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Integrating pharmacists into Aboriginal Community Controlled Health Services (IPAC project): Protocol for an interventional, non-randomised study to improve chronic disease outcomes

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Introduction

Aboriginal and Torres Strait Islander peoples' in Australian communities face many barriers accessing medicines including financial and geographic constraints, failed patient-clinician interactions, poor healthcare delivery systems and complex therapeutic medication regimens.^{1,2} The physical settings of community pharmacies and informational continuity challenges with Aboriginal health services that limit the sharing of patient information, have made it difficult for some Aboriginal and Torres Strait Islander people to have productive relationships with pharmacists.^{3,4} While Australian initiatives under the 6th Community Pharmacy Agreement (6CPA), the section 100 program for remote area Aboriginal health services, and the Closing the Gap (CTG) Pharmaceutical Benefits Scheme (PBS) Co-payment Measure have removed some of the financial barriers to accessing medicines,⁵ the 2013–14 PBS per person expenditure for Indigenous Australians was only 33% of the expenditure for non-Indigenous Australians.⁵ There is still considerable need to improve medicines access, as well as the quality use of medicines for populations that are medically

underserved. Medication adherence, in general for anyone with chronic disease is poor, resulting in disease-related complications, higher levels of hospitalisation, and increased morbidity and mortality,⁶ whilst the economic costs of non-adherence are very high.⁷

Innovative and culturally appropriate models of care to enhance the quality use of medicines for Aboriginal and Torres Strait Islander peoples are necessary. One model is to better integrate pharmacists within primary health care services. The National Health Service in the UK have invested heavily in such an initiative,⁸ whilst New Zealand, Canada and the USA already have pharmacists providing clinical services within general practice settings.⁹ In Australia, the concept has received endorsement from leading medical organizations such as the Australian Medical Association,¹⁰ general practice groups,¹¹ and pharmacists.^{12,13} Currently, registered pharmacists provide only limited clinical pharmacy services to Indigenous Australians due to several barriers.^{14,15} These include prohibitive Home Medication Review (HMR) business rules including processes that are not always possible nor culturally acceptable.^{15,16} Many Aboriginal health services provide few HMR referrals due to issues with the cultural responsiveness of pharmacists,

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and lack of pharmacist relationships with ACCHSs.^{16,17} Yet, when medication reviews are delivered in culturally appropriate settings (such as in Aboriginal health services) there is great potential to increase patients' medication knowledge, medication adherence and to improve chronic disease management.¹⁶

Public inquiries,¹⁸ pharmacists,¹⁹ and independent statutory bodies such as the Australian Productivity Commission,²⁰ have recommended exploring better ways to utilise the full scope of pharmacist roles within collaborative clinical models. Co-location of pharmacists within general practice has enabled greater communication, collaboration and relationship building among health professionals.^{12,21} Pharmacist integration within primary health care services can also improve clinical health outcomes and quality prescribing. Pharmacists that are fully integrated offer improved outcomes especially when providing holistic services to patients on multiple medications and co-morbidities.²² Integrated pharmacists can also significantly reduce medicine errors as shown in UK general practices.²³ An economic analysis found that the integration of pharmacists in Australian general practice has the potential to be cost-effective through broader health savings at a federal, state and consumer level.²⁴

Despite the substantial interest in health reform, the impact of pharmacists on patient health outcomes when working within their scope of practice and integrated within Aboriginal health settings has never been evaluated. In order to investigate the potential gains in health outcomes arising from integrated models of care within Aboriginal health settings, the *Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHSs) to improve Chronic Disease Management (IPAC)* Project was developed. The project is funded by the Australian Government Department of Health, under the Pharmacy Trials Program (Tranche 2) funding as part of the Sixth Community Pharmacy Agreement (6CPA) that seeks to improve clinical outcomes for patients utilizing the full scope of pharmacists role in delivering primary health care services. This Program is also supporting a study of the feasibility of a 6-step medication review service to be delivered by community pharmacy with pharmacists trained to work with clients of Aboriginal health services.²⁵

The IPAC project will determine if including a non-dispensing registered pharmacist as part of the primary health care (PHC) team within ACCHSs (the intervention) leads to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples with chronic diseases. The project will target adult patients with chronic diseases to optimise the pharmacological management of their condition given that coronary heart disease and diabetes contribute 22% and 12% respectively of the mortality gap with other Australians.²⁶ ACCHSs provide comprehensive culturally appropriate primary health care to predominantly Aboriginal and Torres Strait Islander clients and form the vast majority of Aboriginal health services in Australia. They share a community governance model of care employing local Aboriginal and Torres Strait Islander staff, governed by elected Aboriginal and Torres Strait Islander leaders. Although funded largely by the Australian Government, they are independent not-for-profit agencies established by Aboriginal leaders from 1971 in response to significant unmet health needs.²⁷

The IPAC Project makes two clinical claims. Firstly, Aboriginal and/or Torres Strait Islander adult patients with chronic disease who are managed by this model of care, receiving pharmacist services integrated within ACCHSs, will experience superior quality of care outcomes compared to usual care. Secondly, services provided by pharmacists within ACCHSs is likely to lead to superior health care service utilization (towards equity) by patients with chronic disease compared to usual care. This paper describes the development and planned evaluation of the intervention within a community-based participatory research model and complies with the SPIRIT 2013 guidelines for clinical trial protocols ([Supplementary File A](#)).²⁸

Methodology

Study design

The IPAC project is a pragmatic, non-randomized, prospective, pre and post quasi-experimental study (Trial Registration Number and Register: ACTRN12618002002268). The intervention is the integration of a registered pharmacist within the ACCHS primary healthcare team for a 15-month period. Up to 22 ACCHS sites will be recruited for the project across three jurisdictions: Victoria, Queensland and the Northern Territory to ensure a sampling frame that best informs external validity of the outcomes across varied services and patient populations. Pharmacist positions will be aggregated to represent approximately 0.6 full time equivalents (FTE) per site. All eligible ACCHS sites recruited will receive the intervention.

This project characterises pharmacists to be fully integrated within ACCHSs based on a framework defining five key dimensions of 'integration'.²² IPAC pharmacists will: function under an umbrella network of support within ACCHSs with identified positions; have shared access to clinical information systems; provide rational and continuous clinical care to patients; receive administrative and other supports from primary health care staff; and adhere to governance, cultural, and clinical protocols within ACCHSs as part of their shared vision. A sixth dimension pertains to financial integration which cannot be taken into account as the intervention is project funded. As pragmatic trials seek to determine if interventions work under usual conditions rather than under ideal conditions,²⁹ pharmacists will function within existing and usual service delivery systems that will vary considerably from service to service but will be focused on pre-determined core roles to structure the evaluation.

The project will adhere to Indigenous community-based participatory research (CBPR) principles, adapted from the World Health Organization guiding principles³⁰ as described in a previous National Aboriginal Community Controlled Health Organization (NACCHO) project.³¹ This is to ensure clear benefits to project sites, acceptability and sustainability of the intervention within ACCHSs, and ultimately, transferability to other PHC services. For this reason, study outcomes will be compared before and after the intervention without the use of control sites, for within-subject comparisons (with repeated measures). Measures repeated over 15 months will assist with providing reliable post-intervention temporal trends in biometric outcome measures. The project will note changes in study sites that may occur pre to post intervention through serial health systems assessments and qualitative methods.

Project governance

The IPAC project is a partnership between community and professional representative bodies including NACCHO representing ACCHSs and the Aboriginal community, the Pharmaceutical Society of Australia (PSA), and the College of Medicine and Dentistry, James Cook University (JCU). Affiliates of NACCHO are state and territory peak bodies representing ACCHSs at this level and will act to support participating sites. The project will be coordinated by a Project Operational Team with members from the three partners. A Steering Committee with an independent Chair will oversee the project with representatives from partner organizations and the Pharmacy Guild of Australia, plus an independent pharmacist. A Project Reference Group will include representatives from all participating ACCHSs, NACCHO, and its Affiliates to advise on implementation issues. The Evaluation Team will be led by JCU with representatives from the partners, the Affiliates, and content experts. A Memorandum of Understanding was signed by all partners at the time of project development (November 2017) outlining communication and governance processes. [Fig. 1](#) outlines the project governance structure.

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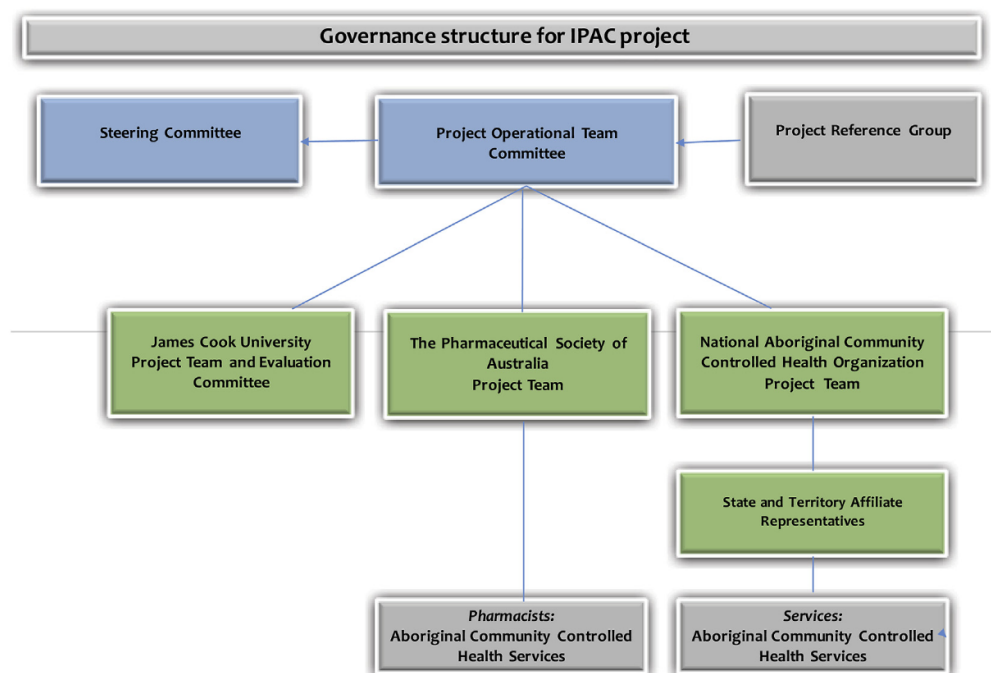


Fig. 1. The IPAC Project governance structure.

Outcomes

The primary expected outcome is an improvement in quality of care indicators (including systolic and diastolic blood pressure, glycated haemoglobin (HbA1c), lipids, estimated absolute cardiovascular disease (CVD) risk, and albumin-creatinine ratio (ACR) in patients with chronic disease.

Expected secondary outcomes include improvements in:

- estimated glomerular filtration rate (eGFR);
- prescribing indices (medication appropriateness, overuse, underuse, and medication-related problems);
- patient use of medicines (medication adherence, self-assessed health status, and patient experience);
- health service utilization indices (Medicare Benefits Schedule claims for: home medicines reviews, care plans, case conferences, team care arrangements and other items), and out-of-home medication management reviews (non-HMRs); and
- stakeholder perceptions (ACCHSs staff; community pharmacies; pharmacists).

An economic evaluation of the IPAC project will ascertain the incremental cost-effectiveness ratio of the pharmacy intervention in relation to usual practice (at baseline) to assess whether the IPAC project represents value for money from a health system perspective.

Theory of change

A theory of change model was proposed to understand the factors influencing the intervention and the underpinning assumptions, such as conditions outside project control. The model outlines that pharmacists will facilitate increased access to medication-related expertise and assessments, which when coupled with increased engagement with participants, staff and other stakeholders, will result in improved services, quality use of medicines, and chronic disease outcomes (Fig. 2).

Timeline

The Project will be conducted in three phases. The establishment phase-one (4–8 months) will comprise ACCHS and pharmacist recruitment, orientation and training, and set-up for the collection of baseline data. During the intervention phase-two (up to 15 months), integrated pharmacists will invite and seek the consent of eligible patients to receive the intervention. Site recruitment times may vary with staged implementation and up to 15 months of patient follow-up. Data analysis will occur in phase-three (6 months), with results dissemination and a final report available in 2020.

Site recruitment

Project sites will be ACCHSs that will be invited by NACCHO and their Affiliates to participate through an ‘expression of interest’ process if they meet the site eligibility criteria (Table 1). The project team agreed to invite services located in three jurisdictions (Northern Territory, Queensland, and Victoria) to enhance the pool of services likely to meet all the criteria. The final sites will be selected by the operational team, with assistance from Affiliates, to ensure geographical dispersal within these jurisdictions as defined by the Australian Statistical Geography Standard-Remoteness Area (ASGS-RA).³² Service agreements will document the written consent of each participating site in the project. The proposed site distribution plan is shown in the Supplementary File B.

Pharmacist recruitment

The PSA will recruit pharmacists who fulfil the following eligibility criteria: pharmacist registration with the Australian Health Practitioners Regulation Agency (AHPRA); more than 2 years’ post-registration experience; and post-graduate clinical qualifications or demonstrated clinical experience. These criteria will enable the selection of pharmacists with skills aligned to the expected scope of practice for this project. Placements within ACCHS will be influenced by the needs of ACCHSs as determined by a site visit and ‘needs assessment’.

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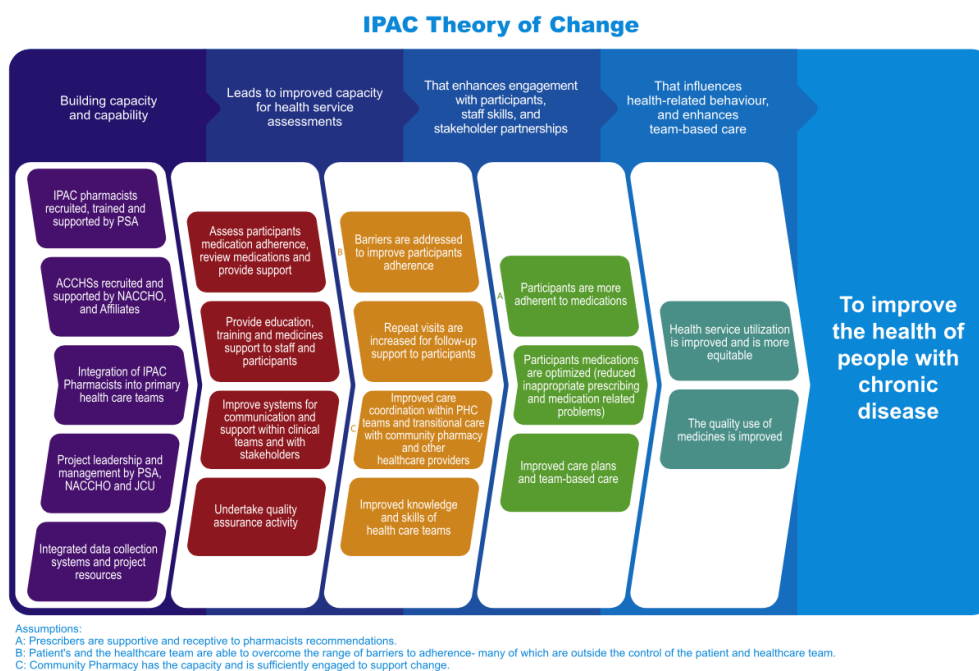


Fig. 2. Theory of change model for the IPAC project.

Table 1

Health Service criteria for participation in the IPAC Study.

- To be involved in the IPAC Project the health service must:
- be an *Aboriginal Community Controlled Health Service* and funded by the Department of Health for the provision of primary health care services to Aboriginal and Torres Strait Islander peoples.
 - be a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
 - be located in Victoria, Queensland, and the Northern Territory.
 - employ at least one full-time- equivalent general practitioner per clinic who is able to prescribe medicines to patients of that organisation.
 - not currently employ a non-dispensing pharmacist at the participating clinic, undertaking similar roles.
 - use Communicare or Best Practice as their clinical information system.
 - participate in continuing quality improvement and reporting on the national Key Performance Indicators for at least 24 months through the use of electronic data extraction tools.
 - participate in the *Quality Assurance for Aboriginal and Torres Strait Islander Medical Services* (QAAMS) program, if conducting 'point of care' testing for glycated hemoglobin and albumin-creatinine ratio.
 - agree to download and install the GRHANITE® software into one computer within the practice, adhere to program business rules and guidelines, data provision requirements, and patient/service consent requirements for the evaluation of the program.
 - provide the IPAC pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system.
 - allocate a staff member who will act as a 'go to' person to assist obtain informed patient consent.
 - be an accredited practice in accordance with the *Royal Australian College of General Practitioners Practice Standards*.
 - be participating or eligible to participate in the Pharmaceutical Benefits Scheme co-payment measure (practice incentive program), if in a non-remote location.
 - be eligible to participate in the section 100 arrangements for the supply of pharmaceutical benefits, if in a remote location.

NACCHO = National Aboriginal Community Controlled Health Organisation.

undertaken by NACCHO. Local community pharmacies will be approached first to see if they are able to provide a pharmacist to work within the ACCHS according to service requirements of the ACCHS. If they are unable, or this is not accepted by the ACCHS in line with principles of Aboriginal self-determination, then the IPAC pharmacist may be employed directly by the PSA (see [Supplementary File C](#)).

Participant recruitment

Participant inclusion criteria comprise patients with chronic disease who have visited a participating ACCHS site at least three times in the past two years relative to the recruitment date into the study (known as 'active' or 'regular' patients). Patients must be aged 18 years and over and have a diagnosis of:

- Cardiovascular (CV) disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease),
- Type 2 diabetes mellitus,
- Chronic kidney disease, or
- Other chronic conditions and at high risk of developing medication-related problems (e.g. polypharmacy).

Convenience sampling of individual patients will occur in keeping with the pragmatic project design. Patients attending sites will be invited to see the IPAC pharmacist after being referred by a doctor, health worker or other healthcare provider. Pharmacists may also approach potentially eligible patients. Respecting patient autonomy, written consent will be required to participate in the project and to provide permission for information and health data to be used for project evaluation. A master participant information brief will inform participants of all aspects of the project to accompany the master participant consent form ([Supplementary file D](#)). Participants written consent will be sourced by pharmacists or another healthcare provider as deemed culturally appropriate within the site. The IPAC Pharmacist will record consent in the service's clinical information system (CIS). Participants will be able to withdraw from the study at any time.

Pharmacists' core roles (the intervention)

IPAC pharmacists will deliver medicines- related services within an ACCHS through a coordinated, collaborative and integrated approach to improve the quality of care of patients. The intervention will: 1) target patients, and 2) target practices (health professionals and systems) and will not include the direct supply or dispensing of medicines. The pharmacist's ten core roles during the intervention phase are shown

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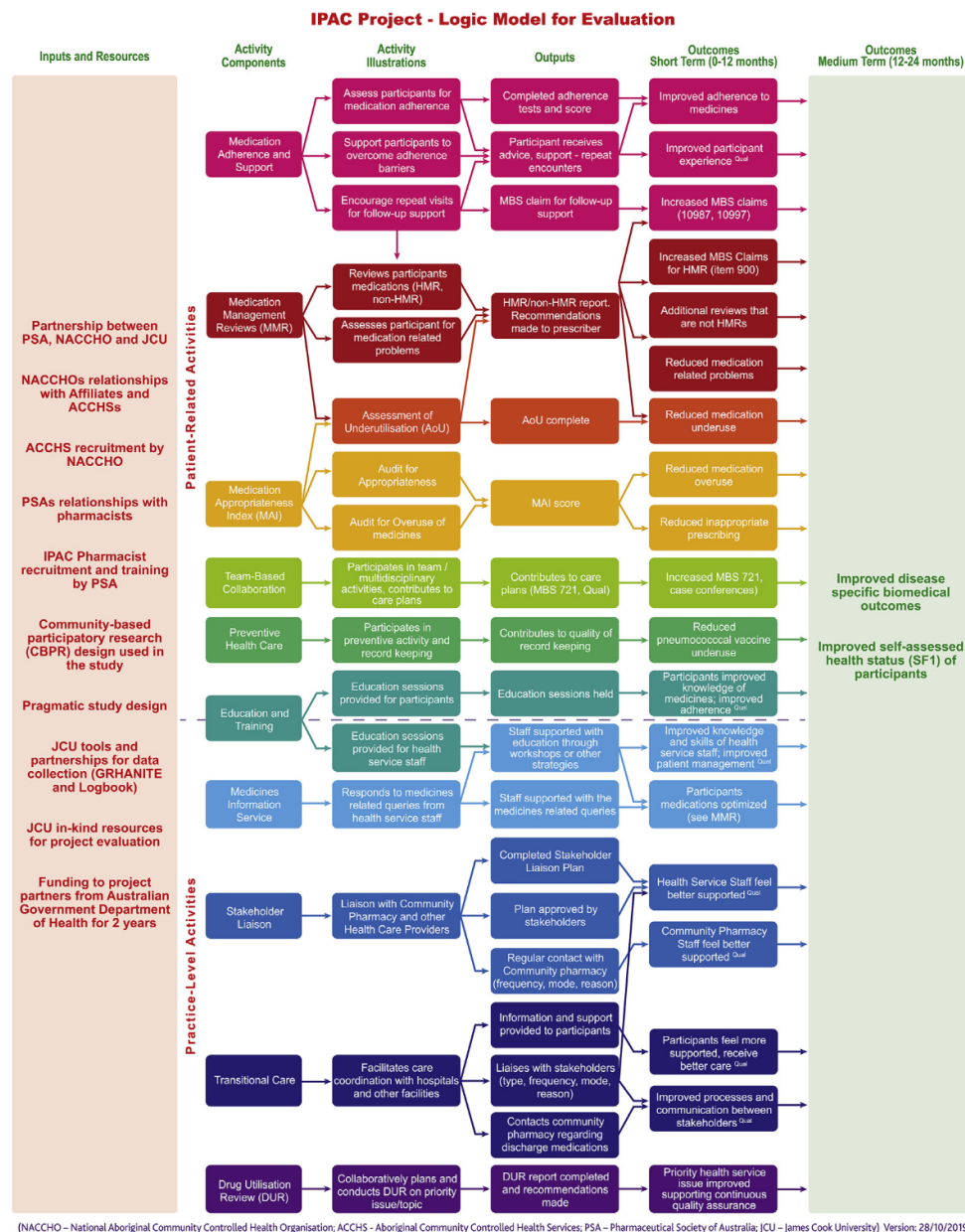


Fig. 3. IPAC Project – Pharmacists 10 core roles and the logic model for project evaluation.

in Fig. 3 as part of the project's logic model for evaluation. Pharmacists will focus on participant recruitment during the first 5 months of their tenure whilst the remainder of this period will comprise patient follow-up.

Patient-specific pharmacist activities will include conducting medication reviews (either at home or elsewhere), assessing medication adherence and medication-related problems, assisting patients with their medications, giving preventive health advice, and participating in case conferences and other team-based activity. Participants will be reviewed according to clinical needs and rules established for the Australian Medicare Benefits Schedule.

Practice-specific pharmacist activities will include responding to medication-related queries and delivering education, reviewing prescribing, conducting a drug utilization review, and liaising with community pharmacy and other stakeholders to ensure informational and management continuity of transitional care such as with hospital

discharges. Pharmacists may undertake additional non-core roles as specified by services reflecting the pragmatic study design.

Pharmacist training

On-site and/or external training will be facilitated by the PSA and delivered by experienced pharmacist educators with years of experience working in partnership with ACCHSs. Learning resources will be developed specifically for the project and approved by the project team with expected learning outcomes addressing all 10 core pharmacist roles. Training will ensure pharmacist skills in cultural safety, clinical interventions, assessment of absolute CVD risk, use of CIS and other software, obtaining patient consent, recording data, and use of all evaluation tools. Training will also be provided in maintaining team-work processes, delivering disease-specific services, and how to explain the pharmacists' role to patients. All pharmacists will be required to

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Table 2

Clinical, demographic, pharmaceutical, health system, economic and qualitative study measures.

Measure	Detail	Source
Patient characteristics	age, year of birth, sex, height and weight, condition (clinical diagnosis of diabetes, hypertension, dyslipidaemia, chronic heart disease, peripheral artery disease, cerebrovascular disease, chronic kidney disease, plus other disease), smoking status, closing the gap (CTG) status, Aboriginal and Torres Strait Islander status, pension/concessional status, year of death.	GRHANITE
Encounters	Consent; number of pharmacist contacts, record status (active); patients identification number.	GRHANITE
Patient self-reported health status	Short Form Health Survey (SF1 of SF-36)	Logbook
Biomedical indices	Systolic and diastolic blood pressure, HbA1c, lipids (HDL, LDL, TG's, and TC), ACR, e-GFR	GRHANITE
Health service utilization: <i>Medicare Benefits Schedule</i>	MBS item claims: 900 (Home medications review-HMR), 721 (GPMP), 732 (GPMP review 3 months later), 715 (Health Check); plus other MBS items.	GRHANITE
Health service utilization: <i>Non-HMR</i>	Services for 'non-HMR', and follow-up to a non-HMR, or a HMR.	Logbook
Medication adherence	Self-reported: a) single-item question; b) patient survey	Logbook
Prescribing quality:		
Medication appropriateness	<i>Medication Appropriateness Index (MAI)</i>	Logbook
Medicines overuse	<i>Medication Appropriateness Index (MAI)</i>	Logbook
Medicines underuse	Potential prescribing omissions (PPO) from HMR/non-HMR, and MAI reviews.	Logbook
Medication Related Problems (MRP)	MRPs from HMR/non-HMR, and MAI reviews	Logbook
Costs	Pharmacist salaries, employment on-costs and overheads, training costs, pharmacist travel, equipment, consumables; health system costs.	Logbook
Health systems assessment	Health system covariates (service and staff characteristics, quality of care, community pharmacy liaison, etc)	Health Systems Assessment
Patient experience	Focus groups and individual interviews	Qualitative
Stakeholder experiences (IPAC pharmacists, health service staff, community pharmacists)	Focus groups, individual interviews and surveys	Qualitative
Pharmacist activities:	Activities undertaken	Logbook
Education and training, medicines information, team-based collaboration.		
Stakeholder liaison (community pharmacy, hospitals, medicines reconciliation)	Activities undertaken	Logbook Qualitative

ACR = albumin-creatinine ratio; BP = blood pressure; CIS = clinical information systems; CKD = chronic kidney disease; CTG = Close The Gap; CV = cardiovascular; CVA = cerebrovascular disease; DMMR = Domiciliary Medication Management Review; DVA: Dept of Veterans Affairs; e-GFR = estimated glomerular filtration rate; GPMP = General Practice Management Plan; GRHANITE = data extraction tool; HDL = high density lipoprotein; HMR = Home Medications Review; LDL = low density lipoprotein; MAI = Medication Appropriateness Index; PAD = peripheral artery disease; TC = total cholesterol; TG = triglyceride.

complete pre-reading, quiz questions, and online modules, contributing 15 h of learning time. The majority of pharmacists will then participate in facilitated 2-day group workshops (an additional 15 h), making up 30 h of training per pharmacist. Pharmacists recruited after this time will be provided with 7.5 h of face-face individual project-specific training in mutually agreed locations followed by another 7.5 h of pre-arranged on-site training with a pharmacist who has workplace skills within ACCHSs.

Data collection

Data will be collected from two existing clinical information systems (CIS) used by ACCHSs (Best Practice and Communicare) to manage patient's electronic health records, and a bespoke online database (pharmacist logbook) to record information about pharmacist activity. Demographic, biomedical and health service utilization indices will be extracted as deidentified data using an electronic tool called GRHANITE.³³ Biomedical results extracted from CISs will reflect those sourced from accredited pathology providers servicing participating ACCHSs and available to clinicians as part of standard clinical care. Anthropometric measures such as blood pressure and BMI will reflect measures entered into CISs by existing ACCHS healthcare staff. GRHANITE will extract data only for consented patients and copy it to a JCU databank employing internationally-recognised point-to-point (P2PE) encryption mechanisms to protect data in transit. The pharmacist logbook will be a secure password protected online database, accessible from any device connected to the internet, with dual recording and reporting functionality. The electronic interface will be intuitive and user-friendly to minimise the burden of data entry and reporting. The CIS patient identification numbers recorded by pharmacists in the logbook will link with patient data in the GRHANITE extractions. Consistent with CBPR

principles, the raw (unanalysed) data extracted by GRHANITE from each project site is acknowledged to be owned by the ACCHS from which it was collected.

Every site will be visited twice by a NACCHO Project Coordinator to conduct a 'health systems assessment'. The initial visit will be prior to the commencement of the pharmacist, with the second visit at the end of study. The 'health systems assessment' will source service details to identify health system-related covariates, such as service size and staff numbers, ancillary services, budgets, quality improvement processes, medicines access information, use of point of care testing, and the self-assessed adequacy of existing communication with the hospital and community pharmacies.

Qualitative data will be collected through structured interviews with each IPAC pharmacist; an online survey including open-ended questions with service managers, community pharmacy, and general practitioners; and three case studies. The case studies will be sourced from three site visits (field work) and three researchers will conduct interviews and observe the activity of relevant staff. The number of interviews will be set by the number of staff working with IPAC pharmacists at each site (estimated to be between six to eight staff). The patient experience will be elicited through focus group discussions and individual in-depth interviews. Patients will be offered a \$20 (AUD) gift card at the conclusion of the interview or focus group to compensate them for their time and travel. Interviews and surveys with key staff at all other sites will be conducted remotely using videoconferencing technology and an online survey.

Sample size calculation

A sample size of 732 patients with chronic disease will achieve power in excess of 80% to detect (1) an absolute CVD risk reduction of

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1% (1-point difference) from baseline if a standard deviation (SD) of 2.7% was assumed³⁴; (2) a clinically relevant reduction of 10 mmHg (SD 20 mmHg) in systolic blood pressure and (3) 5 mmHg (SD 10 mmHg) in diastolic blood pressure³⁵; (4) a reduction in total cholesterol (-0.3 mmol/L; SD 1 mmol/L),^{36,37} (5) an increase in high-density lipoproteins (0.1 mmol/L; SD 0.4 mmol/L),^{36,37} and (6) a reduction in low-density lipoproteins (-0.3 mmol/L; SD 0.9 mmol/L)³⁷; (7) a reduction in triglycerides (-0.9 mmol/L; SD 1.5 mmol/L)^{37,38}; and (8) a 30% decrease in ACR (SD: 23 mg/mmol)^{36,39}, with an overall level of significance of 0.05 (adjusted for multiple testing $k = 8$) using two-sided one-sample paired t-tests. A total of 119 T2DM patients will achieve power in excess of 80% to detect a decrease in HbA1c (in % units) from baseline of at least 0.5% with an assumed SD for change of 1%³⁶ with an overall level of significance of 0.05 using two-sided one-sample paired t-tests.

Our sample size calculations allow for an attrition rate (including missing values) of 50% and assumed a design effect of 1.75^{40,41} to adjust for the cluster sampling approach. Calculations are based on a comparison of mean values in a paired analysis, and were conducted with PASS 2008 (NCSS, Kaysville, Utah, USA).

Quantitative data analysis

The effect of the pharmacist intervention will be investigated by comparing study measures (Table 2) at the endpoint with those at baseline. The baseline measures will refer to the first interaction or assessment between the patient and the IPAC pharmacist, and/or data recorded within CISOs in a 12-month period preceding patient enrolment into the study. As required, participants' continuous and categorical outcome measures will be averaged to derive at baseline measures. The final assessment will refer to the most recent recorded measure prior to the end of the study. The main biomedical outcome measures are systolic and diastolic blood pressure, HbA1c, high and low-density lipoprotein, total cholesterol, triglycerides, estimated absolute CVD risk, and albumin to creatinine ratio in participants with chronic disease.

Absolute CVD risk will be calculated based on the 1991 Framingham Risk Equation (FRE)⁴² to estimate the 5-year risk of a primary cardiovascular event using a composite of sex, age, systolic blood pressure, total cholesterol to HDL ratio, and diabetes plus smoking status measures, except for left ventricular hypertrophy. This equation is recommended for people without existing CVD (primary risk) who are aged 30–74 years as outlined in clinical practice guidelines for the Aboriginal and Torres Strait Islander population.^{43,44} It will not be applied to those with existing CVD (history of coronary heart disease, cerebrovascular disease, and peripheral vascular disease documented in the medical records)^{43,45} nor to others who are already at a clinically high risk for a CV event ($> 15\%$) with any of the following: diabetes mellitus and age > 60 years, diabetes mellitus and microalbuminuria (urinary ACR > 2.5 mg/mmol for males and > 3.5 mg/mmol for females), estimated glomerular filtration rate < 45 mL/min per 1.73 m², systolic blood pressure (BP) ≥ 180 mm Hg, diastolic BP ≥ 110 mm Hg, and total cholesterol > 7.5 mmol/L.⁴³ Absolute risk estimates will not be adjusted upwards given the FRE is known to underestimate absolute CVD risk in the Aboriginal and Torres Strait Islander population as this is subject to clinical discretion.⁴⁴ Estimated GFR as reported in CISOs will be used without derivation from serum creatinine measures.

Medication appropriateness will be measured by assigning a Medication Appropriateness Index (MAI) score to each medicine, based on an internationally validated tool⁴⁶ that will be used by pharmacists. The tool assesses the potential for medicine-related risks to outweigh treatment benefits to the patient. The MAI will be assessed in a subset of participants from each site shortly after recruitment and then again at the end of the study. Pharmacists will select patients who may best benefit from an assessment of their medications to reflect usual care consistent with a pragmatic trial.²⁹ An analysis of differences in

summed mean MAI scores per patient, the mean MAI score per individual medication, and the number and proportion of participants receiving inappropriate medications will be compared at baseline and study end. Overuse of medications, defined as participants' medications deemed to be unnecessary will be measured by assigning a MAI score to three items.⁴⁷ These inform on the overuse of medications as they measure if the prescribed medicine is clinically indicated, effective, or if there is unnecessary duplication of a medicine.

The proportion of participants with a potential prescribing omission (PPO) as a measure of underutilization and the frequency of drug types omitted will be assessed. Underutilization of medicines will be defined as the omission of medicines that are clinically indicated according to pre-specified best practice recommendations.⁴⁸ Prescribing recommendations relevant to the target population will be sourced from evidence-based guidelines (including the CARPA Standard Treatment Manual,⁴⁹ National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (3rd Edition),⁴⁴ Australian Medicines Handbook,⁵⁰ and the Australian Immunisation Handbook⁵¹) and compiled into a reporting tool for this project. Each medication management review will assess for PPOs. Drug types will include cardiovascular and anti-hyperglycaemic medications, chemoprophylaxis for rheumatic heart disease, and other omissions. Analysis will also report the number and type of medication-related problems (MRPs) identified from medication reviews.

Two types of medication reviews will be undertaken by pharmacists: a) Home Medicines Review (HMR, also known as Medicare item 900), and b) non-HMR (a comprehensive review that does not fulfil the MBS HMR criteria, such as a review conducted outside the patient's home or by a non-accredited pharmacist). Change in the frequency of MBS claims from baseline will be measured with data sourced from CISOs. The frequency and characteristics of non-HMRs will be described in the logbook including the reasons for undertaking a non-HMR over a HMR.

Medication adherence scores will be measured at least twice for each participant, at baseline and study end using self-reported, indirect methods of assessment. The extent of adherence will be assessed by a single-item question 'How many days in the last week have you taken this medication?' This will be asked for each medicine with responses ranging from 0 to 7 days, to estimate the proportion of days with the correct number of doses taken. This is a frequent summary statistic used to quantify implementation of a dosing regimen.⁵² This single question and its variations have been used in the Kanyini study involving Aboriginal and Torres Strait Islander peoples in Australia⁵³ and internationally.^{54–56} Medication non-adherence measured objectively by gaps in prescription fills was shown to be significantly associated with self-reported non-adherence defined by at least 'two days missed' taking medicines over the past week.⁵⁴ Multi-item internationally developed psychometric tools that assess both the extent of adherence and reasons for non-adherence will not be used with patients as they have not been validated in our context,⁵⁷ use inappropriate language, and place substantial data burdens on patients. In order to develop a more comprehensive assessment of adherence-related behaviour, a patient-survey exploring the reasons for non-adherence will be developed for the IPAC project and used by pharmacists at baseline and at least one other subsequent patient encounter. These reasons are very context-specific and necessary to interpret change assumptions in our theory (Fig. 2). This survey will be evaluated as a psychometric tool to inform beliefs and behaviour about medications by assessing participants' reasons for non-adherence.

The patient's self-assessed health status will be determined using the first question of the Short Form Health Survey (SF-36) that asks: 'In general, would you say your health is excellent, very good, good, fair, poor, or very poor?'. An extra response option – 'very poor' – was added (as in the SF-8 survey) to reduce the potential for respondents to overstate their health status.⁵⁸ Responses to this single-item (SF-1) question have been shown to correlate well with multi-item tools measuring the same

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construct,⁵⁸ and are used in the National Aboriginal and Torres Strait Islander Social Survey.⁵⁹

The number of claims for relevant MBS services (Table 2) such as claims for a home medicines review (item 900) rendered to each participant will be determined at baseline (12 months period before recruitment to study) and during the follow-up time. Per participant, event rates of MBS item claims will be calculated for pre and post intervention times per person-year of observation. Information on health professional and health systems supports will be collected.

Analyses will use R and Stata MP 14 software. All analyses will be adjusted for the clustering effects of the ACCHSs (primary sampling units). Collected quantitative outcome measures of participating patients will be described at baseline and at final assessment overall and stratified by type 2 diabetes mellitus and other chronic disease groups. Categorical data will be summarised using absolute and relative frequencies. The distribution of numerical data will be assessed; symmetrically distributed numerical data will be presented using mean values and standard deviations (SD) while skewed data will be summarised using median values and inter-quartile ranges (IQR).

For numerical outcome measures, differences of baseline and final assessments will be calculated and summarised depending on their distribution as either mean or median values together with respective 95%-confidence intervals (95% CI). Linear regression models (Stata `svyreg` command) will be applied using the calculated differences as dependent measures to investigate the effects attributable to practice-level factors, including geographical factors, service location and size, and client-level factors including age, sex, and co-morbidity, as well as other covariates appropriate to the measure being evaluated.

For binary outcome measures, differences will be calculated based on baseline and final assessments. These differences will be dichotomised into “improved” versus “unchanged or worse” and presented together with 95% CI. Conditional fixed effect logistic regression (Stata `svylogit` command) will be applied to investigate effects of practice-level and client factors as described above.

SF-1 is the only ordinal outcome measure and will be analysed in a similar manner as the binary outcome measures applying ordinal logistic regression (Stata `svyologit` command) to investigate factors affecting the difference between baseline and final assessments.

Primary outcome measures which are assessed several times during the follow-up phase of the study for most patients will additionally be analysed using GLS random-effect panel data models (Stata `xtreg` or `xtlogit`) with robust estimates of standard errors to adjust for ACCHS clustering effects. Statistical significance will be defined at the conventional 5% level.

Qualitative data analysis

Interviews and focus group discussions will be transcribed verbatim and, with field notes, entered into NVivo 12 (QRS International) software. Themes will be identified and finalized using an inductive approach to analysis. Initial similar themes will be developed from data immersion and refined through researcher triangulation.

Cost-effectiveness analysis

The cost-effectiveness analysis will determine if the intervention is cost effective relative to usual practice (at baseline). Usual practice will be defined as care received at baseline, prior to receiving care from the IPAC pharmacist. The comparison group are patients receiving care from the IPAC pharmacist. Costs will be considered from a health system perspective and cover the value of resources involved in providing the intervention as well as changes in health service use. The primary outcome measure for the economic evaluation will use biomedical indices for subgroups of participants with specific chronic diseases to calculate the incremental cost-effectiveness ratio (ICER). The secondary outcome measure will be the change in the number of

participants with at least one PPO. The incremental cost effectiveness ratio (ICER) for the difference in appropriate medication usage will be estimated, both excluding and including health system costs, using the adjusted cost and outcome data between the usual care and the intervention.

Data security

The JCU data custodian will be responsible for the protection of data from loss, misuse and unauthorised access. Electronic data extracted via GRHANITE and from the Pharmacists Logbook will be stored on password-protected internal server on JCU premises. Data accessed during the analysis phase will be stored in JCU-supported database applications only. Signed pharmacist, site and participant consent forms will be mailed by registered post, scanned and electronically transmitted to the data custodian, and stored in a secure password-protected computer. Hard copies will be stored in a secure cabinet in a lockable room and retained for seven years. Data access will be granted to the investigators established for the purpose of this project including members of the evaluation team.

Qualitative data will be recorded on a digital recorder. Photographs will be taken on a password-protected mobile phone. Consent from any participants photographed will be obtained using talent release forms. All digital files (interviews, focus groups, field notes and photographs) will be downloaded to a password-protected laptop and stored in a password-protected file immediately after field work and removed immediately from recording devices. Identifying information will be removed after interviews and focus group discussions have been transcribed. Survey data collected remotely using an online survey platform will be stored in a password-protected account until the end of the data collection period. At this time, the data will be removed from the online database and stored on a JCU secure server.

Knowledge transfer

Knowledge transfer and communication about the project will honour the agreed governance structure (Fig. 1). Project partners have a responsibility to participants, funders, and the wider community to broadly disseminate a full account of the process and findings of the study. Data dissemination activities will take account of any intellectual property restrictions and culturally sensitive data. Project results will be presented at an aggregate level and no participants or communities will be identifiable from any results approved for public release.

Ethics approval

Ethics approval for the project has been received from four ethics committees in the three jurisdictions including St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC), Victoria (HREC/17/SVHM/280), James Cook University HREC (mutual recognition of SVHM HREC, approval HREC/H7348), Menzies School of Health Research (HREC/2018–3072) and the Central Australian HREC (HREC/CA-18-3085).

Discussion

Healthcare reform depends on ways to improve productivity and ensure the triple aim of: clinically effective healthcare, improved patient experience, and cost-effectiveness (“better health, better health care, and better value”).⁶⁰ This project aims to evaluate a new integrated care model where Australian pharmacists work collaboratively with healthcare staff and patients to improve the quality use of medicines within primary health care settings that target Aboriginal peoples and Torres Strait Islanders. IPAC pharmacists will deliver ten core roles within ACCHSs including providing medication support to patients, home and non-home medication reviews to inform on quality

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prescribing and potential prescribing omissions, team-based activity, preventive health support, medicines information, education and training, transitional care, stakeholder liaison such as with community pharmacy, and a quality assurance activity like a drug utilization review.

The project will recruit adults with chronic disease and patients at high-risk of developing medication-related problems and evaluate the impact of the intervention on clinical outcomes, medication adherence, measures of prescribing quality, health care service utilization, as well as patient, pharmacist, and stakeholder perceptions. The economic evaluation will be a within-trial cost-effectiveness analysis to assess whether the project represents value for money from a health sector perspective.

Following community based participatory research (CBPR) principles, this project will involve Aboriginal and Torres Strait Islander people throughout the design, implementation and evaluation stages. NACCHO will provide Aboriginal governance for all communication with ACCHSs, Affiliates and the NACCHO Board. These CBPR principles have been adapted from the World Health Organization's guiding principles involving Indigenous peoples.³⁰ This approach is also consistent with the National Health and Medical Research Council (NHMRC) guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research so that the benefits of the research are clearly articulated, negotiated and implemented in such a way they build community capacity.⁶¹ Pragmatic project design assists this goal by ensuring the intervention is acceptable and feasible to ACCHS governing structures and their staff, and data collection is minimally intrusive, with analyses exploring if the intervention works under usual real-life conditions. The project aims to produce generalizable knowledge applicable to other ACCHSs, Aboriginal health services delivered by State and Territory Governments, and private general practices providing services to Aboriginal and Torres Strait Islander peoples.

It is anticipated that Aboriginal and Torres Strait Islander patients receiving IPAC pharmacist services will benefit from immediate access to on-site medicines support. Patients will receive tailored and appropriate medication reviews and other integrated care supports to optimise their use of medicines, with support for improved prescribing given to clinicians. Workforce capacity within ACCHSs is expected to be enhanced as pharmacists support multidisciplinary teams with medicines use, preventive healthcare, and foster chronic disease care-related service claims through Medicare. Stakeholder relations, especially with local community pharmacies are expected to improve with more ACCHS engagement and information transfer than was previously possible. Governments and decision-makers will be able to determine whether the intervention falls within an acceptable cost effectiveness range in the context of improving specific health outcomes amongst Aboriginal and Torres Strait Islander people.

The project may face challenges such as insufficient recruitment of services or consented patients, although this may be mitigated by the CBPR and pragmatic study design. The risk that unreliable data may be extracted from CISs is reduced by restricting site inclusion criteria to health services participating in quality improvement activities. Pharmacists may also face challenges working within Aboriginal community-controlled models of care. This requires pharmacists to be a team member, to be flexible and adaptive to holistic services addressing social determinants of health, and receptive to the advice provided by experienced staff. Pharmacists may also spend time in remote and outreach services and must be willing to adapt their style and practice to an environment that best suits the patient. However, culturally responsive settings such as these will assist IPAC pharmacists to better understand the many barriers and hurdles patients face in optimising the use of medicines and help them to build solutions to address these underlying causes.

The IPAC study will be the first to explore the impact of pharmacists integrated within primary health care settings focussed on the health of Aboriginal and Torres Strait Islander peoples who are significantly

medically underserved. The proposed analysis may inform new funding streams to support patient-centred care and assist funding or commissioning bodies such as Primary Health Networks (PHNs) with their workforce financing decisions. This is important given PHNs' role in supporting quality improvement, and in particular, focusing on enhancing health outcomes for the Aboriginal and Torres Strait Islander population in partnership with ACCHSs.⁶² A final report will be produced by the research partners for the Australian Government as a project funded from the Pharmacy Trial Program of the Sixth Community Pharmacy Agreement.

Funding body

The project is funded by the Australian Government Department of Health, under the Pharmacy Trials Program (Tranche 2) funding as part of the Sixth Community Pharmacy Agreement (6CPA). The project funder had no role in study design, data collection, management of the project, analysis and interpretation, writing of the report, or the decision to submit the report for publication. The project funder has a role in approving reports for publication.

CRedit authorship contribution statement

Sophia Couzos: Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Visualization, Supervision, Funding acquisition. **Deborah Smith:** Methodology, Formal analysis, Investigation, Writing - review & editing, Visualization, Project administration. **Mike Stephens:** Conceptualization, Methodology, Writing - review & editing, Supervision, Funding acquisition. **Robyn Preston:** Methodology, Formal analysis, Investigation, Writing - review & editing. **Delia Hendrie:** Methodology, Formal analysis, Writing - review & editing. **Hannah Loller:** Methodology, Writing - review & editing, Supervision. **Megan Tremlett:** Methodology, Writing - review & editing, Project administration. **Alice Nugent:** Methodology, Writing - review & editing, Project administration. **Fran Vaughan:** Methodology, Writing - review & editing, Project administration. **Shelley Crowther:** Conceptualization, Methodology, Funding acquisition. **Douglas Boyle:** Methodology, Software, Resources, Writing - review & editing. **Petra Buettner:** Formal analysis, Writing - review & editing. **Erik Biros:** Methodology, Software, Formal analysis, Investigation, Data curation, Writing - review & editing.

Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sapharm.2019.12.022>.

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