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# Timely post-discharge medication reviews to Improve Continuity—the Transitions Of Care stewardship (TIC TOC) study in rural and regional Australia: a parallel-group randomised controlled trial study protocol

Jonathan Penm ,[1,2] Kingston Yeung ,[1] Rebekah Jane Moles,[1] Deirdre Criddle,[3] Rohan A Elliott ,[4,5] Deborah Rigby,[6] Sepehr Shakib ,[7,8,9] Frank Mario Sanfilippo ,[10,11] Stephen Ross Carter ,[1] Charley Budgeon ,[10,11] Kim Nguyen ,[12] Paul Yates,[13,14,15] Katie Phillips,[16] Jerry Yik,[17] Faye McMillan,[18] Deborah Hawthorne,[19] Cristen Fleming,[20] Anna Packer ,[20] Linda Krogh ,[20] Simon K Poon,[21] Brett Chambers,[20] Shania Liu,[1] Fatemeh Emadi,[1] Jenny Chen,[1] Klaudia Englezos,[1] Ganga Ratnanayagam,[1] Michelle Penm,[22] Andrew Hawthorne,[23] Alexander Khlentzos,[24] Jilian Khlentzos,[24] Manya Angley[25]

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For numbered affiliations see end of article.

**Correspondence to**
Dr Jonathan Penm;
jonathan.penm@sydney.edu.au

## ABSTRACT

**Introduction** Transition of care from hospital is a period when the risks of medication errors and adverse events are high, with 50% of adults discharged having at least one medication-related problem. Pharmacist-led medication reviews can reduce medication errors and unplanned readmission when completed promptly post-discharge; however, they are underutilised. A Transition of Care Stewardship pharmacist has been proposed to facilitate and coordinate a patient's discharge process and facilitate a timely post-discharge medication review. Access to pharmacist medication review in rural and regional areas can be limited. This protocol describes a randomised controlled trial (RCT) to determine whether a virtual Transition of Care Stewardship pharmacist reduces medication-related harm in rural and regional Australia.

**Method and analysis** Multicentre RCT involving patients at high risk of medication-related harm discharged from regional and rural hospitals to a domiciliary residence. Eligible patients must be aged≥18 years, admitted under a medical specialty, be discharged to a domiciliary setting, have a regular general practitioner (GP) or be willing to visit a GP or an Aboriginal Medical Service after discharge for medical follow-up, have a Medicare card and be at high risk of readmission. High risk of readmission is defined as either a previous admission to the hospital or Emergency Department (ED) presentation in the past 6 months AND≥three regular medications OR on at least ONE high-risk medication. A total of 922 participants will be recruited into the study. Enrolled participants will be randomised to the intervention or control (usual care). The intervention will include a virtual Transition Of Care Stewardship pharmacist to ensure that patients receive discharge medication reconciliation, medication counselling, medication list and communicate directly with primary care providers to facilitate a timely post-discharge medication review. Usual care will include informing the patient's clinical inpatient treating team that the patient is at high risk of medication misadventure and may benefit from a post-discharge Home Medicines Review (a GP-referred pharmacist medication review funded by the Australian Government).

Data analysis will be performed on a modified intent-to-treat basis. The primary outcome assessed is a composite of a first unplanned medication-related hospitalisation or ED presentation within 30 days of hospital discharge.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is a large randomised controlled trial, which is typically considered high-quality evidence that supports estimates of intervention effects.
⇒ The study intervention is based on the Consolidated Framework of Implementation Research, which has been used extensively to implement health services.
⇒ The intervention will test a virtual Transition of Care Stewardship model to facilitate timely post-discharge Home Medicine Review services, which are currently available but not necessarily optimised or utilised effectively.
⇒ Exposure of hospital clinicians to the intervention may influence their management of control patients, which may bias our study findings.
⇒ Further qualitative studies will be needed to inform the design and development of an implementation strategy, including adaptability, acceptability, feasibility and context.

Comparisons between the intervention and usual care groups for the primary outcome will be made using a mixed-effects logistic regression model, adjusting for site-level clustering as a random effect.

**Ethics and dissemination** This study is approved to be conducted at the Western New South Wales Local Health District via the Research Ethics and Governance Information System (approval number: 2023/ETH00978). To ensure the needs of Aboriginal and Torres Strait Islander patients are appropriately addressed, ethics for this study were submitted and approved by the Aboriginal Health and Medical Research Council (approval number: 2148/23). Manuscripts resulting from this trial will be submitted to peer-reviewed journals. Results may also be disseminated at scientific conferences and meetings with key stakeholders.

**Trial registration number** ACTRN12623000727640.

## INTRODUCTION

### Background

Transitions of care (TOC) refer to when a patient's healthcare moves between different care providers; it is a period when the risks of medication errors and adverse events are high.[1] Errors during this period may occur from poor communication and incomplete documentation, resulting in poor handover[2] and medication access delays.[3] Medication errors and discrepancies on discharge and TOC issues are common, with 50% of adults having at least one medication error on discharge.[4] Improving medication safety at care transitions is one of the three flagship areas of the WHO Global Patient Safety Challenge: Medication Without Harm.[5 6]

Pharmacists are experts in medication management and are appropriately placed to support a patient's medication management during the TOC from the hospital. Pharmacist interventions, including discharge medication reconciliation, counselling and medication review, can support a patient's TOC and may reduce hospital readmissions and ED revisits.[7–11] To improve patients' quality use of medicines and reduce medication errors, the Australian Federal Government funds collaborative Home Medicine Reviews (HMRs),[12] where a general practitioner (GP) refers a patient at risk of medication misadventure to receive a medication review in the community by a pharmacist credentialled in HMRs. The credentialed pharmacist then prepares a report, which the patient and doctor discuss afterwards, and develops a medication management plan.

Despite Australian Government funding for pharmacist HMRs, on referral from a GP or specialist medical practitioner, the provision of HMRs to high-risk patients after discharge is unacceptably low at 1%–2%.[13 14] Multiple factors have been attributed to the low uptake of post-discharge HMRs. Such factors include limited staffing in hospitals focusing on TOC services, only medical practitioner-referred HMRs being funded, poor awareness among medical practitioners and inefficiencies with current processes (lack of streamlined pathways, inconsistent prioritisation and identification of suitable patients between hospitals and clinicians).[15]

To allow flexibility and improve uptake of HMRs, in 2020, the Federal Government enabled credentialed pharmacists to be remunerated to undertake HMRs when referred by medical practitioners other than GPs, including hospital-based medical specialists. When post-discharge medication reviews are facilitated by the hospital treating team via GP referral or hospital-based medical specialist referral, they are considered 'hospital-initiated medication reviews' (HIMRs). Protocols for HIMRs, including post-discharge HMR, have been developed by Advanced Pharmacy Australia (AdPha) (formerly the Society of Hospital Pharmacy Australia (SHPA)) to ensure clear roles and responsibilities between hospitals and GPs.[16] These protocols also support utilising existing structures by engaging with the patient's usual GP throughout the process. Despite the publication of the HIMR protocols, anecdotally, the uptake of post-discharge HMRs has not changed significantly.[15 17] Additional factors for this low uptake include GPs not being remunerated for participating if the hospital-based medical practitioner refers for HMR, and HMR numbers capped at 30 monthly for each credentialed pharmacist. Furthermore, pharmacists are not funded to participate in case conferences, which poses a further barrier to optimal medication management during TOC.

A Transition Of Care Stewardship (TOCS) approach, with a TOCS pharmacist as steward, has been proposed to help coordinate and facilitate a patient's discharge process and ensure that a timely post-discharge medication review occurs for high-risk patients[15 17] facilitated through the AdPha HIMR–HMR protocol.[16] Utilising the implementation science framework (CFIR)[18] and evidence from systematic reviews,[7 8] the addition of a virtual TOCS pharmacy service to routine care is proposed to assist rural and regional Australians in transitioning back to the community and ensure timely post-discharge HMRs occur to improve continuity and safety of medication management. The virtual TOCS pharmacist can ensure that patients have discharge medication counselling, reconciled discharge medication lists and discharge summaries, and communicate relevant information directly with primary care providers (GPs, practice nurses, community pharmacies and credentialed pharmacists) to ensure accurate and timely medication handover and facilitate timely post-discharge medication reviews.[10 19–21] They will streamline the HMR referral process and provide the link between primary care and the hospital.[18]

Such a service may benefit rural and remote Australians the most as they have been identified as being 2.4 times more likely to experience a potentially preventable hospitalisation than non-rural Australians.[22] Furthermore, Aboriginal and Torres Strait Islander people, who often live in rural and regional areas, are three times as likely to have a potentially preventable hospitalisation than non-indigenous Australians.[22 23] Inappropriate or suboptimal pharmacological therapy and inadequate communication or monitoring are common causes of medication-related readmissions in rural and regional Australian hospitals.[24] Western New South Wales Local Health District

(WNSWLHD) is home to an estimated 309 700 people and is geographically dispersed over 250 000 km$^2$.[25] It has 15% more preventable hospitalisations than the rest of NSW and contains significant vulnerable populations.[25] Previous studies in WNSWLHD have identified patients' at high risk of readmission,[26] which include a previous admission or ED presentation in the past 6 months and taking three regular medications or a high-risk medication. Focussing on improving the discharge process for such patients may reduce medication-related harms.

Despite the prevalence of medication use in WNSWLHD, many rural and remote hospitals do not have onsite pharmacists to optimise patient care and prevent medication errors.[27] Virtual clinical pharmacy services have been demonstrated as a feasible, acceptable and scalable solution to providing clinical pharmacy services in rural and remote hospitals in Western NSW, in hospitals where onsite pharmacists are unavailable to provide direct patient contact.[27 28] Virtual clinical pharmacy services have been successfully implemented in hospitals in NSW to overcome geographical and workforce barriers, providing pharmacy care, including patient counselling about medicines and medication reconciliation.[27 29] Focus groups showed doctors, nurses and allied health professionals endorsed the virtual service and valued having access to specialised medication advice.[27] Data collected from this service also identified improved patient safety by preventing medication errors.[27] However, the current virtual clinical pharmacy service is not routinely involved in the patient's discharge process back to the community.[29]

### Aims

The primary aim of this study is to determine whether a virtual TOCS pharmacist-led intervention can reduce the incidence of medication-related harm, including hospital readmissions and Emergency Department (ED) presentations, compared with usual care in high-risk patients. Medication-related hospital visits will be defined using the AT-HARM10 tool.[30 31] Secondary aims include a range of TOC process measures, including whether the patient received discharge medication reconciliation, discharge summary and post-discharge HMR, and follow-ups where appropriate.

## METHODS AND ANALYSIS

### Study design

This protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement (online supplemental appendix 1). A multicentre randomised controlled trial design is used to determine the effect of a virtual TOCS pharmacist-led intervention on the incidence of medication-related harms. Participant recruitment will occur over 20 months, with follow-ups of all patients for data collection up to 3 months post-discharge.

### Study setting

This study will be conducted in rural and regional hospitals in WNSWLHD. WNSWLHD has many significant vulnerable populations, including 13% Aboriginal and Torres Strait Islander residents, 31% older residents (aged 55 years and over), socially disadvantaged residents (80% of the area occupies the five lowest 1–5 deciles for the index of relative socioeconomic disadvantage) and remote communities (44% are classified as remote or very remote). Nineteen regional and rural hospitals from WNSWLHD will be included as follows: Baradine, Blayney, Canowindra, Coolah, Coonamble, Cowra, Dunedoo, Forbes, Gilgandra, Grenfell, Gulgong, Mudgee, Narromine, Nyngan, Oberon, Parkes, Walgett, Warren and Wellington.

### Inclusion and exclusion criteria

Inclusion criteria for participants will be aged≥18 years, admitted under a medical specialty, discharged to a domiciliary setting, have a regular GP or be willing to visit a GP or Aboriginal Medical Services after discharge for medical practitioner follow-up, have a Medicare card and be at risk of readmission.

Previous studies have identified risk factors associated with readmission in patients from the trial population (WNSLHD) and were used to develop the inclusion criteria. These include:

- Previous admission to hospital or ED presentation in the past 6 months AND≥three regular medications OR
- On at least ONE high-risk medication (online supplemental table 1)

Exclusion criteria include patients who died during their index admission, admission≤24 hours, patients receiving end-of-life care, planned admission (including dialysis, chemotherapy, transfusions and surgery) or previously recruited.

### Recruitment

The research team will screen admitted patients against the inclusion and exclusion criteria. Research assistants will invite participants meeting the eligibility criteria during their admission to participate in the study and provide an information statement (online supplemental information 1) and consent form (online supplemental information 2). Patients will also be encouraged to register their interest in participating either by themselves or through site staff, with participating sites displaying flyers and posters of the trial. Consent forms will include the provision of access to their electronic health record, as well as government-owned linked data. Eligible participants will be included after consent is obtained. The participant will receive a study enrolment number, which will be recorded on all the participant's study documents (figure 1).

### Randomisation and blinding

On enrolment, participants will be randomised in a 1:1 ratio in permuted blocks of 2 and 4 to (1) intervention

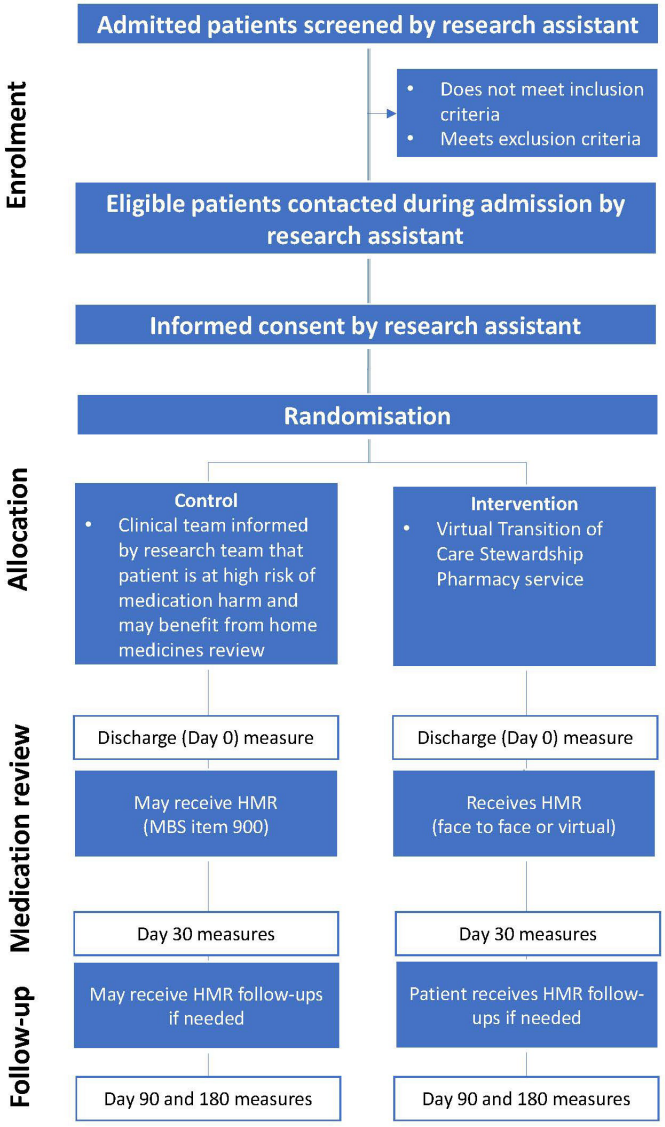


**Figure 1** Flowchart of TIC TOC clinical trial. HMR, Home Medicine Reviews. TIC TOC, Timely post-discharge medication reviews to Improve Continuity—the Transitions Of Care stewardship.

or (2) usual care. Randomisation will be conducted using a centralised service (Research electronic data capture, REDCap (Vanderbilt University Medical Center, Nashville, Tennessee, USA))[32 33] to ensure allocation concealment.

Due to the nature of the intervention, it is not possible to blind the participants, hospitals or clinicians. However, the research staff collecting follow-up data and statisticians completing data analysis will be blinded.

## Intervention

The intervention is based on the CFIR, which has been used extensively to implement health services (figure 2).[18] The intervention will include a virtual TOCS pharmacist whose tasks will ensure patients receive discharge medication reconciliation, counselling and medication lists and communicate relevant information directly with primary care providers (GPs, practice nurses, community pharmacies and credentialed HMR pharmacists). They will provide accurate and timely medication handover to facilitate a timely post-discharge medication review within 10 days of discharge. The medication review process will follow the medication review guidelines of the Pharmaceutical Society of Australia and be consistent with the Australian Government's programme rules for HMRs, including up to two follow-up visits if deemed necessary by the credentialed pharmacists. Patients' autonomy is central to the intervention, as they can choose a face-to-face HMR or a virtual HMR. If patients prefer virtual HMR, all attempts will be made to have an audio and visual component. However, patients may receive an HMR conducted via telephone if this is not feasible. In addition to the credentialed pharmacist providing a comprehensive HMR report to the referring medical practitioner and other relevant parties, patients will receive written information from the credentialed pharmacist, including an updated medication list, to improve their understanding of their medication management. The updated medication list will be patient-centred, including the timings of medications, and will highlight any medication adjustments, cessations or those requiring review with the patient's primary care provider.

Furthermore, collaboration between GPs, credentialed pharmacists, community pharmacists and other relevant parties, as appropriate, will be encouraged through case conferences to discuss complex patients. The intervention will also be adapted to local needs.[18] Pharmacists providing services to Aboriginal and Torres Strait Islander peoples will complete Cultural Responsiveness Training by the Indigenous Allied Health Australia and the Deadly Pharmacist Foundation Training course by the Pharmaceutical Society of Australia.[34]

## Control

Usual care will include the research team informing the patient's clinical inpatient team using the hospital system's electronic health records that the patient is at high risk of readmission and may benefit from a post-discharge HMR. The patient's hospital medical officer may, at their discretion, communicate the need for an HMR to the patient's regular GP via usual pathways (eg, medical discharge summary) without the involvement of a TOCS pharmacist. Patients may have a pharmacist involved in the discharge at the discretion of the treating medical team.

## Sample size calculation

Based on an effect size of 10% absolute reduction (40%–30%)[9 35] in 30-day readmission or ED presentation, an alpha of 0.05 and power of 0.8, 356 patients per group (712 total) is required. Accounting for an attrition rate of 15%, the sample size will be increased to 838 patients. In addition, to allow for the clustering design, using a variance inflation factor of 1.1 (ie, intraclass correlation 0.002 between sites), the total sample size required will be 922.

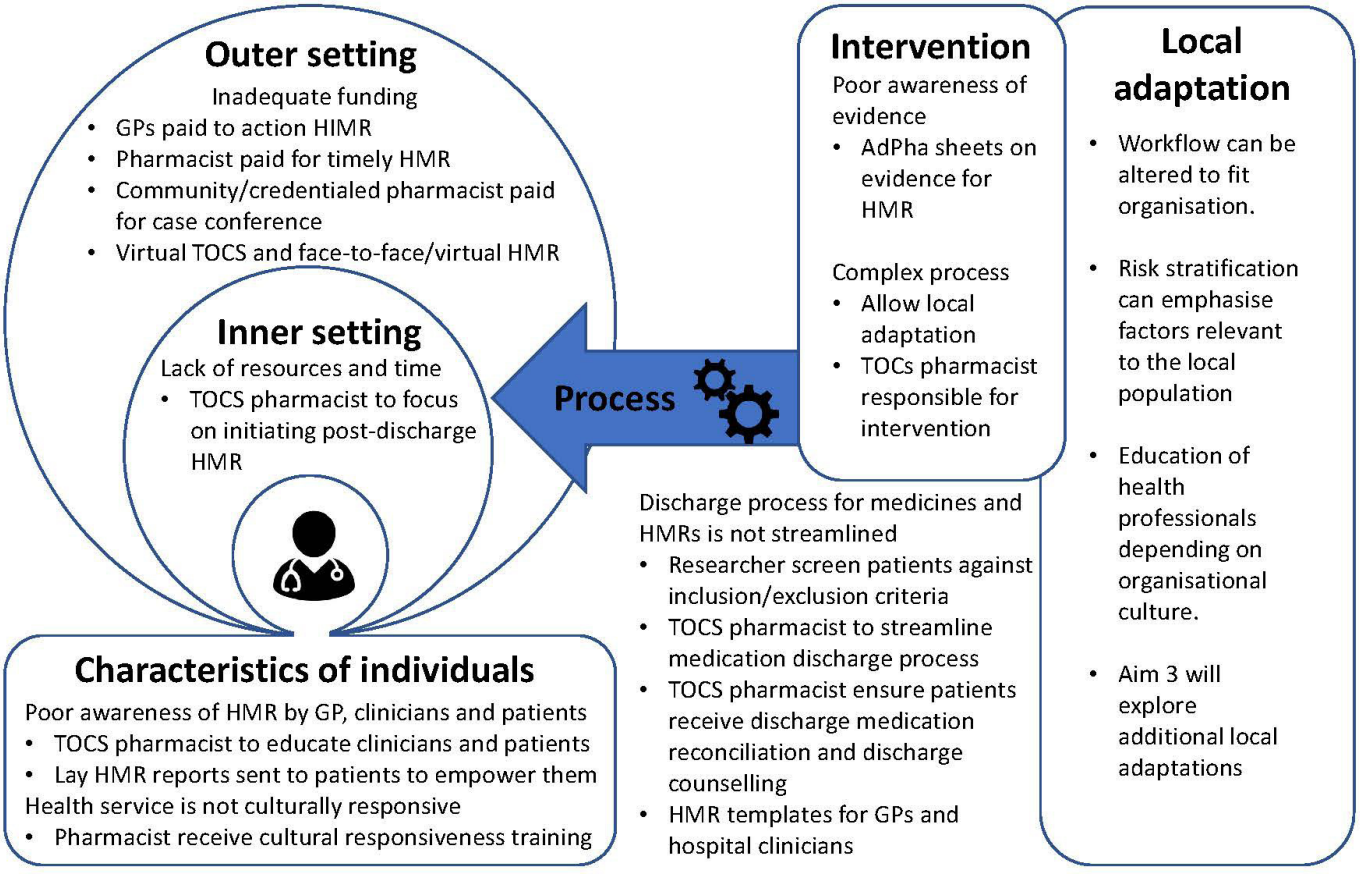


**Figure 2** Intervention components based on the Consolidated Framework for Implementation Research. AdPha, Advanced Pharmacy Australia; GPs, general practitioners; HIMR, Hospital-initiated medicines review; HMR, Home Review Medicine; TOCS, Transition Of Care Stewardship.

### Outcome and process measures

The primary outcome of this study is the composite of a first unplanned medication-related readmission or ED presentation within 30 days of hospital discharge. This will be identified by thoroughly reviewing each case using linked data and the AT-HARM10 tool[30 31] to identify medication-related readmissions or ED presentations. The AT-HARM10 tool is a validated tool consisting of 10 questions to identify possible medication-related hospital readmissions and ED presentations. Other outcome measures and process measures are described in table 1.

Patient demographics, comorbidities, Charlson Comorbidity Index, medications, length of stay and representation information will also be obtained from hospital information systems. Patients will be telephoned 30 and 90 days after discharge to obtain follow-up data through questionnaires. Readmission data will be obtained through linked data from the Australian Institute of Health and Welfare (AIHW) and the NSW Centre for Health Record Linkage (CheReL). Death data will be obtained from death registers.

The start date for trial recruitment is July 2024, and final recruitment of participants should be completed by February 2026. The final participant follow-up will be completed in August 2026.

### Data analysis plan

All analyses will be performed on a modified intention-to-treat basis. Participants will be randomised on consent; however, eligibility status will be confirmed on discharge, and ineligible participants (eg, patients transferred and discharged from other hospitals or discharged to residential aged care facilities) will be excluded from the analysis. Standard summary statistics will be reported for all variables. Comparisons between the intervention and usual care groups for the primary outcome (composite of a first unplanned medication-related hospitalisation or ED presentation within 30 days of hospital discharge) will be assessed using a mixed-effects logistic regression model, adjusting for site-level clustering as a random effect. A competing risk analysis will be performed (with death as the competing risk) using Fine and Gray subdistribution hazard models should there be a considerable number of deaths within 30 days of hospital discharge. Subgroup analyses will also be conducted on Aboriginal and Torres Strait Islander status. Secondary outcomes will be analysed similar to the primary outcome. Poisson regression (dependent on the distribution) will be used to compare the intervention and control groups' medicine counts. Sensitivity analyses using a per-protocol approach will also be performed. A two-sided p-value≤0.05 will be considered statistically significant.

Table 1 Measures and data collected at set time points

| | Data source | Post-discharge (days) 0 | 30 | 90 | 180 |
|---|---|---|---|---|---|
| Outcome measure | | | | | |
| Medication-related readmission/ED presentation | Linked data/AT-HARM10[30 31] | | ✓ | ✓ | ✓ |
| All-cause readmission or ED presentation | Linked data | | ✓ | ✓ | ✓ |
| Total length of unplanned hospitalisation | Patient record | | ✓ | ✓ | ✓ |
| Patient's quality of life | EQ-5D-5L[36] | ✓ | ✓ | ✓ | |
| Patient experience of TOCS service (intervention) | Patient survey[43] | | ✓ | | |
| Process measures | | | | | |
| Patients recruited | Patient record | ✓ | | | |
| Medication reconciliation provided on discharge | Patient record | ✓ | | | |
| Discharge summary provided on discharge | Patient record | ✓ | | | |
| Discharge medication list provided to patient | Patient record | ✓ | | | |
| Time to post-discharge medication review | Credentialed pharmacist | | ✓ | | |
| Received follow-up for HMR | Credentialed pharmacist | | ✓ | ✓ | ✓ |
| Number, type and severity of medication-related problems resolved by TOCS pharmacist | Indicators[44] and expert panel | ✓ | ✓ | | |
| Number, type and severity of medication-related problems resolved during HMR | Indicators[44] and expert panel | | ✓ | | |
| Consumers' self-efficacy for medication use | SEAMS Survey[45] | ✓ | | | |
| Number of medicines | Patient/My Health Record/ Community Pharmacy | ✓ | ✓ | ✓ | |
| Appropriate medicines indicators | Patient/My Health Record/ Community Pharmacy | ✓ | ✓ | ✓ | |

ED, Emergency Department; EQ-5D-5L, EuroQol 5 Dimension 5 Level; HMR, Home Medicine Review; SEAMS, Self-efficacy for Appropriate Medication Use Scale; TOCS, Transition Of Care Stewardship.

## Data management plan and sharing

Data will be collected and stored on a secure online platform approved by the Sponsor. Reidentifiable data will be stored in a password-protected cloud-based software. No data will be stored on personal computers. Data will be stored for 15 years as per the Sponsor's policy. After this period has elapsed, the research data will be destroyed permanently. Random checks of 10% of data will be conducted for quality assurance. Access to these records will be restricted to the research team members.

Data from this study will be made available as soon as possible and available on reasonable request. The project steering committee will review data access requests.

## Cost-effective analysis

A within-trial cost-effectiveness analysis of the Timely post-discharge medication reviews to Improve Continuity—the Transitions Of Care stewardship (TIC TOC) intervention on 30-day hospital readmissions and ED presentations in regional and rural hospitals will be undertaken from the health system perspective. The comparator will be the current model of care, and the primary outcomes of the economic analyses include unplanned readmissions, ED visits and medication-related problems identified during the post-discharge cycle of care. Incremental cost-effectiveness ratios will be calculated as the incremental cost per unplanned hospitalisation/ED visit (for all unplanned and medication-related harm cases).

The analysis will consist of three main parts. First, primary outcomes for each treatment arm are calculated (TIC TOC intervention vs best usual care). Second, all costs to implement the intervention and usual care throughout the trial are accounted for. Costs might include staff time, training and any additional resources required to deliver and engage stakeholders. For each patient, we will collect information related to their health service use within each care cycle. These data can be captured by the hospitals' electronic record systems or by follow-up enquiries (see description below). Costs will be valued based on government charges using publicly available data and reported in Australian dollars. Third, the cost-effectiveness analysis will be modelled using techniques appropriate for randomised controlled trial (RCT) and the non-normal nature of both the cost and outcome variables (eg, a generalised linear model with robust SEs).

Following the base case analysis, univariate and probabilistic sensitivity analyses will be conducted around key parameters likely to influence the cost and effectiveness estimates, including variability in the sampling, trial sites and patient populations by risk factors.[36]

A supplementary economic analysis using an alternative outcome, health-related quality of life measured by the EuroQol 5 Dimension 5 Level (EQ-5D-5L), will be conducted to compare the cost-effectiveness of the TIC TOC intervention to best usual care from a quality-of-life perspective. The EQ-5D-5L scores will be converted into utility, which will be used as the input for the cost-utility analysis. This analysis follows the same procedure and uses similar econometric techniques as the (primary) cost-effectiveness analysis described above. Its outcome will offer additional evidence regarding the cost-effectiveness nature of the intervention.

### Public and patient involvement

The project team will harness consumer engagement mechanisms already existing at WNSWLHD, allowing consumer collaboration for any required material, such as consent forms or patient surveys. In addition to the district-wide engagement process, the region has numerous programme-specific committees with formalised consumer representation mechanisms, which can be utilised for consultation. An Aboriginal Reference Group is established for the study to ensure that the research is community-driven, culturally sensitive and aligned with the specific needs of the Aboriginal community. This group is composed of members from the local Aboriginal community who are actively participating in shaping and informing the research. Their valuable perspectives, cultural insights and lived experiences will ensure that the research is relevant, respectful and beneficial for Aboriginal and Torres Strait Islander patients. A comprehensive invitation letter outlining the study's specific details and objectives has been prepared.

To ensure that the needs of Aboriginal and Torres Strait Islander patients are appropriately addressed, several measures have been implemented. First, an Aboriginal Health Impact statement was developed in collaboration with WNSWLHD. Furthermore, the ethics for this study were submitted through the Aboriginal Health and Medical Research Council (AH&MRC). Seeking ethics approval through AH&MRC ensures that the research aligns with the highest ethical standards and addresses potential risks or concerns for the Aboriginal community. The team also comprises experienced researchers who have conducted trials in Aboriginal and Torres Strait Islander patients, including an Aboriginal (Wiradjuri) pharmacist researcher. Furthermore, AH&MRC is a project partner in the study to provide additional advice and support.

## ETHICS AND DISSEMINATION

### Ethics approval

Ethics for this study was submitted to the Research Ethics and Governance Information System and approved by the Human Research Ethics Committee (approval number: 2023/ETH00978). Site-specific approval was also granted for this study to be conducted at the WNSWLHD. To ensure the needs of Aboriginal and Torres Strait Islander patients are appropriately addressed, ethics for this study were submitted and approved by the Aboriginal Health and Medical Research Council (approval number: 2148/23).

### Ethical and safety considerations

Participant involvement is voluntary, and informed consent is required. At recruitment, participants will be asked to provide consent to linked data sets, including AIHW and CheReL. Participants can withdraw from the study or the collection of linked data at any time. Patients randomised to the control group will receive usual care, and the trial is designed to assess the effects of the intervention. There is currently no evidence that this will be inferior to the intervention group.

Participants will be assigned a unique study identification number to maintain their confidentiality. Participant data will be stored in a secure database, with access to records restricted to the research team. Data received from data custodians (AIHW and ChereL) will first be deidentified to remove personally identifiable information. Unique identifiers are tied to individual participants, and a separate set of linking keys will be created for each record in each database. The linking keys do not contain identifiable information and are unique random codes that allow records to be matched across different databases. Linkage between data sets will be based on matching linking keys, and no personal information will be used during this process. Any identifiable information will be excluded from any presented data.

Similar to standard care, participants randomised to the intervention group who receive a post-discharge HMR may have changes made to their medications in consultation with their healthcare providers. The credentialed pharmacist may recommend reducing the dose or stopping some medicines, alongside other medication changes or medication monitoring, to improve medicine safety or quality use of medicines. These recommendations are implemented (or not) in consultation with the whole team, which may include a medical specialist (where appropriate), GP, pharmacists and participants. The decision to prescribe or deprescribe is ultimately at the discretion of the participant's GP and is implemented in consultation with the participant.

Credentialed pharmacists are trained to prioritise recommendations for resolving or preventing any potential medication-related problems. Any urgent issues identified by a credentialed pharmacist will be verbally communicated to the referring medical practitioner.[37] If necessary, emergency services will be called for the patient.

### Dissemination plan

Manuscripts reporting findings from this trial will be submitted to various targeted peer-reviewed journals. Results may also be disseminated at scientific conferences and meetings with key stakeholders. At this stage, no plans for sharing future data, follow-up research, or secondary use of data are anticipated.

## DISCUSSION

Reducing medication errors and adverse events during TOC has become a global priority.[5 6] Pharmacists, as medication experts, are uniquely placed to provide interventions in hospital, including medication counselling, medication reconciliation and medication reviews, to improve patient outcomes, including a reduction in risk of readmission.[7 8] Post-discharge primary care pharmacist-led medication services, which include medication reconciliations, medication reviews and patient education, further support the TOC journey, reducing adverse drug events and readmissions.[3 38] However, post-discharge pharmacist-led interventions are often underutilised, with approximately 2% of patients receiving an HMR. Barriers to effective utilisation include poor communication, complex medication review referral processes, delayed referral and/or review, limited resources, high patient workload[15] and challenges patients face with access to credentialed pharmacists in regional areas.[39] Alternative pathways that can potentially reduce GP referral delays, such as hospital-based medical specialists referral for post-discharge HMR,[16] also face similar challenges. Introducing a virtual TOCS pharmacist is proposed to overcome these barriers,[17] including geographical challenges, providing additional support and resources to clinicians while simultaneously creating new communication channels, improving handover and coordinated care to facilitate timely post-discharge HMRs, and in turn, reducing medication-related readmissions. While the feasibility of an onsite TOC liaison pharmacist has been demonstrated in facilitating timely post-discharge HMRs in an implementation trial, the study was not designed or sufficiently powered to investigate the TOCS pharmacist role in preventing medication-related harms. This RCT is powered to investigate whether the TIC TOC intervention reduces the incidence of unplanned medication-related readmissions and ED presentations.

The success of this trial requires the development of effective implementation strategies to assist with rolling out the service across WNSWLHD. Notably, this regional and rural area spans a large area, with patients having difficulty accessing regular healthcare professionals, and approximately 13% of the population of WNSWLHD services identifies as Aboriginal and Torres Strait Islander,[25] highlighting the need for culturally safe interventions.[40 41] To ensure the intervention's longevity, adaptability and success, consistent engagement with key stakeholders is required. Several reference groups have been established to enrich the feedback process. This includes an Aboriginal and Torres Strait Islander reference group, a consumer reference group, executives of WNSWLHD and various professional representative reference groups. This collaborative approach will ensure that the needs of multiple perspectives are considered and integrated into the implementation strategy, enhancing its relevance and effectiveness. Previous literature has identified important measures to inform the design and development of an implementation strategy, including adaptability, acceptability, feasibility and context. Formative qualitative interviews will be conducted with key stakeholders, such as clinicians and patients. Interviews will explore potential facilitators, barriers and perceived solutions, as well as the acceptability and adaptability of the service in creating a culturally safe intervention for Aboriginal and Torres Strait Islander patients.

During TOC, medication errors are common, and patients often have a poor understanding of medication changes at discharge. Patient personal medication lists are frequently incomplete, containing several discrepancies, which may confuse patients and clinicians involved in their care. Pharmacists-led post-discharge medication reconciliation and reviews have been identified in previous systematic reviews as effective in identifying and resolving such medication discrepancies. However, patients have expressed interest in receiving further information after medication reviews, which may include a medication list that specifies medication directions and timings. As such, a design feature of the TIC TOC intervention includes credentialed pharmacists completing a medication reconciliation and providing patients with an updated patient-friendly medication list with annotations based on discussions made during the HMR service.

This proposed study design has several strengths, notably its large-scale RCT design, which is considered a robust method for providing high-quality evidence to support estimates of intervention effects.[42] Furthermore, the intervention is proposed to optimise HMR services through the implementation of TOCS pharmacist services. Incorporating reference groups and formative qualitative interviews with key stakeholders will contribute valuable insights into design and implementation strategies, ensuring a tailored approach. The virtual nature of the intervention overcomes geographical barriers and improves access for rural and regional patients. However, there may be several limitations to consider. Exposure of hospital clinicians to the TOCS pharmacist and HMR referral process, who typically are not involved with facilitating post-discharge HMR referral procedures, may influence and increase their recommendations for post-discharge HMRs in discharge summaries for control participants, which may bias our study findings.

**Author affiliations**
[1]School of Pharmacy, Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia
[2]Department of Pharmacy, Prince of Wales Hospital, Randwick, New South Wales, Australia

[3]Complex Needs Coordination Team and Sir Charles Gairdner Hospital Pharmacy Department, Sir Charles Gairdner Hospital, Nedlands, Western Australia, Australia
[4]Pharmacy Department, Austin Health, Heidelberg, Victoria, Australia
[5]Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, ClaytonParkville, Victoria, Australia
[6]DR Pharmacy Consulting, Brisbane, Queensland, Australia
[7]Discipline of Pharmacology, University of Adelaide, Adelaide, South Australia, Australia
[8]Department of Clinical Pharmacology, Royal Adelaide Hospital, Adelaide, South Australia, Australia
[9]Faculty of Health and Medical Sciences, University of Adelaide, Adelaide, South Australia, Australia
[10]School of Population Health and Global Health, The University of Western Australia, Perth, Western Australia, Australia
[11]Cardiovascular Epidemiology Research Centre, University of Western Australia, Perth, Western Australia, Australia
[12]Center for Health Services Research, Faculty of Medicine, The University of Queensland, Brisbane, Queensland, Australia
[13]Faculty of Medicine, Dentistry, and Health Sciences, University of Melbourne, Melbourne, Victoria, Australia
[14]Department of Geriatric Medicine, Austin Health, Heidelberg, Victoria, Australia
[15]The University of Melbourne, Department of Medicine, Austin Health, Heidelberg, Victoria, Australia
[16]Hospital Admission Risk Program, The Royal Melbourne Hospital, Melbourne, Victoria, Australia
[17]Advanced Pharmacy Australia, Collingwood, Victoria, Australia
[18]School of Public Health, University of Technology Sydney, Broadway, New South Wales, Australia
[19]Deborah Hawthorne Consultancy, Melbourne, Victoria, Australia
[20]Western New South Wales Local Health District, Dubbo, New South Wales, Australia
[21]School of Computer Science, Faculty of Engineering, The University of Sydney, Sydney, New South Wales, Australia
[22]Redfern Station Medical Centre, Redfern, New South Wales, Australia
[23]Benalla Church Street Surgery, Benalla, Victoria, Australia
[24]Dubbo Family Doctors, Dubbo, New South Wales, Australia
[25]Manya Angley Research and Consulting, Adelaide, South Australia, Australia

**X** Deborah Rigby @drugby56 and Frank Mario Sanfilippo @CVRG_UWA

**Contributors** Conceptualisation and methodology; writing—original draft; funding acquisition: JP, RJM, SRC, SKP, MA, DC, RAE, DR, KN, SS, FMS, CB, PY, JY, FM, CF, AP, LK, DH, MP, AH, AK, JK and KP. Writing—review and editing: JP, RJM, SRC, SKP, MA, DC, RAE, DR, KN, SS, FMS, CB, PY, JY, FM, CF, AP, LK, DH, MP, AH, AK, JK, KP, BC, SL, FE, JC, KE, GR and KY. Project administration: JP and GR. Guarantor: JP.

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**ORCID iDs**
Jonathan Penm http://orcid.org/0000-0001-9606-7135
Kingston Yeung http://orcid.org/0000-0002-1813-9620
Rohan A Elliott http://orcid.org/0000-0002-7750-9724
Sepehr Shakib http://orcid.org/0000-0002-7199-5733
Frank Mario Sanfilippo http://orcid.org/0000-0003-3639-0787
Stephen Ross Carter http://orcid.org/0000-0002-4670-0884
Charley Budgeon http://orcid.org/0000-0002-1910-5561
Kim Nguyen http://orcid.org/0000-0002-2592-9372
Anna Packer http://orcid.org/0000-0003-0372-4373
Linda Krogh http://orcid.org/0009-0004-5831-7358

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