial, which may overestimate service uptake compared with routine practice if patients are required to pay the full out-of-pocket cost.

The independent analyses and conclusions conducted by external researchers, the comparisons conducted with the published literature and their results, and the processes implemented to reduce the risk of bias, seem to indicate that most of the trial model limitations were addressed.

Conclusion

The PATH-UTI trial is the largest study reported in the literature to date of pharmacist prescribing and management for uUTIs. The study provides valuable insights into the safety, efficacy and accessibility of this care model. The 10-month trial achieved a high level of both pharmacist and participant uptake, positive patient satisfaction and cost-saving potential. The complete symptom resolution rates align with findings reported in the literature, which are generally around 80–90%. However, the service was disproportionately used by women with higher levels of education and for those residing in wealthier areas. A minority of people reported cost as a potential barrier to future use of the service. Additionally, it demonstrated that the model tested may not be applicable to remote and very remote areas.

The research highlights several key outcomes that addressed the primary measures of success defined by the NSW Government. The PATH-UTI trial showed that community pharmacies can effectively expand healthcare access, particularly for women in metropolitan, regional and rural areas, offering a service that is well utilised and valued by patients. While the service reached a proportion of the population, there are indications that remote and very remote areas may face challenges in terms of accessibility. Therefore, further investigation into service models and legislation is necessary to ensure comprehensive coverage in all areas, especially where healthcare resources are limited. Current evidence on community pharmacy management of uUTIs remains limited, but the economic evaluation, conducted across multiple scenarios, including both cost-effectiveness and cost distribution analyses, suggests that involving pharmacists in uUTI care could lead to significant savings for both State and Commonwealth health budgets, although some expenses may shift to patients. Allowing pharmacists to manage uUTIs may also reduce pressure on general practitioners and emergency departments by diverting lower-complexity cases to a more accessible setting. At the same time, this service model could improve timely access to treatment for women experiencing uUTIs. Overall, the findings provide strong support for policymakers considering the expansion or endorsement of community pharmacy-led management for this condition.

The trial, although not a RCT, has contributed a greater and deeper understanding of safe and efficacious care utilisation practices using patient consultation data, feedback from patients and linked data. Importantly, the rates of follow-up care suggest there was continuity of care for those that needed ongoing support with appropriate referrals,

particularly to other healthcare professionals such general practitioners, urgent care clinics and emergency departments. The proportions and numbers of serious side effects from medications prescribed were similar to those in the published data. Antibiotic prescribing was at a similar rate compared to the limited data published for general practitioner prescribing rates. Analysis did not identify an increase in the underlying trend of antibiotic resistance over the study period. The education and training provided for the delivery of the service appears to be appropriate for the delivery of the service. This is evident from low levels of protocol violations as well as high fidelity to protocol adherence with respect to appropriately referring high-risk patients and first choice of antibiotic selection.

Finally, implementation and practice findings emphasised the importance of integrating pharmacy services into existing healthcare structures in a way that is collaborative with other primary healthcare providers, culturally sensitive and financially accessible, especially for vulnerable populations, including Aboriginal and Torres Strait Islander communities. While the service was largely viewed as beneficial, out-of-pocket costs and associated financial barriers for certain population groups persist and must be addressed to promote equity of access to care. As the service transitions to usual practice in NSW and the ACT, several key factors related to sustaining access, supporting quality service delivery, promoting equity and enhancing health system integration should be addressed as a part of future state and federal government policy.

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PATH-UTI
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APPENDICES

UNIVERSITY OF NEWCASTLE AUSTRALIA

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Appendices

Chapter 1

Appendix 1.1 – Research team and consortium

The Chief Investigators included:

- Associate Professor Sarah Dineen-Griffen (Lead Investigator and Chair).
- Emeritus Professor Charlie (Shalom) Benrimoj (Independent Consultant).
- Professor David Peiris (The George Institute for Global Health).
- Dr Belinda Ford (The George Institute for Global Health).
- Dr Gill Schierhout (The George Institute for Global Health).
- Dr Anna Campain (The Geroge Institute for Global Health).
- Associate Professor Kris Rogers (University of Technology Sydney/ The George Institute for Global Health).
- Associate Professor Penny Reeves (University of Newcastle/ Hunter Medical Research Institute).
- Emeritus Professor Julie Byles AO (University of Newcastle/ Hunter Medical Research Institute).
- Dr Indy Sandaradura (Centre for Infectious Diseases and Microbiology, Westmead Hospital).
- Professor Leanne Holt (The University of NSW).
- Associate Professor Kylie Gwynne (The University of NSW).
- Professor Kylie Williams (University of Technology, Sydney).
- Dr Helen Benson (University of Technology, Sydney).
- Associate Professor John Rae (Charles Sturt University, Bathurst).
- Ms Anna Barwick (University of New England).
- Dr Joanna Moulin (Curtin University, WA).
- Ms Jan Donovan (Consumer Health Forum).

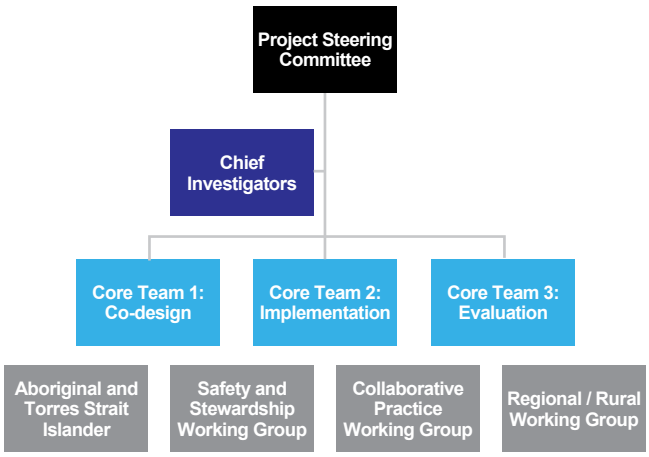
Research team members included:

- Dr Francisco Martinez Mardones (Postdoctoral Research Fellow, University of Newcastle).
- Simone Diamandis (University of Newcastle, Research Project Manager and PhD student).
- Kristin Xenos (University of Newcastle, Education Lead and PhD Student).
- Mitchell Budden (University of Newcastle, PhD Student).
- Victoria Chisari (University of Technology Sydney, PhD Student).
- Dr Joy Bowles (University of New England, Research Assistant).
- Abeer Ellabaan (University of New England, Research Assistant).
- Bradley Rockliff (University of Newcastle, PhD student).
- Dr Valerie Looi (The George Institute for Global Health, Project Manager).
- Dr Noelia Amador Fernandez (University of Technology Sydney).
- Dr Victoria McCreanor (Hunter Medical Research Institute, Head of Health Economics).
- Dr Xenia Dolja-Gore (Hunter Medical Research Institute, Senior Biostatistician).
- Dr Olivia Wynne (Hunter Medical Research Institute, Health Economist).
- Maddie Heenan (The George Institute for Global Health, Research Associate).
- Connie Calvisi (University of Technology Sydney, Masters Research Student).

A total of 13 project partners were part of the research consortium led by the University of Newcastle in collaboration with NSW Health. The partners, divided into three groups across each research phase, were:

1. The Pharmacy Guild of Australia
2. Royal Australian College of General Practitioners
3. Pharmaceutical Society of Australia
4. The George Institute for Global Health
5. Hunter Medical Research Institute
6. University of Technology Sydney
7. University of New England
8. Charles Sturt University
9. Rural Doctors Network New South Wales
10. Co-Design Health Research and Innovation team at UNSW
11. Consumer Health Forum
12. Deloitte Australia
13. MedAdvisor

Appendix 1.2 – Governance structure



Appendix Figure 1.2.1: NSW Pharmacy UTI Trial governance structure, May 2023

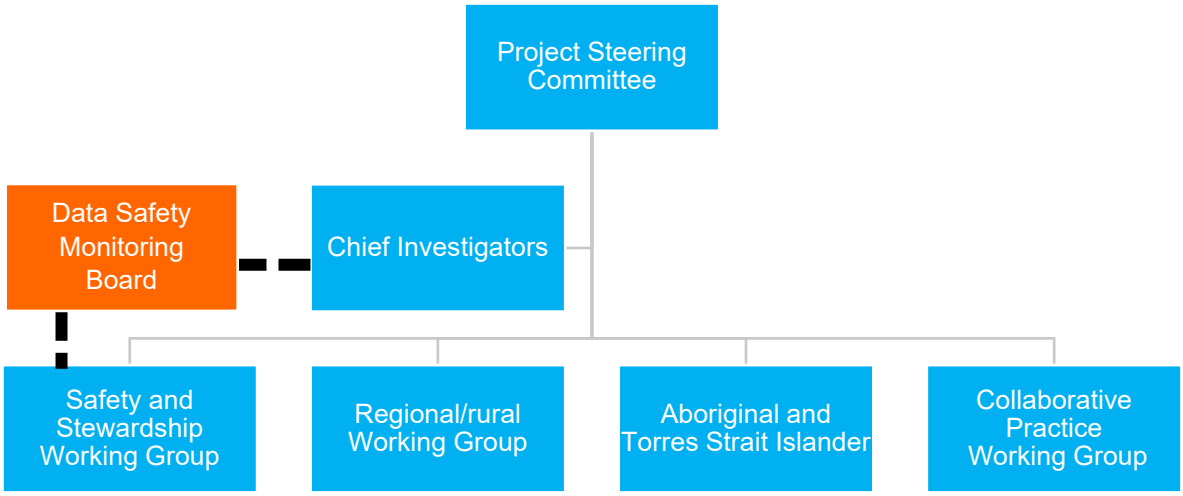
The Project Steering Committee (PSC) was established and approved the governance structure. The first meeting of the PSC was held in March 2023.

The Safety and Stewardship Working Group (SSWG), Collaborative Practice Working Group and the Regional and Rural Working Group (RRWG) had their first meetings in Q4 2023. The Aboriginal and Torres Strait Islander Working Group held its first meeting in Q4 2024.

Weekly, fortnightly or monthly meetings have occurred over the course of the project with the following key stakeholder groups:

- Royal Australian College of General Practitioners (RACGP) (fortnightly)
- Pharmacy Guild of Australia (NSW Branch) (weekly)
- Pharmaceutical Society of Australia (PSA) (fortnightly)
- MedAdvisor (weekly)
- Ministry of Health (fortnightly and ad hoc – re: scope of practice contracts, general advice, communications, IT)

Further to Ethics requirements, an independent Data Safety Monitoring Board (DSMB) was also established to assess, review and provide recommendations to the research team on safety aspects of the trial, including all adverse events reported in patient interviews or through any other reporting channel. Operating as an independent and external body, the first DSMB meeting was convened in August 2023. Following a review in late 2023, the governance structure was amended and approved by the Project Steering Committee. The revised structure saw amalgamation of the three Core Teams into the Chief Investigators group. The four Working Groups were retained.



Appendix Figure 1.2.2: Revised NSW Pharmacy Trial governance structure, November 2023

▬ ▬ *Information exchanged between groups to monitor patient safety, participants interest, data validity and trial credibility*

Membership within the Committees and Working Groups changed over the course of the Project, with representatives from the research team, state-wide partners and key stakeholders present across all Committees and Groups. Each Committee and Working Group had a Terms of Reference (ToR). An overview of the key role of each Committee and Working Group is provided below.

The **Project Steering Committee** provided strategic advice and feedback for the project and facilitated productive working relationship with the external environment and all stakeholders. The main role of the Project Steering Committee was to engage stakeholders, ensure ongoing advice and information on primary healthcare industry developments, and to provide feedback on all matters relating to the trial.

Membership of the Project Steering Committee

- Jan Donovan, Chair, Board Director, Finance Audit, Risk Committee Chair, Consumers Health Forum of Australia.
- Emeritus Prof Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.
- Professor Charlotte Hespe, Member, Head of General Practice and Primary Care Research, Sydney School of Medicines, University of Notre Dame, Australia.
- Chris Campbell, Member, General Manager, Policy and Program Delivery, Pharmaceutical Society of Australia.
- Catherine Bronger, Member, Vice President, Pharmacy Guild of Australia, NSW Branch, General Manager, Chemistworks Group.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Richard Samimi, Member, Co-Founder & Managing Director, Macquarie Health Hub Pharmacy Group, President & Pharmacist, Pharmacy Council of NSW.
- Jess Hadley, Member, Professional Officer NSW/ACT, Pharmaceutical Defence Limited A/Prof Kylie Gwynne, Member, Associate Professor and Research Director, Centre for Indigenous Programs, University of NSW.
- Daniel Gilbertson, Member, Director, Health Consulting Team, Deloitte Australia.
- Professor David Peiris, Member, Chief Scientist, The George Institute for Global Health, Professor, Faulty of Medicine, University of NSW.
- Dr Caitlin Swift, Observer, Medical Advisor, Public Health Physician, Office of the Deputy Secretary, Population and Public Health & Chief Health Officer, NSW Health.
- Jo Root, Observer, Director, Policy and Research, Consumers Health Forum of Australia.
- Sarah Taylor, Secretariat, Operations Manager, NSW Pharmacy Trial, University of Newcastle.

Importantly the structure **included the DSMB,** an independent board was established to review, at regular intervals, the trial data to identify and advise on safety issues and make recommendations to safeguard the interests of study participants.

The primary role of the DSMB was to:

- Review and frequently monitor the trial safety data to identify any emerging safety concerns as rapidly as possible to mitigate the risk of harm.
- Provide recommendations to the Chief Investigators based on an assessment of the data and balance of risks and benefits.
- Maintain confidentiality of unblinded interim results and provide an objective and unbiased assessment of those results.
- Refer matters that arise beyond its expertise to external experts to provide the necessary insight to better respond to issue(s) of concern.

Membership of the DSMB

- Emeritus Professor Arthur Conigrave, Chair, Endocrinologist, Royal Prince Alfred Hospital, Biology Domain Group Leader, School of Life and Environmental Sciences, University of Sydney.
- Dr Margot Woods, Member, General Practitioner, Rozelle Total Health, Discipline Lead, General Practice, Department of General Practice, School of Medicine, University of Notre Dame, Australia.
- Ms Genevieve Adamo, Member, Senior Pharmacist, Poisons Information, NSW Poisons Information Centre.
- Professor Micheal Frommer, External Public Health Expert, Senior Advisor, The Sax Institute.
- Simone Diamandis, Secretariat, Research Manager, University of Newcastle.

Four working groups were established looking at specific patient groups and practice issues related to UTI service delivery and the trial, including the Aboriginal and Torres Strait Islander Working Group, SSWG, Regional and Rural Working Group and the Collaborative Practice Working Group.

The **Aboriginal and Torres Strait Islander Working Group** worked collaboratively to:

- Provide guidance and feedback on Aboriginal and Torres Strait Islander specific issues relating to the project.
- Facilitate communication with key stakeholders that engage with the Aboriginal and Torres Strait Islander community to support project implementation.
- Provide advice and feedback on external communication and resources for the project to the Aboriginal and Torres Strait Islander community.
- Provide advice on the progress and final reports to NSW Health relating to the Aboriginal and Torres Strait Islander community.
- Identify potential risks that may impact service provision to Aboriginal and Torres Strait Islander peoples and provide advice to the project team to mitigate these risks.
- Report recommendations and actions to the Chief Investigators.
- Provided advice on specific issues, where appropriate, that arose relating to Aboriginal and Torres Strait Islander care in relation to the project.

Membership of the Aboriginal and Torres Strait Islander Working Group

- Professor Leanne Holt, Chair, Deputy Vice-Chancellor Indigenous, University of NSW.
- Associate Professor Kylie Gwynne, Member, Associate Professor and Research Director, Centre for Indigenous Programs, University of NSW.
- Dr Cara Cross, Member, Executive Officer of the DVC Indigenous Division, University of NSW.
- Dr Vita Christie, Member, Postdoctoral Research Fellow, University of NSW.
- Dr Uncle Joe Perry, Member, Senior Research Fellow, Heart Research Institute.
- Phillip Obah, Member, Heart Research Institute.
- Associate Professor Sarah Dineen Griffin, Member,
  Chief Investigator, NSW Pharmacy Trials, University of Newcastle.
- Emeritus Professor Shalom (Charlie) Benrimoj, Member,
  Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Sarah Taylor, Secretariat, Operations Manager, NSW Pharmacy Trial, University of Newcastle.

The **Safety & Stewardship Working Group** worked collaboratively to:

- Provide guidance and feedback on issues relating to safety and stewardship throughout the project.
- Provide advice on communication to optimise safety and stewardship throughout the project.
- Identify potential risks that relate to safety and stewardship that may impact service provision or patient outcomes and provide advice to the project team to mitigate these risks.
- Report recommendations and actions to the Chief Investigators.
- Provide advice on specific issues, where appropriate, that arose relating to safety and stewardship in relation to the project.

Membership of the Safety and Stewardship Working Group

- Dr Indy Sandaradura, Chair, Centre for Infectious Diseases and Microbiology, Westmead Hospital.
- Dr Therese Foran, Member (Advisor Oral Contraceptives), Sexual Health Physician; Conjoint Senior Lecturer, School of Women's and Children's Health, University of NSW.
- Dr Titi Chen, Member, Nephrologist and Transplant Physician, Westmead Hospital.
- Associate Professor Deshan Sebaratnam, Member (Advisor Dermatology), University of NSW, Staff Specialist Liverpool Hospital.
- Bradley Rockliff, Member, Antimicrobial Stewardship Pharmacist, Randwick Children's Hospital and University of Newcastle.
- Dr Anna Campain, Senior Biostatistician, The George Institute for Global Health, Conjoint Lecturer, Faculty of Medicine, University of NSW.

- Professor Kylie Williams, Head of Discipline, Pharmacy, Graduate School of Health, University of Technology Sydney.
- Emeritus Professor Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Dr Francisco Martinez Mardones, Data Manager, NSW Pharmacy Trial, University of Newcastle.
- Simone Diamandis, Secretariat, Research Manager, University of Newcastle.

The **Collaborative Practice Working Group** worked collaboratively to:

- Recognise facilitators of collaboration that should be considered in the project.
- Provide guidance and feedback on how to optimise collaboration between pharmacists and medical practitioners and other key stakeholders throughout the course of the project.
- Provide advice on external communication and updates in relation to the project to key stakeholders.
- Identify potential risks to collaborative practice that may impact service provision and provide advice to the project team to mitigate these risks.
- Report recommendations and actions to the Chief Investigators.
- Provided advice on specific issues, where appropriate, that arose relating to collaborative practice in relation to the project.

Membership of the Collaborative Practice Working Group

- Dr Helen Benson, Chair, Senior Lecturer Pharmacy, University of Technology Sydney.
- Catherine Bronger, Member, Vice President, Pharmacy Guild of Australia, NSW Branch, General Manager, Chemistworks Group.
- Karen Carter, Member, Partner, Carter's Pharmacy Gunnedah, Owner, Narrabri Pharmacy, NSW Branch Committee Member, Pharmaceutical Society of Australia.
- Dr Rebekah Hoffman, Member, RACGP NSW/ACT Faculty Chair, General Practitioner, Kirrawee Family Medical Practice.
- Professor Charlotte Hespe, Member, Head of General Practice and Primary Care Research, Sydney School of Medicines, University of Notre Dame, Australia.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.

The **Regional and Rural Working Group** worked collaboratively to:

- Recognise aspects of regional and rural care that should be considered in the project.
- Provide guidance and feedback on regional and rural specific issues relating to the project.
- Facilitate communication with key regional and rural stakeholders.
- Provide advice on external communication for the project to the regional and rural community.
- Identify potential risks that may impact service provision in regional and rural communities and provide advice to the project team to mitigate these risks.
- Report recommendations and actions to the Chief Investigators.
- Provided advice on specific issues, where appropriate, that arose relating to regional and rural care in relation to the project.

Membership of the Regional and Rural Working Group

- Anna Barwick, Chair, Pharmacy Lecturer, University of New England, Founder and Director, PharmOnline Telehealth Service.
- Associate Professor John Rae, Member, Head of School, School of Dentistry and Medical Sciences, Charles Sturt University.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Abeer Ellabaan, Member, Practice Change Facilitator, University of New England.
- Hamish Nott, Member, Community Pharmacist, Director, Phil Davies Pharmacy.
- Dr Rebekah Hoffman, Member, RACGP NSW/ACT Faculty Chair, General Practitioner, Kirrawee Family Medical Practice.
- Associate Professor Kylie Gwynne, Member, Associate Professor and Research Director,

Centre for Indigenous Programs, University of New South Wales.

- Emeritus Professor Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.

Chapter 2

Appendix 2.1 – Clinical management protocol

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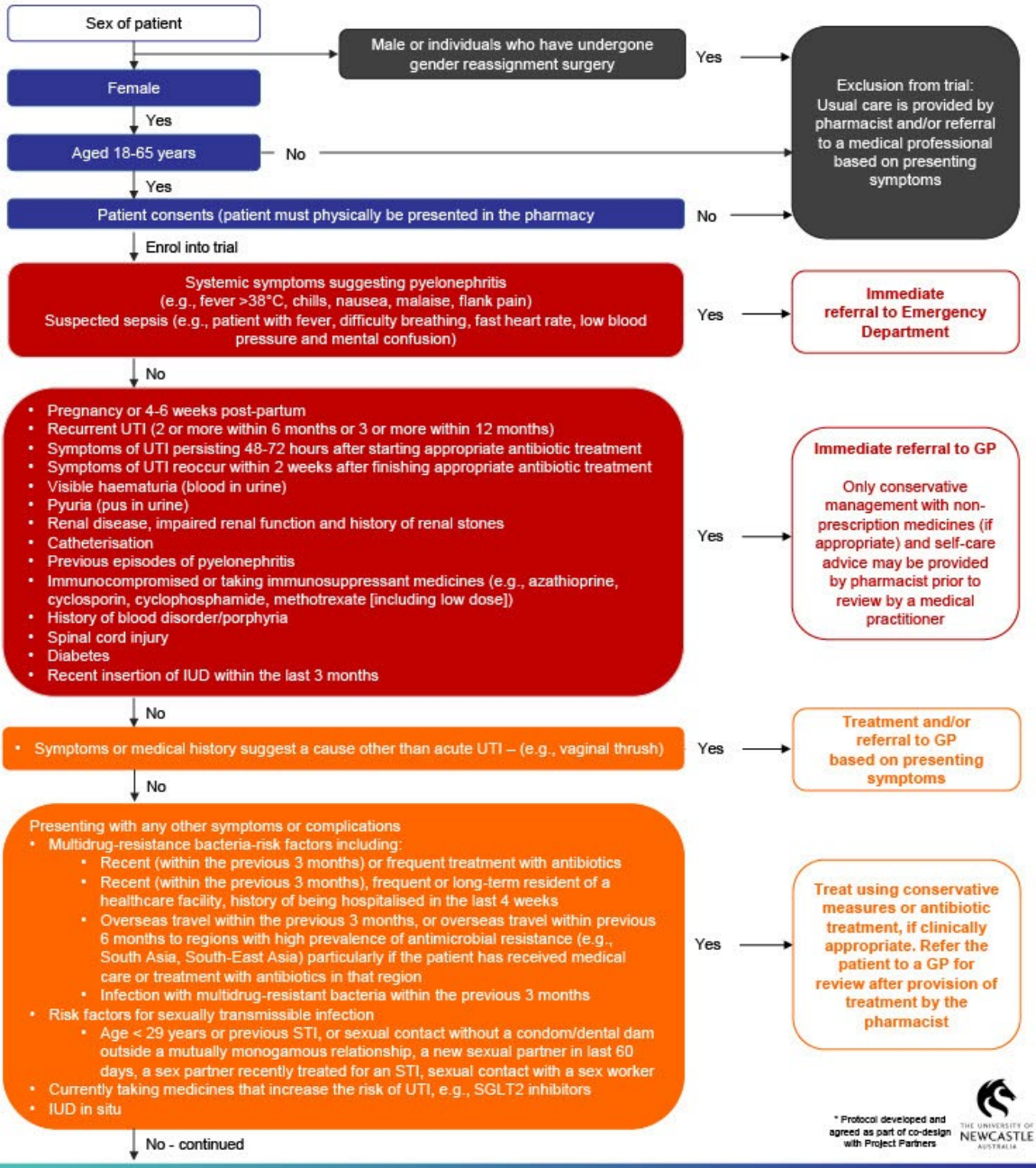
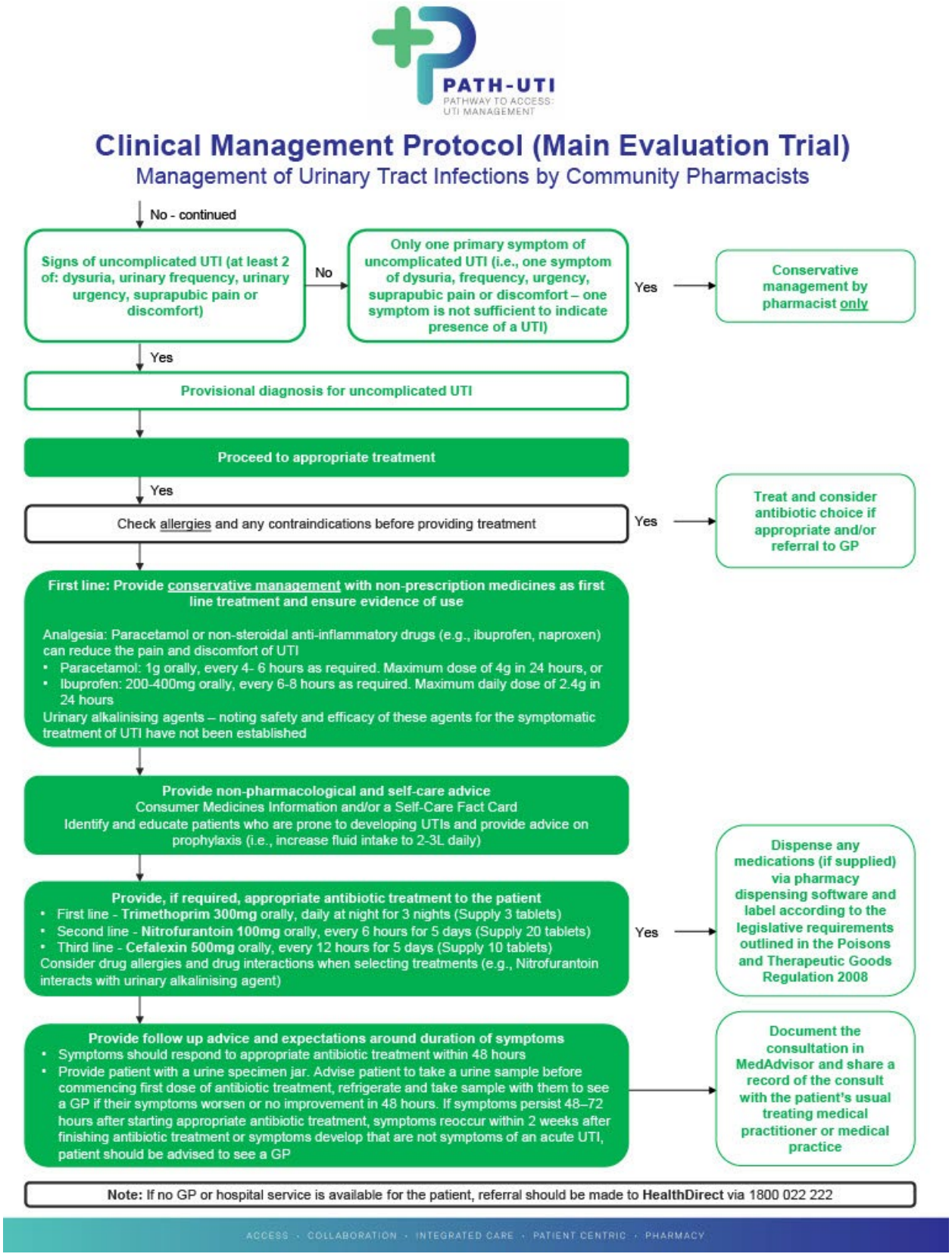
Clinical Management Protocol (Main Evaluation Trial)

Management of Urinary Tract Infections by Community Pharmacists




PATH-UTI
PATHWAY TO ACCESS: UTI MANAGEMENT
Clinical Management Protocol (Main Evaluation Trial)
Management of Urinary Tract Infections by Community Pharmacists
No - continued
Signs of uncomplicated UTI (at least 2 of: dysuria, urinary frequency, urinary urgency, suprapubic pain or discomfort)
No
Only one primary symptom of uncomplicated UTI (i.e., one symptom of dysuria, frequency, urgency, suprapubic pain or discomfort – one symptom is not sufficient to indicate presence of a UTI)
Yes
Conservative management by pharmacist only
Yes
Provisional diagnosis for uncomplicated UTI
Proceed to appropriate treatment
Yes
Check allergies and any contraindications before providing treatment
Yes
Treat and consider antibiotic choice if appropriate and/or referral to GP
First line: Provide conservative management with non-prescription medicines as first line treatment and ensure evidence of use
Analgesia: Paracetamol or non-steroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen) can reduce the pain and discomfort of UTI
• Paracetamol: 1g orally, every 4- 6 hours as required. Maximum dose of 4g in 24 hours, or
• Ibuprofen: 200-400mg orally, every 6-8 hours as required. Maximum daily dose of 2.4g in 24 hours
Urinary alkalinising agents – noting safety and efficacy of these agents for the symptomatic treatment of UTI have not been established
Provide non-pharmacological and self-care advice
Consumer Medicines Information and/or a Self-Care Fact Card
Identify and educate patients who are prone to developing UTIs and provide advice on prophylaxis (i.e., increase fluid intake to 2-3L daily)
Provide, if required, appropriate antibiotic treatment to the patient
• First line - Trimethoprim 300mg orally, daily at night for 3 nights (Supply 3 tablets)
• Second line - Nitrofurantoin 100mg orally, every 6 hours for 5 days (Supply 20 tablets)
• Third line - Cefalexin 500mg orally, every 12 hours for 5 days (Supply 10 tablets)
Consider drug allergies and drug interactions when selecting treatments (e.g., Nitrofurantoin interacts with urinary alkalinising agent)
Yes
Dispense any medications (if supplied) via pharmacy dispensing software and label according to the legislative requirements outlined in the Poisons and Therapeutic Goods Regulation 2008
Provide follow up advice and expectations around duration of symptoms
• Symptoms should respond to appropriate antibiotic treatment within 48 hours
• Provide patient with a urine specimen jar. Advise patient to take a urine sample before commencing first dose of antibiotic treatment, refrigerate and take sample with them to see a GP if their symptoms worsen or no improvement in 48 hours. If symptoms persist 48–72 hours after starting appropriate antibiotic treatment, symptoms reoccur within 2 weeks after finishing antibiotic treatment or symptoms develop that are not symptoms of an acute UTI, patient should be advised to see a GP
Document the consultation in MedAdvisor and share a record of the consult with the patient's usual treating medical practitioner or medical practice
Note: If no GP or hospital service is available for the patient, referral should be made to HealthDirect via 1800 022 222
ACCESS · COLLABORATION · INTEGRATED CARE · PATIENT CENTRIC · PHARMACY

Appendix 2.2 – Service model

Patient /Consumers
Prioritise patient-centric care outcomes and ensure equity and accessibility of care in the community, in a language that is consumer-friendly, culturally safe, and appropriate.

Pharmacists
Ensure adequacy in the training provided, an integrated care delivery model for the extension of care, and a well-considered workflow in the pharmacy, while also increasing workforce recruitment and retention.

GP and ED Clinicians
Strengthen feedback and follow-up mechanisms to ensure fluid communication between pharmacists and clinicians in general practice and/or ED settings, and ensure that ease of and timely referral pathways are available and adopted.

Clinical protocol
A clear and well-defined clinical protocol that encapsulates all key components to ensure the safe and evidence-based management of UTIs by community pharmacists. This includes an emphasis on conversative management and the provision of mid-stream urine testing sampling where clinically indicated.

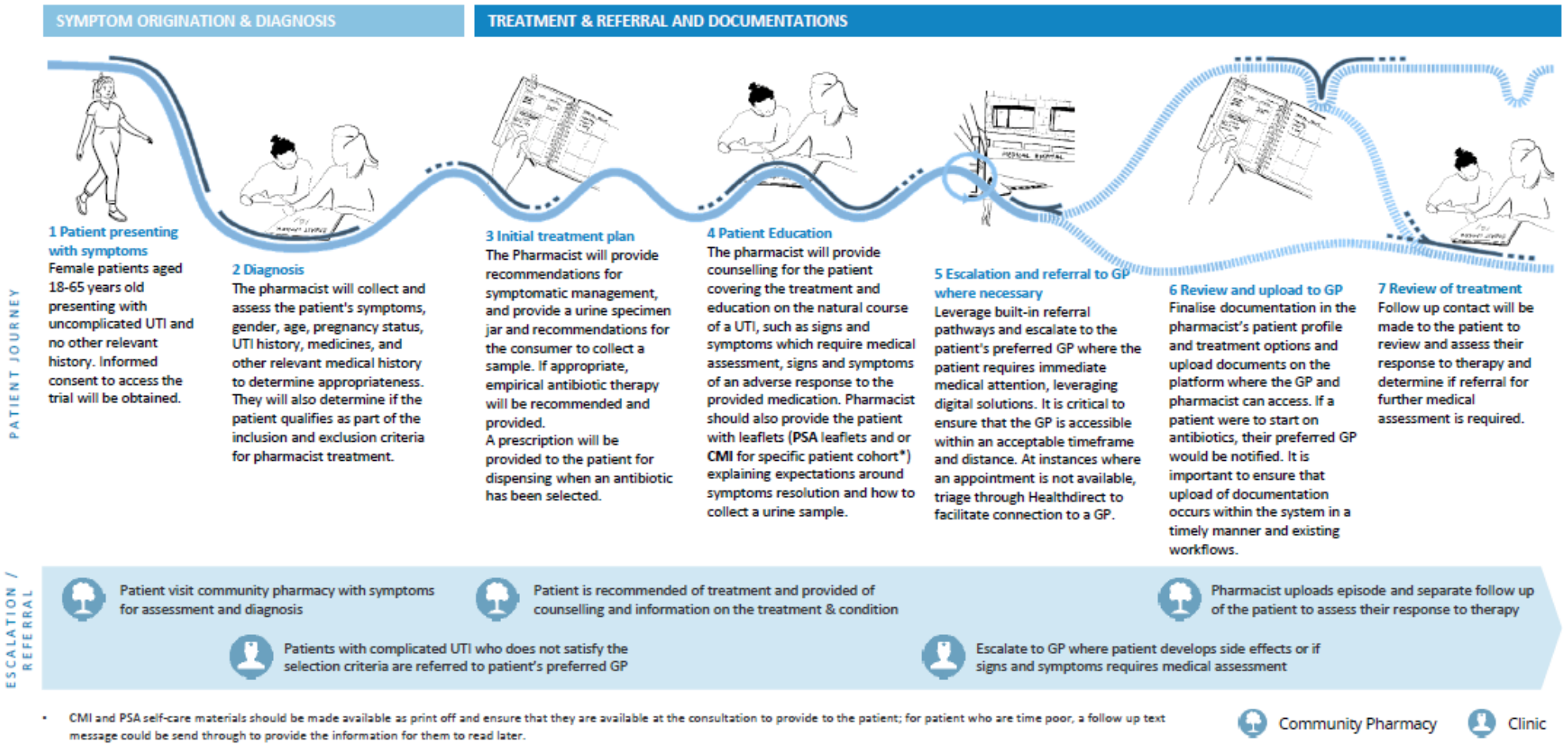
Data evaluation and analysis
Adequate collection of data on the patient, practitioner, and system level needs to be considered for the evaluation of the clinical trial, with key elements carefully thought out to ensure the right data is captured during the implementation phase.

Technology
Technological features necessary for the successful implementation of the trial would need to be carefully considered with vendor partnerships in place to enable appropriate referral pathways, effective data collection, and efficient sharing of data with the intended recipients.

Governance
An adequate level of authority of working groups and ongoing representation of frontline practitioners and consumer engagement for internal collaboration and program governance; externally, it is important to ensure consistency in messaging to the public.

Funding for consultation and treatment
Ensure transparency and sustainability of funding models for the pharmacist consultations and treatment with the aim to enhance and optimise patient access as part of the trial and beyond.

Appendix 2.3 – Patient journey



Chapter 3

Appendix 3.1 – NSW Health Authority

NSW GOVERNMENT Health

POISONS AND THERAPEUTIC GOODS ACT 1966

Section 10 Poisons and Therapeutic Goods Act 1966

Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008

AUTHORITY

I, Dr Kerry Chant, Chief Health Officer, a duly appointed delegate of the Secretary, NSW Health, pursuant to clauses 53, 170, and 171 of the Poisons and Therapeutic Goods Regulation 2008 for the purpose of section 10 of the Poisons and Therapeutic Goods Act 1966, hereby:

1. cancel the instrument signed 19 April 2023; and
2. make this instrument.

Dr Kerry Chant

Chief Health Officer

Dated: 04/07/2023

Authority – Supply of specified restricted substances by pharmacists

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1) Authorisation

This instrument authorises an 'approved pharmacist' to supply to an 'applicable patient' a restricted substance listed in clause 2 otherwise than on prescription subject to the conditions in clause 3 of this instrument for the purposes of the 'clinical trial'.

2) Restricted substance to which this instrument applies

This instrument applies to oral forms of:

a. trimethoprim
b. nitrofurantoin
c. cefalexin

3) Conditions — Limitation on supply

An approved pharmacist may supply the restricted substance listed in clause 2, subject to the conditions that:

a. The pharmacist must only supply nitrofurantoin if trimethoprim is unavailable or inappropriate for treatment of the particular patient.

Page **1** of **3**

b. The pharmacist must only supply cefalexin if both trimethoprim and nitrofurantoin are unavailable or inappropriate for treatment of the particular patient.

c. The pharmacist must not sell a medicine specified in clause 2 in a quantity that exceeds the smallest available size of the manufacturer's pack of the medicine.

d. The pharmacist must comply with the 'Management Protocols', including the requirement that the pharmacist makes a record in MedAdvisor pharmacy software, or an approved system by the Ministry of Health, regarding the supply.

e. The pharmacist must make and keep a clinical record of the consultation for 7 years (at the pharmacy where the patient consultation occurred) that contains:

- sufficient information to identify the patient
- the date of the treatment
- the name of the pharmacist who undertook the consultation
- any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history)
- any clinical opinion reached by the pharmacist
- actions taken by the pharmacist
- particulars of any medication supplied for the patient (such as form, strength and amount)
- notes as to information or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient
- any consent given by a patient to the treatment proposed.

f. The pharmacist must share a record of the supply with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient.

g. The pharmacist must consent to participate in the clinical trial and its evaluation, including by sharing records of applicable patients with the University of Newcastle.

h. The pharmacist must comply with the AHPRA & National Boards Code of Conduct; and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.

4) Publication

This instrument will be published on the NSW Health website.

5) Definitions

In this instrument:

- An 'applicable patient' means a female patient 18 years of age or over and up to and including aged 65 years.
- An 'approved pharmacist' means a pharmacist holding general registration under the *Health Practitioner Regulation National Law* and who is employed or engaged in an 'approved pharmacy' who has successfully completed the following training:

- Australasian College of Pharmacy Uncomplicated Cystitis Treatment – Pharmacist Training; or
- Pharmaceutical Society of Australia Managing uncomplicated cystitis; and
- Training module(s) that have been approved by the Chief Health Officer for the purposes of the clinical trial.

- An 'approved pharmacy' means a pharmacy or class of pharmacies approved in writing by the Chief Health Officer which:
  - offers applicable patients the services specified in this authorisation at all opening hours of the pharmacy; and
  - has a service room, consulting room, or area consistent with the following:
    - the room or area is not to be used as a dispensary, storeroom, staff room or retail area,
    - fully enclosed and provides adequate privacy (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
    - has adequate lighting,
    - is maintained at a comfortable ambient temperature,
    - has a hand sanitisation facility,
    - has ready access to a hand washing facility, and
    - has sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre.
- 'Management protocols' means the protocols established for use by pharmacists in the clinical trial.
- The 'clinical trial' means the trial put in place by the University of Newcastle on behalf of the Ministry of Health regarding the management of urinary tract infections by community pharmacists.
- A 'pharmacy' has the same meaning as in the Health Practitioner Regulation National Law.

6) Commencement

This authority commences on publication.

7) Cancellation

This authority is cancelled on 18 July 2024, unless earlier cancelled.

Appendix 3.2 – Consultation protocol

- Participant eligibility assessment, in which the pharmacist assessed if the participant met the inclusion/exclusion criteria to participate in the study.
- Service offering, during which the pharmacist explained the study and asked the participant if she/they were willing to participate.
- Provision of the participant information sheet and informed consent form via GDS, and electronic consent obtained through the GDS platform
- Patient's clinical assessment. During the assessment the pharmacist covered the relevant clinical information, including medical conditions, medication history and clinically assessed for the possibility of uncomplicated lower UTI, in line with diagnostic guidance and agreed treatment protocols.
- Management by the pharmacist, or general practitioner or emergency department referral. After the clinical assessment, the pharmacist will use agreed management protocols for:
  - Provision of self-care advice (e.g., symptom control, future prevention advice), and supply of antibiotics or referral to the general practitioner, as appropriate. Trimethoprim, nitrofurantoin, cefalexin were the permitted medications that could be supplied under the service for this study and in accordance with the developed clinical management protocols and the Authority from NSW Health. If a medication was prescribed, the participant will be provided with the relevant Consumer Medicine Information (CMI) and/or a self-care card.
  - Provision of follow up advice (e.g., expectation around duration of symptoms which should respond to appropriate antibiotic therapy within 48 hours; and to see general practitioner urgently if their symptoms worsened or no improvement, if symptoms persisted 48–72 hours after starting antibiotic treatment, symptoms reoccurred within 2 weeks after finishing antibiotic treatment or symptoms developed that were not symptoms of an acute UTI [276]).
- The pharmacist shares a record of the supply with the participant's usual treating medical practitioner or medical practice, where the participants had one, following consent by the participant.
- The pharmacist facilitated appropriate and timely referral, if required, according to the following categories:
  - Urgent referral – the participant's condition required immediate medical attention by a medical practitioner or emergency department.
  - General referral – the participant's condition may have been suitable for self-treatment, however medical review with a medical practitioner at the next available appointment was appropriate due to participant circumstances (comorbidity, chronic disease etc.).
  - Considered referral – the participant's condition was suitable for treatment by the pharmacist; however, referral was warranted if symptoms did not resolve within a defined time period.
- The reason for referral was clearly communicated verbally and in writing to the participant and they were provided with the appropriate referral documentation.
- The pharmacist complied with the 'Management Protocols', including that the pharmacist makes a record in the MedAdvisor® IT program, or an approved system by the Ministry of Health, regarding the supply (as per NSW Health Authority (Appendix 3.1)).
- The pharmacist was required to keep a clinical record for 7 years that contained (as per NSW Health Authority (Appendix 3.1)):
  - sufficient information to identify the patient;
  - the date of the treatment;
  - the name of the pharmacist who undertook the consultation;
  - any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history);
  - any clinical opinion reached by the pharmacist;
  - actions taken by the pharmacist;
  - particulars of any medication supplied for the participant (such as form, strength and amount);
  - notes as to information or advice given to the participant in relation to any treatment proposed by the pharmacist who is treating the participant; and
  - any consent given by a participant to the treatment proposed.
- The pharmacist informed the participant that they would receive a follow up survey via email or text 7 days later.

Appendix 3.3 – Supplementary tables

Appendix Table 3-3-1: Medical Benefits Schedule (MBS) item numbers – General practitioner visits, urine pathology tests, and specialist visits

Type	MBS item number
General practitioner visits	3, 4, 23, 24, 36, 37, 44, 47, 123, 124 5000, 5003, 5010, 5020, 5023, 5028, 5040, 5043, 5049, 5060, 5063, 5067, 5071, 5076, 5077 90020, 90035, 90043, 90051, 90054, 91790, 91800, 91801, 91802, 91890, 91891, 91900, 91910, 91920
Medical practitioner visits	52, 53, 54, 57, 58, 59, 60, 65, 151, 165, 179, 181, 185, 187, 189, 191, 203, 206, 301, 303, 733, 737, 741, 745, 761, 763, 766, 769, 772, 776, 788, 789, 2197, 2198, 2200, 5200, 5203, 5207, 5208, 5209, 5220, 5223, 5227, 5228, 5260, 5261, 5262, 5263, 5265, 5267, 90092, 90093, 90095, 90096, 90098, 90183, 90188, 90202, 90212, 90215, 91792, 91794, 91803, 91804, 91805, 91806, 91807, 91808, 91892, 91893, 91903, 91906, 91913, 91916, 91923, 91926
Pathology – urine microscopy, culture and sensitivity, other urine tests	69333, 73805
Specialist Visit (excluding psychiatry)	104, 110, 132, 133, 105, 107, 108, 111, 115, 116, 117, 119, 120, 122, 128, 131
Sexually Transmitted Infection testing	69316, 73813, 73825, 69317, 73813, 73825, 69384, 69387, 69390, 69393, 69396, 69405, 69408, 69411, 69413, 69415, 69378, 69380, 69381, 69382, 69387, 69405, 69408, 69411, 69413, 69415, 69475, 69482, 69483, 69484

Appendix Table 3-3-2: Pharmaceutical Benefits Scheme (PBS) ATC Codes for antibiotics

Antibiotic Type	ACT code
Antibiotics – all	J01
Trimethoprim	J01EA01
Cephalexin	J01DB01
Nitrofurantoin	J01XE01

Appendix Table 3-3-3: International Classification of Diseases 10th Revision (ICD-10) codes for UTI related conditions and treatment related conditions

Condition	ICD-10 code	SNOMED codes
UTI related condition		
Glomerular diseases	N00–N08	36171008, 53298000, 52254009, 236407003, 52845002, 20917003, 197618004
Renal tubulo-interstitial diseases	N10–N16	36689008, 43064006, 49120005, 48631008, 197811007, 190829000, 28689008, 45816000, 7163005, 129128006, 11480007
Acute kidney failure and chronic kidney disease	N17–N19	14669001, 236425005, 425369003, 431856006, 433144002, 431857002, 433146000, 236435004, 42399005, 197663003, 236423003, 90688005, 44730006
Urolithiasis	N20–N23	95566004, 266556005, 236708007, 31054009, 70650003, 20342001, 7093002, 236711008, 17329003, 95570007, 197794008,
Other disorders of kidney and ureter	N25–N29	4996001, 16726004, 19034001, 197659005, 77945009, 111405003, 1776003
Other diseases of the urinary system	N30–N39	38822007, 68226007, 87696004, 197834003, 11251000, 427482006, 40492006, 236645006, 399072004, 28626004, 197866008, 236633002, 42643001, 236632007, 76618002, 86347007, 14981000, 6929003, 68566005, 22220005, 60241006, 87557004, 58972000, 8009008, 413343005, 197871001, 79184009, 197919005, 4009004, 197927001, 197928006, 431309003, 398064005, 425671009, 197870000, 61033006
Inflammatory diseases of female pelvic organs	N70–N77	58949002, 397810006, 88981003, 37610005, 62394006, 24548005, 57044006, 67624004, 161816004, 69430001, 419760006, 237037006, 237044002, 198130006, 70190001, 30800001, 53277000, 63144007, 21711003, 78623009
Noninflammatory disorders of female genital tract	N80–N98	129103003, 76376003, 237116001, 266589005, 26681001, 198251001, 73998008, 252005008, 423633003, 9283009, 24976005, 48230001, 18973006, 398061002, 11374003, 89405008, 2615004, 5552004, 8220004, 11314008, 65576009, 198321009, 237072009, 38280009, 73391008, 83536006, 3754002, 28271003, 51689003, 248861000, 14302001, 52073004, 266601003, 386804004, 88424000, 399221001, 48880000, 268471004, 596004, 82639001, 266599000, 30833006, 162145001, 238968009, 266607004, 266677000, 76742009, 237138004, 21801002, 68811000, 123756000, 52441000, 75993002, 297147009, 5084002, 6738008, 8619003, 30238006, 34571000, 39446004, 129635004, 95598005, 289477004, 289794001, 271939006, 248866005, 86030004, 31908003, 81712001, 12337004, 80182007, 76498008, 62730001, 65619001, 198319004, 285836003, 285838002, 386692008, 314631008, 19155002, 198436008

Condition	ICD-10 code	SNOMED codes
Intraoperative and postprocedural complications and disorders of genitourinary system, not elsewhere classified	N99–N99	111411000, 197805009, 42116007, 405555006
Treatment related condition		
Skin rash	R21	247471006, 271756005, 271807003, 276444007
Adverse effect of a drug	T88.6-7, T78	41291007, 421961002, 29268000, 106190000, 35688006,
Poisoning by adverse effect of and underdosing of systemic antibiotics	T36	62014003
Poisoning by adverse effect of and underdosing of agents primarily affecting the gastrointestinal system	T47	
Diarrhoea, unspecified	R19.7	62315008
Nausea (+ vomiting, fatigue, and similar)	R11	16932000, 422587007, 422400008
Unspecified abdominal pain	R10.9	21522001, 102614006
Candidiasis	B37.0	78048006, 1085006, 72934000, 72605008
Headache	R51	
Sepsis	A41	
Bacteraemia	R78.81	

Appendix Table 3-3-4: Reduction in sample size over time for the linked data analyses

Month	Population size
Prior to care episode	17,219
0 (month of UTI care)	17,219
1	17,218
2	15,336
3	13,049
4	11,362
5	9,512
6	7,687
7	5,788
8	4,259
9	2,831
10	1,436
11	183
12	0

Appendix Table 3-3-5: Participants characteristics by ACT vs NSW (for 18,143 care episodes)[1]

	ACT, n=787 care episodes	NSW, n=17,356 care episodes
Age (Years)		
18–25 years	159 (20%)	3,344 (19%)
26–35 years	170 (22%)	3,872 (22%)
36–45 years	184 (23%)	3,454 (20%)
46–65 years	271 (34%)	6,666 (38%)
Greater than 65 years	3 (0.4%)	20 (0.1%)
Remoteness category (Modified Monash Model (MMM))		
Metropolitan (MMM1)	787 (100%)	12,235 (70%)
Regional centres (MMM2)	0 (0%)	378 (2.2%)
Large rural town (MMM3)	0 (0%)	2,584 (15%)
Medium rural town (MMM4)	0 (0%)	1,376 (7.9%)
Small rural town (MMM5)	0 (0%)	780 (4.5%)
Remote communities (MMM6)	0 (0%)	3 (<0.1%)
Very remote communities (MMM7)	0 (0%)	0 (0%)
Index of Relative Socio-economic Advantage and Disadvantage		
1st quintile – most disadvantaged	9 (1.1%)	1,590 (9.2%)
2nd quintile	10 (1.3%)	2,904 (17%)
3rd quintile	9 (1.1%)	3,832 (22%)
4th quintile	222 (28%)	2,393 (14%)
5th quintile – most advantaged	511 (65%)	6,457 (37%)
Unknown	26 (3.3%)	180 (1.0%)
Employment*		
Working full-time	377 (63%)	7,600 (54%)
Working part-time	134 (22%)	3,731 (27%)
Not in labour force / unemployed	54 (9%)	1425 (10.1%)
Other	34 (5.7%)	1316 (9.3%)
Education level*		
Year 10 or below	11 (1.8%)	1389 (9.9%)
Year 12	97 (16%)	2,251 (16%)
Further education	468 (78.1%)	9724 (69.1%)
Prefer not to say	23 (3.8%)	708 (5%)
Symptoms		
Dysuria	620 (79%)	12,363 (71%)
Suprapubic pain	293 (37%)	6,311 (36%)

	ACT, n=787 care episodes	NSW, n=17,356 care episodes
Urinary urgency	550 (70%)	12,442 (72%)
Urinary frequency	671 (85%)	15,651 (90%)
Vaginal symptoms	11 (1.4%)	269 (1.5%)
Systemic symptoms	5 (0.6%)	433 (2.5%)
Number of UTI Symptoms		
0 to 1 symptom	3 (0.4%)	168 (1.0%)
2 symptoms	353 (45%)	7,393 (43%)
3 symptoms	297 (38%)	7,258 (42%)
4 symptoms	134 (17%)	2,537 (15%)
Hospitalised in the last 4 weeks	6 (0.8%)	114 (0.7%)
History of UTI	8 (1.0%)	326 (1.9%)
Increased STI risk	7 (0.9%)	109 (0.6%)
Patient travelled to a developing country in the last 3 months	14 (1.8%)	282 (1.6%)
Referred to general practitioner following pharmacy assessment	32 (4.1%)	1,228 (7.1%)
Reasons for referral to general practitioner		
Met referral criteria from treatment protocol	24 (3.0%)	1,038 (6.0%)
Symptoms suggestive of cause other than UTI	0 (0%)	13 (<0.1%)
Referral as part of treatment	8 (1.0%)	177 (1.0%)
Antibiotic supplied		
Cefalexin	15 (1.9%)	446 (2.6%)
Nitrofurantoin	19 (2.4%)	282 (1.6%)
Trimethoprim	722 (92%)	15,324 (88%)
None	31 (3.9%)	1,304 (7.5%)

Notes:
1. Values differ from the baseline table in the main document. This table has been analysed based on the combined dataset held at the George institute and reports by episode of care. Table 1 in the main report is by person. Reporting by person can only be done in the secure data platform (SURE) and for privacy reasons State/ Territory of residence is not permitted to be included in the dataset.
**Data available for survey responders only*

Appendix Table 3-3-6: Baseline characteristics by response status per unique care episode

Characteristic	Non-responder n=3,472[1]	Responder n=14,671[1]
Age (Years)		
18–25 years	997 (29%)	2,506 (17%)
26–35 years	898 (26%)	3,144 (21%)
36–45 years	683 (20%)	2,955 (20%)
46–65 years	888 (26%)	6,049 (41%)
Greater than 65 years	6 (0.2%)	17 (0.1%)
Remoteness category (MMM)		
Metropolitan (MMM1)	2,540 (73%)	10,482 (71%)
Regional centres (MMM2)	58 (1.7%)	320 (2.2%)
Large rural town (MMM3)	484 (14%)	2,100 (14%)
Medium rural town (MMM4)	255 (7.3%)	1,121 (7.6%)
Small rural town (MMM5)	135 (3.9%)	645 (4.4%)
Remote communities (MMM6)	0 (0%)	3 (<0.1%)
Index of Relative Socio-economic Advantage and Disadvantage		
1st quintile – most disadvantaged	332 (9.6%)	1,267 (8.6%)
2nd quintile	556 (16%)	2,358 (16%)
3rd quintile	739 (21%)	3,102 (21%)
4th quintile	509 (15%)	2,106 (14%)
5th quintile – most advantaged	1,298 (37%)	5,670 (39%)
Unknown	38 (1.1%)	168 (1.1%)
Employment*		
Working full-time	--	7,977 (54%)
Working part-time	--	3,865 (26%)
Not in labour force / unemployed	--	1,479 (10.1%)
Other	--	1350 (9.2%)
Level of education*		
Year 10 equivalent or below	--	1,400 (9.5%)
Year 12 equivalent	--	2,348 (16%)
Further education	--	10,192 (69.5%)
Prefer not to say	--	731 (5.0%)
Symptoms		
Dysuria	2,449 (71%)	10,534 (72%)
Suprapubic pain	1,317 (38%)	5,287 (36%)
Urinary urgency	2,454 (71%)	10,538 (72%)

Characteristic	Non-responder n=3,472[1]	Responder n=14,671[1]
Urinary frequency	3,050 (88%)	13,272 (90%)
Vaginal symptoms	112 (3.2%)	168 (1.1%)
Systemic symptoms	185 (5.3%)	253 (1.7%)
Number of (urinary tract infection) UTI Symptoms		
0 to 1 symptom	66 (1.9%)	105 (0.7%)
2 symptoms	1,504 (43%)	6,242 (43%)
3 symptoms	1,365 (39%)	6,190 (42%)
4 symptoms	537 (15%)	2,134 (15%)
Hospitalised in the last 4 weeks	35 (1.0%)	85 (0.6%)
History of UTI	130 (3.7%)	204 (1.4%)
Increased sexually transmitted infection (STI) risk	37 (1.1%)	79 (0.5%)
Patient travelled to a developing country in the last 3 months	61 (1.8%)	235 (1.6%)
Referred to general practitioner following pharmacy assessment	490 (14.1%)	770 (5.2%)
Reasons for referral to general practitioner		
Met referral criteria from treatment protocol	430 (12.4%)	632 (4.3%)
Symptoms suggestive of cause other than UTI	9 (0.3%)	4 (<0.1%)
Referral as part of treatment	51 (0.1%)	134 (0.9%)
Antibiotic supplied		
Cefalexin	93 (2.7%)	368 (2.5%)
Nitrofurantoin	45 (1.3%)	256 (1.7%)
Trimethoprim	2,795 (81%)	13,251 (90%)
None	539 (16%)	796 (5.4%)

Notes:
[1]n (%)
**Data available for survey responders only*

Appendix Table 3-3-7: Participant experience responses

The pharmacist allowed me an opportunity to be involved in making decisions about my care						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
4%	1%	1%	3%	5%	10%	75%
I think the care provided by the prescribing pharmacist for my urinary symptoms was as good as my usual care						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
3%	1%	1%	3%	5%	10%	77%
It was more convenient for me to obtain care for my urinary symptoms from a pharmacist compared with another care provider						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
3%	1%	1%	2%	3%	8%	82%
I am satisfied with the amount of privacy I received at the pharmacy						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
3%	1%	1%	3%	6%	10%	76%
I am confident that this pharmacy dispenses medication correctly						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
4%	1%	1%	2%	3%	6%	83%
The staff at this pharmacy have the knowledge to answer my questions about my urinary symptoms						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
4%	1%	2%	4%	6%	11%	73%
Overall, I am satisfied by the consultation provided by the pharmacist for my urinary symptoms						
Strongly disagree	**Disagree**	**Somewhat disagree**	**Neutral**	**Somewhat agree**	**Agree**	**Strongly Agree**
3%	1%	1%	4%	6%	10%	75%

Appendix Table 3-3-8: Top 10 MBS item numbers claimed

Item	Description	%
23	Standard general practitioner attendance (6–20 min)	53.3
91891	Phone general practitioner consult (≥6 min)	19.9
36	Long general practitioner attendance (20–40 min)	12.3
5020	After-hours general practitioner attendance (6–20 min)	4.2
91890	Short phone general practitioner consult (<6 min)	3.1
3	Brief general practitioner attendance (<6 min)	1.7
44	Extended general practitioner attendance (≥40 min)	1.2
185	Standard non-specialist attendance (5–25 min)	1.0
91800	Telehealth general practitioner video consult (≥20 min)	0.7
5040	After-hours general practitioner attendance (20–40 min)	0.5
	Total	**97.8**

Appendix 3.4 – Supplementary tables for data analysis

Appendix Table 3-4-1: Variation in general practitioner/specialist, antibiotic and hospital utilisation

	Proportion of patients[1]		
	0–2 days	**3–6 days**	**7–28 days**
General practitioner or specialist services provided (MBS data for 15,453 people)			
General practitioner consultation	10.48%	12.39%	32.67%
Specialist consultation	0.61%	1.01%	5.02%
Urine sample sent for pathology testing	5.37%	5.42%	8.23%
STI test performed	0.71%	1.02%	2.86%
Antibiotics prescribed other than initial pharmacy prescription (PBS data for 16,453 people)[2]			
Any antibiotic prescribed	4.25%	7.07%	11.72%
Antibiotic from clinical management protocol[3]	3.49%	5.74%	7.62%
• New antibiotic and not supplied an antibiotic at pharmacist consult	1.14%	0.55%	0.66%
• Same antibiotic as supplied at pharmacist consult	0.69%	1.31%	1.97%
• Different antibiotic to that supplied at pharmacist consult	1.68%	3.95%	5.25%
Antibiotic not from clinical management protocol	0.81%	1.50%	4.70%
Hospital utilisation (NSW Health data for 16,479 people)[4]			
All-cause hospitalisations	0.21%	0.28%	0.72%
• Potentially preventable hospitalisations	0.08%	0.13%	0.15%
• Potentially preventable hospitalisations related to genitourinary conditions	0.08%	0.12%	0.12%
• Acute hospital admissions	0.08%	0.12%	0.12%
Emergency department presentations[5]	1.38%	0.98%	2.05%
• Emergency department presentations for triage 3-5 conditions[6]	1.30%	0.89%	1.83%
• Emergency department presentations for genitourinary conditions	0.64%	0.38%	0.38%

Notes:

1. *Denominator varies depending on dataset used*
2. *Any medications recorded in PBS data on the same day as the pharmacy visit were excluded from the count*
3. *Trimethoprim, nitrofurantoin, cephalexin*
4. *Data were not available for ACT participants at the time of writing this report*
5. *Includes multiple emergency department presentations per person*
6. *Triage category descriptions: 1: Immediate treatment needed; 2: Urgent treatment needed; 3: Serious condition; 4: Moderate condition; 5: Non-urgent condition*

Appendix Table 3-4-2: Variation in general practitioner/specialist, antibiotic and hospital utilisation by referral status at the initial pharmacy visit

	Patients referred to general practitioner (n=1,257)			Patients never referred to general practitioner (n=15,962)		
	Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]		
Outcome	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**
General practitioner or specialist services provided	**MBS data available for 1,128 people[2]**			**MBS data available for 14,325 people[2]**		
General practitioner consultation	495 (43.88) [40.78%]	239 (21.19) [18.97%]	680 (60.28) [43%]	1,217 (8.5) [8.09%]	1,880 (13.12) [11.87%]	6,536 (45.63) [31.85%]
Specialist consultation	16 (1.42) [1.33%]	19 (1.68) [1.42%]	90 (7.98) [7.54%]	79 (0.55) [0.55%]	146 (1.02) [0.98%]	798 (5.57) [4.82%]
Urine sample sent for pathology testing	343 (30.41) [30.23%]	84 (7.45) [7.36%]	131 (11.61) [10.64%]	493 (3.44) [3.41%]	770 (5.38) [5.27%]	1,243 (8.68) [8.04%]
STI test performed	43 (3.81) [3.46%]	29 (2.57) [2.57%]	45 (3.99) [3.9%]	79 (0.55) [0.5%]	142 (0.99) [0.9%]	454 (3.17) [2.78%]
Additional antibiotic prescribed other than initial pharmacy prescribed antibiotic	**PBS data avaliable for 1,201 people[2, 3]**			**PBS data avaliable for 15,252 people[2, 3]**		
Any antibiotic prescribed	202 (16.82) [16.65%]	112 (9.33) [9.41%]	203 (16.9) [14.65%]	510 (3.34) [3.28%]	1,095 (7.18) [6.89%]	2,011 (13.19) [11.5%]
Antibiotic from clinical management protocol[4]	172 (14.32) [14.4%]	86 (7.16) [7.24%]	137 (11.41) [9.99%]	403 (2.64) [2.64%]	872 (5.72) [5.63%]	1229 (8.06) [7.44%]
• New antibiotic and not supplied an antibiotic at pharmacist consult	163 (13.57) [13.66%]	77 (6.41) [6.49%]	109 (9.08) [7.99%]	23 (0.15) [0.16%]	13 (0.09) [0.09%]	15 (0.1) [0.09%]
• Same antibiotic as supplied at pharmacist consult	7 (0.58) [0.67%]	1 (0.08) [0.17%]	8 (0.67) [0.75%]	106 (0.69) [0.7%]	214 (1.4) [1.41%]	324 (2.12) [2.07%]
• Different antibiotic to that supplied at pharmacist consult	2 (0.17) [0.25%]	8 (0.67) [0.75%]	20 (1.67) [1.58%]	274 (1.8) [1.8%]	645 (4.23) [4.21%]	890 (5.84) [5.55%]
Antibiotic not from clinical management protocol	30 (2.5) [2.5%]	26 (2.16) [2.25%]	66 (5.5) [5.16%]	107 (0.7) [0.69%]	223 (1.46) [1.44%]	782 (5.13) [4.67%]
Hospital utilisation[5]	**NSW Health data available for 1,203 people**			**NSW Health data available for 15,276 people**		
All-cause hospitalisations	11 (0.91) [0.91%]	5 (0.42) [0.42%]	17 (1.41) [1.25%]	25 (0.16) [0.16%]	45 (0.29) [0.29%]	114 (0.75) [0.71%]

	Patients referred to general practitioner (n=1,257)			Patients never referred to general practitioner (n=15,962)		
	Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]		
Outcome	**0–2 days**	**3–6 days**	**Outcome**	**0–2 days**	**3–6 days**	**Outcome**
Potentially preventable hospitalisations	5 (0.42) [0.42%]	2 (0.17) [0.17%]	3 (0.25) [0.25%]	9 (0.06) [0.06%]	20 (0.13) [0.13%]	22 (0.14) [0.14%]
Potentially preventable hospitalisations related to genitourinary conditions	5 (0.42) [0.42%]	2 (0.17) [0.17%]	2 (0.17) [0.17%]	9 (0.06) [0.06%]	19 (0.12) [0.12%]	18 (0.12) [0.12%]
Acute hospital admissions	11 (0.91) [0.42%]	5 (0.42) [0.17%]	17 (1.41) [0.17%]	25 (0.16) [0.06%]	45 (0.29) [0.12%]	111 (0.73) [0.12%]
Emergency department presentations[6]	82 (6.82) [6.15%]	22 (1.83) [1.66%]	44 (3.66) [2.66%]	156 (1.02) [1.01%]	149 (0.98) [0.93%]	374 (2.45) [2%]
Emergency department presentations for triage 3-5 conditions[7]	79 (6.57) [5.99%]	19 (1.58) [1.41%]	41 (3.41) [2.49%]	145 (0.95) [0.94%]	137 (0.9) [0.85%]	332 (2.17) [1.77%]
Emergency department presentations for genitourinary conditions	43 (3.57) [3.49%]	5 (0.42) [0.42%]	7 (0.58) [0.58%]	64 (0.42) [0.42%]	58 (0.38) [0.37%]	61 (0.40) [0.37%]

Notes:

1. *Denominator varies depending on dataset used*
2. *Due to linkage restrictions, we are not able to determine exact PBS denominators by referral status, and these were estimated based on the expected proportions using the overall PBS consent rate*
3. *Any medications recorded in PBS data on the same day as the pharmacy visit were excluded from the count*
4. *Trimethoprim, nitrofurantoin, cephalexin*
5. *Data were not available for ACT participants at the time of writing this report*
6. *Includes multiple emergency department presentations per person*
7. *Triage category descriptions: 1: Immediate treatment needed; 2: Urgent treatment needed; 3: Serious condition; 4: Moderate condition; 5: Non-urgent condition*

Appendix Table 3-4-3: Variation in general practitioner/specialist, antibiotic and hospital utilisation by self-reported symptom resolution

	Complete symptom resolution (n=11,221)			Improved but not resolved symptoms (n=2,581)			Not improved or worsening of symptoms (n=392)		
	Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]		
Outcome	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**
General practitioner or specialist services provided	**MBS data available for 10,070 people[2]**			**MBS data available for 2316 people[2]**			**MBS data available for 352 people[2]**		
General practitioner consultation	841 (8.35) [8.01%]	916 (9.1) [8.41%]	3945 (39.18) [28.89%]	364 (15.72) [15.03%]	670 (28.93) [25.52%]	1604 (69.26) [46.24%]	72 (20.45) [19.03%]	171 (48.58) [42.05%]	337 (95.74) [56.25%]
Specialist consultation	55 (0.55) [0.56%]	102 (1.01) [1%]	570 (5.66) [4.99%]	21 (0.91) [0.91%]	33 (1.42) [1.34%]	164 (7.08) [5.96%]	5 (1.42) [1.7%]	8 (2.27) [1.7%]	42 (11.93) [8.81%]
Urine sample sent for pathology testing	376 (3.73) [3.72%]	259 (2.57) [2.55%]	565 (5.61) [5.33%]	206 (8.89) [8.89%]	371 (16.02) [15.8%]	471 (20.34) [18.65%]	39 (11.08) [11.36%]	91 (25.85) [25.28%]	122 (34.66) [31.82%]
STI test performed	57 (0.57) [0.49%]	72 (0.71) [0.65%]	267 (2.65) [2.29%]	20 (0.86) [0.86%]	55 (2.37) [2.25%]	99 (4.27) [3.93%]	4 (1.14) [1.42%]	13 (3.69) [3.69%]	20 (5.68) [5.68%]
Additional antibiotic dispenced other than initial pharmacy prescribed antibiotic	**PBS data avaliable for 10,722 people[2,3]**			**PBS data avaliable for 2,466 people[2,3]**			**PBS data avaliable for 375 people[2,3]**		
Any antibiotic prescribed	302 (2.82) [2.8%]	340 (3.17) [3.12%]	1024 (9.55) [8.5%]	195 (7.91) [7.83%]	509 (20.64) [19.91%]	612 (24.82) [21.49%]	45 (12) [12.27%]	141 (37.6) [35.2%]	161 (42.93) [35.47%]
Antibiotic from clinical management protocol[4]	240 (2.24) [2.25%]	253 (2.36) [2.36%]	604 (5.63) [5.2%]	160 (6.49) [6.49%]	429 (17.4) [17.15%]	413 (16.75) [15.45%]	36 (9.6) [9.87%]	115 (30.67) [29.87%]	98 (26.13) [23.47%]
• New antibiotic and not supplied an antibiotic at pharmacist consult	73 (0.68) [0.69%]	26 (0.24) [0.25%]	41 (0.38) [0.36%]	29 (1.18) [1.22%]	23 (0.93) [0.97%]	22 (0.89) [0.85%]	9 (2.4) [2.67%]	5 (1.33) [1.6%]	17 (4.53) [3.73%]
• Same antibiotic as supplied at pharmacist consult	55 (0.51) [0.52%]	70 (0.65) [0.66%]	189 (1.76) [1.73%]	35 (1.42) [1.46%]	96 (3.89) [3.93%]	82 (3.33) [3.33%]	5 (1.33) [1.6%]	17 (4.53) [4.8%]	11 (2.93) [2.93%]
• Different antibiotic to that supplied at pharmacist consult	112 (1.04) [1.05%]	157 (1.46) [1.47%]	374 (3.49) [3.32%]	96 (3.89) [3.93%]	310 (12.57) [12.49%]	309 (12.53) [11.8%]	22 (5.87) [6.13%]	93 (24.8) [25.07%]	70 (18.67) [17.87%]
Antibiotic not from clinical management protocol	62 (0.58) [0.57%]	87 (0.81) [0.8%]	420 (3.92) [3.64%]	35 (1.42) [1.46%]	80 (3.24) [3.24%]	199 (8.07) [7.42%]	9 (2.4) [2.67%]	26 (6.93) [7.2%]	63 (16.8) [14.13%]

	Complete symptom resolution (n=11,221)			Improved but not resolved symptoms (n=2,581)			Not improved or worsening of symptoms (n=392)		
	Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]			Number of events (per 100 people) [percent of participants][1]		
Outcome	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**
Hospital utilisation[5]	**NSW Health data available for 10,739 people**			**NSW Health data available for 2,470 people**			**NSW Health data available for 375 people**		
All-cause hospitalisations	18 (0.17) [0.17%]	20 (0.19) [0.18%]	60 (0.56) [0.52%]	10 (0.4) [0.4%]	8 (0.32) [0.32%]	24 (0.97) [0.93%]	1 (0.27) [0.27%]	12 (3.2) [3.2%]	11 (2.93) [2.93%]
Potentially preventable hospitalisations	5 (0.05) [0.06%]	4 (0.04) [0.05%]	7 (0.07) [0.07%]	6 (0.24) [0.28%]	5 (0.2) [0.24%]	8 (0.32) [0.36%]	0 (0) [0.27%]	10 (2.67) [2.93%]	2 (0.53) [0.8%]
Potentially preventable hospitalisations related to genitourinary conditions	5 (0.05) [0.06%]	3 (0.03) [0.04%]	4 (0.04) [0.05%]	6 (0.24) [0.28%]	5 (0.2) [0.24%]	7 (0.28) [0.32%]	0 (0) [0.27%]	10 (2.67) [2.93%]	2 (0.53) [0.8%]
Acute hospital admissions	18 (0.17) [0.17%]	20 (0.19) [0.18%]	58 (0.54) [0.51%]	10 (0.4) [0.4%]	8 (0.32) [0.32%]	24 (0.97) [0.93%]	1 (0.27) [0.27%]	12 (3.2) [3.2%]	11 (2.93) [2.93%]
Emergency department presentations[6]	95 (0.88) [0.88%]	48 (0.45) [0.45%]	165 (1.54) [1.32%]	49 (1.98) [1.94%]	39 (1.58) [1.46%]	76 (3.08) [2.47%]	10 (2.67) [2.4%]	32 (8.53) [8.53%]	25 (6.67) [5.07%]
Emergency department presentations for triage 3-5 conditions[7]	41 (0.38) [0.39%]	13 (0.12) [0.13%]	26 (0.24) [0.22%]	26 (1.05) [1.05%]	19 (0.77) [0.77%]	19 (0.77) [0.73%]	7 (1.87) [2.13%]	19 (5.07) [5.33%]	6 (1.6) [1.87%]
Emergency department presentations for genitourinary conditions	18 (0.17) [0.17%]	20 (0.19) [0.18%]	60 (0.56) [0.52%]	10 (0.4) [0.4%]	8 (0.32) [0.32%]	24 (0.97) [0.93%]	1 (0.27) [0.27%]	12 (3.2) [3.2%]	11 (2.93) [2.93%]
Emergency department presentations for genitourinary conditions that were admitted to ward	8	1	4	3	2	4	0	9	2

Notes:

1. *Denominator varies depending on dataset used*
2. *Due to linkage restrictions, we are not able to determine exact PBS denominators by referral status, and these were estimated based on the expected proportions using the overall PBS consent rate*
3. *Any medications recorded in PBS data on the same day as the pharmacy visit were excluded from the count*
4. *Trimethoprim, nitrofurantoin, cephalexin*
5. *Data were not available for ACT participants at the time of writing this report*
6. *Includes multiple emergency department presentations per person*
7. *Triage category descriptions: 1: Immediate treatment needed; 2: Urgent treatment needed; 3: Serious condition; 4: Moderate condition; 5: Non-urgent condition*

Appendix Table 3-4-4: Short- and long-term trends in general practitioner, antibiotic, emergency department and hospital utilisation

	Mean weekly rate per 100 people[1]					
	Pre and post trends Mean (95% CI)		First month post intervention			
	Prior to intervention	Post Intervention	Week 1	Week 2	Week 3	Week 4
General practitioner or specialist services provided						
General practitioner consultation	11.62 (10.62, 12.62)	15.9 (11.1, 20.69)	24.79	16.91	14.31	13.67
Specialist consultation	1.75 (1.53, 1.96)	2.29 (1.48, 3.11)	1.68	1.71	1.96	1.80
Urine sample sent for pathology testing	0.61 (0.39, 0.83)	1.72 (0, 5.55)	10.94	4.15	2.53	1.88
STI test performed	0.56 (0.43, 0.69)	0.89 (0.43, 1.36)	1.90	1.23	0.96	0.91
Antibiotics prescribed other than initial pharmacy prescription[2]						
Prescribed an antibiotic	2.21 (1.73, 2.7)	4.34 (0, 12.59)	11.66	5.89	3.64	3.37
• Study specific antibiotic[3]	0.91 (0.61, 1.22)	2.48 (0, 10.37)	9.32	3.85	2.29	1.86
• Non-study specific	1.3 (1, 1.6)	1.86 (1.14, 2.59)	2.35	2.04	1.36	1.51
Hospital utilisation (NSW Health data for 16,479 people)[4]						
All-cause hospitalisations	0.38 (0.13, 0.64)	0.24 (0.12, 0.35)	0.50	0.24	0.23	0.24
• Potentially preventable hospitalisations	0.02 (0, 0.04)	0.03 (0, 0.11)	0.21	0.07	0.05	0.03
• Potentially preventable hospitalisations related to genitourinary conditions	0.01 (0, 0.03)	0.03 (0, 0.1)	0.20	0.06	0.03	0.02
• Acute hospital admissions	0.23 (0.14, 0.32)	0.23 (0.11, 0.35)	0.50	0.23	0.23	0.24
Emergency department presentations[5]	0.63 (0.49, 0.77)	0.75 (0.1, 1.41)	2.38	0.81	0.70	0.81
• Emergency department presentations for triage 3-5 conditions[6]	0.55 (0.42, 0.68)	0.66 (0.03, 1.29)	2.21	0.73	0.63	0.74
• Emergency department presentations for genitourinary conditions	0.04 (0.01, 0.07)	0.1 (0, 0.45)	0.99	0.17	0.10	0.10

Notes:

1. *Denominator varies depending on dataset used*
2. *Any medications recorded in PBS data on the same day as the pharmacy consult were excluded from the count*
3. *Trimethoprim, nitrofurantoin, cephalexin*
4. *Data were not available for ACT participants at the time of writing this report*
5. *Includes multiple emergency department presentations per person*
6. *Triage category descriptions: 1: Immediate treatment needed; 2: Urgent treatment needed; 3: Serious condition; 4: Moderate condition; 5: Non-urgent condition*

Appendix Table 3-4-5: Sub-group analyses

Characteristic	My symptoms have completely resolved n=11,654	My symptoms have improved, but not completely resolved n=2,621	My symptoms have not improved or worsened n=396
Age			
18–25 years	1,988 (79%)	429 (17%)	89 (3.6%)
26–35 years	2,526 (80%)	540 (17%)	78 (2.5%)
36–45 years	2,354 (80%)	524 (18%)	77 (2.6%)
46–65 years	4,773 (79%)	1,125 (19%)	151 (2.5%)
Greater than 65 years	13 (76%)	3 (18%)	1 (5.9%)
Index of Relative Socio-economic Advantage and Disadvantage			
1st quintile – most disadvantaged	984 (78%)	244 (19%)	39 (3.1%)
2nd quintile	1,861 (79%)	433 (18%)	64 (2.7%)
3rd quintile	2,438 (79%)	573 (18%)	91 (2.9%)
4th quintile	1,710 (81%)	342 (16%)	54 (2.6%)
5th quintile – most advantaged	4,524 (80%)	1,000 (18%)	146 (2.6%)
Unknown	137 (82%)	29 (17%)	2 (1.2%)
Remoteness category (MMM)			
Metropolitan (MMM1)	8,292 (79%)	1,904 (18%)	286 (2.7%)
Regional centres (MMM2)	255 (80%)	59 (18%)	6 (1.9%)
Large rural town (MMM3)	1,697 (81%)	345 (16%)	58 (2.8%)
Medium rural town (MMM4)	897 (80%)	193 (17%)	31 (2.8%)
Small rural town (MMM5)	510 (79%)	120 (19%)	15 (2.3%)
Remote communities (MMM6)	3 (100%)	0 (0%)	0 (0%)
State			
ACT	487 (81%)	98 (16%)	14 (2.3%)
NSW	11,167 (79%)	2,523 (18%)	382 (2.7%)
Antibiotic received			
Cefalexin	302 (82%)	63 (17%)	3 (0.8%)
Nitrofurantoin	217 (85%)	34 (13%)	5 (2.0%)
Trimethoprim	10,630 (80%)	2,292 (17%)	329 (2.5%)
None	505 (63%)	232 (29%)	59 (7.4%)
Frequent of service use			
Single use	10,588 (79%)	2,390 (18%)	368 (2.8%)
Multiple use	1,026 (81%)	218 (17%)	25 (2.0%)
Hospitalised in the last 12 months			
Hospitalised	821 (78%)	199 (19%)	35 (3.3%)
Not hospitalised	10,793 (80%)	2,409 (18%)	358 (2.6%)

Note 1: 'Frequency of service use' and 'hospitalised in the last 12 months' were only available for the 13,947 people responding to the 7-day follow-up

Appendix Table 3-4-6: Adverse events and health services engagement by Modified Monash Model (MMM) remoteness category

	Total n=14,671	MMM1 n=10,482	MMM2 n=320	MMM3 n=2,100	MMM4 n=1,121	MMM5 n=645	MMM6 n=3
Adverse events							
Any adverse events, or complications	748 (5.1%)	534 (5.1%)	19 (5.9%)	99 (4.7%)	69 (6.2%)	27 (4.2%)	0 (0%)
Use of acute care services							
Presented at Emergency	195 (1.3%)	109 (1.0%)	6 (1.9%)	45 (2.1%)	24 (2.1%)	11 (1.7%)	0 (0%)
Attended an urgent care clinic	80 (0.5%)	59 (0.6%)	1 (0.3%)	14 (0.7%)	2 (0.2%)	4 (0.6%)	0 (0%)
Attended an urgent care clinic or presented at emergency	7 (<0.1%)	5 (<0.1%)	0 (0%)	1 (<0.1%)	0 (0%)	1 (<0.1%)	0 (0%)
Another healthcare professional seen for the same symptoms in the last 7 days*	**2,402 (16.4%)**	**1,742 (16.6%)**	**51 (15.9%)**	**348 (16.6%)**	**176 (15.7%)**	**85 (13.2%)**	**0 (0%)**
Same pharmacy	70 (0.5%)	53 (0.5%)	1 (0.3%)	8 (0.4%)	4 (0.4%)	4 (0.6%)	0 (0%)
A different pharmacy	91 (0.6%)	63 (0.6%)	2 (0.6%)	16 (0.8%)	7 (0.6%)	3 (0.5%)	0 (0%)
A general practitioner	2,075 (14.1%)	1,540 (14.7%)	43 (13.4%)	274 (13.0%)	148 (13.2%)	70 (10.9%)	0 (0%)
Health information phone line	50 (0.3%)	39 (0.4%)	0 (0%)	8 (0.4%)	2 (0.2%)	1 (0.2%)	0 (0%)
Other professional	65 (0.4%)	44 (0.4%)	1 (0.3%)	17 (0.8%)	3 (0.3%)	0 (0%)	0 (0%)

Appendix Table 3-4-7: Adverse events and health services engagement by symptom resolution response

	My symptoms have completely resolved (n=11,654)	My symptoms have improved, but not completely resolved (n=2,621)	My symptoms have not improved or worsened (n=396)
Adverse events			
Any adverse events, or complications	511 (4.4%)	187 (7.1%)	50 (13%)
Use of acute care services			
Presented at emergency	62 (0.5%)	79 (3.0%)	54 (14%)
Attended an urgent care clinic	26 (0.2%)	36 (1.4%)	18 (4.5%)
Attended an urgent care clinic and presented at emergency	88 (0.8%)	114 (4.3%)	66 (17%)
Another healthcare professional seen for the same symptoms in the last 7 days*	**945 (8.1%)**	**1,148 (44%)**	**309 (78%)**
Same pharmacy	33 (0.3%)	26 (1.0%)	11 (2.8%)
A different pharmacy	41 (0.4%)	38 (1.4%)	12 (3.0%)
A general practitioner	824 (7.1%)	1,002 (38%)	249 (63%)
Health information phone line	62 (0.5%)	79 (3.0%)	54 (14%)
Other professional	26 (0.2%)	36 (1.4%)	18 (4.5%)

** Categories are non-exclusive*

Appendix 3.5 – Incidence of adverse events in PATH-UTI compared to national and international databases at the end of the trial and follow up

Key Points

- An initial report for the incidence of adverse events for antibiotics supplied by pharmacists in the PATH-UTI trial as compared to the national and international data.
- This document includes information until the end of the trial (31/05/2024) and of the follow up period (21/06/2024), including a total of 18,143 consultations and 14,671 follow up surveys.
- The incidence of adverse events for trimethoprim in the PATH-UTI trial (n=13,260) is lower or similar to the numbers reported by national and international databases (risk category green for all adverse events).
- The small numbers of patients using nitrofurantoin (256) and cefalexin (368) prevents us from making significant comparisons.
- Pharmacists appear to have adhered to the clinical management protocol and prescribed trimethoprim as the first line antibiotic.

Methodology

To compare the incidence of adverse events under pharmacist-led prescribing of three antibiotics as part of the PATH-UTI trial, the following databases were identified:

- Database of Adverse Event Notifications (DAEN, Australia): DAEN Medicines (tga.gov.au)
- PI/CMI (TGA, Australia): TGA eBusiness Services
- Vigibase (WHO, Uppsala Monitoring Centre): VigiAccess
- Micromedex solutions (USA): Micromedex Products
- Wolters Kluwer's UpToDate (USA): UpToDate
- Drugs.com (USA): Drugs.com - Prescription Drug Information
- CIMA (Centro de Información de Medicamentos, Spain, European Medicines Agency (EMA)) CIMA Centro de información de medicamentos
- National Health System (NHS) webpage (UK): NHS Medicines Information
- Mayo Clinic (USA): Drugs and Supplements - Mayo Clinic

Website and online clinical resources such as Micromedex, UpToDate, CIMA and NHS include information from the literature (cohort studies, clinical trials, randomised controlled trials and others). Databases such as DAEN and Vigibase depend on active reporting from consumers, health professionals and the industry, thus presenting several limitations for the population incidence of adverse events particularly a bias in which serious adverse events are more likely to be reported than non-serious adverse events. This is evident as they report a much higher incidence of anaphylaxis, hypersensitivity reactions and respiratory adverse events. A second consideration is that some databases report data using non-numerical classifications rather than quantitative data and thus has not been included in the analysis. For example, the Australian Consumer Medicine Information (CMI) and Product Information (PI) do not report most adverse events quantitively. There is also only one Australian database available (DAEN, Database of Adverse Event Notifications from TGA) where all adverse events are registered quantitively. As patients and clinicians often use different terminologies to describe signs and symptoms from adverse events, they were grouped by common categories described in the databases reviewed. Most databases provide a range of probability for the incidence of each adverse effect. For ease of interpretation, we have colour coded as follows:

- Green: the incidence in the PATH-UTI trial data is lower or within the range of all databases.
- Red: the incidence in the PATH-UTI trial data is higher than the range of all databases.

It should be noted that due to the low number of patients prescribed nitrofurantoin and cefalexin in the trial, even one patient reporting a side effect would represent a high incidence from the specific sample. Adverse events are grouped using the 10th version for the International Classification of Diseases (ICD) in alphabetic order. Information about the antibiotics prescribed in the PATH-UTI trial was taken from a database that included both MedAdvisor consultation data and follow up data provided by The George

Institute for global health for 14,671 episodes of care. The number of patients prescribed each antibiotic who completed the follow up survey is included in each respective table.

Appendix Table 3-5-1: Incidence of adverse events for trimethoprim in 9 databases and the PATH-UTI trial*

ICD-10 category	Adverse event	Vigibase % (WHO, Uppsala Monitoring Centre From 12,691 reports)	TGA DAEN % (From 1,306 reports)	Micromedex % Range	CIMA (EMA) % Range (unless lower 0.01% or less)	Drugs.com % Range	UpToDate % or % Range	Mayo Clinic % Range	NHS % Range	PI/CMI % or % Range	PATH-UTI Trial Reported Number (n)	PATH-UTI Trial % of adverse events at follow up (13,260 total surveys)	Risk category
Dermatological	Night sweats	0.05	0.16								2	0.015	
	Skin rash	20	51	1–10	1–10	1–10	7 (1–10)	0.1–1	1–10	8 (1–10)	74	0.56	
	Sunburn	0.5	0.5								1	0.007	
Cardiovascular	Tachycardia	0.41	0.84								2	0.015	
Gastrointestinal	Abdominal pain	3	2		1–10		0.1–1	0.1–1			31	0.23	
	Bloating	0.11	0.1								11	0.08	
	Constipation	0.5	0.4			0.01-0.1			0.01–0.1	0.01–0.1	65	0.49	
	Diarrhoea	2	2			1–10	4 (1–10)	0.1–1	1–10	1–10	109	0.82	
	Dry mouth	0.31	0.38								2	0.015	
	Dysgeusia	0.2	0.2		1–10						5	0.038	
	Loss of appetite	0.78	1.0					0.1–1		0.01–0.1	2	0.015	
	Mouth ulcers	1.1	1.5								2	0.015	
	Nausea	6	7		1–10	1–10		0.1–1	1–10		282	2.1	
	Oral candidiasis	0.04									5	0.038	
	Oral pain	0.28	0.08								2	0.015	
	Vomiting	5	6		1–10		2 (1–10)	0.1–1	1—10		37	0.27	
Genitourinary	Dysuria	0.13	0.16								2	0.015	
	Haematuria	0.2	0.08			0.01-0.1		0.01–0.1	0.01–0.1	0.01–0.1	2	0.015	
	Lack of efficacy	0.61	0.94								30	0.22	
	Thrush	0.2	0.2			1–10			1–10	1–10	114	0.86	
Immunological	Allergic reaction	3.7	1		0.01	0.01–0.1		0.01–0.1	0.01–0.1	0.01–0.1	10	0.075	
	Anaphylaxis	2.5	3.4		0.01	0.01–0.1		0.01–0.1	0.01–0.1	0.01–0.1	1	0.007	
Neurological	Fatigue	3.5	4.2			0.01–0.1			0.01–0.1		117	0.88	
	Headache	4	3			1–10		0.01–0.1	1–10	1–10	44	0.33	
	Somnolence	0.5	0.3			0.01–0.1			0.01–0.1		3	0.023	
Ophthalmological	Blurred vision	0.23	0.47								2	0.015	
Psychiatric	Claustrophobia	0.02	0.07								1	0.007	
	Depression-like symptoms	0.2	0.2								5	0.038	
	Hallucinations	0.63	0.53							0.01–0.1	1	0.007	
	Parasomnia	0.5	0.2			0.01–0.1			0.01–0.1	0.01–0.1	6	0.045	
Respiratory	Difficulty breathing	2	0.3			0.01–0.1		0.01–0.1	0.01–0.1	0.01–0.1	18	0.14	
	Flu-like symptoms	1.5	2			0.01–0.1		0.01–0.1	0.01–0.1	0.01–0.1	3	0.023	
Other	Body pain	1.5	2.5								11	0.08	
	Epistaxis	0.1	0.07			0.01–0.1			0.01–0.1		1	0.007	
	Fever	5	5								3	0.023	
	Flushing	0.3	1.3								1	0.007	

**Note: The databases report incidence of adverse events to a different number of decimal places.*

Appendix Table 3-5-2: Incidence of adverse events for nitrofurantoin in 9 databases and the PATH-UTI trial*

ICD-10 category	Adverse event	Vigibase % (WHO, Uppsala Monitoring Centre From 12,691 reports)	TGA DAEN % (From 1,306 reports)	Micromedex % Range	CIMA (EMA) % Range (unless lower 0.01% or less)	Drugs.com % Range	UpToDate % or % Range	Mayo Clinic % Range	NHS % Range	PI/CMI % or % Range	PATH-UTI Trial Reported Number (n)	PATH-UTI Trial % of adverse events at follow up (256 total surveys)	Risk category
Dermatological	Skin rash	27	23	1–10	0.1–1		0.1–1	1–10			2	0.8	
Gastrointestinal	Abdominal pain	6	5	1–10	1–10	0.1–1	0.1–1	0.01–0.1		0.1–1	0	0	
	Bloating	0.7	0.25			1–10	2 (1–10)	1–10			1	0.4	
	Constipation	0.5	0.25			0.1–1	0.1–1				6	2.3	
	Diarrhoea	4	4		1–10	0.1–1	0.1–1	1–10	1–10	0.1–1	8	3.1	
	Loss Appetite	2.1	3.7								2	0.8	
	Nausea	12	13	1–10	1–10	1–10	8 (1–10)	1–10	1–10	1–10	22	8.6	
	Vomiting	8	10	1–10	1–10	1–10	0.1–1	0.01–0.1	1–10	1–10	1	0.4	
Genitourinary	Haematuria	1	0.5					0.1–1	0.01–0.1		2	0.8	
	Lack of efficacy	1.7	0.4								1	0.4	
	Thrush	0.3	0.4								2	0.8	
Immunological	Anaphylaxis	1	0.7					0.01–0.1	0.01–0.1		1	0.4	
	Allergic reaction	5	1.4					0.01–0.1	0.01–0.1		0	0	
Neurological	Drowsiness	1.5	1			0.1–1	0.1–1	0.1–1	1–10		0	0	
	Fatigue	8.7	9		1–10	0.1–1	0.1–1	0.1–1			8	3.1	
	Headache	8	7			1–10	6 (1–10)	0.1–1	1–10		2	0.8	
Respiratory	Difficulty breathing	9	0.5		0.01		0.1–1	1–10	0.01–0.1		2	0.8	
	Flu-like symptoms	5	6.5		0.01		0.1–1	1–10	0.01–0.1		3	1.2	

**Note: The databases report incidence of adverse events to a different number of decimal places.*

Appendix Table 3-5-3: Incidence of adverse events for cefalexin in 9 databases and the PATH-UTI trial*

ICD-10 category	Adverse event	Vigibase % (WHO, Uppsala Monitoring Centre From 12,691 reports)	TGA DAEN % (From 1,306 reports)	Micromedex % Range	CIMA (EMA) % Range (unless lower 0.01% or less)	Drugs.com % Range	UpToDate % or % Range	Mayo Clinic % Range	NHS % Range	PI/CMI % or % Range	PATH-UTI Trial Reported Number (n)	PATH-UTI Trial % of adverse events at follow up (368 total surveys)	Risk category
Dermatological	Skin rash	60	31	0.1–1	0.1–1	0.01–0.1		0.1–1	0.1–1	0.1–1	4	1.1	
Gastrointestinal	Abdominal pain	9	4		0.01–0.1	0.1–1		1–10	0.1–1	1–10	0	0	
	Bloating	0.16	0.1								1	0.3	
	Constipation	0.43	0.2								2	0.5	
	Diarrhoea	6.2	6		1–10	1–10		1–10	1–10	1–10	5	1.4	
	Nausea	5	5.5	1–10	1–10	0.1–1		1–10	0.1–1	0.01–0.1	4	1.1	
	Vomiting	4.4	5		0.01–0.1	0.1–1			0.1–1	0.01–0.1	0	0	
Genitourinary	Haematuria	0.2	0.2						0.1–1		0	0	
	Lack of efficacy	0.9	0.6		0.01–0.1						0	0	
	Thrush (fungal superinfection)	0.48	0.5		0.01–0.1						7	1.9	
Immunological	Allergic reaction	8.6	2		0.01–0.1			0.1–1		0.01–0.1	0	0	
	Anaphylaxis	3.5	7		0.01–0.1			0.1–-1		0.01–0.1	0	0	
Neurological	Fatigue	3.8	2		0.01–0.1	0.01–0.1			0.1–1		2	0.5	
	Headache	2.2	1			0.01–0.1			0.1–1		0	0	
Respiratory	Difficulty breathing	3.7	0.04			0.01–0.1					1	0.3	
	Flu-like symptoms	1.2	0.7			0.01–0.1			0.1–1		0	0	

**Note: The databases report incidence of adverse events to a different number of decimal places.*

Chapter 4

Appendix 4.1 – Health economic analysis plan (HEAP)

Section 1: Administrative information		
1.1	Title	NSW Government-Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists (Intervention study) PATH-UTI
1.2	Trial registration number HREC approval	ACTRN12623000882628 University of Newcastle HREC ref: H-2023-0119
1.3	Source of funding	NSW Health
1.4	Purpose of HEAP	The purpose of this HEAP is to describe the analysis and reporting procedure intended for the economic analyses to be undertaken. The analysis plan is designed to ensure that there is no conflict with the protocol and associated statistical analysis plan and it should be read in conjunction with them.
1.5	Trial protocol version	2.1 (22 Oct 2024)[3]
1.6	Trial Statistical Analysis Plan (SAP) version	2.5 (8 July 2024)
1.7	Trial HEAP version	1.1 (26 February 2025)
1.8	HEAP revisions	

Date	Section	Details	Reason
26 Feb 2025	3.2 Appendix	Cost–consequence analysis (CCA) removed from method Related table removed from Appendix	An economic summary measure was calculated. The CCA was conducted for each of the scenarios and the output assessed. It was decided by the health economic team that the subsequent outputs did not contribute any additional information that was not described elsewhere to the report.
12 Dec 2025	6. Modelling	Additional analysis	Subsequent analyses were undertaken to explore cost-shifting across payers using a partial societal perspective. These analyses incorporated patient-borne costs, including medication and consultation costs. Consistent with this

[3] *As of writing, the trial protocol has not been published. Details of the intervention can be found in the trial registration with Australia and New Zealand Clinical Trials Registry (https://www.anzctr.org.au identifier: ACTRN12623000882628).*

Section 1: Administrative information					
					perspective, pharmacy consultation costs were allocated to patients, whereas these costs were attributed to the state government in the primary cost-effectiveness analysis.
1.9	Roles and responsibilities	This HEAP was prepared by the Hunter Medical Research Institute Health Economics team • Dr Olivia Wynne • Dr Xenia Dolja-Gore • Dr Victoria McCreanor The trial health economists above are responsible for conducting and reporting the economic evaluation in accordance with the HEAP			
1.10a	Signature(s) of person(s) writing HEAP	Olivia Wynne Xenia Dolja-Gore			
1.10b	Signature of senior health economist	Victoria McCreanor			
1.10c	Signature of Chief Investigator	Sarah Dineen-Griffin			

Section 2: Trial introduction & background		
2.1	Trial background and rationale	The NSW and ACT Governments acknowledged the need for expanding the services of community-based pharmacists to improve access to medications and alleviate the pressure on general practitioners and primary care services. The NSW Government's statewide community pharmacy prescribing trial commenced in June 2023, allowing appropriately trained pharmacists with suitable facilities to provide consultations and prescriptions for the management of uncomplicated urinary tract infections (uUTI) The services were expanded to include prescribing of first-line antibiotics to eligible women aged between 18–65 years presenting with symptoms consistent with uUTI, under the condition women had not had other recent uUTIs or at high risk of complications
2.2	Aim(s) of the trial	The aim of this overall research was to evaluate the implementation and clinical impact of a service model(s) (intervention) delivered by community pharmacists in NSW (and 5 pharmacies in ACT) managing uUTIs to the eligible cohort of women
2.3	Objectives and/or research hypotheses of the trial	The specific **objectives**[4] were to: **1.** Assess implementation uptake of the intervention including the reach, fidelity and adoption of the intervention in community pharmacies, participant characteristics, and variation in uptake by geographic region **2.** Assess the clinical and experience outcomes for patients managed and/or treated by community pharmacists **3.** Assess the safety of the intervention and identify any risks that need to be addressed for future implementation **4.** Evaluate acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service **5.** Identify contextual enablers and constraints to access, adoption, fidelity delivery, impact, sustainability and generalisability of the intervention The primary **hypothesis** is that an intervention (uUTI service) delivered by community pharmacists for women 18–65 years presenting with symptoms suggestive of uUTI will achieve high rates of self-reported symptom resolution rates at 7-day follow-up, be feasible and acceptable to participants and providers and there be no association between the intervention and safety risks
2.4	Trial population	**Pharmacy** Pharmacies included in the trial are those which offer applicable patients the services specified in this authorisation at all opening hours of the pharmacy; and has the appropriate facilities such as consulting room and access to the MedAdvisor® IT program Note: Pharmacy and pharmacist eligibility criteria were set by the legislative authority by the NSW Government and a licence agreement in the ACT **Pharmacist** Individual pharmacists in the trial meet the criteria of 'approved pharmacist' meaning a pharmacist holding general registration with the Australian Health Practitioner Regulation Agency (AHPRA), with no conditions on their registration, and

[4] *Objectives found on page 7 – PATH-UTI Research Protocol dated 22 Oct 2024*

Section 2: Trial introduction & background		
		who is employed or engaged in an 'approved pharmacy' who has successfully completed the request training. Pharmacists holding provisional registration (intern pharmacists) or pharmacists with conditions on their registration are not eligible to participate in the trial **Patients** Eligible patients will be female patients 18 years of age or over and up to and including aged 65 years, presenting to community pharmacies in NSW (and 5 pharmacies in ACT) with uUTI symptoms. Female patients will be opportunistically recruited in participating community pharmacies. Consecutive patients will be identified on presentation to the community pharmacy with symptoms suggestive of an uUTI and either: requesting advice or medication or self-selecting a product for symptoms suggestive of an uUTI See ANZCTR reference number ACTRN12623000882628 for full details
2.5	Intervention(s) and comparator(s)	The proposed intervention has 2 components: **1.** Pharmacist enrolment, training and support Prior to service delivery, pharmacists will be clinically prepared through an accredited program to apply best practice standard of care. A study specific training module will be completed by pharmacists to ensure efficiency in the consultation process, patient consent, recruitment of patients, timely referral, and quality data collection. There will be follow-up training and ongoing support as part of a translational/implementation strategy. Practice change facilitators will visit these pharmacies during the feasibility study to provide ongoing support, answer any queries, ensure quality data is being collected, and collect implementation data **14.** Pharmacy consultation The pharmacist will undertake a structured consultation with the patient in the community pharmacy, anticipated to take 10 minutes, applying a co-designed clinical management protocol which considers the recommendations from the Australian Therapeutic Guidelines [99] As an observational cohort study, there is no comparator group For the purposes of the economic analysis, usual care will be inferred based on participant self-reported responses to the survey distributed to capture the 7-day symptom free rate. Survey questions ask participants to specify what services and clinical pathways they would have selected in the absence of the intervention
2.6	Trial design	See ANZCTR reference number ACTRN12623000882628 for full details Briefly, the trial was an observational cohort study using a mixed methods design to assess the implementation and clinical impact of the management of uUTIs by Community Pharmacists in NSW and ACT over a 12-month study period (2-month feasibility plus approximately 10-month intervention period). The intervention consisted of pharmacy training and support to facilitate a structured consultation with the patient consistent with the Australian Therapeutic Guidelines for uUTIs [99]
2.7	Trial start and end dates	**Trial start:** 31 July 2023 **Trial end:** 31 March 2025

Section 2: Trial introduction & background		
2.8	Trial statistical analysis	The trial statistical analysis will be conducted by statisticians at The George Institute for Global Health, Sydney, Australia. Full details of the analysis can be found in Trial Statistical Analysis Plan (SAP) version 2.5 (8 July 2024) Briefly, the analyses will be conducted primarily using SAS software (Version 9.3 or above) or R software (Version 4.3.1). Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients in whom data are available. Continuous variables will be summarised by using mean and standard deviation (SD) and 95% confidence intervals (CI) where appropriate, and median and interquartile range (Q1–Q3). The descriptive statistics will be presented in tables. The primary analysis will use all available data with no imputation Factors associated with uUTI symptom free event rate will be assessed using baseline data to conduct adjusted analyses. The analysis will use mixed models, a logistic regression and potentially by including a random pharmacy effect to adjust for clustering. In addition, a range of subgroup comparisons for primary outcome across various baseline characteristics including age, Socio-Economic Indexes for Areas (SEIFA), Monash remoteness scale

Section 3: Economic approach/overview		
3.1	Aim(s) of economic evaluation	The economic evaluation aims to assess the change in healthcare resource use associated with the implementation of a community pharmacist service to manage uUTIs in women aged between 18–65 years in NSW and the ACT (PATH-UTI trial intervention). This will be compared to the base case comprised of the alternate clinical pathways of general practice, urgent care, emergency room, and self-care (conservative management)
3.2	Objective(s) of economic evaluation	The primary objective of the health economic evaluation is to estimate the cost-effectiveness community pharmacy management for patients presenting with uUTIs in terms of incremental cost per patient who is symptom free at 7 days. Cost-effectiveness will be determined by comparing PATH-UTI to the base case
3.3	Overview of economic analysis	A modelled economic analysis will be performed using summarised patient level data derived from the statistical analyses conducted by statisticians at The George Institute for Global Health. A decision analytic framework will be informed by the trial data and the evidence from the literature where trial data are unavailable for various parameters Results from the economic analysis will be expressed as: • Cost-consequence results determined by the trial primary outcome (i.e. self-reported 7-day symptom free rate), and trial secondary outcomes indicative of healthcare resource use such the number of patients that received the service, and proportion of patients supplied antibiotics by pharmacists • Cost-effectiveness will calculate the mean incremental cost per unit change in uUTI symptom resolution between the base case and PATH-UTI
3.4	Jurisdiction(s)	The trial is conducted within NSW and the ACT, Australia, which have universal health coverage providing publicly funded health care, primarily free of charge at the point of use for hospital services and a (Federally) subsidised fee for service model of primary[5] healthcare delivery
3.5	Perspective(s)	The analysis will be conducted from a health service perspective (base case) This perspective is appropriate because any ongoing investment in the intervention, if translated into routine practice, would fall on government funded public health systems like NSW Health. Moreover, the economic evaluation aims to assess whether the community pharmacy management trial is effective and has the potential to reduce the current burden on general practitioners, emergency departments and health system costs. Additional costs from the health-consumer's perspective, specifically out of pocket expenses for any medicines or products provided, will be presented separately
3.6	Time horizon(s)	A time horizon of 7 days will be used to correspond with the primary outcome of the trial, patient self-reported 7-day symptom free rate. The trial follow-up period for all patient self-report data is 7 days with no further self-reported data collected

[5] Primary care includes services such as general practitioners for acute illnesses and injuries or to coordinate care among specialists. Secondary care involves specialists such as oncologists. Tertiary care describes a higher level of specialised care within a hospital.

Section 4: Economic data collection & management		
4.1	Statistical software	SAS version 9.4 or higher and/or MS Excel (Version 2412) will be used for the cost-effectiveness analysis, and SAS will be used for modelling
4.2	Identification of resources	**PATH-UTI trial resources** The economic evaluation includes direct costs of the community pharmacy management and medication costs for the purpose of treating uUTIs within the 7-day time horizon. Out-of-pocket costs to the patient for any relevant prescription and non-prescription treatments that may be purchased will reported separately **Base case resources** Direct costs to the health system from healthcare providers included in the alternate clinical pathways for uUTI symptom resolution will be included in the cost-effectiveness model. Out-of-pocket costs to the patient for treatments advised from the alternate clinical pathway healthcare providers will also be included Information on the types of resources used in uUTI symptom resolution will be drawn from the Australian Therapeutic Guidelines (*Acute Cystitis in Adults*, 2019), consultation with clinicians (including general practitioners, urologists, and pharmacists), and published literature
4.3	Measurement of resource-use data	**PATH-UTI trial resources** Where appropriate resource use data will be utilised from the trial survey data from both pharmacies and patients. The PATH-UTI data may be supplemented with data from the feasibility study conducted before PATH-UTI trial **Base case resources** Resource use for the alternate clinical pathways will be determined by generating a simulated data set. Derived from calculating the proportion of women aged 19–64 years living in NSW in 2023 [40] multiplied by the proportion diagnosed with a uUTI each year [158]
4.4	Valuation of resource-use data	All resource use will be valued in monetary terms using appropriate Australian unit costs at the time of data collection (2023-2024). Adjustments will be made for inflation using appropriate Consumer Price Inflation (CPI) [166] indexed to 2024 where necessary. The cost of prescription medication will be sourced from the Pharmaceutical Benefits Scheme (PBS) website[6] and general practitioner services will be sourced from the Medicare Benefits Schedule (MBS) website[7]. General practitioner online and urgent care clinic fee schedules will use market rates. Pharmacist reimbursement costs will be drawn from the NSW Health reimbursement rates considered in the trial. Cost for emergency department visits will be taken from the Independent Health and Aged Care Pricing Authority (IHACPA) 2022-23 [161]. Over the counter medication costs will be assigned retail market value

[6] *https://www.pbs.gov.au/*
[7] *https://www.mbsonline.gov.au/*

Section 4: Economic data collection & management		
4.5	Identification of outcome(s)	**PATH-UTI trial outcome** The effectiveness outcome will be the rate of patient reported uUTI symptom-free at 7 days. The economic evaluation will use results from the trial statistical analysis conducted by statisticians at The George Institute for Global Health **Base case outcome** Consistent with the PATH-UTI trial data, the effectiveness outcome for the alternate clinical pathways will be patient self-reported symptom free rate, sourced from the available published literature where possible
4.6	Measurement of outcome(s)	**PATH-UTI trial outcome** A survey administered by research team will collect the primary outcome self-reported *complete absence of urinary tract infection symptoms* at 7 days **Base case outcome** Outcome data for the alternate clinical pathways will be drawn from published sources. Literature searches will be conducted systematically to estimate parameters not available from the trial data
4.7	Valuation of outcome(s)	The outcome will be valued in its 'natural' unit, that is, will be reported as measured. The three response options presented in the PATH-UTI patient follow-up survey will be transformed into a binary value. That is 'Resolved' for those responses recorded as 'symptoms completely resolved' at follow-up; and 'Not resolved' which will include the remaining two response options, 'symptoms improved but not completely resolved' and 'symptoms not improved or worsened' at follow-up The symptom resolution rate for other pathways will be established via a review of the literature

Section 5: Economic data analysis		
5.1	Analysis population	The analysis will include the PATH-UTI population described in Section 2: Trial introduction & background
5.2	Timing of analyses	The analysis will be conducted after all patients have been followed for 7 days after their enrolment in the trial
5.3	Discount rates for costs and benefits	The time horizon of 7 days means discounting is not necessary
5.4	Cost-effectiveness threshold(s)	There is no established threshold for cost-effectiveness of uUTI symptom resolution. We will compare the incremental cost per patient with symptom resolution against the usual costs of treating these patients
5.5	Statistical decision rule(s)	Mean differences in costs and benefits between the PATH-UTI pathway and the alternate clinical pathways will be estimated with associated 95% confidence intervals
5.6	Analysis of resource use	Differences in the use of services between the pathways will be described but not compared statistically
5.7	Analysis of costs	All descriptive analysis showing the mean, standard deviation, median, minimum and maximum costs per treatment path considered will be provided
5.8	Analysis of outcomes	All descriptive analysis showing the mean, standard deviation, median, minimum and maximum proportions per clinical pathway considered will be provided
5.9	Data cleaning for analysis	Any cleaning of the PATH-UTI data will be conducted as part of the statistical analysis. Details can be found in the Trial Statistical Analysis Plan (SAP) version: 2.5 (8 July 2024)
5.10	Missing data	There will be no missing data for the purposes of the economic evaluation
5.11	Analysis of cost-effectiveness	A cost-effectiveness analysis will calculate the mean incremental cost per unit change in uUTI symptom resolution between the base case and PATH-UTI
5.12	Sampling uncertainty	Non-parametric bootstrapping will be used to generate uncertainty intervals around the costs and the outcome
5.13	Subgroup analyses or analyses of heterogeneity	Subgroup analyses will be conducted in the case where there is known heterogeneity in treatment effect or the baseline risk based on patient characteristics or where other biases may arise. Such analysis will rely on there being sufficient numbers in the specified subgroup
5.14	Sensitivity analyses	Sensitivity analysis will include a set cost for the proportion of women who worsen and need to seek other treatment before the follow-up at 7 days. The use of probabilistic input parameters and of sensitivity analyses will be included to address imprecision

Section 6: Modelling		
6.1	Extrapolation or decision analytic modelling	Decision analytic modelling will be used to generate the comparator (base case) for estimating costing and cost-effectiveness introduce an additional comparator or other evidence
6.2	Model type	Decision trees
6.3	Model structure	Decision analytic modelling will be undertaken (e.g. to extrapolate costs & outcomes including clinical pathways other than PATH-UTI), irrespective of statistical significance in trial results. If appropriate, analysis to estimate the cost-effectiveness of PATH-UTI compared to the base case will be conducted The treatment pathways in the decision model include the pharmacist-led management intervention pathway (PATH-UTI). To evaluate the cost of PATH-UTI outcomes relative to other available clinical pathways, those pathways need to be included in the model. The treatment pathways included in this analysis are: **1.** PATH-UTI (pharmacist) **2.** Conservative management **3.** General practitioner **4.** Online general practitioner **5.** Emergency department/urgent care **6.** HealthDirect website
6.4	Treatment effect beyond the end of the trial	n/a
6.5	Other key assumptions	The main assumptions underpinning the decision model are listed below • The data from published literature may be from countries other than Australia. If so, every effort will be made to use sources most relevant to the Australian healthcare system, e.g., the United Kingdom and/or Canada • The sample population will include a proportion of women with worsening symptoms and need further healthcare services. Sensitivity analysis will be performed to account the potential effect on the economic evaluation • For the conservative management pathway, resource use associated with 'do nothing/wait & see' and non-prescription treatments will be included in calculating the average cost of resource use The model structure maybe subject to change, following initial exploratory analysis of trial data
6.6	Methods for identifying and estimating parameters	The model will require several parameters, which are expected to be mainly derived from • Pharmacy UTI general questions and the PATH-UTI feasibility study analysis report on the first 927 patients in the trial • Available published literature Regarding the types of quantities used: proportions on a scale from 0 to 1, and absolute numbers were drawn from feasibility study analysis

Section 6: Modelling		
6.7	Model uncertainty	Parameter uncertainty will be assessed using probabilistic sensitivity analysis via bootstrapping methods producing 10,000 samples will be generated, 95% confidence intervals will be calculated providing upper and lower estimates for the trial mean cost estimates by clinical pathway
6.8	Model validation	For face validity, the models will be reviewed by clinical experts. Model plausibility will be formalised using the trial data and expert opinions. Where parameters are sourced from the literature plausible ranges will be compared and checked for inconsistency due to differences in study design Data collection will be subject to the identification of plausibility and consistency of the patient responses. The George Institute for Global Health with the support of the PATH-UTI research team will assess and resolve any data quality issues in the data prior to the economic analysis being undertaken
6.8	Subgroup analyses/heterogeneity	If appropriate, the model will be used to evaluate the cost-effectiveness of the intervention in categories regionality (Metropolitan/non-metropolitan) and patient age

Section 7: Reporting/publishing		
7.1	Reporting standards	CHEERS guidelines will be followed when reporting the health economic evaluation, in a format appropriate to stakeholders and policymakers
7.2	Deviations from the HEAP	Any deviation from HEAP will be described and justified in the final published report

Proposed tables and figures

Proposed tables for methods

Appendix Table XX: Perspective and associated cost categories and sources (example content)

Perspective	Cost categories	Specification of costs	Data source
Healthcare perspective	Costs in PATH-UTI trial resources	Pharmacist costs	Pharmacy – PATH-UTI protocol
	Costs for general practitioner/general practitioner-online services	General practitioner consultation costs Pathology test costs	MBS Online services Website
	Costs in emergency department services	Emergency department visit costs (including appropriate tests incurred)	Independent Health and Aged Care Pricing Authority (IHACPA) website handbook
	Costs in Urgent care services	Urgent Care service costs	

[†]*No time related costs are included*

Data on the consultation by various health professionals in providing each service will be measured from the services directly. The information includes the purpose, place and type of consultation for the patients.

Appendix Table XX: Economic evaluation resource use measures (example content)

Resource use category	Description of resource used	Unit of measurement	Unit of cost
Service use	General practitioner	Per visit	$
	Emergency department medical visit	Per visit	$
	Pharmacist	Per visit	$
	Urgent care	Per visit	$
Pharmacist Protocol adherence	Referrals to general practitioners	Per visit	$

Proposed tables and figures for Results

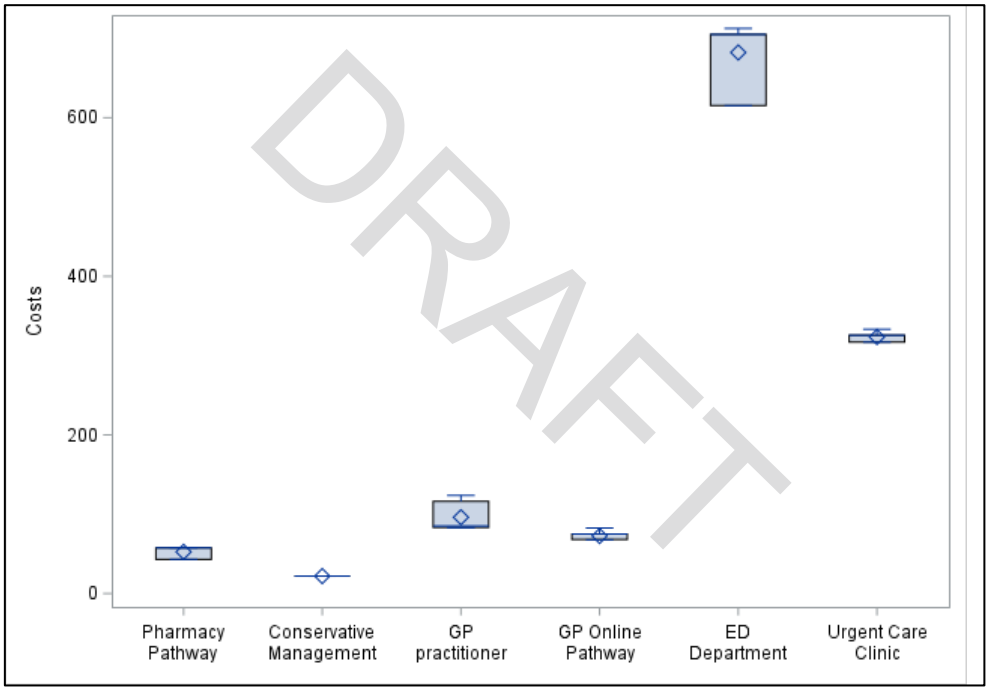
Costing

Appendix Table XX: Parameters used for the economic model and distributions for uncertainty analysis

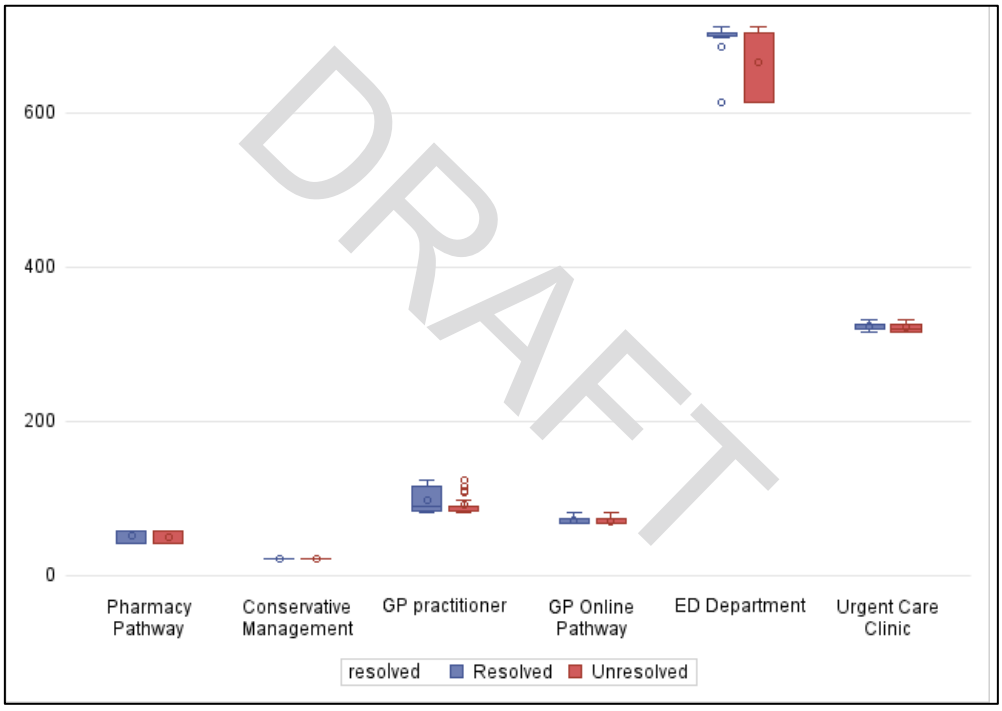
	Percent of patients (N=XXX)	Cost Mean (Std Dev)	Cost (Minimum, Maximum)
Symptom resolution			
Total	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Medication	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Clinical pathway			
Pharmacy	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
General practitioner	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
General practitioner online	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Emergency department	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Urgent care clinic	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Overall		$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Pathway treatment			
Pharmacy Protocol			
One primary symptom	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Two or more symptoms	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
All women			
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Medication management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Pharmacy			
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Medication management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
General practitioner/general practitioner online combined			
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Medication management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Emergency department/urgent care combined			
Conservative management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)
Medication management	XX.X%	$XXX.XX ($X.XX)	($XX.XX, $XX.XX)

Appendix Table XX: Estimated mean cost of patient pathways

	Mean cost per patient $ (Standard Deviation)					
Cost item	**Pharmacy**	**Conservative**	**General practitioners**	**General practitioners online**	**Emergency department**	**Urgent care**
Consultation	$XX.XX	$XX.XX	$XX.XX	$XX.XX	$XX.XX	$XX.XX
Non-prescription medicine	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)
Prescription medicine	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)	$XX.XX ($X.XX)



Appendix Figure XX: Distribution of costs per treatment pathway



Appendix Figure XX: Distribution of costs by treatment pathway and resolution of uUTI

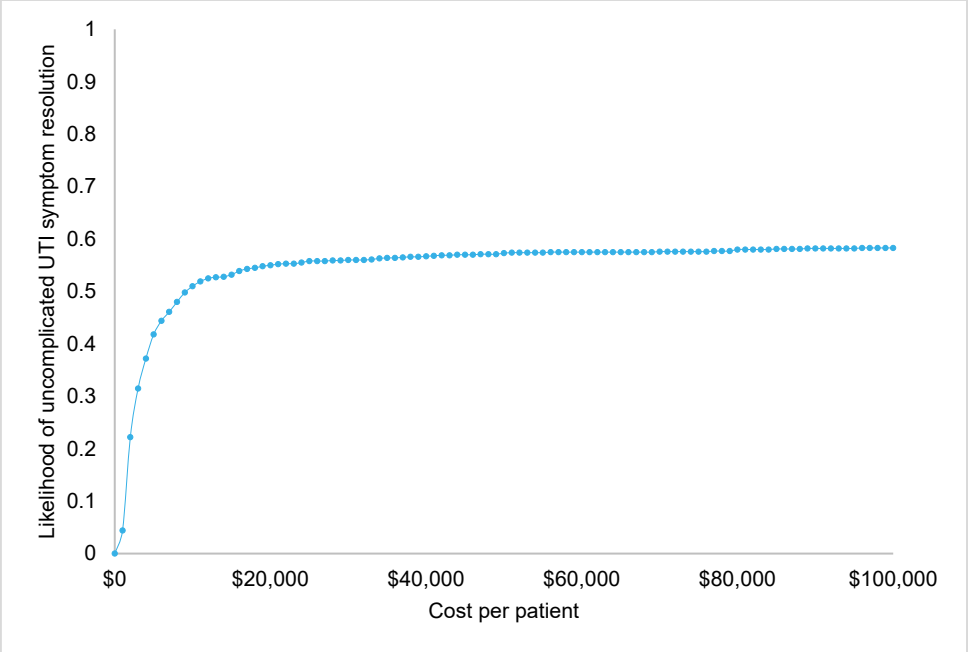
Cost-effectiveness

Appendix Table XX: Proportions of pathway utilisation and costs per pathway

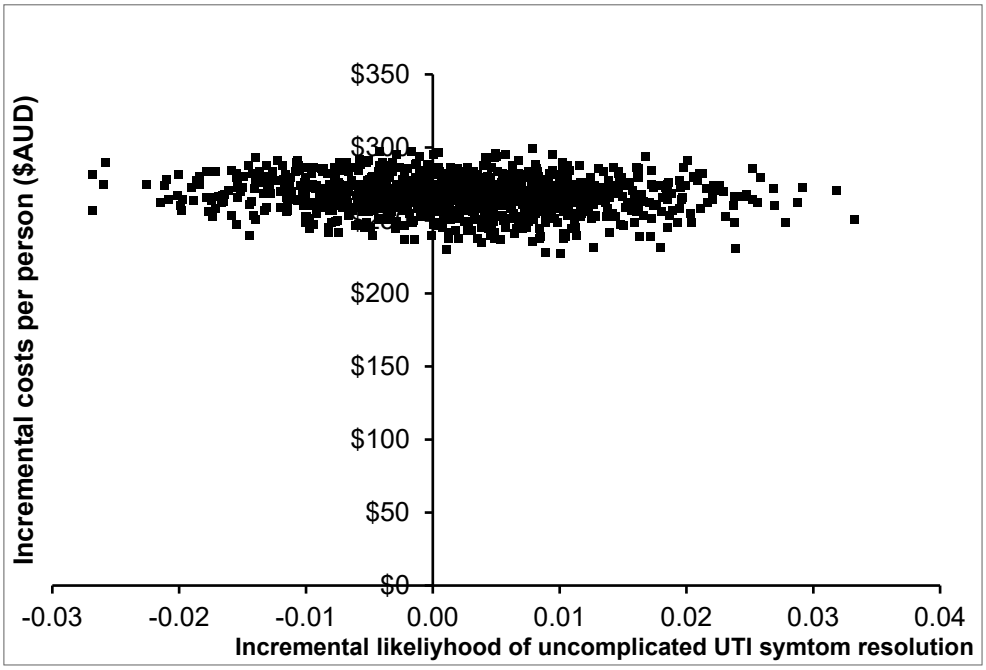
Clinical pathway	Mean (Std Dev) costs	Pre- PATH-UTI probabilities	PATH-UTI probabilities
Pharmacy	$XX.XX ($X.XX)	XX.X%	XX.X%
Conservative management	$XX.XX ($X.XX)	XX.X%	XX.X%
General practitioner	$XX.XX ($X.XX)	XX.X%	XX.X%
General practitioner online pathway	$XX.XX ($X.XX)	XX.X%	XX.X%
Emergency department	$XX.XX ($X.XX)	XX.X%	XX.X%
Urgent care clinic	$XX.XX ($X.XX)	XX.X%	XX.X%
Overall	$XX.XX ($X.XX)	100%	100%

Appendix Table XX: Base case analysis with and without the introduction of the Community Pharmacy Management trial

		Pre- PATH-UTI		PATH-UTI		
Clinical pathway	**Mean cost**	**N**	**Total Cost**	**N**	**Total Cost**	**Cost Difference**
Pharmacy	$XX.XX			XX,XXX	$XXX	$XXX
Conservative management	$XX.XX	XX,XXX	$XXX	XX,XXX	$XXX	$XXX
Emergency department	$XX.XX	XX,XXX	$XXX	XX,XXX	$XXX	$XXX
General practitioner online	$XX.XX	XX,XXX	$XXX	XX,XXX	$XXX	$XXX
General practitioner	$XX.XX	XX,XXX	$XXX	XX,XXX	$XXX	$XXX
Urgent care clinic	$XX.XX	XX,XXX	$XXX	XX,XXX	$XXX	$XXX
Total		XX,XXX	$XXX	XX,XXX	$XXX	
Total difference						**$ XXX**



Appendix Figure XX: Cost-effectiveness acceptability curve for PATH-UTI compared to the base case.



Appendix Figure XX: Cost-effectiveness plane for PATH-UTI compared to the base case.

Deviations from Health Economic Analysis Plan

The HEAP (Version 1, 30 January 2025) Section 3.2 states that a cost-consequence analysis would be conducted and reported to calculate cost-consequence results for the trial based on trial outcomes. A cost-consequence analysis enables the comparison of the costs and multiple consequences (outcomes) of different interventions. The HEAP describes an analysis using a scorecard approach to show a comparison of the costs and benefits associated with the w/PATH-UTI and the base case (pre-PATH-UTI) models. An economic summary measure was calculated. The cost-consequence analysis was conducted for each of the scenarios and the output assessed. It was determined by the health economics team that the subsequent outputs did not contribute any additional information beyond what was already presented elsewhere in the report. The HEAP has been updated to Version 1.1.

The Health Economics Analysis Plan (HEAP) Version 1.1 (26 February 2025) states that cost-effectiveness analysis will be conducted to calculate the mean incremental cost per unit change in uUTI symptom-free rate between the base case and PATH-UTI. The CEA was conducted and reported, however it took health system perspective, therefore excluding patient out of pocket costs.

Following review of the initial work, the focus of the analysis was reframed to understand cost-shifting within the health system and across payers.

This re-analysis uses a partial societal perspective, replacing the previous health system perspective. Given the similarities in 7-day symptom-free rates in the pre-PATH-UTI and PATH-UTI arms, the overall story, showing PATH-UTI to be cost-effective is unlikely to have changed.

Appendix 4.2 – Approach to valuation and sources for costs in cost distribution analysis

Table 4-2-1 Approach to valuation – consultation costs

Pathway	Patient OOP	Government	Source Patient OOP	Source Government
Pharmacy	Costs specified in guidance for community pharmacists in Queensland [168] will be used to determine the likely range of fees patients may be charged	Current BAU has no government subsidy	Chronic Conditions Pilot Handbook. Queensland Health [168]	Expanded scope pharmacy services – Information for pharmacists [277]
General practice	Values reported in the AIHW report [167]. We will report average, minimum, and maximum values. Minimum and maximum costs determined by value reported for the highest and lowest average costs for Local government areas (LGAs). A proportion will be assigned a patient cost of $0 to account for bulk billed general practitioner appointments	MBS items for general practitioner appointment accounting for appointment type. Costs assigned to the NSW State Government	Australian Institute of Health of Welfare (AIHW) report [167] and the Royal Australian College of General Practitioners (RACGP) report [278] on costs of general practitioner attendance	MBS website (e.g., Items 23[1], 24[2], and 36[3]). AIHW report [167] and RACGP report [278] on costs of general practitioner attendance
General practitioner online	Market price, calculated as the average of listed costs from a sample of general practitioner online websites. We will report average, minimum, and maximum values	As MBS rebates/bulk billing are unlikely, due to eligibility requirements, government cost will be considered $0	See Table 4.2.3	
Emergency department	Eligible patients to public Emergency departments incur no OOP cost	Mean cost calculated using codes reported in the linked data will be used to estimate government costs. Costs assigned to the Commonwealth Government	NSW Health[4]	IHACPA values [161]

[1] *Medicare Benefits Schedule - Item 23. Available at: https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23. Accessed April 2026.*
[2] *Medicare Benefits Schedule - Item 24. Available at: https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=24&qt=ItemID. Accessed April 2026.*
[3] *Medicare Benefits Schedule - Item 36. Available at: https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=36&qt=ItemID. Accessed April 2026*
[4] *NSW Health. Emergency Departments. Available at: https://www.health.nsw.gov.au/Hospitals/Going_To_hospital/Pages/emergency-departments.aspx. Accessed April 2026.*

Pathway	Patient OOP	Government	Source Patient OOP	Source Government
Urgent care	An average cost determined by market price for private calculated as the average of listed costs from a sample of NSW providers. We will report average, minimum, and maximum values	As MBS rebates/bulk billing are unlikely, due to eligibility requirements, government cost will be considered $0	See Table 4.2.4	Medicare Urgent Care Clinics Program Evaluation: First Interim Report [279]
Conservative management	Patients seek no consult for their symptoms. Patient cost will be considered $0	Patients seek no consult for their symptoms. Government cost will be considered $0		

Table 4-2-2 Approach to valuation – medication costs

Pathway	Patient OOP	Government	Source Patient OOP	Source Government
Pharmacy	Base cost for each prescription medication will be the general patient charge plus the max safety net value listed on the MBS. Range will be estimated by market price for private prescriptions calculated as the average of listed costs from a sample of pharmacy websites	Pharmacists are private prescribers. As such, the medication is not eligible for a PBS subsidy. Government cost will be considered $0	MBS website for medications listed in the protocol, and pharmacy websites	MBS website for medications listed in the protocol
General practice	The mean value will be the general patient charge listed on PBS. Range will be estimated by market price for private prescriptions calculated as the average of listed costs from a sample of pharmacy websites	The average of relevant PBS items, applying 100% of the listed benefit. If relevant, the average, minimum, and maximum will be reported. Costs assigned to the NSW State Government	MBS website for medications listed in the protocol, and pharmacy websites	MBS website for medications listed in the protocol
General practitioner online	Base cost for each prescription medication will be the general patient charge plus the Max safety net value listed on the MBS. Range will be estimated by market price for private prescriptions calculated as the average of listed costs from a sample of pharmacy websites	PBS rebates on prescriptions written during a general practitioner online consult are unlikely due to eligibility requirements. Government cost will be considered $0	MBS website, pharmacy websites for medications listed in the trial protocol	
Emergency department	Assumption that medications from Emergency department to be supplied at the presentation/visit not dispensed at a community pharmacy	Assumed to be included in the IHACPA. Government cost will be considered $0		

Pathway	Patient OOP	Government	Source Patient OOP	Source Government
Urgent care	Base cost for each prescription medication will be the general patient charge plus the max safety net value listed on the MBS. Range will be estimated by market price for private prescriptions calculated as the average of listed costs from a sample of pharmacy websites	The average of relevant PBS items, applying 100% of the listed benefit. If relevant, the average, minimum, and maximum will be reported. Costs assigned to the NSW State Government	MBS website for medications listed in the protocol, and pharmacy websites	
Conservative management	Market price calculated as the average of listed costs from a sample of pharmacy websites. We will report average, minimum, and maximum values	Products considered conservative management are not eligible for PBS subsidy. Government cost will be considered $0	Pharmacy websites for products listed in the trial protocol	

Table 4-2-3 Sources used to value patient costs for general practitioner online consult

Business name	Appointment type	Cost ($)	Website
Instant scripts		49.00	instantscripts.com.au/gp-online
Updoc	Standard	49.95	updoc.com.au
	Priority	99.95	
Hola Health	Standard	39.00	hola.health
	Long	49.00	
Doctors on demand	Standard	62.95	doctorsondemand.com.au/
	After hours	92.95	
My telehealth clinic		39.95	https://mytelehealthclinic.com.au
Teledoc Australia		45.00	https://teledocaustralia.com.au/
Qoctor.com.au		49.99	https://www.qoctor.com.au/online-gp-telehealth/
Medmate		39.90	https://medmate.com.au/frequently-asked-questions/
Teldoc	Standard	49.00	https://teldoc.com.au/price/
	Weekend/ public holiday	69.00	
	Mean	**56.59**	
	Minimum	**39.00**	
	Maximum	**99.95**	

Table 4-2-4 Sources used to value patient costs for private urgent care consult

Business name	Cost ($)	Website
Heal	350.00	https://www.healurgentcare.com.au/pricing/
Brunker Road Medical	115.00	https://www.brunkermedical.com.au/faqs/
EUC Specialist Emergency and Urgent Care Clinic	290.00	https://www.emergencyurgentcare.com.au/fees/
WiSE Specialist Emergency	340.00	https://www.wisemedical.com.au/fees/
Mean	**273.75**	
Minimum	**115.00**	
Maximum	**350.00**	

Table 4-2-5 Costs and sources for medications reported in the trial

Medication	Dispensed Price by Maximum Quantity (DMPQ) ($)	Max safety net ($)	General patient charge ($)	Diff b/t DMPQ & general charge ($)	Link
Trimethoprim	24.56	25.00	25.00	0.44	https://www.pbs.gov.au/medicine/item/10785P-2666H-2922T
Nitrofurantoin	27.78	25.00	25.00	-2.78	https://www.pbs.gov.au/medicine/item/1693D
Cefalexin	19.22	20.70	23.49	4.27	https://www.pbs.gov.au/medicine/item/10778G-11934D-3119E-3318P
Norfloxacin*	17.70	19.18	21.97	4.27	https://www.pbs.gov.au/medicine/item/3010K
Ciprofloxacin*	18.20	19.68	22.47	4.27	https://www.pbs.gov.au/medicine/item/1209P

**Not listed in the Authority for pharmacists. Reported in the linked data as supplied/prescribed by clinicians*

Appendix 4.3 – Probability tables

Tables probabilities used for the pharmacy management trial models. Models assumed that 13.00% of women will use the pharmacist instead of the standard care. Pathway probabilities have been sourced from Butler *et al.* [159].

Responses to the question: 'If you could not have accessed this service in the pharmacy, where would you have gone/what would you have done?'

Table 4-3-1 Probability table – pre-PATH-UTI

	%	N	New N	New %	Adjusted for Pharmacist
A general practitioner	71.90	520	550	76.07	66.18
General practitioner online	-	-	16	2.21	1.93
The hospital emergency department	11.80	85	87	12.03	10.47
Urgent care clinic	3.70	27	28	3.87	3.37
Health information/nurse phone line like HealthDirect	0.80	6	6	0.83	0.72
Other	11.80	85	85		
Try to get a general practitioner appointment	35.30	30			
Waited for symptoms relief (wait and see)	27.10	23	31.00	4.29	3.73
Use an online general practitioner service	18.80	16			
Don't know	9.40	8			
Used over-the-counter products (conservative management)	5.90	5	5.00	0.69	0.60
Emergency department	2.40	2			
Urgent care clinic	1.20	1			
Total		**723**	**723.00**	**100.00**	**87.00**
				Adjusted %:	**87.00**

Table probabilities used to populate the table assuming standard care (without the introduction of the community pharmacy management trial). Women who responded as 'Other' were collapsed into the relevant categories such as 'A general practitioner' and 'Try to get a general practitioner appointment' were combined or 'Waited for symptoms relief' and 'Used over-the-counter products' combined as 'Wait and See'. Accounting for HealthDirect participants was proportioned as 20.7% (conservative management), 70% (general practitioner) and 9.3% (emergency department visits).

Responses to the question: 'If you could not have accessed this service in the pharmacy, where would you have gone/what would you have done?'

Table 4-3-2 Probability table PATH-UTI (unadjusted)

	%	N	Adjusted %	Accounting for Healthdirect[2] %	Probabilities in the model
A general practitioner	71.9%	520	76.06%	76.76%	0.766
Health information/nurse phone line like HealthDirect	0.8%	6	0.00%		
Other	11.8%	85			
The hospital emergency department	11.8%	85	12.08%	12.17%	0.122
Urgent care clinic	3.7%	27	3.84%	3.84%	0.038
Online general practitioner			2.22%	2.22%	0.022
Wait and see			5.00%	5.20%	0.052
Total	**100.0%**	**723**	**99.20%**	**100.20%**	**1.0**

[2] *Remove the HealthDirect and reassign to the assigned pathways as done previously*

The column 'adjusted %' is calculated as the total proportion of women in the study who opted for the following options. The new 'Adjusted' proportions have been calculated after removing the women who selected 'Don't know' bringing the total from 85 to 77 participants. This changed the proportion of women selecting 'Other' from 11.89% to 10.78%.

Table 4-3-3 Probability table PATH-UTI (adjusted)

Please specify 'Other'	N	%	Adjusted %[2]	New Adjusted proportions
Try to get a general practitioner appointment	30	35.3	0.353	4.165
Waited for symptoms relief	23	27.1	0.271	3.193
Use an online general practitioner service	16	18.8	0.188	2.221
Don't know[1]	8	9.4	0.094	1.111
Used over-the-counter products	5	5.9	0.059	0.694
Emergency department	2	2.4	0.024	0.278
Urgent care clinic	1	1.2	0.012	0.139
Total	**85**	**100.0**	**1.000**	**0.118**

[1] *'Don't know' participants from the study.*
[2] *The 'Don't know' (8 women) of the 'Other' group of participants, have been added to the 'Wait and See' group.*

Probabilities for re-presentation – Scenario 3 CEA and Scenario 2 Cost Distribution (using linked data)

Probabilities for re-presentation have been sourced from both the published literature and the trial study. Since the pharmacy trial did not collect data for all modelled clinical pathways reliable peer reviewed sources have been retrieved to provide clarity where appropriate.

Table 4-3-4 Probability table for re-presentation

Pathway	Reference	Probability unresolved
Pharmacy pathway	Pharmacy trial linked data	18.7%
Conservative management	Zare	37.0%
General practitioner/general practitioner online	Tsuyuki and Beahm	23.9%
Emergency department	The George Institute for Global Health final report	17.8%
Urgent care clinic	The George Institute for Global Health final report	17.5%

Expected number of women within NSW over a calendar year potentially accessing health care for an uUTI are shown in the table below. Proportions have been estimated using the probabilities derived by women accessing healthcare services in the 7-day follow-up of the trial study. Linked data sources have provided valuable information to help better understand the services accessed if second-line treatment is required

Table 4-3-5 Re-presentation data and sources

				Re-presentation				Re-presentation		
Pathway	**Reference**	**Number treated**	**Number resolved**	**Number for general practitioner**	**Number for Emergency department**	**Number for Hospital**	**Number unresolved**	**Number for general practitioner**	**Number for Emergency department**	**Number for Hospital**
Pharmacy pathway	Pharmacy trial linked data	36,199	29,416	4,830	153	24	6,783	2,917	176	22
Conservative management	Zare	12,485	7,866	1,292	41	6	4,619	1,986	120	15
General practitioner / General practitioner online	Tsuyuki and Beahm	183,700	139,853	22,964	727	112	43,847	18,854	1,140	140
		5,230	4,222	693	22	3	1,008	433	26	3
Emergency department	The George Institute for Global Health final report	28,076	23,088	3,791	120	18	4,988	2,145	130	16
Urgent care clinic	The George Institute for Global Health final report	9,340	7,702	1,265	40	6	1,638	704	43	5
Total		**275,030**	**212,147**	**34,835**	**1,103**	**170**	**62,883**	**27,040**	**1,635**	**201**

Appendix 4.4 – Statistical analysis of linked data

Table 4-3-1 was provided to HMRI Health Economists by The George Institute for Global Health statisticians reproduced here without alteration for reference when reading the current economic evaluation report. This table was used to guide the re-presentation rate of women to different healthcare providers in Scenario 3 economic models. It should be noted that due to the uncertainty about hospital admissions for an uUTI, only emergency department presentations for a genitourinary condition followed by a hospital admission were included as a re-presentation.

Table 4-4-1 Variation in general practitioner/specialist, antibiotic and hospital utilisation by self-reported symptom resolution

	Complete symptom resolution (n=11,221)			Improved but not resolved symptoms (n=2,581)			Not improved or worsening of symptoms (n=392)		
Outcome	**Number of events (per 100 people) [percent of participants][1]**			**Number of events (per 100 people) [percent of participants][1]**			**Number of events (per 100 people) [percent of participants][1]**		
	0–2 days	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**
General practitioner or specialist services provided	**MBS data available for 10,070 people[2]**			**MBS data available for 2,316 people[2]**			**MBS data available for 352 people[2]**		
General practitioner consultation	841 (8.35) [8.01%]	916 (9.1) [8.41%]	3,945 (39.18) [28.89%]	364 (15.72) [15.03%]	670 (28.93) [25.52%]	1,604 (69.26) [46.24%]	72 (20.45) [19.03%]	171 (48.58) [42.05%]	337 (95.74) [56.25%]
Specialist consultation	55 (0.55) [0.56%]	102 (1.01) [1%]	570 (5.66) [4.99%]	21 (0.91) [0.91%]	33 (1.42) [1.34%]	164 (7.08) [5.96%]	5 (1.42) [1.7%]	8 (2.27) [1.7%]	42 (11.93) [8.81%]
Urine sample sent for pathology testing	376 (3.73) [3.72%]	259 (2.57) [2.55%]	565 (5.61) [5.33%]	206 (8.89) [8.89%]	371 (16.02) [15.8%]	471 (20.34) [18.65%]	39 (11.08) [11.36%]	91 (25.85) [25.28%]	122 (34.66) [31.82%]
Additional antibiotic dispensed other than initial pharmacy prescribed antibiotic	**PBS data available for 10,722 people[2,3]**			**PBS data available for 2,466 people[2,3]**			**PBS data available for 375 people[2,3]**		
Any antibiotic prescribed	302 (2.82) [2.8%]	340 (3.17) [3.12%]	1,024 (9.55) [8.5%]	195 (7.91) [7.83%]	509 (20.64) [19.91%]	612 (24.82) [21.49%]	45 (12) [12.27%]	141 (37.6) [35.2%]	161 (42.93) [35.47%]
Antibiotic from management protocol[4]	240 (2.24) [2.25%]	253 (2.36) [2.36%]	604 (5.63) [5.2%]	160 (6.49) [6.49%]	429 (17.4) [17.15%]	413 (16.75) [15.45%]	36 (9.6) [9.87%]	115 (30.67) [29.87%]	98 (26.13) [23.47%]
Same antibiotic as supplied at pharmacist consult	73 (0.68) [0.69%]	26 (0.24) [0.25%]	41 (0.38) [0.36%]	29 (1.18) [1.22%]	23 (0.93) [0.97%]	22 (0.89) [0.85%]	9 (2.4) [2.67%]	5 (1.33) [1.6%]	17 (4.53) [3.73%]
Different antibiotic to that supplied at pharmacist conult	55 (0.51) [0.52%]	70 (0.65) [0.66%]	189 (1.76) [1.73%]	35 (1.42) [1.46%]	96 (3.89) [3.93%]	82 (3.33) [3.33%]	5 (1.33) [1.6%]	17 (4.53) [4.8%]	11 (2.93) [2.93%]

	Complete symptom resolution (n=11,221)			Improved but not resolved symptoms (n=2,581)			Not improved or worsening of symptoms (n=392)		
Outcome	**Number of events (per 100 people) [percent of participants][1]**			**Number of events (per 100 people) [percent of participants][1]**			**Number of events (per 100 people) [percent of participants][1]**		
	0–2 days	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**	**0–2 days**	**3–6 days**	**7–28 days**
New antibiotic and not supplied an antibiotic at pharmacist consult	112 (1.04) [1.05%]	157 (1.46) [1.47%]	374 (3.49) [3.32%]	96 (3.89) [3.93%]	310 (12.57) [12.49%]	309 (12.53) [11.8%]	22 (5.87) [6.13%]	93 (24.8) [25.07%]	70 (18.67) [17.87%]
Antibiotic not from management protocol	62 (0.58) [0.57%]	87 (0.81) [0.8%]	420 (3.92) [3.64%]	35 (1.42) [1.46%]	80 (3.24) [3.24%]	199 (8.07) [7.42%]	9 (2.4) [2.67%]	26 (6.93) [7.2%]	63 (16.8) [14.13%]
Hospital utilisation[5]	**NSW Health data available for 10,739 people**			**NSW Health data available for 2,470 people**			**NSW Health data available for 375 people**		
All-cause hospitalisations	18 (0.17) [0.17%]	20 (0.19) [0.18%]	60 (0.56) [0.52%]	10 (0.4) [0.4%]	8 (0.32) [0.32%]	24 (0.97) [0.93%]	1 (0.27) [0.27%]	12 (3.2) [3.2%]	11 (2.93) [2.93%]
Potentially preventable hospitalisations	5 (0.05) [0.06%]	4 (0.04) [0.05%]	7 (0.07) [0.07%]	6 (0.24) [0.28%]	5 (0.2) [0.24%]	8 (0.32) [0.36%]	0 (0) [0.27%]	10 (2.67) [2.93%]	2 (0.53) [0.8%]
Potentially preventable hospitalisations related to genito-urinary conditions	5 (0.05) [0.06%]	3 (0.03) [0.04%]	4 (0.04) [0.05%]	6 (0.24) [0.28%]	5 (0.2) [0.24%]	7 (0.28) [0.32%]	0 (0) [0.27%]	10 (2.67) [2.93%]	2 (0.53) [0.8%]
Acute hospital admissions	18 (0.17) [0.17%]	20 (0.19) [0.18%]	58 (0.54) [0.51%]	10 (0.4) [0.4%]	8 (0.32) [0.32%]	24 (0.97) [0.93%]	1 (0.27) [0.27%]	12 (3.2) [3.2%]	11 (2.93) [2.93%]
Emergency department presentations[6]	100 (0.93) [0.92%]	56 (0.52) [0.51%]	187 (1.74) [1.46%]	52 (2.11) [2.02%]	42 (1.7) [1.54%]	82 (3.32) [2.63%]	11 (2.93) [2.4%]	34 (9.07) [8.8%]	29 (7.73) [5.87%]
Emergency department presentations for triage 3–5 conditions	95 (0.88) [0.88%]	48 (0.45) [0.45%]	165 (1.54) [1.32%]	49 (1.98) [1.94%]	39 (1.58) [1.46%]	76 (3.08) [2.47%]	10 (2.67) [2.4%]	32 (8.53) [8.53%]	25 (6.67) [5.07%]
Emergency department presentations for genito-urinary conditions	41 (0.38) [0.39%]	13 (0.12) [0.13%]	26 (0.24) [0.22%]	26 (1.05) [1.05%]	19 (0.77) [0.77%]	19 (0.77) [0.73%]	7 (1.87) [2.13%]	19 (5.07) [5.33%]	6 (1.6) [1.87%]
Emergency department presentations for genito-urinary conditions that were admitted to ward	8	1	4	3	2	4	0	9	2

Notes

1. *Denominator varies depending on dataset used*
2. *We are not able to determine exact MBS and PBS numbers by referral status, and these were estimated based on the expected proportions*
3. *Any medications recorded in PBS data on the same day as the pharmacy visit were excluded from the count*
4. *Trimethoprim, cephalexin, nitrofurantoin*
5. *Data were not available for ACT participants at the time of writing this report*
6. *Includes multiple emergency department presentations per person*

Appendix 4.5 – Re-presentation

To perform the analysis for Scenario 2 (initial presentation and re-presentation), we applied rates gathered from both the trial data results and the literature.

Bootstrapping performed with ~137,520 participants allocated to either the Pre-PATH-UTI or w/PATH-UTI trial arm. In the bootstrap simulation, 5,000 random samples of cost-effect pairs were selected with replacements from the original generated dataset.

Using the self-reported data from the PATH-UTI trial the proportion of women that sought another healthcare professional (re-presentation) in the 7-day follow-up period was estimated at 16.4% (see Table 4-5-1). The 'Proportion seeking treatment (resolved)' was estimated at 60% of the estimated proportion who re-present. Likewise, the remaining 40% of the estimated proportion re-presenting were assigned to women in the 'Unresolved' group.

Due to the granularity of the pathway probabilities, we were unable to further refine this proportion by the categories 'Improved, but not completely resolved' and 'Not improved or worsened'.

The average cost for accessing another healthcare professional in the 7-day period (re-presentation) was adapted from the trial data. The responses to the self-report survey question 'Another healthcare professional seen for the same symptoms in the last 7 days' was used as a guide to calculate an average cost of re-presentation ($104.27) per patient.

Table 4-5-1 Number of women who re-present

			With pharmacy (PATH-UTI)				
Healthcare provider	**Resolved**	**Unresolved**	**Re-present – Resolved (N) (60.9%)**	**Re-present – Unresolved (N) (39.1%)**	**Re-presentation Treatment (N)**	**Estimated proportion to re-present**	**Reference**
Conservative management	3,933	2,310	425	166	591	18%	[280]
Emergency department	11,544	2,495	831	120	951	12%	[281]
General practitioner online pathway	2,112	505	152	24	176	12%	[281]
General practitioner	69,930	21,922	5,035	1,052	6,087	12%	[281]
Pharmacy pathway	14,706	3,392	1,471	217	1,688	16.40%	PATH-UTI Trial
Urgent care clinic	3,851	820	277	39	317	12%	[281]
Subtotal	10,6076	31,444			9810		
Overall total		**137,520**					

Without pharmacy (Pre- PATH-UTI)							
Healthcare provider	**Resolved**	**Unresolved**	**Re-present – Resolved (N) (60.9%)**	**Re-present – Unresolved (N) (39.1%)**	**Re-presentation Treatment (N)**	**Estimated proportion to re-present**	**Reference**
Conservative management	4,505	2,645	487	190	677	18%	[280]
Emergency department	13,780	2,979	992	143	1,135	12%	[281]
General practitioner online pathway	2,444	583	176	28	204	12%	[281]
General practitioner	80,189	25,136	5,774	1,207	6,980	12%	[281]
Pharmacy pathway	0	0	0	0	0	16.40%	PATH-UTI
Urgent care clinic	4,304	916	310	44	354	12%	[281]
Subtotal	105,222	32,259			9,350		
Overall total		**137,481**					

Chapter 5

Appendix 5.1 – Practice Change Facilitators (PCF) checklist for the identification and evaluation of implementation determinants

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UTI, OC and DERM Main Study PCF Checklist

Pharmacy Name	
Pharmacy Category	☐0-1 ☐2-5 ☐6-12 ☐12+
Consultation Rate and Response	Does this pharmacy have >5 consultations with 0% response rate? ☐ Yes ☐ No
Date of Visit	

Consultation room checklist- NSW UTI, OC and Skin Trials

Consult room	Met *(Yes/No)*	Additional Measures that need to be taken prior to service commencement *(N/A or stipulate change required)*
Mandatory requirements		
Must not be used as a dispensary, storeroom, staff room or retail area		
Must provide adequate privacy		
Must have adequate lighting		
Must be maintained at a comfortable ambient temperature		
Must have a hand sanitisation facility		
Must have ready access to a hand washing facility		
Must have sufficient floor area		
Must ensure the area is clear of equipment and furniture to accommodate the person receiving the consultation and an accompanying person		
Must ensure area allows the pharmacist adequate space to manoeuvre		

Background information:

		Answer	CFIR Factor[1]
1	**Does the consultation room comply with the NSW Health Authority for the UTI, OC and Skin Trial?** *If no, please take photos of different aspects (position in pharmacy and consult area) and attach to form.*	☐Yes ☐No	Inner Setting -> Structural Characteristics -> Physical infrastructure
2	**Confirm the pharmacy has MedAdvisor operating for both UTI, OC and Skin**	☐Yes ☐No	Inner Setting -> Structural Characteristics -> IT Infrastructure
3	**Does the pharmacist have any issues operating MedAdvisor?** – *If yes, please specify.*	☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability
4	**Has the old QR Code been replaced with the new QR code and is it visible?**	☐Yes ☐No	Inner Setting -> Available resources -> Materials & Equipment
5	**Have you confirmed the pharmacist understands the e-consent process? (Patient scans QR Code, consents and is sent a verification code that must be entered in MedAdvisor)**	☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability
6	**Is the pharmacy offering the services during all operating hours?** *If no, why is this?*	☐Yes ☐No	Implementation Process -> Engaging -> Innovation Recipients
7	**Have all pharmacists participating in the UTI, OC and DERM trial at the pharmacy completed the required training modules? (UTI/OC/DERM Module PSA or ACP AND UoN education modules required)** - UTI Module – PSA OR ACP - UoN education modules (UTI)	☐Yes ☐No ☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability

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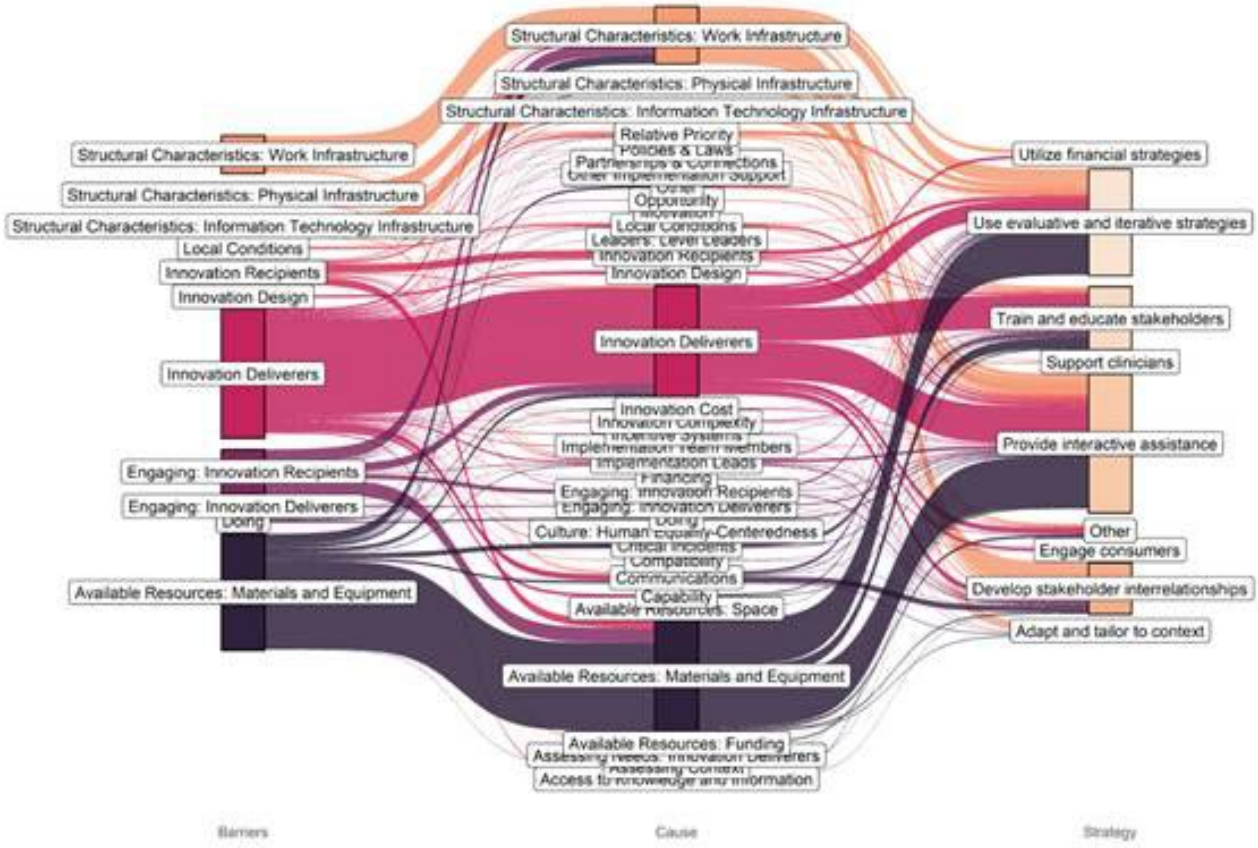
	- OC Module – PSA OR ACP - UoN education modules (OC) - DERM Module- PSA OR ACP - UoN education modules (DERM) *If no, please inform that pharmacist immediately that they are not permitted to deliver the service until they have completed the required training.*	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No	

	Please record the name of the pharmacist(s) who have completed the required training (certificates cited):	Name of Pharmacist(s)	Certificate cited		
			UTI	OC	DERM

8	**Service Delivery Fidelity** Internal info only. DO NOT share any trial data on consultations or response rates. ☐ UTI ☐ OC ☐ DERM	
	Review consultation process Does the pharmacist use appropriate counselling techniques to determine patient eligibility (e.g., open ended questions)?	☐Yes ☐No
	Application of the Clinical Management Protocol Does the pharmacist follow the clinical management protocol? Checking for allergies to antimicrobials? Discussing symptom improvement within 48hr and referral/follow-up?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
	Patient instructions and counselling Does the pharmacist communicate the consultation with the patients GP? *If yes, please select option.*	☐Yes ☐No ☐ Letter printed (patient) ☐Email ☐Fax ☐Other
	Does the pharmacist remind the patient of the 7 day follow up survey?	☐Yes ☐No
9	**General observations/other notes have you made, i.e., *Have you identified any other barriers/facilitators?* if yes, please specify and record in REDCAP implementation database.**	☐Yes ☐No

Appendix 5.2 – Sankey diagrams to link implementation barriers and strategies that solved them during the 10 months of the study

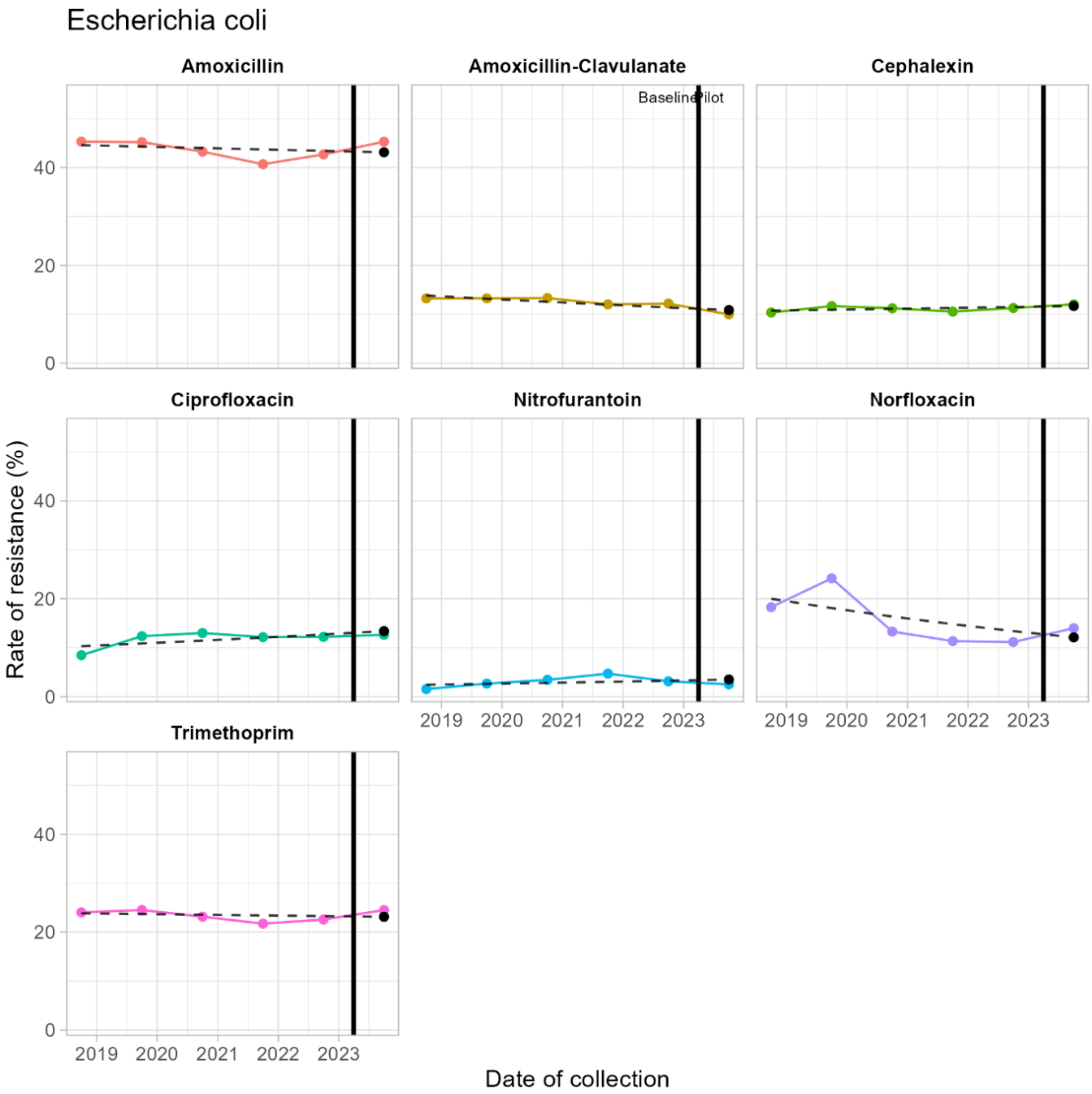


Chapter 6

Appendix 6.1 – Information about exclusions made on the study sample

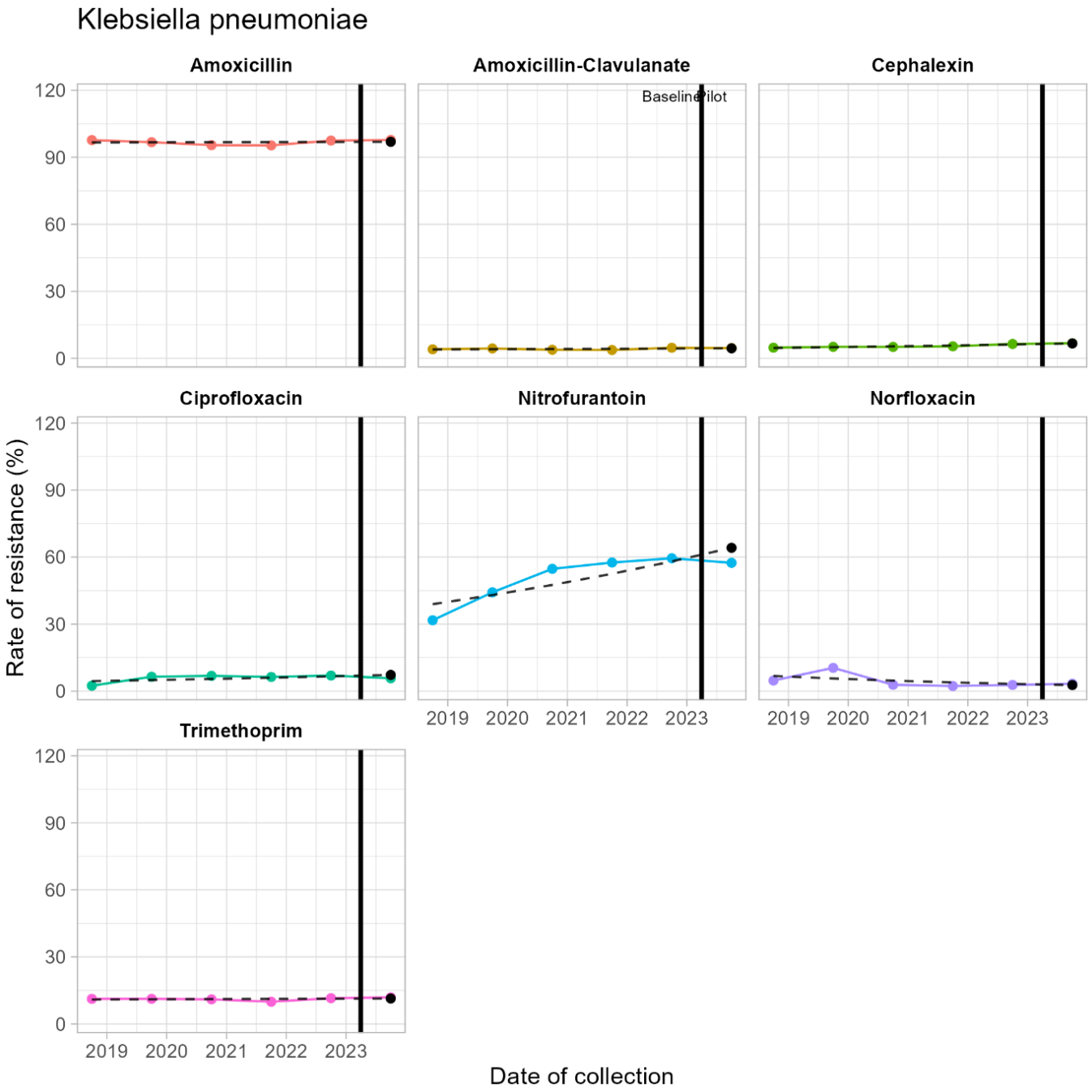
Data included	Reason for exclusion	Number of samples	Samples excluded
Original		849,933	
	Invalid test result		17
	Drug not in inclusion criteria		240,662
	Organism not in inclusion criteria		173,623
	<18 years of Age		48,394
	Postal Area not in NSW		28,201
Final		**599,046**	

Appendix 6.2 – Rates of resistance by organism and drug



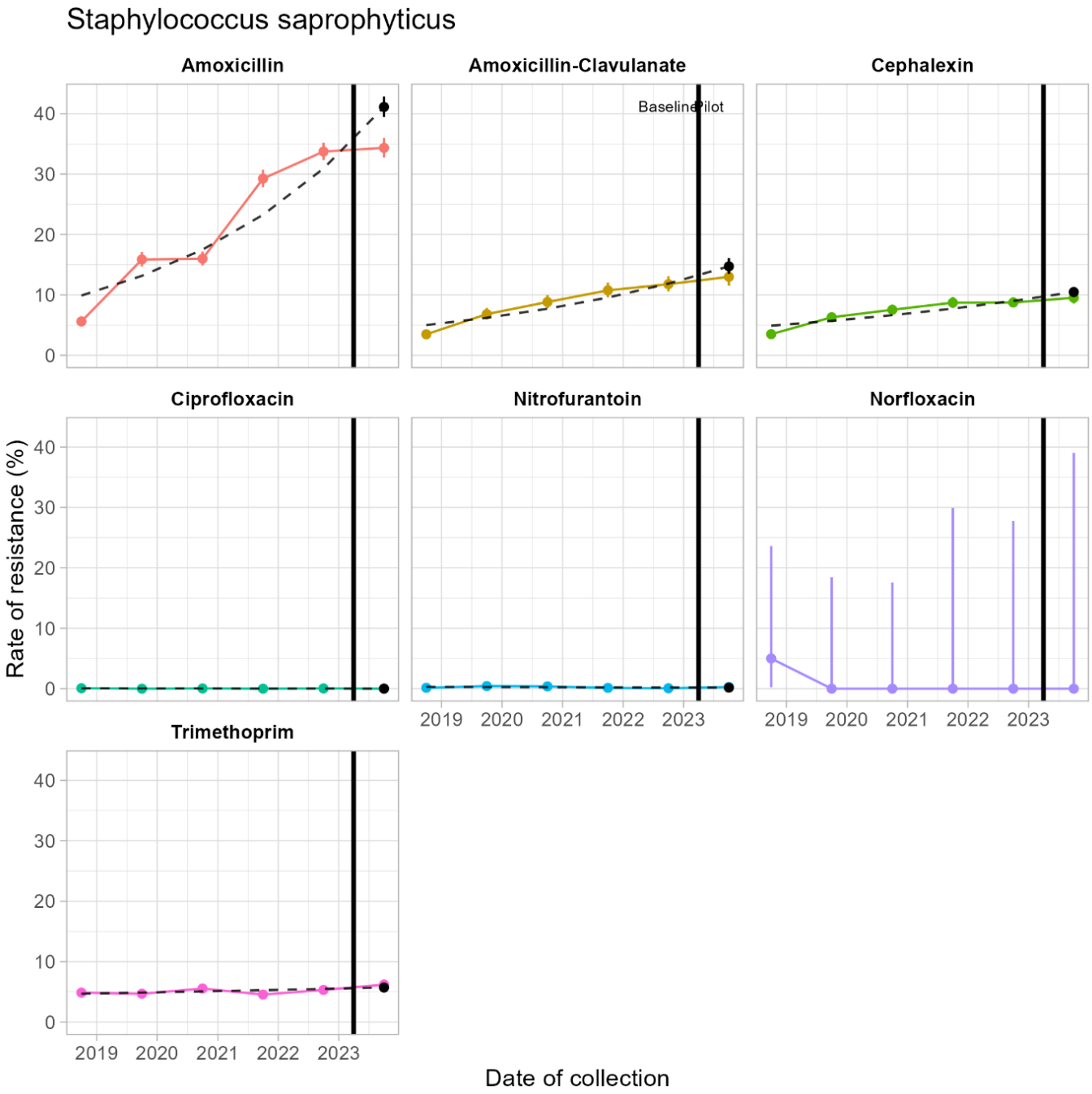
Appendix Figure 6.2.1: Rate of resistance in *Escherichia coli* by drug

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



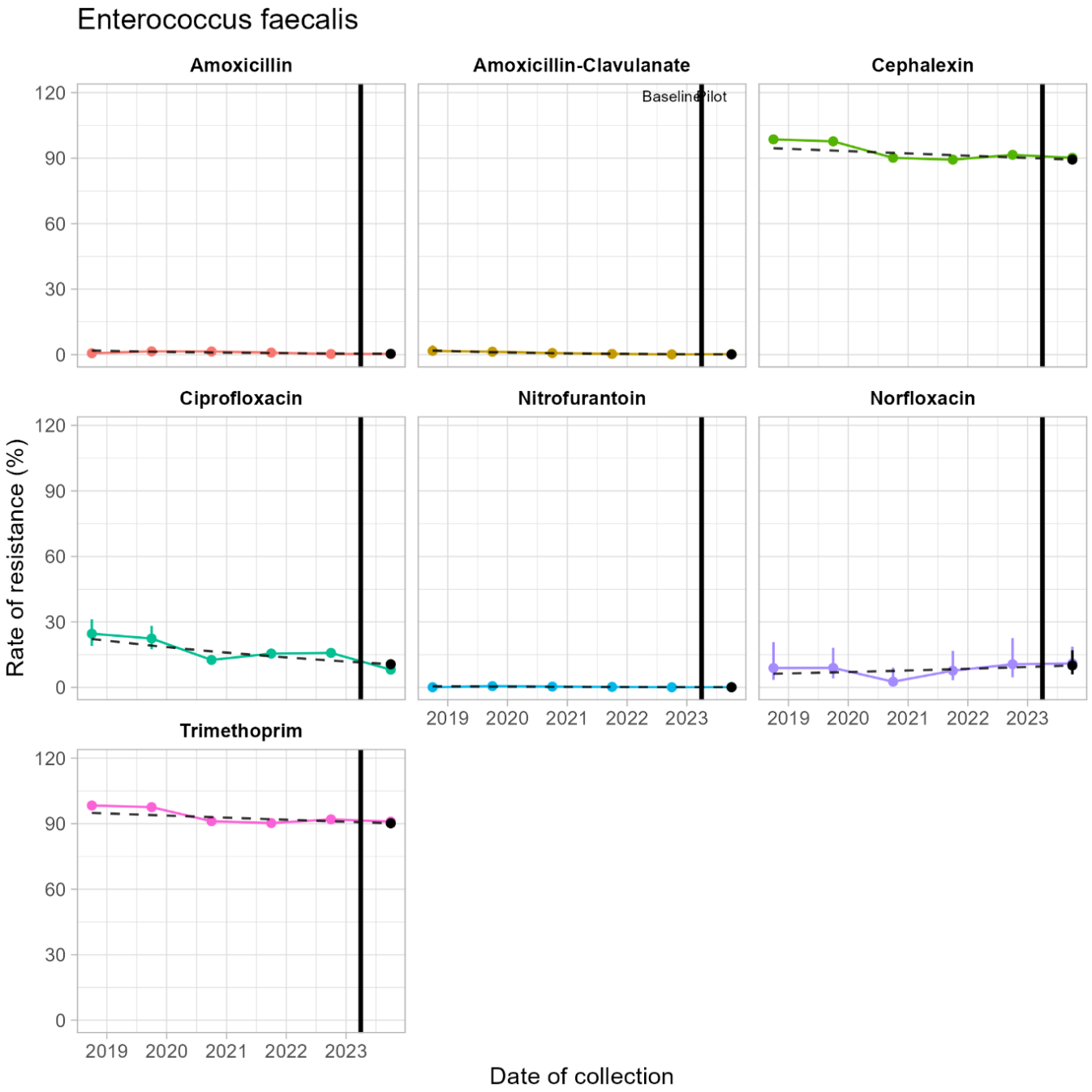
Appendix Figure 6.2.2: Rate of resistance in *Klebsiella pneumoniae* by drug

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



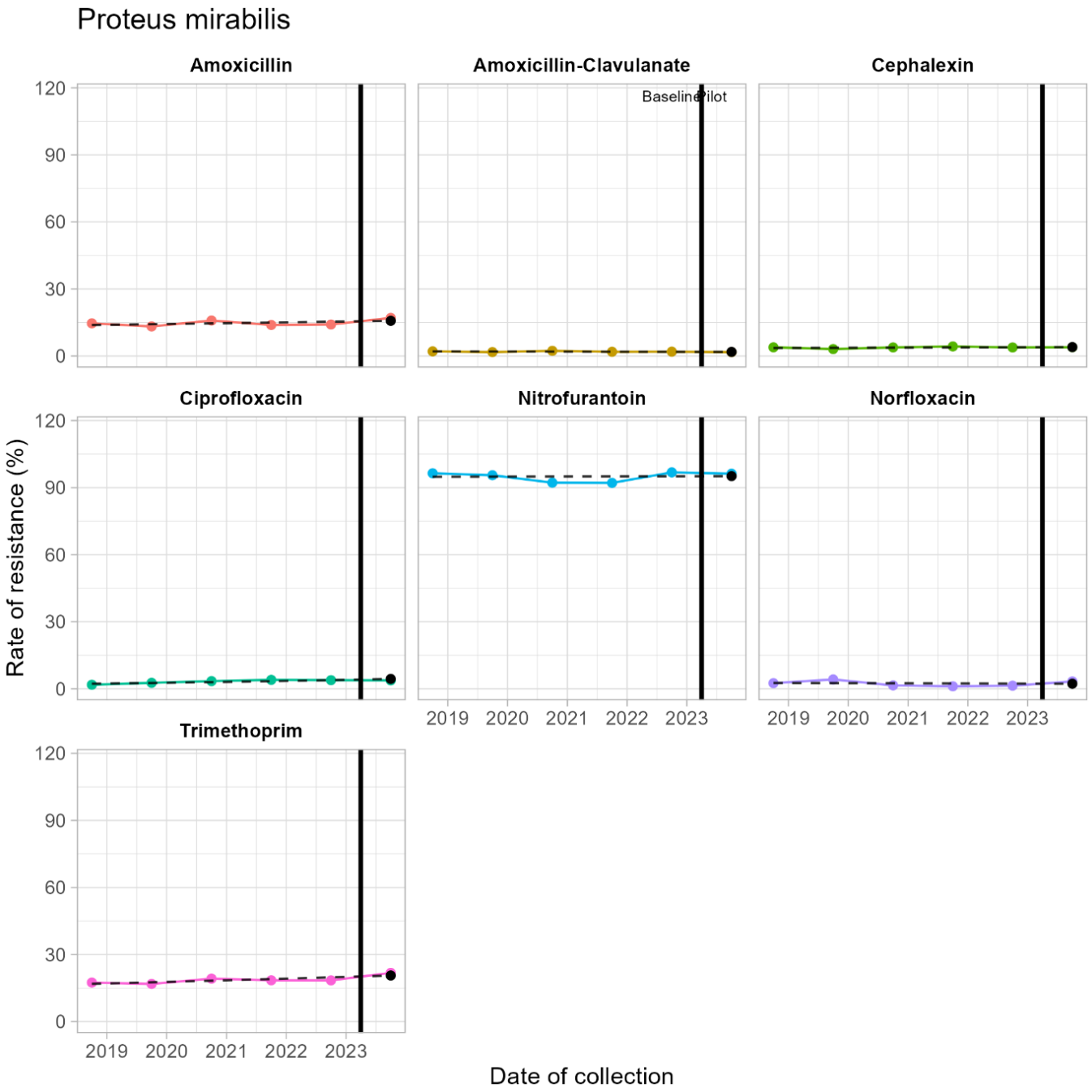
Appendix Figure 6.2.3: Rate of resistance in *Staphylococcus saprophyticus* by drug

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



Appendix Figure 6.2.4: Rate of resistance in *Enterococcus faecalis* by drug

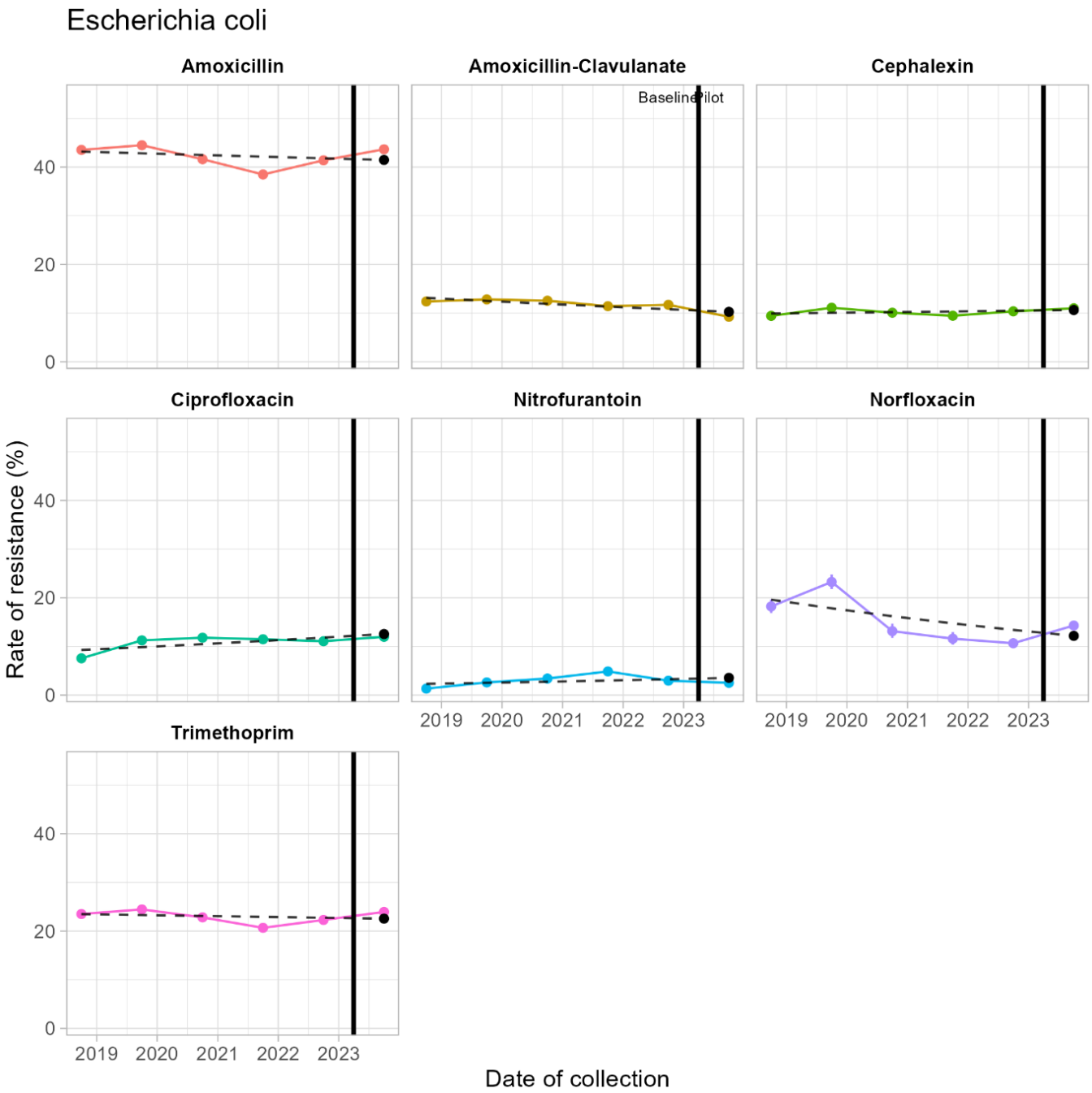
Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



Appendix Figure 6.2.5: Rate of resistance in *Proteus mirabilis* by drug

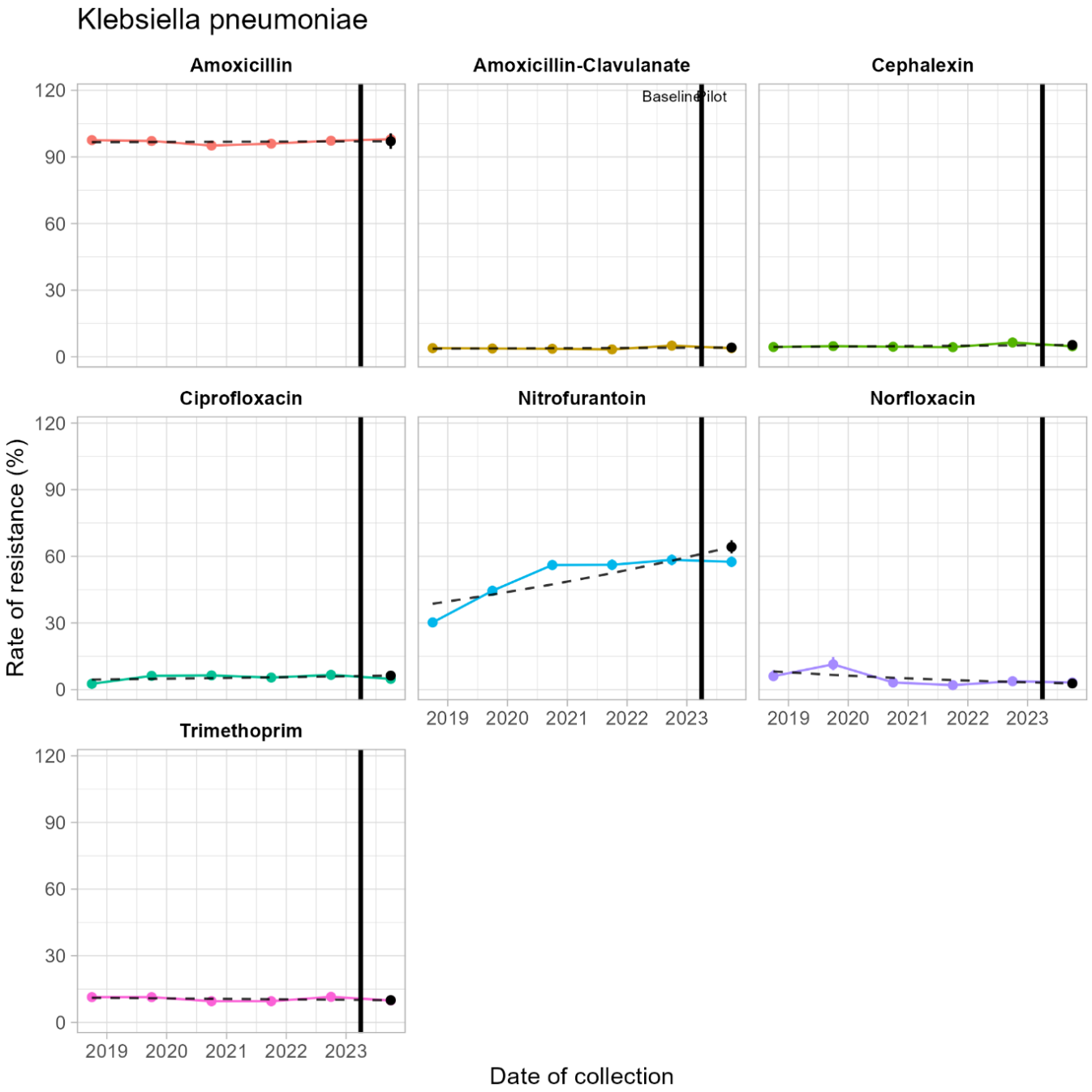
Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)

Appendix 6.3 – Rates of resistance by organism and drug, results from postal areas with pharmacy participating in the trial



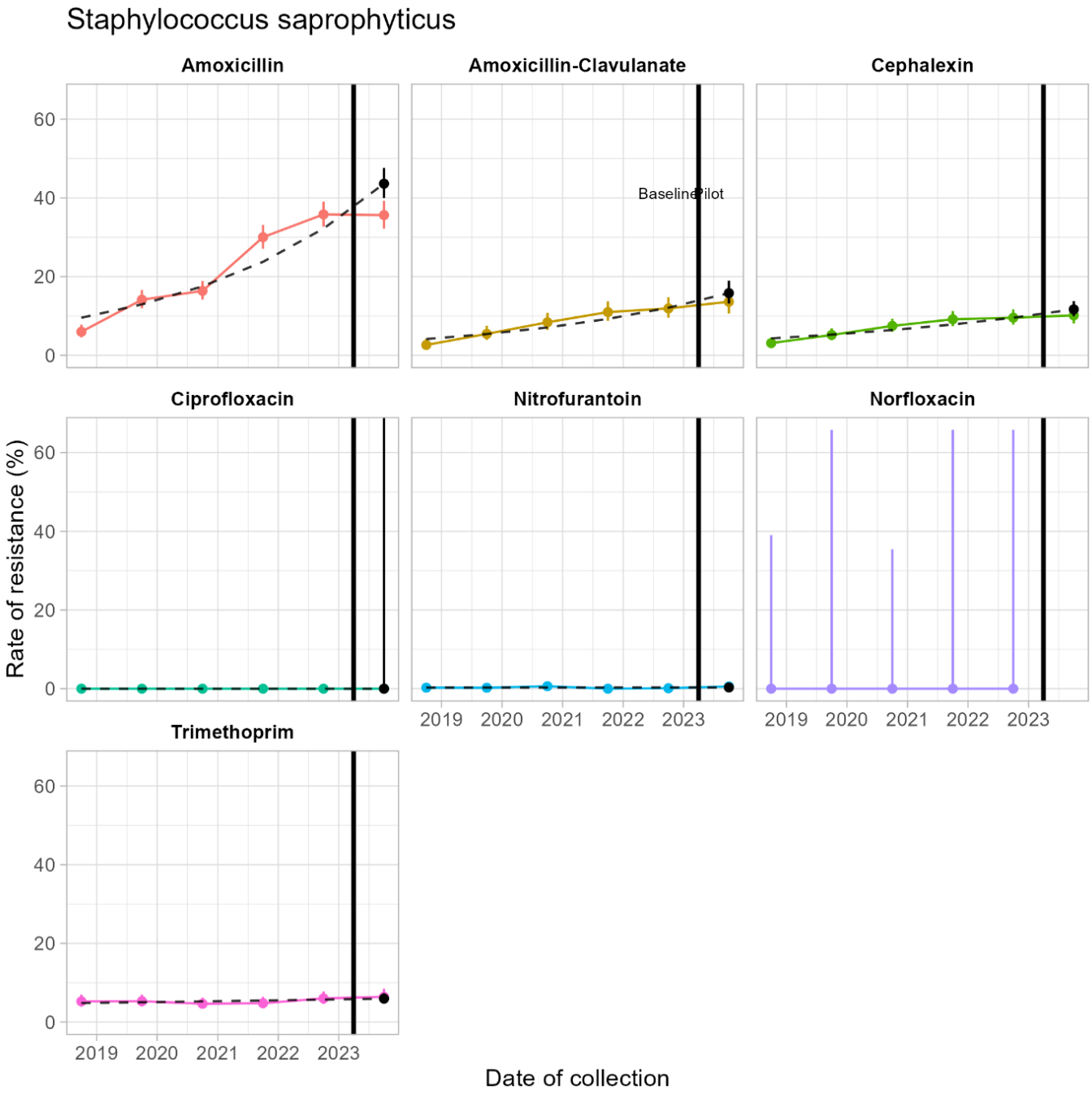
Appendix Figure 6.3.1: Rate of resistance in *Escherichia coli* by drug (in postal areas with pharmacy participating in the trial)

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



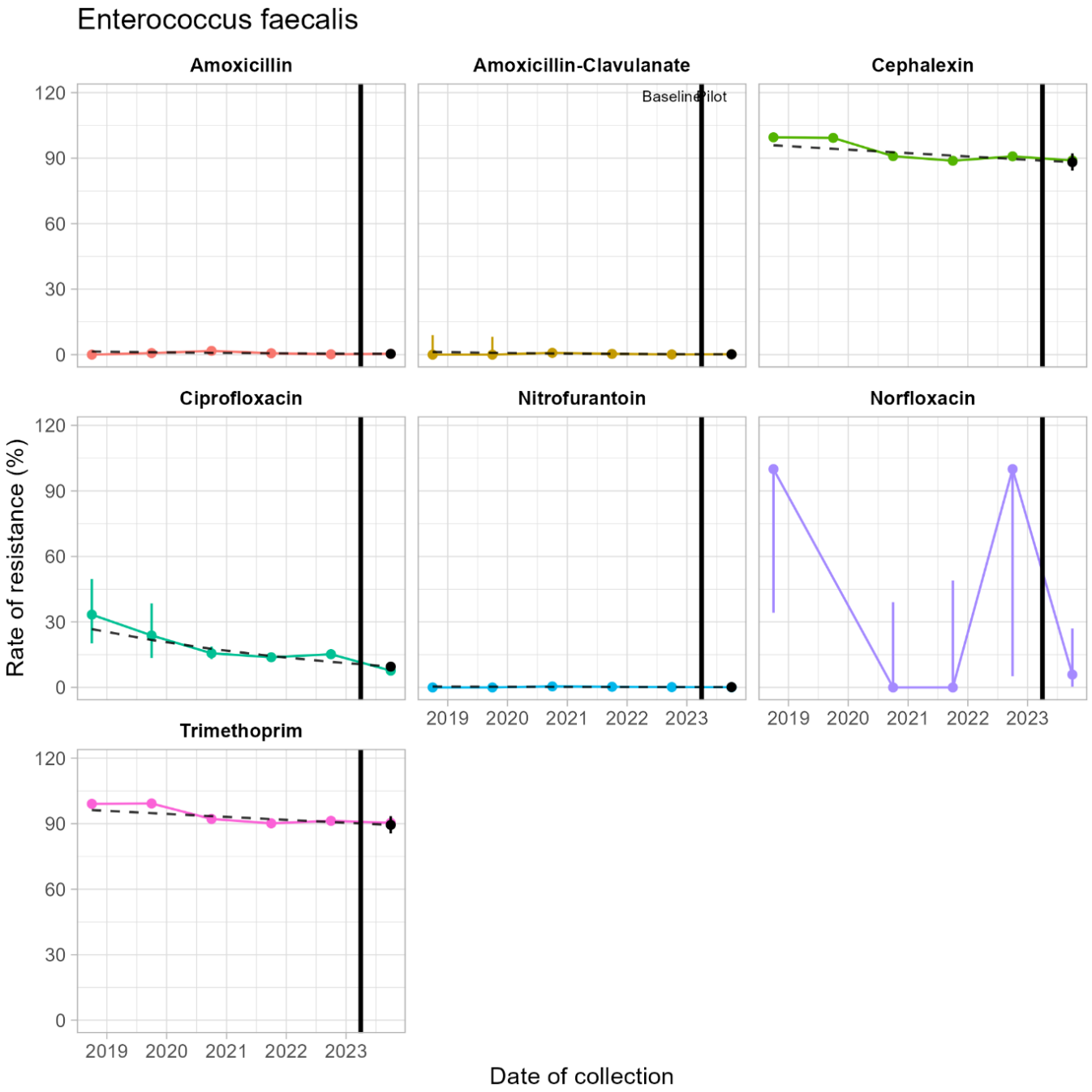
Appendix Figure 6.3.2: Rate of resistance in *Klebsiella pneumoniae* by drug (in postal areas with pharmacy participating in the trial)

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



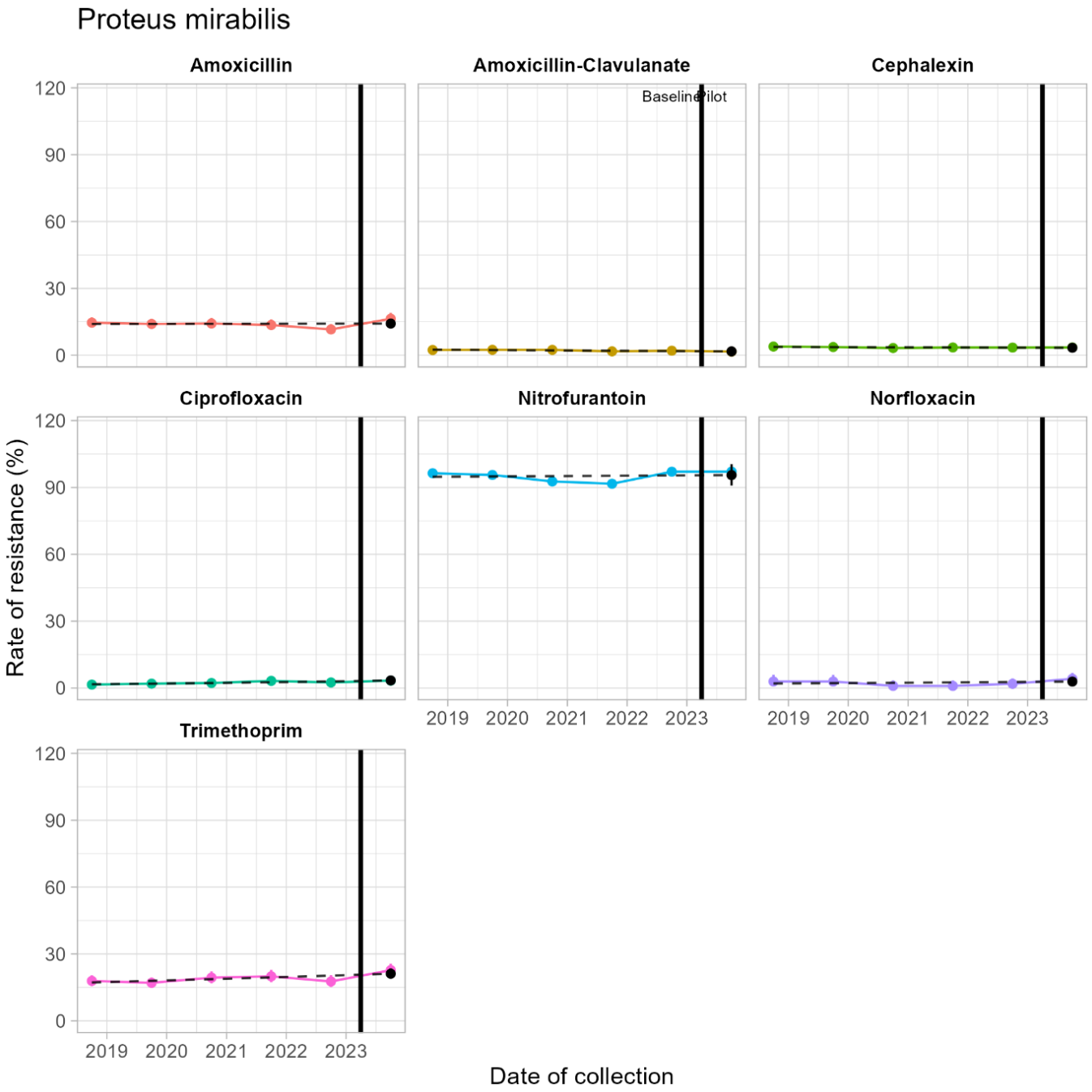
Appendix Figure 6.3.3: Rate of resistance in *Staphylococcus saprophyticus* by drug (in postal areas with pharmacy participating in the trial)

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



Appendix Figure 6.3.4: Rate of resistance in *Enterococcus faecalis* by drug (in postal areas with pharmacy participating in the trial)

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)



Appendix Figure 6.3.5: Rate of resistance in *Proteus mirabilis* by drug (in postal areas with pharmacy participating in the trial)

Coloured solid lines and dots represent observed AMR rate (with whiskers showing 95% confidence intervals). Dotted lines show the fit of the model used to project the counterfactual rate in the 2023 period (black dot)

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