University Human Research Ethics Committee (UHREC)

# APPLICATION FOR REVIEW OF NEGLIGIBLE / LOW RISK RESEARCH INVOLVING HUMAN PARTICIPANTS

May 2019

**NOTE**
- *All answers should be written **in simple and non-technical language** that can be **easily understood by the lay reader**.*
- *You must provide an answer to each questions – **N/A is not acceptable**.*

## SECTION A: RESEARCH PROPOSAL OVERVIEW

### A1 Summary Information

**A1.1 Project title** (200 character limit including spaces)

Evaluation of the prescribing pilot: Urinary Tract Infection Pharmacy Pilot-Queensland (UTIPP-Q)

**A1.2 Brief project summary in LAY LANGUAGE**

(i.e. in plain English and ensure when using acronyms you spell them out in the first instance)

The aim is to evaluate the benefits of suitably trained registered pharmacists treating uncomplicated urinary tract infections (UTIs) in the community pharmacy setting i.e. the prescribing pilot run as the Urinary Tract Infection Pharmacy Pilot-Queensland (UTIPP-Q).

The UTIPP-Q in its entirety consists of two components: 1) a clinical service component i.e. NOT research, and 2) a research evaluation of the clinical service provision using non-identifiable clinical records, and an anonymous clinical service evaluation survey (completed by the patient) i.e. research (Appendix 1).

The UTIPP-Q steering advisory group has also identified and highlighted the value of an additional research component - seeking pharmacists' experiences and opinions about their involvement with delivering the UTI service in UTIPP-Q, through an online survey.

- Upon completion of the survey, participants are asked if they would be happy to be contacted for a short semi-structured interview via telephone or other online medium to provide more information and feedback about their participation in UTIPP-Q. If they select yes, they are then redirected to another survey where they can enter their email address to ensure that the email contact cannot be linked back to the survey response.
- An amendment for conducting the semi-structured interviews will be submitted after the survey results are analysed to identify where further in-depth exploration of themes will be of value.

The **clinical service** component includes:

- Recruitment of patients when they present to the pharmacy with symptoms of a urinary tract infection (UTI). Pharmacists will explain the prescribing pilot to the patients, and answer any questions they might have about the clinical service.
- Pharmacists consult with the patient and makes a clinical decision about the care they will provide i.e. prescribe and supply an appropriate antibiotic if the symptoms are indicative of an uncomplicated UTI, *vs* referral to a general practitioner (GP) if patient symptoms are suggestive of a complicated UTI, or another condition that is beyond the scope of practice for a pharmacist.
- The pharmacist will follow-up with the patient by telephone, one-week after the initial interaction to complete the episode of care and clinical record. This follow up will differ depending on the treatment provided by the pharmacist i.e. supply of antibiotic *vs* referral.
  - Participants who were prescribed and supplied antibiotic treatment by the pharmacist will be asked about the outcomes of their treatment, and whether they needed to seek further advice from any other healthcare professional.
  - Participants who were NOT prescribed and supplied antibiotic treatment by the pharmacist and were referred to a GP will be asked about when they got an appointment to see the GP, and what treatment they received, if any.

**As a part of standard care and standard work practices, the pharmacist will create a clinical record

to document both the episode of care and telephone follow-up provided to the patient using the proprietary software - GuildCare. GuildCare is used in community pharmacies to record episodes of care. As per standard care provided in a pharmacy, these GuildCare clinical records will contain identifiable information i.e. name, address, phone number, and email; and these pharmacist-patient interactions will not be audio recorded.

The proprietors of the GuildCare software can interrogate the database and only elicit the non-identifiable components of the clinical records of patients who have consented to participate in the research. This is exported as an Excel spreadsheet. The proprietors of the GuildCare will be instructed to check and ensure that all identifiable patient information i.e. name, address, phone number, and email is removed from the spreadsheet before it is provided to the research team (Appendix 1).

The **research evaluation** component includes:

- Inviting patients who elect to take up the clinical service component of the UTIPP-Q to also participate in the research evaluation component.
- The pharmacist providing information about the research evaluation (participant information sheet) to the patient, and answer any questions they might have about the research evaluation.
- The pharmacist will record the patient consent in GuildCare on behalf of the research team.
- For patients who agree to be participants, they will be consenting that the following data (i.e. the non-identifiable components of the GuildCare clinical records related to the UTIPP-Q) be provided to the research team to evaluate the service:-
    - their **non-identifiable** data related to the UTI treatment and other resources provided e.g. self-care tips, pamphlets provided by the pharmacist. This also includes the "screening questions": gender, age, occupation (not mandatory), and "eligibility criteria" which includes determining if presenting symptoms are indicative of a complicated vs uncomplicated UTI, or whether it might be another condition: presenting symptoms, vaginal & systemic symptoms, pregnancy, sexually transmitted infection risk, UTI history / recurrent UTI, co-morbidities, immunosuppressants, travel to developing country, blood disorder/porphyria.
    - their **non-identifiable** data related to the one-week telephone follow-up provided by the pharmacist. During this interaction, the pharmacist will confirm whether the patient/primary research participant still consents for their non-identifiable data to be used as part of the research evaluation. Follow up questions for participants who were prescribed and supplied antibiotic treatment by the pharmacist will be asked about the outcomes of their treatment, and whether they needed to seek further advice from any other healthcare professional. Participants who were NOT prescribed and supplied antibiotic treatment by the pharmacist and were referred to a GP will be asked about when they got an appointment to see the GP, and what treatment they received, if any.
- A clinical service evaluation survey: At the one-week telephone follow-up, the patients will also be asked whether they consent to the pharmacist emailing a link to the service evaluation survey to them to complete in their own time. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email. The service evaluation survey is anonymous, and consists of 5 questions which will take less than 2-3 minutes to complete. If the patient agrees to receive this link, the pharmacist will email the link to them via GuildCare. Examples of questions include: overall, how satisfied are you with the service you received?, if this service was not available, where would you have got advice / treatment for your symptoms?, Would you recommend this service to others?

- Pharmacist evaluation survey: The pharmacists who are registered and consented to participate in UTIPP-Q will be invited to complete an online survey about their participation in the pilot. The survey will collect demographic information about the pharmacist themselves, the community pharmacy (UTIPP-Q site), their experience with delivering the service, and the training modules related to the pilot. The survey contains up to 49 questions (depending on the branching and options), and will take approximately 15 minutes to complete. Examples of questions include: When did you start participating in UTIPP-Q?; Is the community pharmacy part of a banner group?; What made it difficult / challenging to deliver the UTI service?; Based on patient response/feedback to the UTI service, the main reason(s) patients sought this service from you (the pharmacist) was because …. (please select all that apply); Please rate your overall satisfaction with the training module.

NB: The pharmacists registered in delivering UTI services as part of UTIPP-Q were originally deemed to be secondary research participants due to the role they played in 1) inviting patients to participate in the research evaluation, providing information about the UTIPP-Q and its research evaluation, and answering any questions, and 2) seeking and recording consent (via GuildCare) from the patient participants for their data to be provided to the research team in a non-identifiable format for analysis.

**Patients can receive clinical treatment and advice as a part of the UTIPP-Q i.e. the clinical service component, WITHOUT agreeing to the contribution of non-identifiable data to the research evaluation.

** The research project is the evaluation of the UTIPP-Q using non-identifiable patient records completed by a pharmacist, and the anonymous clinical service evaluation survey. The enrolment of patients, treatment including the prescribing and supply of the antibiotic, one-week telephone follow-up, and documenting the details related to the episode of care i.e. the clinical aspect is NOT for QUT's research purposes.

**A1.3 Provide an overview of your <u>research participants and their involvement</u>** (max 250 words)

The purpose of this question is to gain a sense of who the participants will be, and what you expect them to do within the research.

<u>Primary research participants</u>

People presenting to community pharmacies with symptoms of an UTI for treatment by a pharmacist, who are also over 18 years of age, and able to give informed consent. These people when opting to take up the clinical service provided by the pharmacist, will also be invited to participate in the research evaluation. Participating in the research evaluation includes agreeing for the GuildCare clinical record related to their episode of care i.e. UTI treatment and one-week telephone follow-up, to be provided to the research team in a non-identifiable format, and receiving a link via email, to an anonymous clinical service evaluation survey to complete in their own time. Therefore, participants will be recruited into the research evaluation opportunistically.

The non-identifiable data (see Appendix 1) will consist of the following from the UTIPP-Q GuildCare clinical record: screening questions, eligibility criteria for treatment, treatment supplied, other resources provided e.g. self-care tips, pamphlets, and one-week telephone follow-up e.g. did the treatment work, did they need to seek further advice from another healthcare professional.

**The enrolment of patients, treatment, telephone follow-up, and documentation of the required details relating to the episode of care into GuildCare i.e. clinical record, will take place in accordance with the clinical service component of the UTIPP-Q protocol. This aspect of care does

NOT form part of QUT's responsibilities.

Secondary research participants

Community pharmacists employed in pharmacies participating in UTIPP-Q will be invited to participate after they complete the approved course of training for UTIPP-Q on management of uncomplicated UTIs. Pharmacist participation includes 1) inviting patients to participate in the research evaluation, providing information about the UTIPP-Q and its research evaluation, and answering any questions, and 2) seeking and recording consent (via GuildCare) from the patient participants for their data to be provided to the research team in a non-identifiable format for analysis. When conducting the one-week telephone follow-up, the pharmacist will confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email.

- The UTIPP-Q steering advisory group has also identified and highlighted the value of an additional research component - seeking pharmacists' experiences and opinions about their involvement in delivering the UTI service in UTIPP-Q, through an online survey.Pharmacist evaluation survey: The pharmacists who are registered and consented to participate in UTIPP-Q will be invited to complete an online survey about their participation in the pilot. The survey will collect demographic information about the pharmacist themselves, the community pharmacy (UTIPP-Q site), their experience with delivering the service, and the training modules related to the pilot. The survey contains up to 49 questions (depending on the branching and options), and will take approximately 15 minutes to complete. Examples of questions include: When did you start participating in UTIPP-Q?; Is the community pharmacy part of a banner group?; What made it difficult / challenging to deliver the UTI service?; Based on patient response/feedback to the UTI service, the main reason(s) patients sought this service from you (the pharmacist) was because …. (please select all that apply); Please rate your overall satisfaction with the training module.

Pharmacy sites

Pharmacies participating in the UTIPP-Q will be invited to participate in the research evaluation as a study site, and provide permission for non-identifiable aspects of the UTIPP-Q GuildCare clinical records from consenting participants to be shared with the research team, and. It will also involve them agreeing for their pharmacists to:-

- Complete the approved course of training for the UTIPP-Q, and demonstrate an acceptable level of knowledge associated with the treatment of uncomplicated UTIs.
- Invite patients to participate in the research and provide information about the UTIPP-Q and its research evaluation, and answer any questions.
- Agree for the research team to use, and to share their contact details (phone number and email address) with Queensland Health for the purposes of communicating with them about the UTIPP-Q.
- Seek and record consent (via GuildCare software) from the patient participants for their data to be provided to the research team in a non-identifiable format for analysis, and to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email.

**As a part of standard care and standard work practices, the pharmacist will create a clinical record to document both the episode of care and telephone follow-up provided to the patient using the proprietary software - GuildCare. GuildCare is used in community pharmacies to record episodes of

care provided by pharmacists. As per standard care provided in a pharmacy, these GuildCare clinical records will contain identifiable information i.e. name, address, phone number, and email; and these pharmacist-patient interactions will not be audio recorded.

**The non-identifiable data (see Appendix 1) will consist of the following from the UTIPP-Q GuildCare clinical record: screening questions, eligibility criteria for treatment, treatment supplied, other resources provided e.g. self-care tips, pamphlets, and one-week telephone follow-up e.g. did the treatment work, did they need to seek further advice from another healthcare professional.

**A1.4 Provide a summary of the merits of this proposed research (in LAY LANGUAGE) including the aims / hypotheses / research questions** (refer to Section 1 of the National Statement, NS1.1, when preparing your response)**.**

- Include potential contributions to the body of knowledge and methodological rigor (max **250** words).Briefly provide evidence that the proposed research is based on knowledge of the relevant literature, and provide a list of key references.You are encouraged to attach a research plan / protocol which does not substitute for the summary above – this attachment should be no longer than **6** pages.**NOTE:** Unless proposed research has merit (and the researchers who are to carry out the research have integrity) the involvement of human participants in the research cannot be ethically justified.

UTIs are a common condition seen by GPs, with about 250,000 Australians developing a UTI each year.[1] UTIs occur more frequently in women than men, with 1 in 3 women and 1 in 20 men developing a UTI at some point in their lifetime.[2] UTIs may be classified as uncomplicated (occur in a structurally and functionally normal urinary tract), or complex (occur in an abnormal urinary tract or in the presence of other complicating factors).[3] The diagnosis of uncomplicated UTI is based primarily on history and symptoms of dysuria, urgency and frequency.[4-6]

In Australia, symptomatic treatments for UTIs that are available over the counter from community pharmacies include alkalinising agents, cranberry products and analgesia. Although alkalinising agents, for example, have typically been used to relieve the symptoms of UTI, there is little evidence to support the effectiveness of their use.[7]

On 3 May 2018, the Legislative Assembly referred to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee, an inquiry into the establishment of a pharmacy council and the transfer of pharmacy ownership in Queensland. One of the four key issues the Committee focused on was the benefits of extending the scope of practice for pharmacists and pharmacy assistants.

One of the Committee recommendations was that the Department of Health develop options to provide low-risk emergency and repeat prescriptions through pharmacies subject to a risk-minimisation framework. To address this recommendation, Queensland Health was tasked with developing, implementing and evaluating a state-wide trial of the management of UTIs by community pharmacists.[8] Several models of care have been developed which permit pharmacists to treat and supply antibiotics to patients with uncomplicated UTIs in international jurisdictions e.g. UK,[7,9] Canada,[10-11] and New Zealand.[12-13]

Following a review of relevant literature and existing models of care, it is proposed that the pilot "Urinary Tract Infection Pharmacy Pilot (UTIPP-Q) adopt the management of uncomplicated UTIs using best evidence antibiotic therapy. As a part of the UTIPP-Q, details of the clinical service provided will recorded. After one-week, the pharmacist will follow-up, via telephone, with the patient with regards to the outcomes of the treatment to complete the episode of care and clinical record in GuildCare. During this follow-up, the patient will also be asked to confirm whether they still consent to receiving via email, a link to the anonymous clinical service evaluation survey to complete in their own time. Once the consent to receiving the anonymous clinical service

evaluation survey is recorded, GuildCare will send the link to the patient's email. This anonymous survey consists of 5 questions, and is anticipated to take 2-3 mins to complete. Furthermore, per the UTIPP-Q protocol, pharmacy sites and pharmacists must participate in the evaluation of the outcomes in order to be enrolled in the UTIPP-Q. Accordingly, if pharmacy sites withdraw from the research evaluation, the pharmacists at this site will not be able to provide treatment for uncomplicated UTIs, even if the pharmacists have completed the relevant training. Similarly, if pharmacists withdraw from the research evaluation, they will not be able to continue providing treatment for uncomplicated UTIs.

Therefore, the aim is to evaluate the benefits of suitably trained registered pharmacists treating uncomplicated urinary tract infections (UTIs) in the community pharmacy setting by analysing GuildCare clinical records collected in the UTIPP-Q, and the anonymous service evaluation survey.

As this is a new role and service delivery for the profession, it is also of value to explore the experience and perceptions of the pharmacists involved in delivering this UTI service in UTIPP-Q. All pharmacists who have consented to participating in UTIPP-Q and its research evaluation will be emailed an invitation to complete an online survey that is anticipated to take 15 minutes to complete.

** The research evaluation of the UTIPP-Q uses the non-identifiable parts of GuildCare clinical records from consenting patients, which are completed by a pharmacist. The enrolment of patients, treatment, telephone follow-up, and documentation of the required details relating to the episode of care into GuildCare i.e. clinical record, will take place in accordance with the clinical service component of the UTIPP-Q protocol. This aspect of care does NOT form part of QUT's responsibilities (Appendix 1).

References

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8. Queensland Government. Queensland Government Response to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's Report No.12 - Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland. Brisbane, Queensland: The State of Queensland; 2019.
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11. Bhatia S, Simpson SH, Bungard T. Provincial Comparison of Pharmacist Prescribing in Canada Using Alberta's Model as the Reference Point. The Canadian journal of hospital pharmacy. 2017;70(5):349-57.
12. Gauld N. Improving access to urinary tract infection treatment: the reclassification of trimethoprim. J SelfCare. 2012;3(6):115-20.
13. 13. Gauld NJ, Zeng IS, Ikram RB, Thomas MG, Buetow SA. Treatment of uncomplicated cystitis: analysis of prescribing in New Zealand. The New Zealand medical journal. 2016;129(1437):55-63.

**A1.4 Has the scientific or academic merit of the research project been evaluated?**

**b** Review of the scientific or academic merit of the research project should be robust, formal and independent of the researcher team (i.e. typically by a competitive funding or other agency). Peer review of the protocol/proposal/research plan may have occurred at confirmation of candidature, or the researcher may have sought peer review from an independent expert. A template is in the kit for you to seek a peer review.

Prof Lisa Nissen chairs the consortium tasked with overseeing the UTIPP-Q. The consortium has reviewed the scientific and academic merit of the research evaluation. The consortium consists of academics from all Queensland pharmacy schools, and representatives from industry partners (Pharmacy Guild of Australia-Qld Branch, the Pharmaceutical Society of Australia-Qld Branch), and international research partners with New Zealand and Canada. The international research partners bring experience in implementation and evaluation of the pharmacist UTI management model in NZ and Canada respectively.

**A1.5 Why should this be considered a negligible OR low risk application?**

Refer to Section 2.1 of the National Statement when preparing your response and note that:

- 'Negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience (e.g. filling in a form, participating in a street survey, or giving up time to participate in research).
- 'Low risk research' describes research in which the only foreseeable risk is one of discomfort (e.g. minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview).
- Research in which the risk for participants is more serious than discomfort (e.g. where a person's reactions include pain or becoming distressed) the research cannot be considered low risk.

This research evaluation is considered low risk.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

There is no foreseeable risk of harm or discomfort to the primary research participants to give consent for the GuildCare clinical record related to their episode of care to be provided by the pharmacist, to the research team in a non-identifiable format. There is also no foreseeable risk of harm or discomfort to the primary research participants to give consent to receive via email, a link to the anonymous service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email. The patient can complete the anonymous service evaluation survey in their own time. The pharmacist and the research team will not know which patients did / did not complete the survey. The survey consists of 5 questions which will take less than 2-3 minutes to complete. Any foreseeable risk to the primary research participants is no more than inconvenience, to give up time to read and understand the participant information sheet, provide consent, and to complete the clinical service evaluation survey. The GuildCare clinical record related to their episode of care is documented by the pharmacist as a part of standard care and the UTIPP-Q.

However, it is acknowledged that some patients may experience some discomfort when discussing via telephone, the follow-up with pharmacists about the effectiveness of treatment e.g. if the prescribed treatment was not effective. Nevertheless, this is a part of standard care provided for

patients by pharmacists. It is important to point out that patients answering questions to this telephone follow-up is part of the clinical service component of UTIPP-Q, and is NOT the responsibility of QUT. When conducting the one-week telephone follow-up, the patient will be given the opportunity to confirm whether they still consent for their non-identifiable data to be used as part of the research evaluation.

The non-identifiable data (see Appendix 1) will consist of the following from the UTIPP-Q GuildCare clinical record: screening questions, eligibility criteria for treatment, treatment provided, other resources provided e.g. self-care tips, pamphlets, and one-week telephone follow-up e.g. did the treatment work, did they need to seek further advice from another healthcare professional.

Secondary research participants: Community pharmacists

There is no foreseeable risk of harm or discomfort to the secondary research participants. Any foreseeable risk would be no more than the inconvenience of giving up time to provide information about the UTIPP-Q, invite the primary research participants to participate in the research evaluation, answer any questions, record their consent, and indicate in GuildCare that the patient consents to receiving via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email.

However, it is acknowledged that some pharmacists may experience some discomfort when discussing the follow-up with patients via telephone, about the effectiveness of treatment e.g. if the prescribed treatment was not effective. Nevertheless, this is a part of standard care provided by pharmacists to patients. It is important to point out that pharmacists following-up on clinical care is part of standard care. Therefore, this telephone follow-up is a part of the clinical service component of the UTIPP-Q, and is NOT the responsibility of QUT. When conducting the one-week telephone follow-up, the pharmacist will confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation.

Pharmacist evaluation survey and semi-structured interview: There is no foreseeable risk of harm or discomfort to the pharmacist participants. Any foreseeable risk would be no more than the inconvenience of giving up time to complete an online survey (15 mins).

- The invitation to participate in the survey will be emailed directly to the pharmacist using the email they supplied for the purposes of receiving information about UTIPP-Q. Their decision to participate /not participate in the survey will not impact on their participation in the clinical and research evaluation aspects of UTIPP-Q. The pharmacy site and research team will not know whether the pharmacist does/does not complete the survey.

**The enrolment of patients, treatment, telephone follow-up, and documentation of the required details relating to the episode of care into GuildCare i.e. clinical record, will take place in accordance with the clinical service component of the UTIPP-Q protocol. This aspect of care does NOT form part of QUT's responsibilities.

Pharmacy site

There is no foreseeable risk of harm to the pharmacy site to participate in the research evaluation, and is a requirement of the UTIPP-Q protocol. The pharmacy site can withdraw from the research evaluation at any time. However, if they withdraw from the research evaluation, the pharmacists at the site will not be able to continue providing treatment for uncomplicated UTIs as a part of the UTIPP-Q.

## A2 Potential Risks and Benefits (refer to Section 2.1 of the National Statement when preparing your response)

**A2.1 Describe ALL the identified potential risks and who may be affected by these risks e.g.**

**researchers, participants, participant community and / or the wider community. Ensure all risks mentioned at A2.1 are addressed, and that the risks and their management are consistent throughout the application and are addressed where applicable in the Participant Information Sheet and Consent Form.**

When gauging the level of risk ensure you take into account:

- The kinds of harm, discomfort or inconvenience that may occur.
- The likelihood of these occurring.
- The severity of any harm that may occur.
- The choices, experience, perceptions, values and vulnerabilities of different populations of participants will also be relevant.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

The foreseeable risk of taking the time to read and understand the participant information sheet, provide consent via the pharmacist, and to complete the anonymous clinical service evaluation survey would be no more than inconvenience. Therefore, the risks are minimal. When conducting the one-week telephone follow-up, the patient will have the opportunity to confirm whether they still consent for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. The survey will consist of 5 questions, and take 2-3 minutes to complete. The patient would complete this survey in their own time. The pharmacist and research team will not know whether the patient did/did not complete the survey.

Secondary research participants: Community pharmacists

Any foreseeable risk would be no more than the inconvenience of giving up time to provide information about the UTIPP-Q, invite the primary research participants to participate in the research evaluation, answer any questions, and to record their consent. Therefore, the risks are minimal. Documenting patient details, details related to the episode of care, and follow up after an interaction constitutes standard care provided a pharmacist, and is a part of the clinical service component of the UTIPP-Q. When conducting the one-week telephone follow-up, the pharmacist will confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email. The survey will consist of 5 questions, and take 2-3 minutes to complete. The patient would complete this survey in their own time. The pharmacist and research team will not know whether the patient did/did not complete the survey.

Pharmacist evaluation survey: There is no foreseeable risk of harm or discomfort to the pharmacist participants. Any foreseeable risk would be no more than the inconvenience of giving up time to complete an online survey (15 mins).

- The invitation to participate in the survey will be emailed directly to the pharmacist using the email they supplied for the purposes of receiving information about UTIPP-Q. Their decision to participate /not participate in the survey will not impact on their participation in the clinical and research evaluation aspects of UTIPP-Q. The pharmacy site and research team will not know whether the pharmacist does/does not complete the survey.
- While the survey does not collect identifiable information, for some pharmacists who work as single pharmacists in very remote areas, it may be possible to potentially re-identify the pharmacist from the demographic information. However, the likelihood of this happening is extremely rare as the research team does not maintain a list of which pharmacists work in what locations. Pharmacists can move places of employment, or secure employment in different

pharmacies, and there is no central register anywhere which records or reports this information. Similarly, pharmacies can change locations, banner groups, opening hours etc at any time, and the research team has no way of knowing or sourcing this information.

- The pharmacist can choose to stop answering the survey questions at any time and withdraw from participating at any time up until they submit the survey. However, as no identifiable information is collected, the pharmacist will not be able to withdraw their participation after the survey is submitted.

**The enrolment of patients, treatment, telephone follow-up, and documentation of the required details relating to the episode of care into GuildCare i.e. clinical record, will take place in accordance with the clinical service component of the UTIPP-Q protocol. This aspect of care does NOT form part of QUT's responsibilities.

Pharmacy sites,
There is no foreseeable risk of harm to the pharmacy site to participate in the research evaluation, and is a requirement of the UTIPP-Q protocol. The pharmacy site can withdraw from the research evaluation at any time. However, if they withdraw from the research evaluation, the pharmacists at the site will not be able to continue providing treatment for uncomplicated UTIs as a part of the UTIPP-Q.

Participant community, Research team, Wider community
There are no anticipated risks associated with the research team reviewing non-identifiable data for the pharmacist site, participant community, research team, or wider community.

**A2.2 How are the risks to be minimised? And how will they be managed if they were to occur during the study or arise after the completion of the study?**

**NOTE:** The greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are taking on. Ensure all risks mentioned at A2.1 are addressed here, that the risks and their management are consistent throughout the application and relevant information is included in the Participant Information Sheets and Consent Forms.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI
The pharmacist will explain to the primary research participant that they can receive treatment for their uncomplicated UTI without agreeing to the contribution of data to the research evaluation. The pharmacist will provide the participant info sheet and give them sufficient time to read this information before seeking consent. Participants will also be reminded that their decision to participate is voluntary, and any decision to participate / not participate will in no way affect their usual pharmacist care. It will also in no way affect any existing or future relationship with the pharmacist, the pharmacy, the research team, or collaborating organisations. Furthermore, the primary research participants will be reminded that they can withdraw from the research evaluation at any time. However, if they withdraw from the research evaluation after receiving the episode of care from the pharmacist, their non-identifiable data may still be included. When conducting the one-week telephone follow-up, the patient will also have the opportunity to confirm whether they still consent for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. The survey will consist of 5 questions, and take 2-3 minutes to complete. The patient would complete this survey in their own time. The pharmacist and the research team will not know which patients did / did not complete the survey, so if they have completed and submitted the survey, it will not be possible to withdraw that data.

**The one-week follow-up with the pharmacist via telephone is part of the clinical service component of UTIPP-Q. Nevertheless, if participants do not feel comfortable with having this telephone follow-up discussion with the pharmacist, they can opt to not pick up the phone, or to not answer the questions.

Secondary research participants: Community pharmacists

The pharmacists will be reminded that their decision to participate is voluntary. Any decision to not participate will in no way affect their employment. It will also in no way affect any existing or future relationship with their patients, their employer, the research team, or collaborating organisations. The pharmacists will also be reminded that they can withdraw from the research evaluation at any time. If they withdraw from the research evaluation, non-identifiable data collected to date may still be included. However, if they withdraw from the research evaluation, they will not be able to continue providing treatment for uncomplicated UTIs as a part of the UTIPP-Q. This is clearly stated in the pharmacist information sheet and pharmacist consent form When conducting the one-week telephone follow-up, the pharmacist will confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email. The survey will consist of 5 questions, and take 2-3 minutes to complete. The patient would complete this survey in their own time. The pharmacist and the research team will not know which patients did / did not complete the survey.

A pharmacist evaluation survey: There is no foreseeable risk of harm or discomfort to the pharmacist participants. Any foreseeable risk would be no more than the inconvenience of giving up time to complete an online survey (15 mins).

- The invitation to participate in the survey will be emailed directly to the pharmacist using the email they supplied for the purposes of receiving information about UTIPP-Q. Their decision to participate /not participate in the survey will not impact on their participation in the clinical and research evaluation aspects of UTIPP-Q. The pharmacy site and research team will not know whether the pharmacist does/does not complete the survey.
- While the survey does not collect personal identifiable information, in some rare instances where some pharmacists who work as single pharmacists in very remote areas, it may be possible to potentially re-identify the pharmacist from the demographic information. However, the likelihood of this happening is extremely rare as the research team does not maintain a list of which pharmacists work in what locations. Pharmacists can move places of employment, or secure employment in different pharmacies, and there is no central register anywhere which records or reports this information. Similarly, pharmacies can change locations, banner groups, opening hours etc at any time, and the research team has no way of knowing or sourcing this information. To mitigate this possible, but unlikely risk, the research team will only be reporting and publishing data in aggregate such that no respondent or pharmacy site can be identified or potentially identified.
- The pharmacist can choose to stop answering the survey questions at any time and withdraw from participating at any time up until they submit the survey. However, as no identifiable information is collected, the pharmacist will not be able to withdraw their participation after the survey is submitted. The research team will not know which pharmacist has / has not participated. The participant information sheet clearly explains that participation in the survey is voluntary, and will not impact on the pharmacist's participation in the clinical nor research evaluation of UTIPP-Q. The pharmacist's decision to participate / not participate will also not impact on existing or future relationships with the pharmacy site, the research team or collaborating organisations.

**The one-week follow-up with the patient via telephone is part of the clinical service component

of UTIPP-Q. Following-up with patients after providing treatment and/or advice forms part of the roles and responsibility of a pharmacist, and is part of standard everyday practice and duty of care.

Pharmacy sites

The decision to participate as a research site is voluntary. Any decision to not participate will in no way affect any existing or future relationship the research team or collaborating organisations. The pharmacy sites will also be reminded that they can withdraw from the research evaluation at any time. If they withdraw from the research evaluation, non-identifiable data collected to date may still be included. However, if they withdraw from the research evaluation, the pharmacists at the site will not be able to continue providing treatment for uncomplicated UTIs as a part of the UTIPP-Q. This is clearly stated in the site information sheet and site consent form.

**A2.3 What are the potential benefits of the research and who would benefit from these?**

- Benefits of research may include, e.g. gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.
- Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

The research will evaluate the benefits of suitably trained community pharmacists treating uncomplicated UTIs. The convenience and accessibility of a community pharmacist will contribute to timely treatment and improved quality of life for people experiencing uncomplicated UTIs.

Secondary research participants: Community pharmacists

There is no direct benefit to the secondary research participants. However, community pharmacists participating in this research evaluation must complete an approved training program to prepare them for prescribing antibiotics as a part of the treatment of uncomplicated UTIs. This training provides the pharmacist with additional knowledge and skills, and contributes to their continuing professional development.

Pharmacist evaluation survey: There is no direct benefit to the pharmacist participants, but they may appreciate the ability to share their experience and perceptions. The outcomes of this evaluation will also be of benefit to informing future work which involves professional services and expanded or extended scope of practice, of which they may be future participants.

Pharmacy sites

There is no direct benefit to the pharmacy site. However, there may be a chance that some pharmacies might become more popular with patients due to offering an additional professional service.

Wider pharmacy profession

The findings of this research evaluation will contribute to the wider pharmacy profession by demonstrating the ability of pharmacists to treat uncomplicated UTIs.

Wider community

There are benefits to people in the wider community who may experience uncomplicated UTIs to be able to access treatment in a more convenient and timely manner. Moving forward, this research adds to the body of evidence that investigates the benefits and contribution community pharmacists may make with prescribing and supplying of medicines for other minor ailments.

Researchers

Findings from this research evaluation will contribute to an increased body of knowledge regarding pharmacist prescribing. This data will provide a basis for further refinement and improvement of service provision for other minor ailments within the community.

The research team consists of academics who are also registered pharmacists. There may be a perceived risk of bias as a positive UTIPP-Q research evaluation may benefit the profession more broadly. It is important to point out that the research team consists of highly experienced researchers who are familiar with responsible research conduct, consistent with national and international codes of research integrity to produce credible and high-quality research. Furthermore, as registered pharmacists, the researchers are also bound by the profession's code of ethics, and code of conduct which encompass research activities.

**A2.4 How do the benefits justify the risks?**

- Research is ethically acceptable only when its potential benefits justify any risks involved in the research.

The risks are negligible. The benefits and significant gains in knowledge outweigh possible risks. The direct benefit to the primary research participants is significant as they are able to access treatment for uncomplicated UTIs in a convenient and accessible location in a timely manner. The findings of this research evaluation can be used by policy makers and stakeholders to refine and review service provision for other minor ailments within the community at large, which will generate benefits to the healthcare system and the wider community.

The findings of the pharmacist evaluation survey will also be of interest for informing future work that involves professional services and expanded or extended scope of practice, of which they may be future participants.

## A3 Other General Information

**A3.1 Where will the data be collected?** (e.g. on site at QUT or other location)

**NOTE:** If you would like to conduct your study at the premises of an external organisation/association please ensure you provide a copy of your intended approach letter which requests their support/permission for this, or provide evidence of this if already gained.

| | **QUT** | **X** | **Other – details:** | Within community pharmacies |
|---|---|---|---|---|

**A3.2 Is the QUT Human Research Ethics Committee (UHREC) the primary or only ethics committee reviewing this proposal?**

If **NO**, provide details of any other institutional HREC involved and the role of each institution (including QUT) in the project. If the project involves more than one institution that also has a HREC, please provide details on the role of QUT UHREC; whether arrangements can be put in place for to minimise multiple review; arrangements for communication of the roles/responsibilities between the institutions HRECs, e.g. who will monitor etc.

Yes

**A3.3 What are the estimated timeframes for the project? (mm / yyyy)**

**NOTE:** Data collection cannot commence until you have received formal written UHREC approval.

| | | | |
|---|---|---|---|
| **Start of project** | 1 April 2020 | **Start of data collection** | 1 April 2020 |
| **End of project** | 30 December 2022 | **End of data collection** | 31 December 2021 |

**A3.4 Describe the qualifications and relevant experience of the researcher team**

**NOTE:** Include the training and experience student researchers have in the relevant research methodologies.

| **QUT research team** | | |
|---|---|---|
| **Queensland University of Technology – Discipline of Pharmacy** | **Professor Lisa Nissen**<br>BPharm, PhD, AdvPracPharm, FPS, FHKAPh, FSHP<br><br>**Dr Esther Lau**<br>B.Pharm(Hons) PhD, GCResComm, GradCert Acad Prac, SFHEA, | Brings experience in implementation and evaluation of previous large state-wide pharmacist immunisation pilot in Queensland (QPIP) including education resource design, research design and development, ethics, steering committee and stakeholder management and extensive media experience related to high profile research programs. |

| | | |
|---|---|---|
| | AACPA, MPS | Collaboration for QPIP was consortium with industry organisation (Guild and PSA) and university research partners |
| **Subcontractors** | | |
| **James Cook University – Discipline of Pharmacy** | **Professor Beverley Glass**<br><br>**Ms Selena Taylor** | Brings experience in implementation and evaluation of previous large state-wide pharmacist immunisation pilot in Queensland (QPIP) including education resource design, research design and development, ethics, steering committee and stakeholder management. Collaboration for QPIP was consortium with industry organisation (Guild and PSA) and university research partners. JCU focused on coordination of north QLD / rural sites. |
| **Griffith University – Menzies Institute** | **Professor Amanda Wheeler**<br><br>**Dr Jean Spinks**<br><br>**Dr Fiona Kelly** | Brings experience in outcome evaluation and assessment of large pharmacist practice model pilots in the community. Currently managing a number of research programs in collaboration with the Pharmacy Guild of Australia and the Commonwealth Government to evaluate Quality Use of Medicines services and Medicines Management by pharmacists. Skilled in pharmacoeconomic and health economics and research design and evaluation. |

## SECTION B: PARTICIPANT OVERVIEW

(refer to Section 2.2 of the National Statement when preparing your response)

**B1.1 Who will be approached to participate? Clearly outline each participant group.**

Provide details of the potential participant pool. If you are accessing secondary data please provide full details, including whether permission has been sought. If you are accessing confidential health information e.g. Queensland Health data, the Public Health Act specifies the approvals required (see link below) and QUT requires a Hospital Access Agreement. Contact the Division of Research & Commercialisation for assistance.

http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

Pharmacy sites

Pharmacies participating in the UTIPP-Q will be invited to participate in the research evaluation. Involvement will consist of consenting to the pharmacy being a study site, providing permission for non-identifiable GuildCare records from consenting participants to be shared with the research team.

It will also involve them agreeing for their pharmacists to:-

- Complete an approved course of training for the UTIPP-Q and demonstrate an acceptable level of knowledge associated with the treatment of uncomplicated UTIs.
- Agree for the research team to use, and to share their contact details (phone number and email address) with Queensland Health for the purposes of communicating with them about the UTIPP-Q.
- Invite patients to participate in the research, provide information about the UTIPP-Q and its research evaluation, and answer any questions.
- Seek and record consent (via GuildCare software) from the patient participants for their data to be provided to the research team in a non-identifiable format for analysis.

Secondary research participants: Community pharmacists

Community pharmacists employed in pharmacies enrolled in the UTIPP-Q will be invited to participate in the research evaluation. The pharmacist will be asked to provide consent for the research team use, and to share their contact details (phone number and email address) with

Queensland Health for the purposes of communicating with them about the UTIPP-Q. The pharmacist's involvement will consist of 1) inviting patients to participate in the research evaluation, providing information about the UTIPP-Q and its research evaluation, and answering any questions, and 2) seeking and recording consent (via GuildCare) from the patient participants for their data to be provided to the research team in a non-identifiable format for analysis. This includes confirming at the one-week telephone follow-up, whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email.

Pharmacist evaluation survey: The pharmacists who have registered and provided consent for participating in UTIPP-Q will be invited to complete the online survey. The survey link will be sent to the email address they supplied for the purposes of receiving information about UTIPP-Q.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

When the patient consents to receiving the clinical service as a part of the UTIPP-Q, the pharmacist will also invite them to participate in the research evaluation. This will consist of providing consent for their non-identifiable to being provided to the research team for analysis. At the one-week telephone follow-up, they will have the opportunity to confirm whether they still consent for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email.

**Consent for the research evaluation will be in addition to that required to enter the UTIPP-Q i.e. over 18 years of age and able to give informed consent. The pharmacist will explain to the patients that they can participate in the clinical service component UTIPP-Q without being required to take part in the research evaluation. That is, participants can receive treatment as a part of the UTIPP-Q for the management of uncomplicated UTIs without agreeing to the contribution of data to the research evaluation.

**B1.2 How many participants do you need for your study and approximately how many will you need to approach?**

Pharmacy sites

There is no minimum or maximum number of pharmacy sites. All pharmacy sites involved with the UTIPP-Q will be invited to participate.

- All Queensland pharmacies that are accredited with the Quality Care Pharmacy Program (QCPP) will be invited to submit an expression of interest to participate in the UTIPP-Q. QCPP is a quality management system that ensures a community pharmacy is equipped to provide a high standard of professional service and customer care.
- There are approximately 1600 QCPP accredited pharmacies in Queensland.

Secondary research participants: Community pharmacists

There is no minimum or maximum number of secondary research participants. All pharmacists who are employed in pharmacies participating in the UTIPP-Q, will be invited to participate after they complete the specified training for management of uncomplicated UTIs.

- Pharmacists who are employed in pharmacy sites participating in the UTIPP-Q will be invited to participate in the UTIPP-Q after they complete the approved course of training for UTIPP-Q on

management of uncomplicated UTIs.
- There are approximately 4500 pharmacists working in Queensland pharmacies.

Pharmacist evaluation survey: There is no minimum or maximum number of pharmacist respondents. All pharmacists who have registered and provided consent for participating in UTIPP-Q will be invited to complete the online survey. To date, there are almost 1800 pharmacist participating in UTIPP-Q.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

There is no minimum or maximum number of primary research participants. All patients who are receiving pharmacist treatment for an uncomplicated UTI in the UTIPP-Q will be invited to participate.
- An estimated 250,000 Australians develop a UTI each year. Based on experience and advice from the UTIPP-Q consortium, it is anticipated there will be 1-2 uncomplicated UTI presentations at a pharmacy each week. This translates to approximately 50-100 presentations per pharmacy each year.
- If all QCPP accredited pharmacies participated in the UTIPP-Q, and all patient presentations were enrolled in the UTIPP-Q, it is anticipated that potential participants for the research evaluation would be in the range of 80,000 – 160,000.

**B1.3 How will potential participants be identified and approached?**

**NOTE:** If you would like to recruit participants via an external organisation/association please ensure you provide a copy of your intended approach letter which requests their support/permission, or provide evidence of this if already gained.

Pharmacy sites

All Queensland pharmacies accredited with the Quality Care Pharmacy Program (QCPP) will be invited to submit an expression of interest to participate in the UTIPP-Q. QCPP is a quality management system that ensures a community pharmacy is equipped to provide a high standard of professional service and customer care.
- All pharmacy sites that are enrolled into the UTIPP-Q will receive an invitation through the QCPP management system, inviting them (the pharmacy owner/delegate/manager) to participate in the research evaluation. This invitation will include the **site** information sheet, and **site** consent form.

Secondary research participants: Community pharmacists

Pharmacists who are employed in pharmacy sites participating in the UTIPP-Q will be able to participate in the UTIPP-Q after they complete the specified training for management of uncomplicated UTIs.
- Upon completion of the training module, the pharmacists will receive an invitation through the training module, inviting them to participate in the research evaluation. This invitation will include the **pharmacist** information sheet, and **pharmacist** consent form.

A pharmacist evaluation survey: The pharmacists who have registered and provided consent for participating in UTIPP-Q will be invited to complete the online survey. The survey link will be sent to the email address they supplied for the purposes of receiving information about UTIPP-Q. The research team will send four follow-up reminder emails over a 4-8 week period to all pharmacists, to remind them about the invitation to participate in the survey.

Primary research participants: People presenting to community pharmacies with symptoms of an UTI

All patients who are receiving pharmacist treatment for an uncomplicated UTI in the UTIPP-Q will be invited to participate.

- When the participants consent to receiving the service as a part of the UTIPP-Q, the pharmacist will also invite the patients to participate in the research evaluation. At this time, the pharmacist will also provide a copy of the **participant** information sheet, and **participant** consent form.

**B1.4 How will the participants provide their consent to participate?**

Outline the consent process you will use, what type of consent will be requested (i.e. specific, extended or unspecified – see NS2.2.14), what material will be provided to participants, how long participants will have to consider their decision to participate and what discussion will occur with participants.

**NOTE:**

- A person's decision to participate in research must be voluntary and informed i.e. not forced, coerced or obtained by improper inducements AND based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it (the purpose, methods, demands, risks and potential benefits of the research).
- The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

All consent will be recorded electronically using QUT Key Survey or the GuildCare software.

Pharmacy sites

All pharmacy sites that are enrolled into the UTIPP-Q will receive an invitation through the QCPP management system, inviting them (the pharmacy owner/delegate/manager) to participate in the research evaluation. This invitation will include the **site** information sheet, and **site** consent form.

- Once the pharmacist owner/delegate/manager has had the opportunity to read and consider the information in the site information sheet, and where required contacted the research team and had any questions answered to their satisfaction, they can provide their consent by clicking on the QUT Key Survey link.
- After clicking on the QUT Key Survey link, the pharmacy owner/delegate/manager will be asked to input the following information.
    - Owner / Delegate / Manager
    - Pharmacy Name
    - Pharmacy Address
    - Contact Phone Number
    - Contact Email Address
- Submission of this information will be taken to be consent to participate in the research evaluation.

Secondary research participants: Community pharmacists

Upon completion of the training module, the pharmacists will then receive an invitation through the training module, inviting them to participate in the research evaluation. This invitation will include the **pharmacist** information sheet, and **pharmacist** consent form.

- Once the pharmacist has had the opportunity to read and consider the information in the pharmacist information sheet, and where required contacted the research team and had any questions answered to their satisfaction, they can provide their consent by clicking on the QUT Key Survey link.
- After clicking on the QUT Key Survey link, the pharmacist will be asked to input the following information:
    - Pharmacist Name
    - Australian Health Practitioner Regulation Agency (AHPRA) Registration number – to confirm they are a registered pharmacist
    - Contact Phone Number – as the pharmacists are the secondary research participants,

the research team needs to be able to contact the pharmacist independent of the pharmacy.
    - Contact Email Address – as the pharmacists are the secondary research participants, the research team needs to be able to contact the pharmacist independent of the pharmacy.
    - Pharmacy Name and Address – to ensure the pharmacy is enrolled in the UTIPP-Q
- Submission of this information will be taken to be consent to participate in the research evaluation.

A pharmacist evaluation survey: As the online survey does not collect any identifiable information, submission of the survey will be taken as implied consent to participate in the evaluation survey.

<u>Primary research participants: People presenting to community pharmacies with symptoms of an UTI</u>

When the patient consents to receiving the service as a part of the UTIPP-Q, the pharmacist will also invite them to participate in the research evaluation. The pharmacist will then provide a copy of the **participant** information sheet, and **participant** consent form. The participant can also have a copy of the participant information and participant consent emailed to them.

NB: Patients must be over 18 years of age and consent to receiving clinical care in the UTIPP-Q. This will ensure potential primary research participants have the capacity to give consent for the research evaluation.

- Once the patient has had the opportunity to read and consider the information in the participant information sheet, and had any questions answered to their satisfaction by the pharmacist and where required the research team, they can provide their consent to the pharmacist.
- The pharmacist will record the consent on behalf of the primary research participants in GuildCare when enrolling the patient into the UTIPP-Q and documenting details about the episode of care as a part of standard work practice. These are the options in GuildCare when the pharmacist starts a new clinical record.
    - Checkbox #1 Patient has received and reviewed information about the research evaluation
    - Checkbox #2 Patient has verbally agreed to participate in the research evaluation
    - Checkbox #3 Patient has consented to participate in the clinical service, however, does not consent to having their data used for the research evaluation
    - Checkbox #4 Patient has declined the clinical service
- The pharmacist will need to click onto checkbox 1 AND either 2 or 3 to proceed into documenting details about the clinical record.
- When conducting the one-week telephone follow-up, confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. Once the consent to receiving the anonymous clinical service evaluation survey is recorded, GuildCare will send the link to the patient's email. The survey will consist of 5 questions, and take 2-3 minutes to complete. The patient would complete this survey in their own time. The pharmacist and the research team will not know which patients did / did not complete the survey. Submission of the completed survey will be taken as implied consent to participate in the clinical service evaluation survey.

**The patient, treatment, and documenting details relating to the episode of care will take place in accordance with the clinical service component UTIPP-Q protocol. This aspect of care does NOT form part of QUT's responsibilities.

** Participants can receive treatment as a part of the UTIPP-Q for the management of

uncomplicated UTIs without agreeing to the contribution of data to the research evaluation.

**B1.5 Will the project involve participants who are unable to give voluntary or informed consent?**

If **YES**, what special arrangements will be put in place to protect your participants' interests/welfare?

These questions refer to research involving:

- Children and young people whose particular level of maturity has implications for whether their consent is necessary and/or sufficient to authorise participation (see Section 4.2 of the National Statement).
- Persons with a cognitive impairment, and intellectual disability, or a mental illness (permanent or temporary) which impacts upon their ability to supply voluntary and informed consent (see Section 4.5 of the National Statement).
- Persons who are highly dependent on medical care, e.g. unconscious or unable to communicate their wishes (see Section 4.4 of the National Statement).
- Covert observation of behaviour, particularly if this relates to sensitive, contentious or illegal activity consent (see Section 2.3 and Section 4.6 of the National Statement).

**NOTE:** Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

No

**B1.6 Do you propose to screen or assess the suitability of the participants for the project?**

If **YES**, clearly state and explain the criteria (inclusion and exclusion, as applicable) for selecting potential participants.

No. However, as a part of the clinical aspect of the UTIPP-Q, pharmacists will be screening eligibility of patients for treatment *vs* referral. Eligibility criteria for enrolling into the UTIPP-Q (Appendix 1) includes being over 18 years of age, and able to provide informed consent.

**B1.7 Will participants be offered reimbursements, payments or incentives?**

If **YES**, also provide the specific details (type and value), how and when it will be provided and whether its offer could compromise the voluntary nature of the consent obtained from participants. See Guidance on prize draws.

**NOTE:**

- Details of these should be provided on the Participant Information Sheet.
- It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable (NS2.2.10)
- Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted (NS2.2.11)

No

**B1.8 Do you, or others involved in facilitating or implementing the research, have a pre-existing relationship with the proposed participants? Could this result in the proposed participants feeling obliged or coerced into participation?**

Refer to Section 4.3 of the National Statement and the QUT Classroom Research guidance when considering/preparing your response.

If **YES**, describe this relationship and how you will address the special ethical issues this raises (e.g. potential coercion in recruitment). Also outline what special arrangements will be put in place to protect the interests / welfare of potential participants.

**NOTE:**

- Pre-existing relationships may compromise the voluntary nature of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other.
- Examples may include relationships between employers or supervisors and their employees; teachers and their students; carers and people with chronic conditions or disabilities or people in residential care or supported accommodation; etc (see Section 4.3 of the National Statement for more examples).
- While this influence does not necessarily invalidate the decision, it does mean that particular attention

should be given to the process through which consent is negotiated.

Yes

Pharmacy sites and research team

There is potential for the research team to have pre-existing professional relationships with the pharmacy sites. The site information sheet will clearly state that the owner/delegate/manager's decision to enrol the pharmacy as a study site is voluntary. Any decision to not participate will in no way affect the site's relationship with their patients, employees, research team, or collaborating organisations. The owner/delegate/manager will also be reminded that they can withdraw the site from the research evaluation at any time. If they withdraw the site from the research evaluation, non-identifiable data collected to date may still be included. However, withdrawal from the research evaluation will also mean the pharmacists at the site will not be able to continue providing treatment for uncomplicated UTIs as a part of the UTIPP-Q.

Secondary research participants and research team

There is potential for the research team to have pre-existing professional relationships with the pharmacists (secondary research participants). The pharmacist information sheet will clearly state that the pharmacist's decision to participate is voluntary. Any decision to not participate will in no way affect their employment. It will also in no way affect any existing or future relationship with their patients, their employer, the research team, or collaborating organisations. The pharmacists will also be reminded that they can withdraw from the research evaluation at any time. If they withdraw from the research evaluation, non-identifiable data collected to date may still be included.

A pharmacist evaluation survey: The pharmacists invited to complete the evaluation survey are currently registered in UTIPP-Q and have a pre-existing relationship with the research team. The pharmacist information sheet will clearly state that the pharmacist's decision to participate is voluntary. Any decision to not participate will in no way affect their participation in the clinical and research evaluation of UTIPP-Q. It will also in no way affect any existing or future relationship with their patients, their employer, the research team, or collaborating organisations. The pharmacists will also be reminded that they can withdraw from the research evaluation at any time up until when they submit the survey. If they withdraw from the research evaluation, non-identifiable data collected to date may still be included.

Primary and secondary research participants

There is potential for the pharmacist (secondary research participant) providing the UTI treatment to have a pre-existing professional relationship with the patient (primary research participant). However, the patients will be self-presenting to the pharmacist with symptoms. Pharmacists will remind patients that participation in the research evaluation is voluntary and they can still receive the service i.e. treatment for an uncomplicated UTI without participating in the research evaluation. Any decision to participate / not participate will in no way affect their usual pharmacist care. It will also in no way affect any existing or future relationship with the pharmacist, the pharmacy, the research team, or collaborating organisations. Furthermore, the primary research participants will be reminded that they can withdraw from the research evaluation at any time. However, if they withdraw from the research evaluation after receiving the episode of care from the pharmacist, any non-identifiable data already collected will still be included, as it will not be possible to identify and delete this information. If participants do not feel comfortable with having this telephone follow-up discussion with the pharmacist, they can opt to not pick up the phone, or to not answer the questions. When conducting the one-week telephone follow-up, the patient will be given the opportunity to confirm whether they still consent for their non-identifiable data to be used as part

of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey. The patient would complete this survey in their own time. The pharmacist and research team will not know whether the patient did/did not complete the survey, so if they have completed and submitted the survey, it will not be possible to withdraw that data.

**B1.9 Will you conduct a debriefing session at the end of the research or at the end of each participant's involvement?**

If **YES**, please provide the details of this session. **NOTE:** Such a session is required for research involving limited disclosure (see Section 2.3 of the National Statement), and may be appropriate if the research is likely to cause discomfort to participants.

No

**B1.10 The National Statement indicates feedback should be provided to research participants (NS1.5). How will feedback and/or the research results be reported to participants?**

- If **YES**, explain how this will be done and in what form this reporting will occur.
- If **NO**, explain why the participants are not to be provided with such a report.

Yes. The findings from the research evaluation of the UTIPP-Q will be provided as reports to the Queensland Department of Health (the Health Minister and Chief Health Officer). A copy of the reports will also be provided to the consortium members for dissemination to their members, who can provide feedback to their patients.

## SECTION C: DATA MANAGEMENT

### C1 Future Use of Data

**C1.1 Is it possible that any of the data collected will be used by you or others for any research other than that outlined in this application?** See Section 2.2 and Section 3 when preparing your response.

**If YES, describe below and ensure this is outlined in all your participant information sheets and consent forms.**

- Participants should be fully informed of the possibility of any future use of data collected and their 'extended' or 'unspecified' consent gained. Failure to do this may restrict the future use of the data.
- Any restrictions on the use of participants' data should be recorded and the record kept with the collected data so that it is always accessible to researchers who want to access those data for research.
- Please note that data sharing is increasingly being encouraged to gain maximum benefit from research, so a **YES** response is encouraged in most cases. If **YES**, describe below and ensure this is outlined in all your Participant Information Sheets and Consent Forms.

Yes – participants will be asked to provide consent that non-identifiable data from the research evaluation may be used for future research studies.

### C2 Procedures & Protection

**C2.1 What data collection procedures will be utilised?**

Place an '**X**' in the relevant boxes below **AND** provide a copy (draft or finalised, labelled as such) of the relevant instrument, protocol or other written form used to guide (e.g. interview questions/guide) or collect data (e.g. survey) or include an explanation of the method by which the data will be collected. Clinical experimental measures / tools or creative works are considered "Other Instrument".

| | | | |
|---|---|---|---|
| X | **Questionnaires/Surveys** | | **Archival records** |
| | **Interviews** | | **Focus groups** |
| X | **Other instrument – provide details:** | | |

(If there is insufficient space below, provide details in an additional separate document.)

Clinical records will be collected using the GuildCare UTIPP-Q Module. GuildCare is a proprietary software used in community pharmacies to record episodes of care provided by pharmacists, and includes identifiable patient information. Details collected as a part of the GuildCare clinical record for the episode of care includes: name, address, phone number, email, gender, age, eligibility criteria for the UTIPP-Q, medication supplied, self-care advice and other resources provided, correspondence to GP about episode of care. This will include the follow-up that will be conducted

by the pharmacist, by telephone, one-week after the interaction with the primary research participant. During this one-week follow-up interaction, the pharmacist will check patients they still consent to receive via email, a link to the anonymous clinical service evaluation survey. The survey will consist of 5 questions, and take 2-3 minutes to complete. Examples of questions include: overall, how satisfied are you with the service you received?, if this service was not available, where would you have got advice / treatment for your symptoms?, Would you recommend this service to others?

**The enrolment of patients, treatment, follow-up, and documentation of the required details relating to the episode of care into GuildCare i.e. clinical record, will take place in accordance with the clinical service component of the UTIPP-Q protocol. This aspect of care does NOT form part of QUT's responsibilities.

For the purposes of this research evaluation GuildCare will also be the platform used to record patient consent to participate in the research evaluation as primary research participants. When conducting the one-week telephone follow-up, the pharmacist will confirm whether the patient still consents for their non-identifiable data to be used as part of the research evaluation, and whether they still consent to receive via email, a link to the anonymous clinical service evaluation survey.

All identifiable patient information i.e. name, address, phone number, email, will be permanently removed prior to the GuildCare clinical record being provided to the research team (Appendix 1). Therefore, the research team will only receive non-identifiable data as identifiers have been permanently removed such that no specific individual can be identified by the researchers.

Pharmacist evaluation survey: the survey is built on the Qualtrics platform accessed through QUT https://qutc.syd1.qualtrics.com/jfe/preview/SV_50bUmMsKSBcgiQ6?Q_CHL=preview&Q_SurveyVersionID=current. Please see attached for a static copy of the survey.

**C2.2** **Describe the human data that will be collected, stored and used/reported in terms of the level of identifiability of the data?** For example data may be being collected, stored and/or used in various forms throughout the lifecycle of a project; describe each phase. Data may be reasonably identifiable at the individual level i.e. data from which the identity of a specific individual can be ascertained e.g. name, image, date of birth, and/or address. Data may be in a form that is readily or potentially re-identifiable i.e. data from which identifiers have been removed and replaced by codes, but it remains possible to re-identify individuals, e.g. by using the code or linking different data sets. Alternately, data that has **never been labelled** with individual identifiers OR from which **identifiers have been permanently removed** such that no specific individual can be identified by the researchers may be the form in which it is collected. (See NS Section 3.1 Element 4)

In accordance with documenting episodes of standard care provided by a pharmacist, clinical records in GuildCare are identifiable. All identifiable patient information i.e. name, address, phone number, and email, will be permanently removed before the clinical records are provided to the research team. Therefore, non-identifiable data will be stored, and used / reported.

The clinical service evaluation survey will be anonymous, and there will never have been labelled with individual identifiers.

Pharmacist evaluation survey: for the majority of the survey responses, they will be anonymous, and there will never have been labelled with individual identifiers. No identifying information is collected in the survey, but there is potential that in rare cases if only a single pharmacist works in a very remote area, that the collected data is potentially identifiable. However, there is no practical or realistic way of actually identifying this individual. The data will be analysed and reported in

aggregate, such that it will not be possible to identify pharmacists or pharmacy sites.

**C2.3 How is this project funded?**

Outline what rights the funder of the study will have to data obtained from the study, and in what format e.g. aggregate reports only, access to raw data or other. **NOTE:** Any access by the funder should be made clear to participants.

The UTIPP-Q is funded by the Queensland Department of Health through the Allied Health Professions' Office of Queensland (AHPOQ). AHPOQ will receive interim, progress and a final report of aggregated data only, and will not have access to raw data.

**C2.4 How will confidentiality of the study records be protected during the study and in the publication of results?**

**NOTE:** If you intend to identify participants or organisations, this needs to be made clear on the Participant Information Sheet.

The secondary research participants i.e. community pharmacists will have access to their own patient(s)' GuildCare clinical records as a part of their workflow practice of documenting episodes of care.

The primary participant clinical records provided to the research team will be in non-identifiable format, thereby protecting the confidentiality of the clinical records during the research evaluation. Consequently, only non-identifiable data, in aggregated form, will be published. The clinical service evaluation survey will be anonymous, and there will never have been labelled with individual identifiers.

The pharmacist evaluation survey will only be reported in aggregate form, such that no pharmacist or pharmacy site is identifiable.

**C2.5 Is this a collaborative project?**

If **YES**, also provide brief detail on data-sharing arrangements e.g. open – all parties have access to each other's data; partial – data held by collaborator completing particular component.

No. There is a consortium which acts as the steering committee for the UTIPP-Q. In terms of the research evaluation *per se*, the funding and intellectual property agreements with the Queensland Department of Health sit with QUT.

**C2.6 Who will own the resulting research data and the created intellectual property?**

Place an '**X**' in the relevant box/es below – at least one box must be checked. If relevant you can check more than one box, ie QUT and an external organisation. Please refer to the D/3.1 Intellectual property (IP) policy for further information.

| | |
|---|---|
| **X** | **QUT**<br>QUT is the owner of IP created by staff members in the course of their employment. |
| | **STUDENT/S**<br>The IP generated is personally owned by the student if not assigned to QUT or other organisation. |
| | **BOTH QUT & STUDENT/S**<br>If the IP for a student project has been assigned to QUT, ownership of data and IP is shared. (see Student IP protocol) |
| | **EXTERNAL ORGANISATION**<br>Give details: |

**NOTE:** QUT requires an IP agreement to be in place if IP ownership is to deviate from that described in D/3.1 Intellectual property (IP) policy. If you require any further assistance, please contact the relevant section of the Division of Research & Commercialisation.

## C3 Storage & Security

Ensure you have completed your QUT Data Management Plan **BEFORE** completing this section.

- Data should be stored in a **locked filing cabinet at QUT** and/or electronically on a **QUT mainframe drive**.
- **Data must not be stored solely at home**.

**C3.1** [X] **YES** **Confirm that your research data and other records will be stored for the required period.**

Refer to the Management research data.

**C3.2 HARD/PAPER COPIES...**

(e.g. **Signed consent forms** are required to be kept securely for **15 years** as per the University Sector Retention and Disposal Schedule)

| | |
|---|---|
| **C3.2.1 What is the location/s of storage?** (i.e. QUT room/building location and/or offsite storage location) | N/A – no hard copies / paper copies will be generated. |
| **C3.2.2 How will access to the stored data be controlled?** | N/A – no hard copies / paper copies will be generated. |
| **C3.2.3 Who will have access to the stored data?** | N/A – no hard copies / paper copies will be generated. |

**C3.3 ELECTRONIC DATA...**

| | |
|---|---|
| **C3.3.1 What is the location/s of storage and back-up?** (i.e. a secure computer/server and/or offsite storage location) | A QUT Data Management Planning Tool will be used as a living document to assist with data management during the life of this research.<br>The data will be stored on QUT's secure network, on password protected H:/ and restricted access U:/. |
| **C3.3.2 How will access to the stored data be controlled?** | Access to H:/ and U:/ will be controlled per university privacy policies with password protection. |
| **C3.3.3 Who will have access to the stored data?** | Only members of the research team will have access to the data. |

Pharmaceutical Society of Australia

This document is designed to provide guidance to pharmacists on a range of issues including appropriate and effective processes, desired behaviour of good practice, how professional responsibilities may be best fulfilled, and expected outcomes. At all times, pharmacists must meet any legislative requirements and are expected to exercise professional judgment in adapting the guidance provided here to presenting circumstances.

# Guidance for provision of antibiotics for acute uncomplicated cystitis in females

2020

## Consider professional obligations

A Professional standards
B Privacy
C Documentation

## Assess patient needs

Consider:
D Presenting symptoms
E Age
F Patient history
G Pregnancy

## Refer when

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

## Confirm recommendation is appropriate

Consider:
H Treatment options
I Contraindications and precautions
J Lactation
K Drug interactions

## Supply and/or refer if necessary

- First time symptoms
- Symptoms not previously diagnosed by a medical practitioner
- Contraindications and precautions
- Concurrent medicines

## Provide counselling (supported by written information)

Consider:
L Dose
M Additional dosing advice
N Treatment expectations
O Adverse effects
P Self-care strategies
Q Follow-up advice



PSA Committed to better health

## Explanatory notes

Note: In this guidance document, the term 'female' refers to a patient with anatomy characteristic of a biologic female.[1] This guidance document focuses on treatment of urinary tract infection (UTI) in a person with a biologic female urinary tract. Pharmacists may need to consider whether this guidance applies to a transgender person.

### A. Professional standards

The *Professional Practice Standards* (PPS)[2] outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in response to a direct product- or symptom-based request.

The *Code of Conduct for Pharmacists*[3] and the *Code of Ethics for Pharmacists*[4] provide guidance on the ethical framework through which effective health services should be delivered.

The *Guidelines for Advertising Regulated Health Services*[5] provides guidance about obligations of pharmacists under the National Law with respect to advertising. All advertisements for the service must comply with relevant Commonwealth, state and territory legislation.

### B. Privacy

Pharmacists must meet their obligations in relation to respecting the patient's privacy and confidentiality in the provision of antibiotics for acute uncomplicated cystitis, and associated patient counselling.[2] This includes offering patients a private consultation area where conversations can occur at normal speaking volumes without being overheard.

All written communication, including electronic communication (e.g. email), that contains the patient's health information should be secure.[6]

### C. Documentation

Pharmacists are advised to document the service provided according to the PPS. In addition, pharmacists should record the supply of antibiotics for acute uncomplicated cystitis in accordance with relevant legislation and professional responsibilities.[2] Documentation of referral, and any education or counselling provided to the patient is also advised.

If the patient provides consent, pharmacists are advised to inform the patient's preferred medical practitioner in writing of the supply of an antibiotic for acute uncomplicated cystitis.

### D. Presenting symptoms

Most UTIs occur when bacteria from the bowel spread into and up the urethra to the bladder. Sometimes the bacteria also spread up the ureters to the kidneys. Occasionally, bacteria or other micro-organisms spread into the kidney from the bloodstream.[7,8,9,10]

The female urinary tract is particularly susceptible to UTIs because the urethral meatus is close to the anus and the urethra (distance to the bladder) is short. In females, UTI most commonly causes inflammation of the urethra (urethritis) and bladder (cystitis), but UTI can also involve the ureters (ureteritis) and kidneys (pyelonephritis).[7,11,12,13]

The most common cause of UTIs is *Escherichia coli.* Other bacteria that cause UTI include Proteus, Klebsiella, Enterococci, group B Streptococci, Staphylococcus and Pseudomonas species.[14]

#### Symptoms of cystitis

The primary symptoms of acute cystitis are[7,9,14]:

- dysuria (pain, discomfort, stinging or burning when urinating)
- urinary urgency
- urinary frequency
- suprapubic (above the pubic bone) pain or discomfort.

Cystitis may also cause cloudy, bloody or strong-smelling urine. However, urine colour and odour are not reliable signs of UTI as they can be influenced by food intake, hydration status, and other conditions or factors.[7,11]

The symptoms of cystitis are often caused by UTI, but similar symptoms can be caused by a number of other conditions—see examples in Table 1.[7,8,15]

If the patient is a female with two or more primary symptoms of acute cystitis, and no other symptoms, consider providing an appropriate antibiotic. See *E. Age, F. Patient history* and *H. Treatment options*.

If the patient's symptoms are suggestive of vulvovaginal candidiasis or bacterial vaginosis, consider recommending treatment with an appropriate *Pharmacist Only* medicine. Refer the patient to a medical practitioner if symptoms suggestive of other conditions are present. See Table 1.

**Table 1. Some conditions with symptoms similar to cystitis**

| Cause | Symptoms similar to cystitis | Other symptoms |
|---|---|---|
| **Vulvovaginal candidiasis** | • Dysuria (when urine is in contact with vulvar skin) | • Vulvovaginal itch (most common symptom)<br>• Vulvovaginal soreness and burning<br>• Vulvovaginal redness and swelling<br>• Dyspareunia<br>• Odourless vaginal discharge that may be thick and white, or watery |
| **Bacterial vaginosis** | • Dysuria | • Vaginal itching<br>• Unpleasant fishy vaginal odour<br>• Thin, grey or white vaginal discharge |
| **Vulvovaginal atrophy** | • Dysuria<br>• Urethral discomfort<br>• Urinary urgency and frequency | • Vulvovaginal dryness, burning, irritation, itching<br>• Vulvar or vaginal bleeding<br>• Milky or yellow vaginal discharge<br>• Dyspareunia |
| **Vulvar lichen sclerosus** | • Dysuria | • Vulvar itching and discomfort<br>• Vulvar white patches<br>• Anal itch and painful defecation<br>• Dyspareunia |
| **Sexually transmissible infections**<br>• **chlamydia**<br>• **gonorrhoea**<br>• **trichomoniasis** | • Dysuria<br>• Urinary frequency<br>• Lower abdominal or pelvic pain | • Vaginal bleeding between periods<br>• Dyspareunia<br>• Abnormal vaginal discharge (e.g. mucopurulent, malodorous, thin and frothy)<br>• Vulvar itch<br>• Rectal pain, bleeding or discharge |
| **Genital herpes** | • Dysuria (when urine is in contact with ulcers)<br>• Lower back pain | • Genital blisters/painful ulcers<br>• Genital itch<br>• Headache, malaise, myalgia<br>• Fever |

**Table 1. Some conditions with symptoms similar to cystitis (continued)**

| Cause | Symptoms similar to cystitis | Other symptoms |
|---|---|---|
| **Pelvic inflammatory disease** | • Dysuria<br>• Urinary frequency<br>• Lower abdominal or pelvic pain | • Vaginal bleeding between periods<br>• Dyspareunia<br>• Malodorous, mucopurulent vaginal discharge<br>• Fever (+/-chills) |
| **Bladder cancer** | • Dysuria<br>• Urinary urgency and frequency<br>• Back or pelvic pain<br>• Haematuria | |
| **Bladder calculi (stones)** | • Dysuria<br>• Urinary frequency<br>• Lower abdominal pain<br>• Haematuria | • Difficulty urinating or interrupted urine flow |
| **Interstitial cystitis** (bladder pain syndrome) | • Dysuria<br>• Urinary urgency and frequency<br>• Suprapubic pain | • Perineal pain<br>• Pelvic pain<br>• Bladder pain, pressure or spasms<br>• Pubic pressure<br>• Dyspareunia |
| **Haemorrhagic cystitis** (e.g. due to cyclophosphamide, ifosfamide, or radiation therapy) | • Dysuria<br>• Urinary urgency and frequency<br>• Suprapubic pain<br>• Haematuria | |
| **Appendicitis** | • Dysuria<br>• Urinary frequency<br>• Lower abdominal pain | • Pain worsens with jarring movements<br>• Nausea and vomiting<br>• Loss of appetite<br>• Abdominal bloating<br>• Constipation or diarrhoea<br>• Flatulence<br>• Fever |
| **Diverticulitis** | • Dysuria<br>• Urinary urgency and frequency<br>• Suprapubic pain<br>• Lower abdominal pain | • Nausea and vomiting<br>• Constipation or diarrhoea<br>• Fever |
| **Transvaginal mesh implant** | • Urinary urgency<br>• Back or pelvic pain<br>• Haematuria | • Urinary retention<br>• Urinary incontinence<br>• Poor urine flow<br>• Vaginal bleeding between periods<br>• Dyspareunia<br>• Recurrent UTI or vaginal infection |

References: Mayo Clinic[11]; Sobel[18]; Ross[19]; Hsu[20]; Ghanem[21]; Albrecht[22]; Murtagh[16]; Lotan[23]; Martin[24]; Bachman[25]; Cooper[26]; Clemens[27]; ACSQHC[28]; Trabuco[29]; Linder[30]; Pemberton[31]; ASHA[32]



### Symptoms of pyelonephritis

Signs and symptoms of acute pyelonephritis include fever (≥38 °C), chills, rigors, back or side (flank) pain, and nausea/vomiting, with or without signs and symptoms of cystitis. Pyelonephritis can lead to sepsis or kidney damage.[8,10,14,11,16] Guidelines recommend urine culture and antimicrobial sensitivity testing before starting antibiotics.[14,17] Refer the patient to a medical practitioner if signs and symptoms of pyelonephritis are present, or if the patient has a history of previous episodes of pyelonephritis.

## E. Age

The incidence of UTIs increases with older age. The elderly are at increased risk of UTI due to factors such as faecal impaction, incontinence, atrophy of the vaginal and perineal mucosa, impaired bladder emptying, chronic diseases (e.g. diabetes), catheters and medicines that cause urinary retention or constipation.[33,34]

In older people, UTI symptoms can be typical (see *D. Presenting symptoms*) and/or atypical, such as confusion or behavioural changes. Existing chronic urinary symptoms and cognitive impairment make it difficult to accurately assess symptoms of UTI.[14,33,34]

Refer patients >65 years to a medical practitioner for further investigation. See also *F. Patient history*

In children, the signs and symptoms of UTI vary with age. In addition, signs and symptoms can be non-specific, so a urine sample is needed for diagnosis.[35] Refer patients <18 years to a medical practitioner for further investigation.

## F. Patient history

UTI can be classified as uncomplicated (simple) or complicated (complex). A UTI is usually considered uncomplicated when it occurs in a non-pregnant, pre-menopausal female with no relevant comorbidities or urinary tract abnormalities.[8,14,17]

### Complicated UTI

UTIs are usually considered complicated when they occur in people with risk factors or medical conditions that increase the likelihood of complications or treatment failure.[8,14,17] Complicated UTI is caused by a wider range of bacteria than uncomplicated UTI, and the bacteria are more likely to be antibiotic resistant.[17] Refer patients with risk factors for complicated UTI to a medical practitioner. See Table 2.

### Recurrent UTIs

Many females experience recurring UTIs. Recurrent UTI is defined as two or more UTIs within 6 months or three or more UTIs within 12 months.[14,12,17,38]

Recurrent infections can be due to reinfection, or to relapse caused by bacterial persistence. Most recurrences are thought to represent reinfection. UTI is considered to be a relapse if the recurrence occurs within 2 weeks of completion of treatment for the original infection and the infecting bacterial strain is the same.[8,38]

Factors that increase the risk of UTI (and recurrent UTI) in females include[8,12,17,38,39]:

- sexual intercourse
- use of spermicide
- a new sexual partner
- intrauterine device (IUD)
- mother with a history of UTI
- UTI during childhood
- UTI before menopause
- atrophic vaginitis due to oestrogen deficiency
- pregnancy
- diabetes
- immunosuppression
- urinary tract obstruction (e.g. pelvic organ prolapse, kidney stones)
- foreign objects (e.g. catheter, bladder calculi)
- abnormalities of the urinary tract (e.g. vesicoureteral reflux)
- urinary incontinence
- increased post-voiding residual urine
- ABH blood group antigens nonsecretor phenotype.

Patients with recurrent UTI may require further investigation. In addition, recent or frequent antibiotic use for recurrent UTI is a risk factor for antibiotic resistance.[17,38] Refer patients presenting with symptoms of UTI to a medical practitioner if they have already had one UTI within the last 6 months or two UTIs within the last 12 months.

### Residents of long-term care facilities

Many residents of long-term care facilities have risk factors for complicated UTI, such as comorbidities and age-related changes that affect genitourinary function. In addition, the presence of multidrug-resistant bacteria is common in long-term care facilities.[14,40,41] See Table 2. Refer patients in long-term care with genitourinary symptoms to a medical practitioner for further investigation.

### Risk of sexually transmissible infection (STI)

In females, symptoms of cystitis and symptoms of certain STIs (e.g. chlamydia, gonorrhoea, trichomoniasis, genital herpes) can be similar. See *D. Presenting symptoms*. Relevant risk factors for STI in females include[42,43,44,45]:

- age ≤29 years
- previous STI
- sexual contact without a condom/dental dam outside a mutually monogamous relationship
- a new sex partner in last 60 days
- multiple sex partners
- a sex partner with multiple other sex partners
- a sex partner recently treated for an STI
- sexual contact with a sex worker.

Refer patients with relevant risk factors for STI to a medical practitioner for further investigation.

## G. Pregnancy

Pregnancy-related effects on the bladder and ureters increase the risk that bacteriuria will progress to pyelonephritis. In addition, bacteriuria or UTI during pregnancy increases the risk of adverse pregnancy outcomes. [39,46] Refer pregnant patients presenting with symptoms of UTI to a medical practitioner.

Females can develop urinary tract complications, including infection, in the postpartum period after childbirth.[36] Refer patients presenting with symptoms of UTI who are in the postpartum period to a medical practitioner.

**Table 2. Risk factors for complicated UTIs in females**

| Risk factor | Examples |
|---|---|
| **Patient factors** | • Age <18 years or >65 years<br>• Pregnancy<br>• Postpartum |
| **Immunocompromised** | • Diabetes<br>• Immunosuppressant medicines |
| **Anatomical or functional abnormalities of urinary tract** | • Vesicoureteral reflux<br>• Obstruction (e.g. kidney stones)<br>• Neurogenic bladder (e.g. spinal cord injury, multiple sclerosis, stroke, Parkinson's disease)<br>• Renal disease or impaired renal function |
| **Instrumentation of urinary tract** | • Urinary catheter within the previous 48 hours<br>• Nephrostomy tube<br>• Ureteral stent |
| **Microbial** | • Multidrug-resistant bacteria—risk factors include:<br>  • recent (within the previous 3 months) or frequent treatment with antibiotics<br>  • recent (within the previous 3 months), frequent or long-term resident of a healthcare facility<br>  • lack of response to initial antibiotic treatment<br>  • overseas travel within the previous 3 months<br>  • infection with multidrug-resistant bacteria within the previous 3 months<br>• Unusual microorganism—risk factors include recent travel to a country with high rates of multidrug resistance |

References: Hooton[7]; eTG[14]; Chung[15]; Bonkat[17]; Berens[36]Dorsher[37]

## H. Treatment options

In females with acute uncomplicated cystitis, the diagnosis can be reliably based on symptoms alone. When at least two primary symptoms of cystitis are present, with no vaginal discharge, the probability of cystitis is >90%. Guidelines recommend starting empirical antibiotic treatment to decrease the duration and severity of symptoms, and reduce the risk of progression to acute pyelonephritis or sepsis.[7,8,9,14,17]

The options for empirical antibiotic treatment of acute uncomplicated cystitis in non-pregnant females are as follows[14]:

1. Trimethoprim—first line treatment unless the patient has been treated with trimethoprim in the previous 3 months, or has a condition that contraindicates its use.
2. Nitrofurantoin—second line treatment when trimethoprim cannot be used, and there are no contraindications to use of nitrofurantoin.
3. Cefalexin—reserve for use when trimethoprim and nitrofurantoin cannot be used. Cefalexin oral suspension may be a suitable choice for patients with swallowing difficulties.

The appropriate antibiotic choice for a particular patient will depend on the patient's history of antibiotic use, medical conditions, and medicines. See *I. Contraindications and precautions, K. Drug interactions, M. Additional dosing advice and O. Adverse effects*.

## I. Contraindications and precautions

### Trimethoprim

Trimethoprim is contraindicated in patients with[47,48,49]:

- history of hypersensitivity to trimethoprim
- severe haematological disorders
- megaloblastic anaemia due to folate deficiency
- renal impairment (CrCl <10 mL/min); dose reduction is recommended in patients with CrCl <15 mL/min
- porphyria.

Trimethoprim should be used with caution in patients with[47,48]:

- hepatic impairment
- electrolyte disturbances—may worsen hyperkalaemia or hyponatraemia (low risk if treatment ≤3 days)
- folate deficiency—may worsen folate deficiency (low risk if treatment ≤3 days).

### Nitrofurantoin

Nitrofurantoin is contraindicated in patients with[47,48]:

- history of hypersensitivity or severe adverse effects from nitrofurantoin
- renal impairment (CrCl <60 mL/min), anuria or oliguria
- G6PD, enolase or glutathione peroxidase deficiency.

There is an increased risk of peripheral polyneuropathy when nitrofurantoin is used in patients with renal failure, anaemia, diabetes mellitus, electrolyte disturbances or vitamin B deficiency.[48]

**Cefalexin**

- Cefalexin is contraindicated in patients with history of hypersensitivity to cephalosporins, or immediate or severe hypersensitivity to penicillins.[47,48]
- Dose reduction should be considered in patients with renal impairment (CrCl <20 mL/min).[47,48]

The patient's My Health Record (MHR) may provide information needed to choose the most appropriate antibiotic treatment for the patient. However, do not assume the information in the MHR is a current or complete record. It is good practice to advise the patient of the MHR access, and document relevant information from the MHR in the patient's profile in the pharmacy's documentation system.[50]

Consult relevant reference texts and product information monographs if use of the most appropriate antibiotic requires caution.

Refer the patient to a medical practitioner if:

- insufficient information, contraindications or precautions compromise the safe use of each antibiotic
- the patient has impaired renal function.

## J. Lactation

Trimethoprim is considered safe to use during breastfeeding. Advise the mother to observe the breastfed infant for possible adverse effects (e.g. rash, vomiting, diarrhoea).[47,51]

Nitrofurantoin is considered safe to use during breastfeeding. However, use an alternative medicine in patients who are breastfeeding infants who are less than 1 month old, or who have glucose-6-phosphate dehydrogenase (G6PD) deficiency, as there is a risk of haemolysis in these infants.[47,51]

Cefalexin is safe to use during breastfeeding. Advise the mother to observe the breastfed infant for possible adverse effects (e.g. thrush, rash, vomiting, diarrhoea).[47,51]

## K. Drug interactions

Consider choosing an antibiotic that does not put the patient at risk of drug interactions. Refer the patient to a medical practitioner if potential drug interactions compromise the safe use of each antibiotic.

**Trimethoprim**

Trimethoprim can[47,48,52]:

- increase the risk of hyperkalaemia if taken with medicines that increase serum potassium (e.g. ACE inhibitors)
- increase concentrations and risk of toxicity of phenytoin, digoxin, lamivudine and zidovudine
- increase the anticoagulant effect of warfarin
- have an additive myelosuppressive effect if taken with other medicines that have a myelosuppressive effect (e.g. methotrexate, pyrimethamine, clozapine).

The risk of clinically significant interactions is low if trimethoprim is used for ≤3 days.[47,52]

**Nitrofurantoin**

Antibacterial activity of nitrofurantoin is lost if urine pH is >8. Urinary alkalinisers should not be used in patients being treated with nitrofurantoin.[49,52]

Uricosuric drugs such as probenecid can inhibit renal tubular secretion of nitrofurantoin, resulting in increased serum levels and decreased urinary levels of nitrofurantoin. Consequently, the risk of nitrofurantoin toxicity may increase and its effectiveness in treating UTI may decrease.[48,52]

**Cefalexin**

Cefalexin is not associated with clinically important adverse drug interactions.

## L. Dose

For treatment of acute uncomplicated cystitis in females use the following doses[14,47]:

- Trimethoprim 300 mg orally, daily at night for 3 nights.
- Nitrofurantoin 100 mg orally, every 6 hours for 5 days.
- Cefalexin 500 mg orally, every 12 hours for 5 days.

## M. Additional dosing advice

Trimethoprim should be taken at night to maximise urinary concentrations. Trimethoprim can be taken with food to reduce gastrointestinal adverse effects.[48]

Nitrofurantoin should be taken with food or milk to increase absorption and decrease gastrointestinal adverse effects.[48]

## N. Treatment expectations

Symptoms of acute uncomplicated cystitis should respond to appropriate antibiotic therapy within 48 hours. Dysuria usually improves within a few hours.[7]

## O. Adverse effects

**Trimethoprim**

Common adverse effects of trimethoprim include rash, itch, nausea and vomiting, and fever. Electrolyte disturbances (hyperkalaemia, hyponatraemia) can occur, but are more likely in patients taking high doses or who have renal impairment. In rare cases, trimethoprim can cause haematological disorders (e.g. thrombocytopenia, leucopenia, megaloblastic anaemia) or severe hypersensitivity reactions (e.g. anaphylaxis, Stevens–Johnson syndrome or toxic epidermal necrolysis).[47,48]

**Nitrofurantoin**

Common adverse effects of nitrofurantoin include nausea, abdominal pain, diarrhoea and headaches. Nitrofurantoin can cause brown discolouration of urine. Rare but serious adverse effects of nitrofurantoin include peripheral polyneuropathy (including optic neuritis), hypersensitivity reactions (including Stevens–Johnson syndrome and anaphylaxis), hepatic toxicity, pulmonary toxicity and haematological disorders (e.g. haemolytic anaemia, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia).[47,48]

**Cefalexin**

Adverse effects of cefalexin are rare. They include nausea, diarrhoea, abdominal pain, *Clostridium difficile*-associated disease (pseudomembranous colitis), hypersensitivity reactions, cholestatic jaundice and haematological disorders.[47,48]

Treatment with cefalexin can lead to superinfection with *Candida* spp., which may cause vulvovaginal candidiasis. A patient with dysuria may have vulvovaginal candidiasis secondary to use of cefalexin. See Table 1.[47,48]

## P. Self-care strategies

Advise patients that paracetamol or nonsteroidal anti-inflammatory drugs (e.g. ibuprofen, naproxen) can reduce the pain and discomfort of UTI.[14]

Urinary alkalinising agents may relieve dysuria, however their safety and efficacy have not been established.[14] They are not effective if CrCl <30 mL/min, are contraindicated in hypernatraemia and renal failure, and should be used with caution in patients with sodium restriction.[34,48] In addition, they should not be used concurrently with nitrofurantoin. See *K. Drug interactions*.

Counsel female patients about self-care strategies that may reduce the risk of further UTIs. These include[14,17,38]:

- increase fluid intake to 2–3 L daily
- reduce or stop use of spermicides
- empty bladder soon after sexual intercourse
- wipe from front to back when toileting
- empty bladder completely when urinating (e.g. by double voiding).

Provide the patient with the relevant Consumer Medicines Information (CMI) leaflet, and a *Urinary tract infection* Self Care Fact Card or other consumer information.

## Q. Follow-up advice

Advise the patient to consult a medical practitioner promptly if[7,38]:

- symptoms of cystitis persist 48–72 hours after starting antibiotic treatment
- symptoms of cystitis reoccur within 2 weeks after finishing antibiotic treatment
- symptoms develop that are not symptoms of acute cystitis.

Pharmacists should contact patients 7 days after providing the antibiotic to assess whether their symptoms have resolved. Refer the patient to a medical practitioner for further investigation if all symptoms have not completely resolved.

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PSA5318

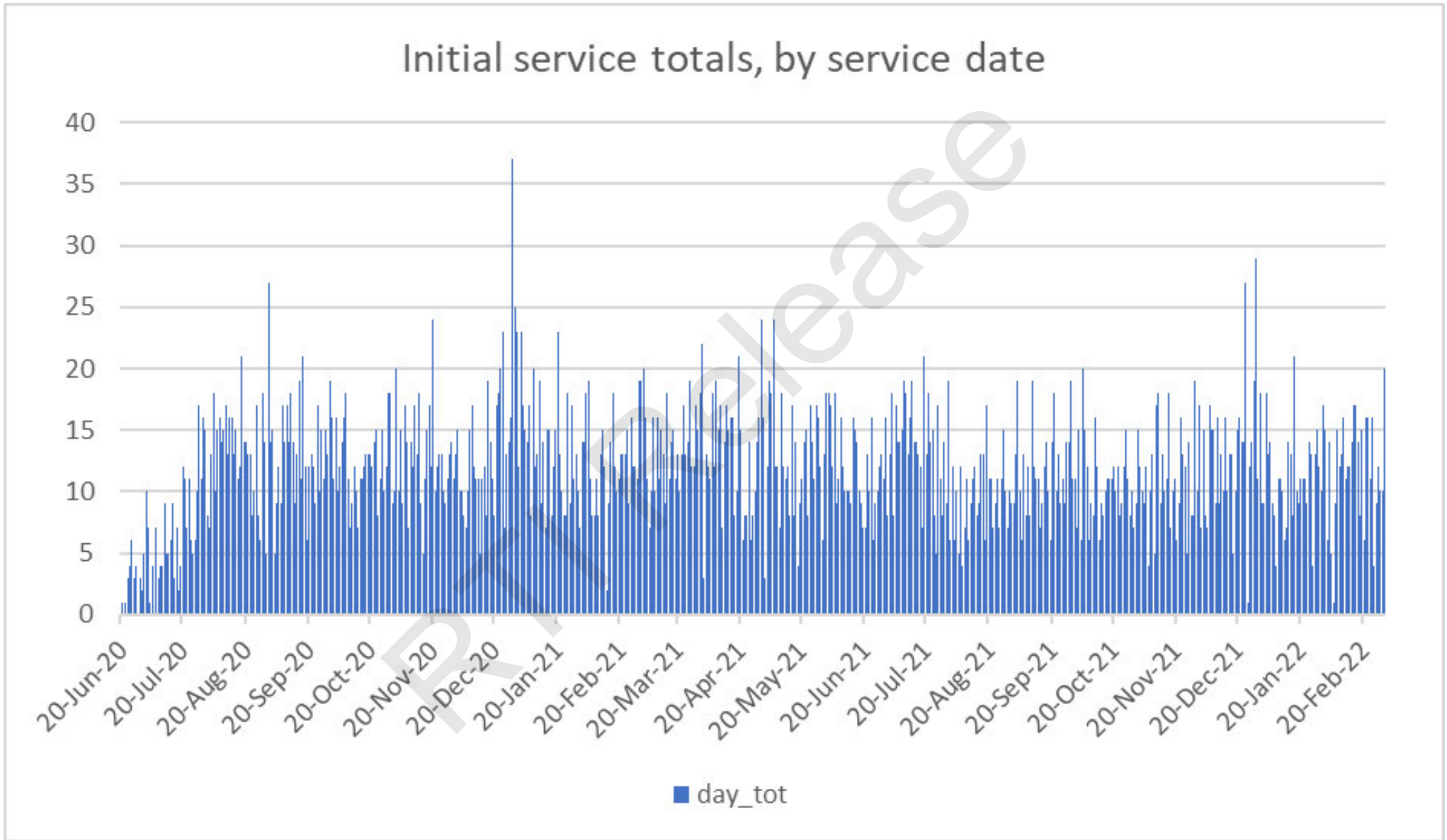
Endorsed April 2020.

# Summary of services – March 2022

| Approached, not completed‡ | Ineligible | | | Declined initial | Declined FU or uncontactable† | No evaluate | Initial only | Initial & FU# |
|---|---|---|---|---|---|---|---|---|
| | referred | not referred | unknown | | | | | |
| **89** | 347 | 74 | 72 | 215 | 1,639 | 904 | **4,913** | **2,538** |

Data scrape 3rd Mar 2022

- Total 7,451 services provided
- 34.1% (2,538/7,451) follow-up rate to date.
- Of the 4,913 initial services without follow-up, 33.3% (1,639/4,913) or 22.7% (1,639/7,451) of all initial services, declined follow-up or were uncontactable by pharmacists after three reasonable attempts.
- 1.3% (65/4,913) of initial services without FU were conducted within 7 days of the data scrape (therefore data on follow-up is still pending).
- Approved Sites: 817 Approved Pharmacists: 1999
- Patient satisfaction: 69


Initial service totals, by service date
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30
25
20
15
10
5
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20-Jun-20
20-Jul-20
20-Aug-20
20-Sep-20
20-Oct-20
20-Nov-20
20-Dec-20
20-Jan-21
20-Feb-21
20-Mar-21
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20-Jun-21
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20-Jan-22
20-Feb-22
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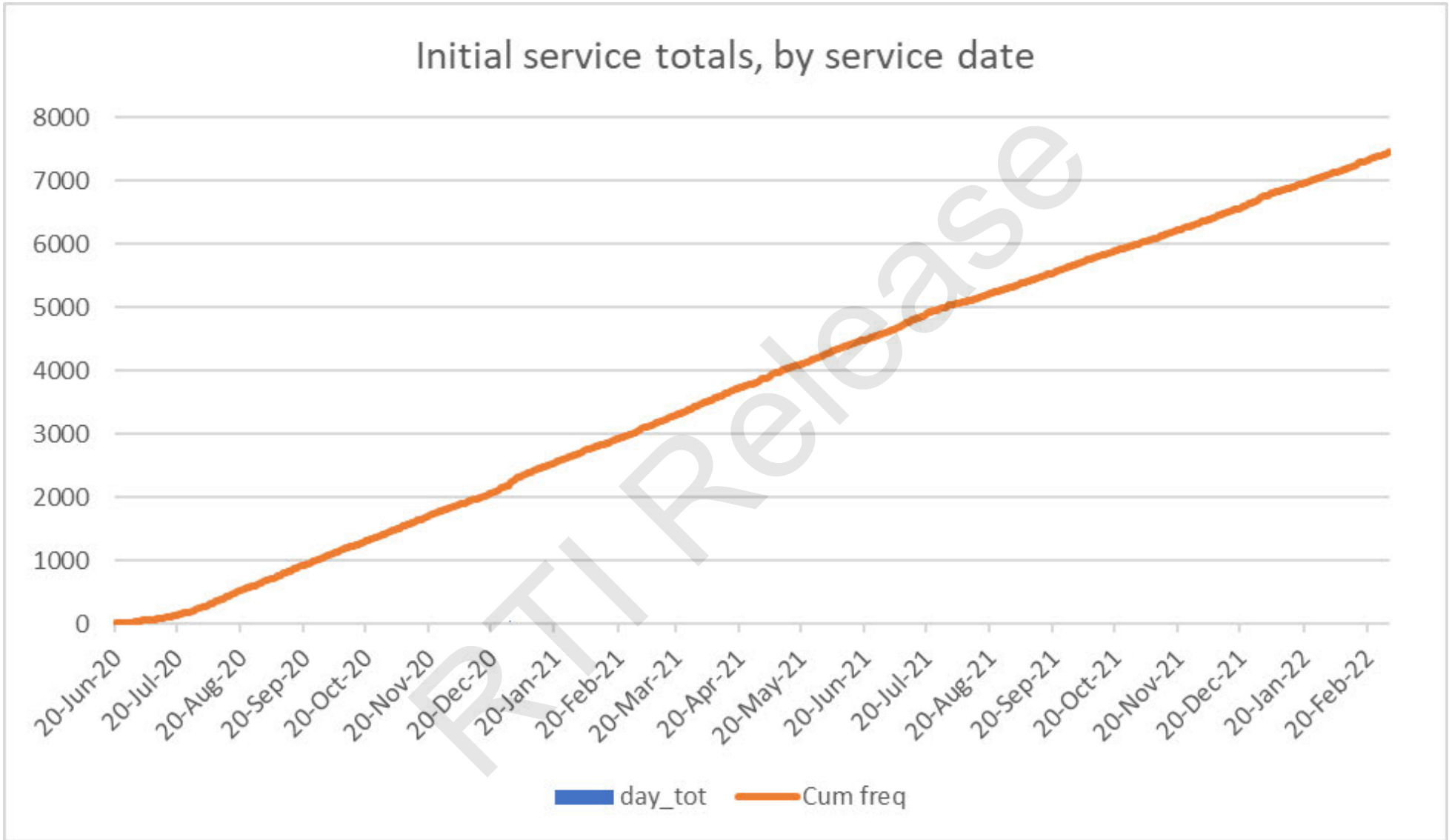
Initial service totals, by service date
8000
7000
6000
5000
4000
3000
2000
1000
0
20-Jun-20
20-Jul-20
20-Aug-20
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20-Oct-20
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