

BMJ Open Protocol for a feasibility study of an Indigenous Medication Review Service (IMeRSe) in Australia

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ABSTRACT

Introduction The age-adjusted rate of potentially preventable hospitalisations for Aboriginal and Torres Strait Islander people is almost five times the rate of other Australians. Quality use of medicines has an important role in alleviating these differences. This requires strengthening existing medication reviewing services through collaboration between community pharmacists and health workers, and ensuring services are culturally appropriate. This Indigenous Medication Review Service (IMeRSe) study aims to develop and evaluate the feasibility of a culturally appropriate medication management service delivered by community pharmacists in collaboration with Aboriginal health workers.

Methods and analysis This study will be conducted in nine Aboriginal health services (AHSs) and their associated community pharmacies in three Australian states over 12 months. Community pharmacists will be trained to improve their awareness and understanding of Indigenous health and cultural issues, to communicate the quality use of medicines effectively, and to strengthen interprofessional relationships with AHSs and their staff. Sixty consumers (with a chronic condition/pregnant/within 2 years post partum and at risk of medication-related problems (MRPs) per site will be recruited, with data collection at baseline and 6 months. The primary outcome is the difference in cumulative incidence of serious MRPs in the 6 months after IMeRSe introduction compared with the 6 months prior. Secondary outcomes include potentially preventable medication-related hospitalisations, medication adherence, total MRPs, psychological and social empowerment, beliefs about medication, treatment satisfaction and health expenditure.

Ethics and dissemination The protocol received approval from Griffith University (HREC/2018/251), Queensland Health Metro South (HREC/18/QPAH/109), Aboriginal Health and Medical Research Council of New South Wales (1381/18), Far North Queensland (HREC/18/QCH/86-1256) and the Central Australian HREC (CA-18-3090). Dissemination to Indigenous people and communities will be a priority. Results will be available on the Australian Sixth Community Pharmacy Agreement website and published in peer-reviewed journals.

Trial registration number ACTRN12618000188235; Pre-results.

BACKGROUND AND RATIONALE

Access to medicines, and the quality use of medicines, is critical to closing the substantial gap in morbidity, mortality and life expectancy

Strengths and limitations of this study

- This study is the first Australian attempt to develop and assess the feasibility of a culturally appropriate, strengths-based, Indigenous Medication Review Service (IMeRSe).
- In addition to serious medication-related problems, consideration will be given to other culturally appropriate outcomes including potentially preventable medication-related hospitalisations, and participants' growth and empowerment.
- IMeRSe should demonstrate effectiveness in reducing medication-related problems and potentially preventable medication-related hospitalisations, the findings will inform the development of a large randomised controlled trial.
- As this is a feasibility study, there is no control group, and the comparison is made between the outcome indicators observed pre intervention and post intervention.
- This study makes a unique contribution to the pharmacy outcome literature in trialling the use of potentially preventable medication-related hospitalisations as a primary outcome measure.

between Aboriginal and Torres Strait Islander and other Australians.¹ Health inequalities are particularly apparent among Indigenous Australians with chronic diseases.² Despite these health differentials, access to health services is only 1.1 times higher than the non-Indigenous rate due to barriers including cost, lack of culturally appropriate services and location of services.¹ Solely on the basis of the proportionally poorer health of Indigenous Australians, access rates would be expected to be at least two to three times higher.

Strategies to prevent medication-related problems (MRPs) have attracted much research, policy and practice interest in

¹Please note that the use of the term 'Indigenous' in this manuscript includes all Aboriginal and Torres Strait Islander people and acknowledges their rich traditions and heterogeneous cultures.



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Australia over the past 20 years.^{3 4} There is a well-defined need for a medication management service that is flexible and responsive to the needs of Indigenous people.^{5 6} Disparities in health literacy, and the lack of culturally responsive practices in some pharmacies, are problematic issues.⁷⁻⁹ Addressing the high rates of medication misadventure, adherence issues and the resulting increase in hospitalisations among Indigenous people is a priority,^{10 11} particularly given that potentially avoidable hospitalisations are almost five times those of non-Indigenous Australians, with over half associated with chronic conditions.¹²

Pharmacist-led medication management services including MedsCheck/Diabetes MedsCheck¹³ and Home Medicines Review¹⁴ (HMR)ⁱⁱ have reported positive results,¹⁵ with studies also demonstrating cost-effectiveness outcomes.^{16 17} While high-risk consumers (eg, those recently discharged from hospital and/or with chronic conditions) benefit most from medication management reviews,¹⁸⁻²⁰ Australian studies show that these are not well used by Indigenous people,^{21 22} which is unlikely to change unless their specific needs are addressed.^{17 23} Barriers to Indigenous people accessing medication review services include cultural and linguistic challenges, geographical isolation and the one-off, short-term, focus of interventions.^{6 24 25} Making medication management review services culturally safe for Indigenous people requires involvement from an Aboriginal health practitioner or Aboriginal health worker (AHW), family member/s and/or an interpreter. However, current funding models often prohibit these staff accompanying an Indigenous person to a medication review.^{6 15} Additional pharmacist training and mentoring, alongside interprofessional relationship building, may also be required to address the specific health and cultural needs of Indigenous consumers and their communities.

The costs of delivering medication management services are typically higher due to consumer choice of location and the need to provide a culturally responsive service; both factors suggest reconfigured funding models.²⁶ The potential for well-designed medication management review services to avoid the high costs of potentially preventable hospitalisations is expected to offset higher delivery costs. Moreover, engaging a culturally responsive, community-focused, approach has been shown to have significant economic benefits.²⁷

ⁱⁱThe MedsCheck and Diabetes MedsCheck Programme provides for in-pharmacy reviews of consumers who are taking multiple medications and/or have newly diagnosed or poorly controlled type 2 diabetes. These reviews are aimed at enhancing the quality use of medicines and reducing the number of adverse drug events experienced by consumers. A Home Medicines Review (HMR) is designed to enhance the quality use of medicines and reduce the number of adverse medicine events by assisting consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient's home (<http://www.6cpa.com.au/medication-management-programs>).

This Indigenous Medication Review Service (IMeRSe) will optimise individuals medication management via a culturally responsive service, delivered by community pharmacists integrated with Aboriginal health services (AHSs).

Evidence gap

As the IMeRSe intervention has not been previously tested, the methods and evidence required to undertake a randomised controlled trial (RCT) are not available. They include

1. Training framework for pharmacists to work more effectively with Indigenous consumers, family members and communities; develop effective communication strategies and pathways; ensure culturally responsive health practices; and necessary documentation and processes to deliver IMeRSe.
2. Training for AHS staff to work more effectively with pharmacists to identify and support Indigenous consumers to manage their medicines.
3. Systems for effective communication between all health professionals involved in the medicines-related care of Indigenous consumers.
4. Baseline data on the number of MRPs in the Indigenous population.
5. Likely effect size of the intervention.

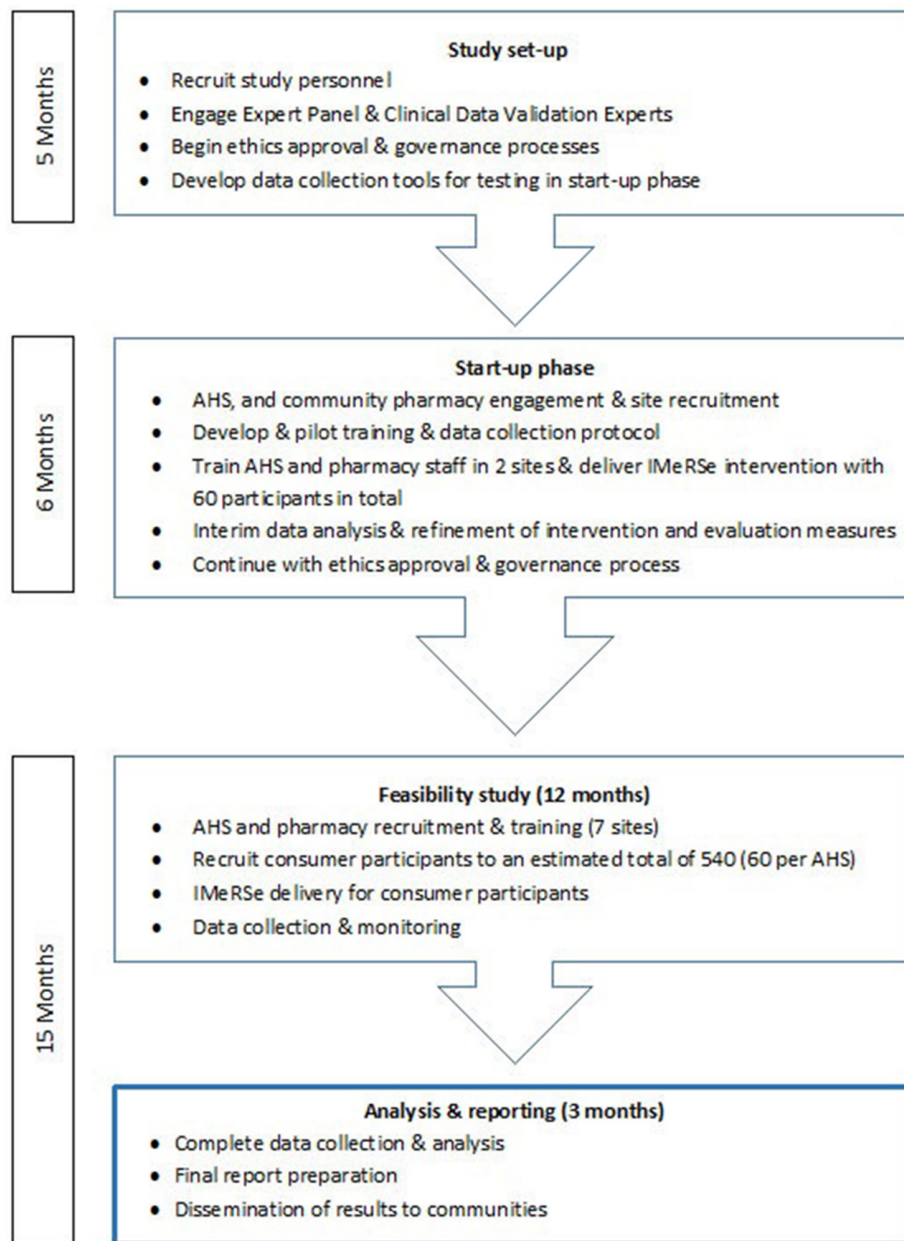
The feasibility of conducting the IMeRSe intervention will be tested in nine sites, with the results informing a future RCT.

Study objectives

1. To develop a high-quality intervention (IMeRSe) for improving medication management for Indigenous consumers through enhanced integration of community pharmacists and AHSs.
2. To ensure the intervention is acceptable and implementable across a range of settings (including urban, regional/rural and remote) and AHS types (Aboriginal Community Controlled Health Services and government AHSs), including study enrolment and retention rates.
3. To describe current understandings of 'usual care' and key differences in understanding evoked by this term across a range of settings and service types.
4. To investigate the practicality of identifying serious MRPs through the use of a prespecified list of potentially preventable medication-related hospitalisations (PPMRHs) that can be used to estimate the effect of the IMeRSe intervention.

METHODS

An overview of the IMeRSe feasibility study is provided in [figure 1](#). Key to the success of this study is genuine engagement with Indigenous people, communities and associated organisations. The engagement process will be informed by the National Health and Medical Research Council's Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.²⁸ Principles include Reciprocity, Respect, Equality Responsibility, Survival and



AHS=Aboriginal Health Service

Figure 1 Overview of the Indigenous Medication Review Service (IMeRSe) feasibility study.

Protection, underpinned by working with Spirit and Integrity. An Expert Stakeholder Panel (including Indigenous advisers) will provide the research team with guidance on the practicalities and cultural sensitivities of implementation and evaluation, engagement and communication strategies, development and piloting of training materials and resources, recruitment and retention of participants and local stakeholders, and research translation. A Clinical Validation Group will be established to identify the list of serious PPMRHs that will be used as the primary outcome measure.

Study setting and population

This study will be conducted in nine sites comprising AHSs and their associated community pharmacies in three

Australian regions (Queensland, New South Wales and the Northern Territory). Two sites (one in Queensland and in the Northern Territory) will serve as initial start-up sites to test study processes over 6 months prior to the implementation of the feasibility study in remaining sites (table 1).

AHS sites that are heterogeneous, spanning remote, rural, regional and urban locations will be identified and offered a provisional invitation. Interviews will then be conducted to determine the management and staff capacity of services to participate; community pharmacies providing medication for consumers of the selected AHSs will be asked to consider participating. A screening

Table 1 Distribution of Aboriginal health services (AHSs) and community pharmacies

State or territory	Queensland	New South Wales	Northern Territory
Setting	AHS n (community pharmacy n)	AHS n (community pharmacy n)	AHS n (community pharmacy n)
Urban	2* (up to 10 CPs)	1 (up to 5 CPs)	–
Regional/Rural	1 (2 CPs)	1 (2 CPs)	–
Remote	2 (2 CPs)	1 (1 CP)	1* (1 CP)

*One start-up site from Queensland (urban) and one from Northern Territory (remote).
CP, community pharmacy.

questionnaire and interviews will be conducted with key staff in these pharmacies and those with sufficient capacity to release staff for training and facilitate consistent delivery of IMeRSe will be considered for participation.

Eligibility for Indigenous consumers will include receiving healthcare from one of the nine AHSs and meeting the following inclusion criteria:

- ▶ At risk of MRPs (as identified by any health professional involved in their care, family members or self-identified) including but not limited to the following:
 - Instability of health status and/or medicines therapy.
 - Using a high-risk medicine(s).
 - Likelihood of compromised adherence.
 - New therapeutic goals.
 - Potentially incomplete understanding of pattern of medicine use.
 - Failure to respond to treatment in an expected way.
- ▶ Aged 18 years and over.
- ▶ Living in the community.
- ▶ Have used the clinical services of the AHS at least three times in the past 2 years.²⁹
- ▶ Use a community pharmacy that is participating in the study.
- ▶ Have a chronic condition, and/or pregnant, and/or within 2 years post partum.
- ▶ Able to provide written informed consent.

Receiving any existing Medication Management Programme (such as HMR, MedsCheck/Diabetes MedsCheck) in the previous 12 months will be an exclusion criteria.

Consumer participants will be enrolled in the study for a period of 6 months (12 months for participants in both start-up sites).

IMeRSe intervention

The intervention is a six-step process comprising a medication review (Tier 1) and additional structured follow-up and monitoring if required (Tier 2) conducted by a community pharmacist, with a consumer participant (with family and/or support people), and an AHW or clinician as described below:

Step 1: Consumer identification and informed consent

A range of strategies will be used to enrol consumers at risk of a MRP including opportunistic identification by health workers (eg, general practitioners (GPs), nurses, AHWs), at scheduled and unscheduled appointments; and/or community pharmacists when dispensing medication; and/or via outreach workers identifying MRPs at home; and consumers or family members may also self-identify MRPs. More targeted identification may be undertaken using clinical databases, for example, reviewing databases for eligible consumers on a specific combination of medicines, or multiple medications. Once identified, the IMeRSe Coordinator (a trained AHS clinical staff member) will screen potential participants to ensure that they meet eligibility criteria, explain the intervention process, provide an information sheet and complete the consent process. The participant's GP will be notified and invited to provide input into clinical considerations and the potential usefulness of IMeRSe for the participant.

Step 2: Referral, information exchange and appointments

The IMeRSe Coordinator will document baseline information (including demographic and social characteristics, current medications, beliefs about medicines, treatment satisfaction, adherence, psychological well-being and empowerment, etc, as outlined in table 2), book an appointment for the *Medicines Talk* conversation (see Step 3) with the pharmacist and in preparation for this conversation provide them with the participant's health summary, and organise an appointment with the relevant GP (see Step 4) as soon as possible thereafter. The IMeRSe Coordinator will facilitate information exchange between all participants and arrange all appointments.

Step 3: Medicines Talk

This initial conversation (referred to as Tier 1), at a location nominated by the participant, will include the pharmacist, the AHW or nominated AHS staff member and any other requested support person such as family member(s). This first meeting will support the participant having a conversational review of all their medicines, treatment satisfaction, confidence and adherence with medicines, and identification of problems and goals related to their medicines or general health. This conversation will be based on the *Stay Strong App*,³⁰ a

Table 2 Consumer participant data collection framework.

Time point	Baseline	6 months	12 months (only in two start-up sites)	Data source
Informed consent	x	–	–	IMeRSe Coordinator and participant
Assessments			–	
Demographics	x	–	–	IMeRSe Coordinator and participant
Cultural identification	x	–	–	IMeRSe Coordinator and participant
Support networks	x	–	–	IMeRSe Coordinator and participant
AHS attendance and use	x	x	x	IMeRSe Coordinator and participant
Clinical history (including medications, hospital admissions and MRPs)	x	x	x	IMeRSe Coordinator and participant health records
Health resource use	x	x	x	MBS, PBS and pathology records
Care coordination	x	x	x	IMeRSe Coordinator and participant
Beliefs about Medicines Questionnaire-specific ⁴⁰	x	x	x	IMeRSe Coordinator and participant
Medication adherence (RAMS ⁴⁰)	x	x	x	IMeRSe Coordinator and participant
Treatment Satisfaction Questionnaire for Medication ⁴¹	x	x	x	IMeRSe Coordinator and participant
Health and well-being (GEM ⁴³ ; Kessler–10) ³⁹	x	x	x	IMeRSe Coordinator and participant
Medicines review and follow-up				
<i>Medicines Talk</i> (Stay Strong Plan)	x (+follow up)	–		Pharmacist and participant
MRPs	x (+follow up)	–		GuildCare records (identified by pharmacist)
<i>Medicines Report</i>	x (+follow up)	–		GuildCare records (compiled by pharmacist)
<i>My Medicines Plan</i>	x (+follow up)	–		GuildCare records (compiled by GP)
Participant feedback about IMeRSe				
Satisfaction and experience	–	x	x	IMeRSe Coordinator and participant Interview with researcher

Reported Adherence to Medication Scale⁴⁰; Growth and Empowerment Measure.⁴³

AHS, Aboriginal health service; GP, general practitioner; IMeRSe, Indigenous Medication Review Service; MBS, Medicare Benefits Schedule; MRPs, medication-related problems; PBS, Pharmaceutical Benefits Scheme.

resource culturally adapted for Indigenous people. This four-step App uses a holistic, strengths-based approach, combining problem-solving therapy and motivational interviewing in a visually appealing intervention, positioning health worker and patient as collaborative partners. It explores family and connections, strengths, worries and goals for change and was selected for this study to increase pharmacists confidence when talking with Indigenous participants about their health and well-being concerns and goals.^{30 31} Resolution of problems may occur during this initial conversational review (eg, via explanation/education and/or resource provision) as part of a three-way (ie, participant, pharmacist and AHW) learning process where each party has the opportunity to share, and learn from, others. It is expected to take approximately 60 min.

Step 4: Medicines Report

After the *Medicines Talk* a report, written by the community pharmacist in consultation with any AHS staff who attended the appointment, will be shared with the IMeRSe Coordinator and GP, saved to the participant's electronic health record and uploaded into *My Health Record*ⁱⁱⁱ (where available).³² The report will include recommendations for the GP to develop a *My Medicines Plan*.

ⁱⁱⁱMy Health Record is a secure opt-out online summary of an individual's health information, introduced in 2018 and available to all Australians. Healthcare providers authorised by their healthcare organisation can access My Health Record to view and add to their patient's health information. Information available includes: a patient's health summary, medication prescribing and dispensing history, pathology reports, diagnostic imaging reports and discharge summaries (<http://www.myhealthrecord.gov.au>).

Step 5: My Medicines Plan

The GP will prepare a medication management plan (*My Medicines Plan*) in collaboration with the participant, community pharmacist and other relevant AHS staff. *My Medicines Plan* will be filed in the participant's electronic medical record, *My Health Record*, and the pharmacy record, so that all practitioners at the AHS and community pharmacy can access it. *My Medicines Plan* will also be provided to the consumer in a printed format.

Step 6: Structured follow-up and monitoring

My Medicines Plan will include any follow-up actions agreed by the participant, community pharmacist and GP. These will be considered as Tier 2 of the intervention and will include any additional community pharmacist follow-up and review needed to address ongoing problems such as adherence strategies, administration technique support (eg, inhalers, spacers), monitoring, side effects and symptom management/resolution, smoking cessation and other health-related goals. Tier 2 may also involve recommendations for other services, such as Dose Administration Aids or referral to other health professional services. The IMeRSe Coordinator will facilitate any further face-to-face follow-up meetings as needed. The community pharmacist will update the *Medicines Report* so that the treating GP can incorporate ongoing or new recommendations in the participant's *My Medicines Plan*.

Training

For the IMeRSe intervention to be effective, it is essential that strong working relationships are fostered between: the pharmacist and the AHS staff; the pharmacist and the consumer participant; and AHS staff and community pharmacy staff. This includes the building/strengthening of interpersonal and interprofessional relationships, participants developing the skills and confidence to ensure effective communication, and familiarising health professionals with the administrative and IT tasks involved with IMeRSe delivery. Training will be delivered in three interrelated components:

1. Pharmacist cultural responsiveness, communication and IMeRSe delivery training and mentoring.
2. Introduction and orientation at the AHS site and training.
3. Community pharmacy site visit.

An expected outcome of this training approach is the establishment of a 'community of practice' whereby pharmacists (and their teams) develop sustainable and meaningful relationships with their local AHS staff. The 'community of practice' will emerge as a result of groups of people with a shared purpose sharing their experiences and finding common understandings about the importance of medicines and the optimal ways Indigenous peoples seek, and prefer to receive, healthcare. Details of the three interrelated training components are outlined below.

Pharmacist cultural responsiveness, communication and service delivery training and mentoring

The development of training and resource materials for pharmacists to improve their awareness and understanding of Indigenous health and cultural issues, and ability to communicate quality use of medicines more effectively, are critical to the success of the study.

Training for pharmacists will be delivered by experienced Indigenous trainers and experienced pharmacy trainers and will focus on increasing awareness and understanding of Indigenous health and cultural issues and delivering a strengths-based medication review service (IMeRSe). It will be piloted face-to-face in a 1-day workshop for the relevant start-up phase pharmacists. A key element will be developing effective communication strategies for building relationships with Indigenous consumers and AHS staff. Case vignettes and role-plays will reinforce key aspects, such as the initial conversation between the consumer participant, pharmacist and AHW using the *Stay Strong App*^{30 31} (as part of the *Medicines Talk*). Training will take pharmacists through the various steps involved in delivering IMeRSe, data collection and the recording procedures.

Elements of the training workshop will be filmed, in particular the role-play examples, to ensure consistent training messages are delivered throughout the feasibility study and available subsequently to be used as resources for the proposed future RCT.^{33 34} The trainers will deliver workshops for all pharmacists involved in the feasibility study (up to a maximum of 46 pharmacists), providing them with opportunities to work together to build their confidence and skills to provide effective medication review services for their Indigenous consumers, and to share their experiences with colleagues, thereby establishing a community of practice. The trainers will continue to support the community pharmacists in a mentoring role that will be ongoing throughout the recruitment and intervention delivery period. Feedback from community pharmacists in a previous study³⁵ rated the mentoring support they received highly, and the mentors acknowledged the importance of the unique skills and expertise they provided to support pharmacists deliver the intervention and model the importance of effective relationships and good collaborative practice.

Introduction and orientation at the AHS and training

An introduction, traditional welcome and orientation will be facilitated through each local AHS, led by local members of the community and AHS staff. Each AHS will provide local and regionally specific information that will form the basis of sharing a deeper understanding of the history of that community and their particular cultural protocols. The research team will facilitate a formal arrangement about study processes including the days and times the pharmacist(s) will be at the AHS and/or locations where they can meet with consumer participants and AHS staff; completing required documentation for the feasibility study; and any other site-specific

information deemed necessary by the AHS, including locally approved processes to facilitate communication.

Additionally, the research team will train the IMeRSe Coordinator and other AHS staff (GPs, nurses and AHWs) to discuss how the intervention may benefit their service and community; identify and recruit eligible participants; identify the most frequent types of MRPs encountered at the AHS and how these are typically managed. A discussion between the pharmacist(s) and AHS staff will be facilitated to ensure that everyone involved in the intervention and follow-up activities understands their roles and responsibilities, particularly regarding data collection processes and the use of the IMeRSe module within GuildCare NGTM. A Standardised Operating Procedure will be developed to provide specific detail on the protocol for the coordinator and pharmacists.

Community pharmacy site visit

The last training component will comprise site visits by the research team and/or the IMeRSe Coordinator to the community pharmacy(ies). As community pharmacy support staff are often the first point of contact for consumers, it is important that they are aware of their pharmacy's involvement in the study and are encouraged to make potential consumer participants feel comfortable about seeking pharmacist advice. If mutually agreed, AHS staff may provide further training for the wider pharmacy team with respect to locally specific communication issues and cultural protocols.

Study outcomes

The primary outcome is the difference in the cumulative incidence of serious MRPs for the 6 months after IMeRSe introduction compared with the mean serious MRPs that occurred in the 6 months prior. The definition of serious MRPs will be prespecified by reviewing the existing literature³⁶ and refined by the Clinical Validation Group (CVG); a group of 15 clinical experts using a modified Delphi technique.^{37 38} Indicators will be described by a hospital admission, preceded by the presence or absence of particular patterns of care which can include the presence or absence of medication or laboratory tests/diagnoses/previous hospital admissions. A final list of MRPs will be generated through input from the CVG experts. Occurrence of serious MRPs will be extracted from each participant's clinical records at the end of the 6-month follow-up such that a period of 6 months prior to study enrolment and 6 month follow-up is included (12 months for start-up site participants).

The following secondary outcomes will be assessed at baseline and 6 months after IMeRSe introduction (6 and 12 months after for start-up participants):

- ▶ Difference in cumulative incidence and type of all MRPs.
- ▶ Difference in cumulative incidence of PPMRHs by identifying participants who have experienced a hospitalisation during this period and extracting the hospital record for the admission.

- ▶ Difference in psychological distress (using the Kessler-10.³⁹)
- ▶ Difference in beliefs about medicines (using the Beliefs about Medicines Questionnaire-specific⁴⁰).
- ▶ Difference in medication satisfaction and confidence (using the Treatment Satisfaction Questionnaire for Medication⁴¹).
- ▶ Difference in medication adherence (using the Reported Adherence to Medication Scale⁴⁰ and the Medication Possession Ratio⁴²).
- ▶ Difference in psychological and social empowerment (using a validated Indigenous specific questionnaire, the Growth and Empowerment Measure⁴³).
- ▶ Difference in federal government healthcare resource use (measured as the total of primary health carer services, laboratory tests and medications). This information will be sought from the Australian Government Department of Human Services, with participant consent.

The study will also collect data on acceptability and feasibility outcomes including: recruitment rates; rates of drop-out and loss to follow-up over 6 months; participants' acceptability of the IMeRSe intervention; acceptability of training and mentoring by pharmacists; acceptability of the intervention delivery and participant outcomes by AHS staff and pharmacists; choice of outcome measures; timing of events in relation to intervention initiation; and feasibility of using serious MRPs and PPMRHs as primary outcome measures in a future RCT.

Data collection

The IMeRSe intervention delivery, data collection tools and data collection processes will be refined at the two start-up sites. Data will be collected from consumer participants, pharmacy and AHS staff and other relevant sources.

Consumer participants will be required to consent to the use of their AHS medical records, pharmacy records and hospital records as part of the informed consent process. Six months of clinical records and hospitalisation data (12 months for start-up site participants) will be collected retrospectively. Separate consent will be obtained to access health resource use (data including Medicare Benefits Schedule (MBS) items,⁴⁴ Pharmaceutical Benefits Scheme (PBS) items⁴⁵ and pathology data). [Table 2](#) outlines the data collection framework.

The recording and exchange of information between the AHS and pharmacy (eg, appointment bookings, *Medicines Report* and *My Medicines Plan*) will be conducted on a purpose-built IMeRSe module within the pharmacy software platform known as GuildCare NGTM. This cloud-based software platform is used by the majority of community pharmacies in Australia for the delivery of professional service programmes such as MedsCheck, vaccination recording, blood pressure, blood glucose, inhaler technique check, etc, and links to dispensing systems. All participating pharmacies will be provided with the IMeRSe module and AHS staff (ie, IMeRSe

Coordinator, AHW and GP) and will be provided with access to their individual consumer participant's records to facilitate timely access to, and exchange of, shared information.

Qualitative interviews will be undertaken at mid-study point with a purposive sample of up to 10 AHS staff and pharmacists and 5 consumer participants at the two start-up sites. A semistructured interview guide will be used to obtain feedback about the opportunities and the challenges or barriers to implementation and facilitators which were effective in overcoming these. The research team will use this information to adapt the implementation strategy for the remaining seven sites. End-of-study interviews will be conducted with a purposive sample of up to 50 AHS staff and pharmacists representing a mix of urban, rural and remote settings to obtain feedback on the IMerSe implementation and sustainability in the respective AHS and the associated community pharmacy(ies). A convenience sample of up to 50 consumer participants will also be invited to contribute in-depth interviews to explore their experiences and provide feedback about the IMerSe intervention. Semistructured interview guides will be prepared to explore participants' views and prompt discussion.

Participating AHSs and pharmacies will receive funding to support their involvement in the research: AHS sites will receive an administration fee to cover data management, training and Coordinator time (AUS\$1600/month); and a per-participant fee for each completed Tier 1 appointment attended (AUS\$50) and any Tier 2 appointments completed (AUS\$50); pharmacies will receive an administration fee ranging between AUS\$7400 and \$10700 depending on degree of remoteness, and a per-participant fee for each completed Tier 1 (AUS\$128) and any Tier 2 appointments (AUS\$128). In addition, incentives in the form of a fruit/vegetable or maternity basket to the value of AUS\$50 will be provided to all consumer participants at the completion of the 6-month (and 12 months for start-up site participants) data collection point in recognition of their time for completing study data collection processes that would not normally be a necessary part of their healthcare.⁴⁶ The size and nature of this incentive is not uncommon in research studies involving Indigenous peoples and the value would not be considered excessive to induce a person to do something against their better judgement, that is, be coercive. The Australian National Health and Medical Research Council consider participant payment to disadvantaged populations as a legitimate part of the research process.^{47 48}

Sample size

Sample size calculation for this feasibility study was based on the primary outcome: serious MRPs. To estimate the mean number of MRPs at baseline, we have assumed from a previous study¹⁶ that 30% of participants will have complex MRPs, with an average of 3.5 MRPs in a 6-month period. We have assumed 30% of participants will have less complex MRPs (an average of one MRP in a 6-month

period) and that the remaining 40% will not have any MRPs in the 6-month study period. This brings the total and mean MRPs for 100 participants in each 6-month period to 135 and 1.35, respectively. Based on previous studies,^{16 49} we have assumed that 5% of all MRPs would be classified as 'serious'. This leads us to assume that 6.75 MRPs will be serious in 100 participants and the mean rate of serious MRPs before any intervention will be approximately 0.07 per person per 6-month period.

We have assumed that, due to the intervention, the rate of serious MRPs among enrolled participants will decrease by 30%, that is, the mean number of serious MRPs in the 6-month postintervention period will be 0.049 per person. We have conservatively assumed that the SD in the difference of serious MRPs will be 0.14 with power=80% and alpha=0.05. Consequently, 6-month data are required for a total of 351 participants. If a 25% attrition rate is assumed for the study, then the minimum number of participants needed is 540; or 60 participants per site.

Data analyses

Demographic, social and clinical data will be summarised using descriptive statistics. For continuous outcomes, either mean and SD, or median and 25th–75th percentile will be used depending on the distribution of the variable; for categorical outcomes, frequency and percentage will be reported. To investigate the potential impact of attrition, baseline characteristics will be compared for participants who are, and are not, successfully followed-up at 6 months. Between-group differences will be investigated using linear regression for continuous data and Fisher's exact test for categorical data.

The primary outcome will be analysed using mixed-effects linear regression models to examine differences between the preintervention and postintervention periods. In all analyses, time (pre–post) will be entered as a fixed effect and individual will be entered as a random effect to account for the non-independence of each pre–post data pair. The effect of the service will be described using mean differences and 95% CI. For secondary outcomes measured on the interval scale, within individual differences will be assessed using mixed-effects linear regression. For secondary outcomes measured with dichotomous outcomes, within individual differences will be assessed using mixed-effects logistic regression and presented as ORs. Initially, all participants will be included in the analyses. The analyses will then be repeated after stratifying by geographical location of the service (urban, rural and remote). Statistical significance will be set at <0.05. Data will be analysed using Stata statistical software (StataCorp).

Qualitative interviews will be digitally recorded and transcribed verbatim by an external transcribing company. Transcriptions will be quality checked and thematic analysis using NVivo V.11 will be conducted by two researchers experienced in qualitative research. Analysis will involve coding and categorising units of data until themes emerge.

Transcripts will be constantly compared and contrasted so that higher-order themes are identified (ie, constant comparison method). The target number of interviews is 50 for both groups of participants (consumers and health practitioners); however, data collection will cease when no new information is offered, that is, data saturation has been reached.

Economic evaluation

The economic evaluation of IMerSe will be limited to a cost-consequence analysis (a form of cost–benefit analysis) due to absence of a usual care comparator. A pre–post comparison at the individual level will be undertaken for the 6 months prior to IMerSe compared with 6 months after. The analysis will be from an Australian government healthcare perspective.

The cost per serious MRP and PPMRH avoided for the 6 months following the IMerSe intervention compared with the 6 months prior will be the primary economic outcome. The cost of hospital admission data for particular PPMRH indicators will be requested from individual hospitals. Where this is not possible, an indicative cost will be identified from existing Queensland Health administrative datasets. Hospital data are state-based in Australia and not linked. Queensland was chosen because it has a large Indigenous population spread across diverse geographical locations and relatively representative of the national population. The average cost of a particular PPMRH will be calculated using these records and matched to participants' outcomes.

We expect to see a difference in average costs per MRP and PPMRH avoided across the geographic strata (urban, rural and remote). Provision of remote services in particular is expected to be more costly, in line with the provision of other health-related outreach services. In addition, local unit prices and staff mix are also likely to differ. The source of variation (if observed) as well as the cost 'drivers' will be investigated with a Seemingly Unrelated Regression model using a standard statistical software package (Stata). As cost data are not likely to be normally distributed, a gamma log-link function or similar will be used, with appropriate testing of the generalised linear model (GLM) specification using the modified Park test and link test.

In addition, the cost of an additional participant adherent to medication for a chronic condition will also be estimated. Adherence will be tested both with respect to self-reported and quasi-compliance measures constructed from dispensing records, such as a Medication Possession Ratio (while acknowledging the limitations of this approach).⁴²

Included costs

The economic analysis will quantify the costs associated with IMerSe in the eligible population. Cost data will be collected for the nine AHSs and their associated community pharmacies, who will recruit consumer participants. Costs will be estimated from the market value of the

resources consumed, whenever available. Costs from the study include

- ▶ The training and mentoring of clinical staff to provide and include IMerSe into usual care.
- ▶ Incentive payments and fee-for-service to pharmacists and AHWs involved in the service.
- ▶ Travel costs for pharmacists, where relevant.
- ▶ Clinical software adaptation to facilitate medication review documentation sharing within AHSs and community pharmacies.
- ▶ IMerSe training and mentoring for pharmacists.
- ▶ Incentives for consumer participation in the feasibility study.

Financial appraisal and full costing will be provided for the study. If certain costs are not included in the economic evaluation, any assumptions and the effect of their exclusion will be specified in the analysis.

Costing of IMerSe will be undertaken in the following way:

- ▶ Identification of administrative resources used for study management, with study-specific administrative resources to be separated from activities that would be included if the intervention was rolled out nationally.
- ▶ Some resource use will be measured in natural units (eg, clinical staff time spent delivering IMerSe and Coordinator administrative time) and will be valued in monetary units.
- ▶ Other resources can be directly valued (eg, incentive payments to staff and services).
- ▶ If delivery of IMerSe requires additional equipment (eg, laptop/tablet), market costs will be estimated with amortisation applied over the useful life of the equipment. Community pharmacy and AHS overheads will be apportioned to IMerSe using specified attribution formulae.
- ▶ Fixed and variable costs for IMerSe will be collected. Fixed costs include durable items of equipment, time involved in development and delivery of training materials and modification of IT/clinical recording systems. Variable costs include incentive payments and travel costs for pharmacists, AHS staff.

Total healthcare resource use analysis

In a separate analysis, total healthcare resource use including MBS, PBS, laboratory tests and cost of medication-related hospitalisations will be collected for 12 months prior, and 6 months after, enrolment into the study. This allows comparison of time periods that allow for seasonal effects (ie, if a participant receives IMerSe during July to December 2018, costs can be compared with July to December 2017). This time frame will be extended to 12 months for consumer participants recruited in both start-up sites. The purpose is to inform ideal data collection time points for a future RCT within the resource limitations of a feasibility study.

Hospital records will be requested from the relevant hospital where a participant self-reports a hospitalisation in the previous 12 months (asked at baseline) or for the

previous 6 months (asked at follow-up). Reasons for the admission, length of stay and total cost of stay will be requested from the hospitals.

Uncertainty analysis

Variability in effect sizes and cost differences result in a degree of uncertainty around the estimated cost–consequence ratio. This uncertainty will be explored using parametric and non-parametric methods which allows the estimation of CI/quasi CI around estimates of costs and benefits (since the non-parametric bootstrap method does not generate true statistical confidence intervals for a proportion). A GLM will be used to analyse differences in costs, matched for annual time periods to account for any seasonal differences that may be present.

Patient and public involvement

Patient and public involvement in this protocol has been achieved, and will be ongoing over the study lifetime, through extensive collaboration with the relevant representatives of both partner organisations. As described above (section 'Methods'), working with key Indigenous groups, both locally and as members of the Expert Panel, will be integral to the ongoing engagement process (eg, via the inclusion of community juries, councils and boards). This process will be informed by the local requirements at each site throughout this feasibility study. Acceptability outcomes for consumer participants will be assessed as described previously (section 'Study outcomes'). Dissemination to Indigenous participants and communities will be a priority, with processes guided by the Expert Panel and informed by key stakeholders at a local site level.

DISCUSSION

This feasibility study has the potential to address the health inequalities reported by Indigenous peoples, particularly those with chronic diseases who experience barriers in accessing primary healthcare and quality use of medicines services. The proposed IMeRSe intervention has been designed to incorporate the essential clinical elements and objectives of existing medication review programmes and to address the known barriers to access including lack of cultural appropriateness, restrictive referral pathways and eligibility criteria, lack of integration with AHSs, poor collaboration between healthcare providers and geographic isolation.

The study aims to address knowledge deficits with respect to the acceptability and feasibility of the IMeRSe intervention and study procedures. The process evaluation will inform future research by enabling modification and improvements to the delivery of the IMeRSe intervention including how to optimise the engagement process with AHSs using a range of models of care and communities in different Australian settings; utility of training processes, research tools and data collection methods; satisfaction with the service and study procedures for consumer participants and healthcare professionals; the

degree of service integration into community pharmacy and health service operations and its sustainability; and the design and implementation of a future RCT.

Undertaking this feasibility study (figure 1) has numerous challenges, not least of which will be meeting the recruitment and retention targets within the 12-month time frame; each AHS and associated community pharmacy(ies) need to recruit 60 consumer participants into the 6-month study. Another challenge will be minimising missing outcome data. We have estimated 25% consumer participant attrition over the 6-month follow-up period as participants in this study are known to be more mobile and thus may be difficult to follow-up once the medication review service has been completed. Site remoteness and communication difficulties including poor IT coverage increases these difficulties. However, MBS, PBS and laboratory data will be used to estimate outcomes for those lost to follow-up and to maximise retention, and an incentive (to the value of AUS\$50) will be provided to all consumer participants at completion of the final data collection. An additional challenge, digital health innovations, introduced over the life of the study, may significantly influence future study procedures. For example, major changes to *My Health Record* are expected as the system is implemented Australia-wide and consequently the number of patients, pharmacies and primary healthcare services registering and using this electronic health record as a primary source of clinical information is expected to continually increase. Correspondingly, there will be significant increases in the amount of real-time clinical information available as hospitals and private health providers establish systems to automatically upload electronic clinical summaries and records. However, predicting consumer rates of opt-out from *My Health Record* remains an unknown.

Finally, the lack of a comparator group means that the primary outcome and economic evaluations are limited to a quasi-experimental (pre–post) design; however, information from this feasibility study will inform sample size calculations and study design for subsequent studies testing the effectiveness of IMeRSe, if found to be appropriate.

Ethics and dissemination

This protocol has been approved by the Griffith University Human Research Ethics Committee (2018/251), the Queensland Government Metro South Hospital and Health Service Human Research Ethics Committee (HREC/18/QPAH/109), Aboriginal Health and Medical Research Council of New South Wales (1381/18), Far North Queensland HREC (18/QCH/86-1256) and the Central Australian Human Research Ethics Committee (CA-18-3090). Additionally, the Australian Government Department of Human Services External Request Evaluation Committee has approved MBS and PBS information extraction (MI9435). The trial has been registered with Australia and New Zealand Clinical Trials Registry, ACTRN12618000188235. At the completion of the study, a report will be submitted to the Australian Government

Department of Health and partner institutions. A dissemination plan will be developed by the research team and project partners (The Pharmacy Guild of Australia and the National Aboriginal Community Controlled Health Organisation), the Expert Panel and representatives from the nine AHS sites. Dissemination to Indigenous peoples and communities will be a priority. Results of this study will be published as manuscripts in international peer-reviewed journals (including open-access journals) and presented at national and international conferences and symposia.

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Contributors AJW, JS and FK designed the research protocol. AJW is the principal investigator and led the intervention and training development, and evaluation plan. JS developed the economic evaluation plan, led the selection of primary outcome measures and datasets and led the Department of Human Services data application. FK led the ethics application process and contributed to the intervention and training development and evaluation plan. RSW provided statistical expertise and sample size calculations for the study. AM provided cultural oversight to the study design and contributed to the training components. PAS provided expert oversight of the economic evaluation section. AJW, JS, FK, AM, PAS and RSW were named investigators on the funding proposal. EV and MS conceived the initial funding proposal (including the need for the study and a new model of care) as representatives of their respective organisations and contributed to the development of the research protocol. MS undertook the initial literature review. All authors were involved in the revision of this protocol and made a significant contribution towards its intellectual content, and approved the final version of the article.

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