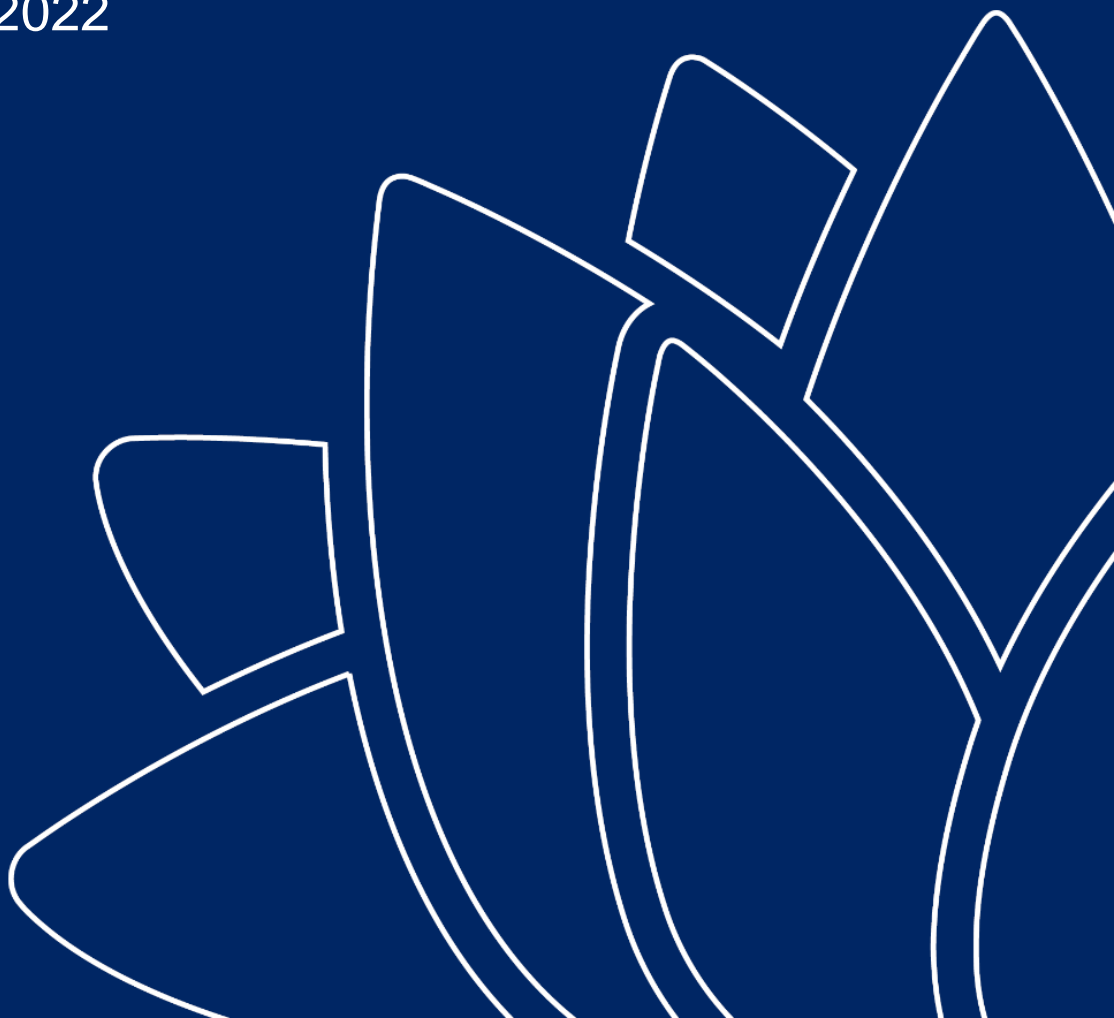


# Expression of Interest Guidance document

## Clinical trial - management of urinary tract infections by community pharmacists funding grant

14 November 2022



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## Introduction

The New South Wales (NSW) Government has committed to piloting the management of urinary tract infections (UTIs) by community pharmacists under a clinical trial framework to capture robust outcome data to inform the future scope and role of community pharmacists in the management of common acute conditions.

The implementation of a large-scale pilot across NSW will help the government and NSW Health to better understand the benefits and risks to patients of pharmacy prescribing and supply within a specific patient cohort.

Expressions of Interest (EOI) are invited from research institutions in NSW to conduct the clinical trial and report on robust outcome measures to the NSW Government – this includes measurements of treatment success, complications and any recommendations regarding safe implementation for pharmacist prescribing for UTI in NSW.

## Context

### Recent pilots in Australia

Further to a two-year pilot program, the Queensland Government will be implementing regulatory changes to allow Queensland community pharmacists to manage UTIs through supply of antibiotics to a select patient cohort.

Further information on the outcomes of the Queensland pilot is available at: [The management of urinary tract infections by community pharmacists: A state-wide trial : Urinary Tract Infection Pharmacy Pilot - Queensland \(Outcome Report\) | QUT ePrints.](#)

### NSW context

There are significant differences in primary care arrangements in Australia, and overseas programs are not directly comparable to the more fragmented system of primary care in NSW.

Whilst earlier appropriate treatment of UTIs may assist in reducing symptoms and distress, it is important to ensure that any risks for individuals and the population will be balanced by the benefits.

To better understand both qualitatively and quantitatively, the benefits and risks of pharmacist prescribing of antibiotics in NSW, a clinical trial

(including systematic collection of patient outcomes and experienced side effects) is proposed.

The clinical trial will be broad scale across NSW, with a particular emphasis on rural and regional areas where timely primary care access can be more challenging. Independent verification and documentation of outcome measures will also be critical to ensure any future changes to scope of practice and/or role of community pharmacists in patient management have been holistically considered and evaluated within the NSW primary care setting.

### Grant funding

The clinical trial will be eligible for a grant of up to \$3 million for 12 months implementation, followed by the evaluation and reporting of outcomes.

Funding will support the establishment, implementation and evaluation of the clinical trial.

## Call for applications

NSW Health invites eligible individuals to submit an EOI for a funding grant to undertake a clinical trial for the management of UTIs by community pharmacists.

## Purpose

Consideration of community pharmacists' management of UTIs in the context of balancing the benefits of increased early intervention and mitigating risks to patient safety, as well as appropriate use of antibiotics.

## Objectives

The key objectives are to:

- better understand, both qualitatively and quantitatively, the benefits of community pharmacists managing UTIs for a specific patient cohort (women aged between 18 years and 65 years); and
- identify any specific risks that can be mitigated in a broader roll out.

## Design principles

- Pharmacists confident when to prescribe and when not to prescribe, including referral to GP or hospital.

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

## Key measures of success

The following key measures of success have been identified:

Community pharmacists' management of UTIs:

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

## Assessment criteria for the EOI

Selection will be determined by an evaluation panel and judged against the assessment criteria below.

1. Approach to co-design with relevant stakeholder groups such that the trial assists in understanding future implementation.
2. Proven expertise in utilisation of MBS, PBS and hospital admission data to assist in the routine monitoring of outcomes from the trial.
3. Expertise and experience that is highly relevant to the proposed research.
4. Ability to demonstrate experience in translational research.
5. The host organisation is NSW based.

## Application process

### Submission of applications

All applications must be completed using the EOI application form and include supporting evidence. The form can be found at:

[www.medicalresearch.nsw.gov.au/community-pharmacists-uti-management-clinical-trial/](http://www.medicalresearch.nsw.gov.au/community-pharmacists-uti-management-clinical-trial/)

All applications must be submitted by email to:

[moh-pharmacytrial@health.nsw.gov.au](mailto:moh-pharmacytrial@health.nsw.gov.au)

by 5pm, 4 December 2022.

Late or incomplete applications will be deemed ineligible.

Enquiries may be directed to:

Email: [moh-pharmacytrial@health.nsw.gov.au](mailto:moh-pharmacytrial@health.nsw.gov.au)

### Indicative timeline

The application process will be held in two stages:

1. Call for applications 14 November 2022
2. EOI applications close 4 December 2022
3. Short-listed applicants to present a high-level research proposal to evaluation panel on 16 December 2022
4. Announcement of successful applicant 14 January 2023.