

INTEGRATING PHARMACISTS WITHIN ACCHSs TO IMPROVE CHRONIC DISEASE MANAGEMENT

PROJECT PROTOCOL

**THE PHARMACEUTICAL SOCIETY OF AUSTRALIA,
NATIONAL ABORIGINAL COMMUNITY CONTROLLED
HEALTH ORGANISATION, AND JAMES COOK
UNIVERSITY COLLEGE OF MEDICINE AND
DENTISTRY CONSORTIUM**

**PHARMACY TRIAL PROGRAM TRANCHE 2
H1617G013**

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26 March 2019	Deborah Smith	Updated Evaluation Team membership: Removal of Emily Callender, Nicole Bates and Mark (Joseph) Thomas; Addition of members to the Evaluation Team: Dr Delia Hendrie from Curtin University, Dr Lucy Morris from QAIHC; Dr Aaron Drovandi, A/Prof Kerriane Watt and A/ Prof Petra Buettner from JCU;	1.5	Project Partners

		Note change of facility for A/Prof Michelle Bellingan and Dr Robyn Preston; Addition of roles invited for focus groups and interview at site visits (CEOs / Managers / GPs) p 62 Addition of online questionnaire for CEOs and Managers p 63 Updated Steering Committee Membership details		
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Glossary

6CPA	The Sixth Community Pharmacy Agreement
ACE	Angiotensin converting enzyme inhibitor
ACCHO	Aboriginal Community Controlled Health Organisation [SEP]
ACCHS	A comprehensive primary health care service delivering culturally appropriate care to predominantly the Aboriginal and Torres Strait Islander community, that has been developed by Aboriginal peoples for Aboriginal peoples.
AIHW	Australian Institute of Health and Welfare
AHW	Aboriginal Health Worker
AMSANT	Aboriginal Medical Services Alliance of the Northern Territory
ARB	Angiotensin receptor blocker
ASGS	Australian Statistical Geography Standard
ATSIHP	Aboriginal and Torres Strait Islander Health Practitioner [SEP]
CAT4	Clinical Audit Tool developed by Pen Computing Systems Pty Ltd
CBPR	Community-based participatory research
CHD	Coronary heart disease
CVD	Chronic Kidney Disease
CMD	College of Medicine and Dentistry, James Cook University
CQI	Continuing Quality Improvement
CVD	Cardiovascular disease
DAA	Dose Administration Aid (e.g. Webster pack, blister pack) [SEP]
DMMR	Domiciliary Medication Management Review
FTE	Full time equivalent
GP	General practice
GRHANITE	Data Extraction Tool developed by the Research Information and Technology Unit of the Faculty of Medicine, University of Melbourne
HCH	Health Care Home
HMR	Home Medicine Review [SEP]
HREC	Human Research Ethics Committee
ICER	Incremental cost-effectiveness ratio
JCU	James Cook University

KPI	Key Performance Indicator/s
MAI	Medication Appropriateness Index. A validated tool to measure the quality of medicines prescribing for each patient. Each medicine is assigned a weighted score and scores can be aggregated for multiple medicines.
MBS	Medicare Benefits Schedule
MMR	Medication Management Review. An umbrella term used to describe pharmacist-led medication management services including HMRs and MURs.
MUR	MedsCheck/Diabetes Meds Check are 6CPA in-pharmacy MMR services
NACCHO	National Aboriginal Community Controlled Health Organisation Ltd <small>[SEP]</small>
NEAF	National Ethics Application Form
NHA	<i>National Health Act 1953</i> (the Act that governs PBS supply and includes section 100 remote Aboriginal Health arrangements) <small>[SEP]</small>
nKPI	National Key Performance Indicator/s reported by Aboriginal health services to the Australian Government
PAT CAT	Practice Aggregation Tool for the Clinical Audit Tool developed by Pen Computing Systems Pty Ltd
PBS	Pharmaceutical Benefits Scheme
PHN	Primary Health Network/s
PIP	Practice Incentive Payment
PR	Participatory Research
PRG	Program Reference Group
PSA	The Pharmaceutical Society of Australia <small>[SEP]</small>
QAIHC	Queensland Aboriginal and Islander Health Council
QI PIP	Quality Improvement Practice Incentive Payment
QOC	Quality of care
QUM	Quality Use of Medicines <small>[SEP]</small>
QUMAX	6CPA QUM program for Aboriginal and Torres Strait Islander peoples
The Guild	The Pharmacy Guild of Australia <small>[SEP]</small>
T2DM	Type 2 diabetes mellitus
VACCHO	Victorian Aboriginal Community Controlled Health Organisation
WHO	World Health Organisation

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1. Overview

The *Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management* (IPAC) project is a large project that will determine if including a registered non-dispensing practice pharmacist as part of the primary health care team within Aboriginal community controlled health services (ACCHSs) leads to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples.

The project will explore improvements in prescribing by doctors, if patients are more likely to take their medicines, and if indicators of their health are improving over time, by measuring these factors before and after the pharmacist is appointed.

Practice pharmacists will provide relevant healthcare activities within their scope of practice to patients, but they will also provide education and training to existing staff within the services as appropriate, improve relations with community pharmacies to overcome barriers that patients may face in accessing medicines, and assist in managing medications at transitions of care (such as discharge from hospital). This project will also explore the cost-effectiveness of pharmacist integration within these services.

This project is a tripartite partnership between the Pharmaceutical Society of Australia (PSA), the National Aboriginal Community Controlled Health Organisation (NACCHO), and James Cook University (College of Medicine and Dentistry). The project will involve up to 22 ACCHSs invited to participate in the project from three jurisdictions- Queensland, Victoria, and the Northern Territory.

The Australian Government under the Pharmacy Trials Program of the 6th Community Pharmacy Agreement has funded the project for 29 months.

This document details this project, and its guiding principles. This Protocol complies with the principles of the SPIRIT 2013 guidelines for clinical trial protocols.¹ The trial is registered with the Australian and New Zealand Clinical Trials Registry (Trial Registration Number and Register: ACTRN12618002002268).

1.1 Purpose of the Project Protocol

This protocol has been developed to provide a framework for the management and conduct of the IPAC project to guide the participation of all Aboriginal Community Controlled Health Services (ACCHSs) as project sites.

This protocol documents the specific requirements of the project and has been developed through input from the Evaluation Team and Project Partners, which include the NACCHO, with NACCHO Affiliates- the Victorian Aboriginal Community Controlled Health Organisation (VACCHO); the Queensland Aboriginal and Islander Health Council (QAIHC), and the Aboriginal Medical Services Alliance in the NT (AMSANT).

The Protocol will be provided to the NACCHO Board for endorsement.

1.2 Summary of the Project Protocol

Title of the study:

Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management (IPAC)

Background:

Aboriginal and Torres Strait Islander peoples experience a much higher burden of chronic disease due to cardiovascular, diabetes, and other health problems, and yet have poorer access to needed medicines.^{2 3} Adverse health outcomes from these illnesses are minimised if prescribing quality is improved, and patients are better supported with medicines use, which is a key health equity issue.

Non-dispensing pharmacists are not currently funded consistently or reliably to work within primary health care settings in the public health sector in Australia. Despite this, several ACCHSs across Australia have innovatively sourced funds and/or developed partnerships with community pharmacy's to source pharmacists in non-dispensing roles. This project is modeled on these pharmacists' roles and international research evidence. There is extensive global evidence that practice pharmacists co-located within general practice clinics can enhance chronic disease management and quality use of medicines.⁴

The National Aboriginal Community Controlled Health Organisation (NACCHO) has promoted the need for this project for many years. The project will help the Australian Government make decisions about the role practice pharmacists may play as members of primary health care teams within ACCHSs and potentially other settings in Australia.

Project Governance and Collaboration:

This project is a partnership between the Pharmaceutical Society of Australia (PSA), the National Aboriginal Community Controlled Health Organisation (NACCHO), and James Cook University (College of Medicine and Dentistry), guided by a Memorandum of Understanding that outlines communication and governance processes.

The PSA, as the lead agency, is responsible for managing the Funding Agreement with the Australian Government Department of Health, and service agreements with partners and ACCHSs, and will coordinate the appointment of practice pharmacists, their recruitment, selection, placement, and training. The NACCHO will provide Aboriginal governance leadership for the project and coordinate all communication with ACCHSs, Affiliates and the NACCHO Board. JCU will undertake the project evaluation, having developed the research methodology based around a pragmatic, community-based participatory research model.

Other Aboriginal community representative bodies involved include the VACCHO; QAIHC, and AMSANT. These organisations are NACCHO Affiliates and will be responsible for state-based service support to registered ACCHSs, and provide guidance to the project as members of the evaluation team.

Ethics approval:

Ethics approval will be sought from the following Human Research Ethics Committees for the project:

- St Vincent's Public Hospital HREC (Victoria)
- James Cook University HREC (Qld)
- Menzies School of Health Research HREC (NT)
- Central Australia HREC (NT)

Project Objectives:

The aim of this project is to improve quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease by integrating a practice pharmacist within the primary health care team of ACCHSs.

Study Design:

There are three project phases over a 29-month project duration: Phase 1: Establishment (4-8 months); Phase 2: Implementation/intervention (up to 15 months); Phase 3: Analysis and Reporting (6 months).

The project will invite ACCHSs in geographically diverse settings Victoria, Queensland, and Northern Territory that initially meet the established site eligibility criteria to participate as project sites. Up to 22 ACCHSs will be able to participate. Each service will be offered a practice pharmacist (aggregated 0.57 FTE across 22 sites each for 15 months duration) under a service agreement with the PSA. Service selection aims to recognise the diversity of Aboriginal peoples and Torres Strait Islanders and models of care across Australia, to deliver an impact assessment that can best be generalizable to other Australian sites/settings in the future.

The IPAC project is a pragmatic, non-randomized, prospective, pre and post quasi-experimental study with a cost-effectiveness analysis, where the pharmacist intervention will be added to standard primary health care practice within ACCHSs. The trial will adopt a community-based participatory research (CBPR) design, to ensure clear benefits to project sites, to ensure acceptability and sustainability of the intervention within ACCHSs, and ultimately, transferability to other PHC services.

All eligible ACCHS sites will receive the intervention, with study measures referring to periods prior to and after implementation, activities within ACCHSs, and aggregated ACCHSs. Outcome measures will focus on Aboriginal and Torres Strait Islander patients with chronic disease (≥ 18 years of age) who are regular patients of the ACCHSs, including indices of best practice prescribing, and quality of care measures. Deidentified patient data will be collected from the clinical information systems (CIS) of ACCHSs pertaining to consented patients through an electronic data extraction tool known as GRHANITE. Additional deidentified data on patients and health systems interactions will be collected by practice pharmacists through an electronic log-book. Qualitative and cost-effectiveness analysis data will be collected during site visits.

Data analysis:

Analysis will comprise comparative assessment of mixed data and subsets, contextual assessments, findings and evaluation limitations, CBPR methodology, and policy implications and interpretation. A cost-effectiveness analysis will explore if the intervention was cost effective relative to standard practice (at baseline). Quantitative analyses will use mixed effects models and quantify the variability attributable to practice-level and client-level factors. For qualitative analysis, themes will be developed and finalized through the constant comparison method, and refined through coder triangulation.

The project results will be reported at an aggregate level, and will not identify individual participants, communities, or ACCHSs.

Funding:

The Australian Government under the Pharmacy Trials Program of the Sixth Community Pharmacy Agreement has funded the project for 29 months.

2. Background

Aboriginal and Torres Strait Islander peoples experience a much higher burden of chronic disease due to cardiovascular, diabetes, and other health problems, and yet have poorer access to needed medicines. Adverse health outcomes from these illnesses are preventable if prescribing quality is improved, and patients are better supported with medicines use, which is a key health equity issue.

This project aims to significantly improve Aboriginal and Torres Strait Islander medication understanding, adherence to treatment, and improve the quality of care that is delivered by integrating pharmacists within Aboriginal Community Controlled Health Services (ACCHSs). Providing practice pharmacists with the appropriate cultural, communication, clinical systems training, and integration within ACCHSs, may significantly improve the quality of health care received and experienced by Aboriginal and Torres Strait Islander peoples.

2.1 Background to the development of the project

On 1st March 2016, the NACCHO Board of Directors strongly endorsed the need to develop a project proposal to explore the role and impact of pharmacists employed by ACCHSs as members of the primary healthcare (PHC) team.

This project was developed as a result of that call by Aboriginal health leaders, and links with community, regional, jurisdictional and national Aboriginal health priorities.

In November 2016, all three NACCHO Affiliates and NACCHO provided letters of support for the development of the project proposal that was submitted to the Australian Government Department of Health in December 2016. The November 2016 letters of support provided by ACCHS Affiliates and the NACCHO Board of Directors gave in-principle support to the draft project proposal at that time (see Appendix).

The project partners established a Memorandum of Understanding in November 2017, to guide the development of the project (see Appendix).

2.2 Aboriginal Community Controlled Health Services

ACCHSs were first established in 1971 in response to the poor quality of health services they were receiving and the significant financial, cultural and social barriers to health care access experienced by Aboriginal and Torres Strait Islander people. ACCHSs are operated by the local Aboriginal and Torres Strait Islander community to deliver holistic, comprehensive and culturally-appropriate *primary health care* to the community they serve. ACCHSs are culturally safe environments that support an Aboriginal patients' sense of choice and power.

2.3 Pharmacists within ACCHSs

The pharmacists integrated within the ACCHS will be immersed in the ACCHS model of care and the systems that have been shown to provide effective primary health care to Aboriginal people and Torres Strait Islanders.

Several ACCHSs across Australia have sourced adhoc funding to employ pharmacists in similar and also quite different roles in these settings, but these appointments are few in number. These pharmacists may already have significant experience working with ACCHSs in the past. Pharmacists will be inducted for cultural safety training into the ACCHS as all staff working within these services.

Pharmacists working within ACCHSs will provide the patients, staff and their service with valuable skills congruent with the identified needs of the service. They will assist

individual patients with their medication needs as well as support chronic disease care, including prevention and management, as part of the primary health care team.

They will play an important role in assisting the ACCHS with the range of medicines related health policies and programs dependent on their geographical location. In particular, practice pharmacists will be able to support Home Medicines Review (HMR) programs and medication management reviews on-site within services.

Medication management reviews conducted within the ACCHS and HMRs for Aboriginal and Torres Strait Islander patients have the potential to increase patients' medication knowledge, medication adherence and thus improve chronic disease management, particularly when these are delivered in a culturally appropriate way.⁵

Currently, concerns have been raised about the low uptake of HMRs provided to Aboriginal and Torres Strait Islander peoples, largely due to lack of health provider awareness, lack of health professional training, and the logistics of navigating the HMR program rules. ACCHSs provide few HMR referrals due to complexities of patients' needs, shortage of time and lack of trust in pharmacists' ability to appropriately manage their patients.^{6 7} Because of their immersion into the ACCHS model of care, integrated pharmacists are clearly in the best position to deliver holistic medication management services to ACCHS clients.

Practice pharmacists can also provide valuable medication-related education for Aboriginal and Torres Strait Islander people and health professionals.⁸ Pharmacists have been shown to provide safe and effective medicine use, increased patient and health staff medication knowledge, and are particularly needed in remote areas, where there is often a scarcity of medical practitioners and lack of continuity of health professional staff.⁹

Practice pharmacists within ACCHSs will be able to perform an important liaison role with community pharmacy to enhance a patients access to medicines, medication adherence, continuity of care, and assist in transitions of care (such as discharge from hospital). ACCHS practice pharmacists will be well placed to appraise a community pharmacy's value proposition to an ACCHS and then broker the best outcome for both parties.

2.4 Gaps in current healthcare management

Adherence to a medication regimen is central to good health outcomes. Medication adherence for many people with chronic disease is extremely poor, resulting in disease-related complications, higher levels of hospitalisation, and increased morbidity and mortality.¹⁰ The economic costs of non-adherence are high.¹¹

Aboriginal and Torres Strait Islander patients have been subject to lack of appropriate or tailored information, and lack of health professional engagement and patient support.^{12,13} Disparities in health literacy have been identified for Aboriginal and Torres Strait Islander clients¹⁴ and the cultural appropriateness of some pharmacies has been identified as a problem across Australia.^{15 16}

Barriers to accessing medicines for remote Aboriginal and Torres Strait Islander people may include financial and geographic constraints, failed patient-clinician interactions, poor healthcare delivery systems and complex therapeutic medication regimens.¹⁷ Other barriers include economic hardship or poverty, racism, dispossession, the stigma associated with a diagnosis of chronic disease, educational disadvantage, shared crowded households, increased patient mobility, and inadequate health professional support.^{18,19}

Currently, inter-professional communication about medicines is often incomplete or ineffective. Dispensing protocols, the lack of pharmacist interaction and cultural training, and the physical settings of community pharmacies have made it difficult for some Aboriginal and Torres Strait Islander people to have productive relationships with their community pharmacists.²⁰

While some 6CPA initiatives, S100 and the Closing the Gap (CTG) PBS Co-payment measure have removed some of the financial barriers to accessing medicines, the 2013-14 PBS per person expenditure for Indigenous Australians was only 33% of the expenditure for non-Indigenous Australians.²¹ There is still considerable need for improvement.

Currently, registered pharmacists are providing limited clinical pharmacy services to Aboriginal Australians due to barriers to service provision.^{22 23} These barriers include, but are not limited to, the absence of pharmacist-ACCHS relationships and prohibitive HMR business rules including HMR processes that are not always possible nor culturally acceptable.^{24 25}

A doctor working in a ACCHS may call on the specialist skills of an embedded AHW, nurse, physiotherapist or psychologist through the Medicare Benefits Schedule (MBS),^{26,27} yet a pharmacist can't easily be included in the practice team to review and advise on the person medicines regimen. Given the central role of medicines in the care and treatment of Aboriginal and Torres Strait Islander people with chronic disease, this acts as a barrier to optimising the quality of care.

Investigations conducted by NACCHO have estimated there are currently approximately 10 pharmacists working on average 30 hours per week within ACCHSs in Australia. The majority of these practitioners rely on remuneration from the ACCHS global budget or specific grant funding.²⁸ The absence of remuneration for practice pharmacist-delivered services has been identified as the biggest barrier to the advancement to this area of practice in Australia.^{29,30} This is despite the fact that over 300 pharmacists have registered their interest in working in collaborative practice models.

2.5 International and cost-benefit evidence for practice pharmacists

The integration of pharmacists within the general practice setting has been adopted by the National Health Service (NHS) in the UK.³¹ Many other countries, including New Zealand, Canada and USA, have pharmacists providing clinical services in general practice settings.³² In Australia, the concept has received endorsement from leading medical organisations such as the Australian Medical Association.^{33 34} The growth of the model, however, has been limited to a small number of practices due to the absence of funding. This is in contrast to the UK, where significant national investment has occurred as a result of the overwhelmingly positive response from clinics.³⁵

Co-location also enabled greater communication, collaboration and relationship building among the health professionals.^{36, 37} Practice pharmacists are shown to increase medication review recommendations by the GP.³⁸ Moreover, the 2010 UK PINCER and PRACTICE studies^{39,40} found that pharmacists play a critical role in reducing medicine errors in general practice.

GP-based practice pharmacists in the UK have been said to *"contribute hugely to patient care and support the medicines optimisation agenda. Patient empowerment is enabled and patients have a forum whereby complex medicines-related queries can be answered, thus supporting adherence and improvement in health outcomes."*⁴¹

In addition to this existing evidence, a 2015 report by Deloitte Access Economics (DAE) demonstrated that the integration of pharmacists in general practice has the potential to generate \$1.56 in health system savings for every \$1 invested in the

program.⁴² The analysis estimated that investment in the program would cost the Government \$969.5 million over four years, however, this investment is more than offset by the broader health savings at a federal, state and consumer level.⁴³

Integrating pharmacists in general practice is expected to yield a net saving of \$544.87 million to the health system over four years. Specifically, these savings are expected to result from⁴⁴; hospital savings of \$1.266 billion; PBS savings of \$180.6 million; individual savings of \$49.8 million; and MBS savings of \$18.1 million – due to reduced number of GP attendances following a moderate or severe adverse drug event. This initiative may contribute to a more sustainable PBS and MBS as well as minimising upward pressure on patient co-payments, improving future access and affordability for Australians.

3. Project Objectives

3.1 Project Objective

This project aims to explore if quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease can be improved by integrating a practice pharmacist within the primary health care team of Aboriginal Community Controlled Health Services (ACCHS), when compared with prior care.

3.2 Clinical claim

This project makes two clinical claims:

1. Patients who are managed by this model of care, involving delivery of services by a pharmacist integrated within Aboriginal Community Controlled Health Services (ACCHS), experience either equivalent or superior quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease compared to baseline data representing pre-intervention.
2. Appropriate funding for services provided by pharmacists within ACCHSs is likely to lead to superior health care service utilisation (towards equity) of patients with chronic disease compared to utilisation at baseline (pre-intervention).

3.3 Expected project outcomes

Our expected project outcomes are:

Primary outcomes: improvements in *quality of care outcomes* (biomedical measures such as BP, HbA1c, lipids, CV risk assessment (levels and risk), and albumin-creatinine ratio (ACR) for patients with chronic disease.

Expected secondary outcomes include improvements in:

- estimated glomerular filtration rate (eGFR);
- *prescribing indices* (measures of medication appropriateness such as indicators of optimum medication use and the Medication Appropriateness Index, measures of overuse, and underuse);
- *patient use of medicines* (patient survey for *medication adherence*);
- *health service utilisation indices* (MBS Domiciliary Medication Management Reviews or Home Medication Reviews (HMR), and non- HMR (out-of-home interviews; chronic disease care MBS claims such as care plans and follow-up visits; chronic care indicators, and preventive care indicators);
- *perceptions of stakeholders* (ACCHSs staff; community pharmacies; pharmacists);
- *cost-effectiveness* of the intervention: Economic (cost –effectiveness analysis):
 - The incremental cost-effectiveness ratio of the pharmacist intervention will be compared with the comparator.

3.4 Intervention

The study intervention is a registered practice pharmacist integrated within the primary health care team of an ACCHS for up to a 15-month period (aggregated to represent 0.57 FTE per site at 22 ACCHS sites).

3.5 Comparator

To investigate the effect of pharmacist intervention, study measures at intervention will be compared with those at baseline. The baseline measures will refer to the first interaction between the patient and the practice pharmacist, plus study measures in the period 12 months preceding initial patient interaction with the practice pharmacist. These measures refer to deidentified data extracted from the clinical information system (CIS) within the ACCHS [using a data extraction tool (DET) called GRHANITE].

4. Project participants

This project involves the following participants:

1. The project partners
2. ACCHSs
3. Patients attending ACCHSs
4. Practice Pharmacists
5. NACCHO Affiliates.

4.1 The project partners/team

This project partners include the Pharmaceutical Society of Australia (PSA), the National Aboriginal Community Controlled Health Organisation (NACCHO), and James Cook University (College of Medicine and Dentistry), guided by a Memorandum of Understanding that outlines communication and governance processes.

The project partners are the Project Team and are members of the Evaluation Team, the Steering Committee, and the Project Operational Team (*see earlier*).

4.2 ACCHSs as Project Sites

Site participants will include 22 ACCHS sites in Victoria, Qld and the NT. (A letter of support from NACCHO representing ACCHSs across Australia is in the Appendix).

4.2.1 Site inclusion criteria:

ACCHSs will be invited to consider participation in the project through an initial 'expressions of interest' process managed by NACCHO (see 4.2.2). To be involved services will need to meet the following conditions:

- The health service must be an "ACCHS". This means an Aboriginal Community Controlled Health Organisation funded by the Australian Government Department of Health for the provision of primary health care services to Aboriginal and Torres Strait Islander peoples.
- The ACCHS is located in Victoria, Queensland, and the Northern Territory.
- The ACCHS employs at least one (1) full-time- equivalent (FTE) general practitioner per clinic who is able to prescribe medicines to clients of that organisation.
- The ACCHS does not currently employ a non-dispensing practice pharmacist at the participating clinic.
- The ACCHS uses a clinical information system such as Communicare, Best Practice, and Medical Director.
- The ACCHS has participated 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.
- The ACCHS is participating in the *Quality Assurance for Aboriginal and Torres Strait Islander Medical Services* (QAAMS) program, if it is conducting 'point of care' testing.
- The ACCHS agrees to download the GRHANITE data extraction tool into one computer within the practice, adhere to program business rules/protocol and guidelines, data provision requirements, and patient/service consent requirements for the evaluation of the program.

- The ACCHS can provide the practice pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system used by the practice.
- The ACCHS can allocate a staff member who will act as a 'go to' person to assist the practice to obtain informed patient consent.
- The ACCHS is a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
- The ACCHS is an accredited practice in accordance with the RACGP Practice Standards.
- In non-remote locations, the ACCHS must be participating or eligible to participate in the PBS co-payment measure (practice incentive program).
- In remote locations, the ACCHS must be eligible to participate in the remote Section 100 arrangements for the supply of pharmaceutical benefits

4.2.2 Site recruitment

ACCHSs will be invited to participate in the project by NACCHO and Affiliates through an 'expression of interest' process. The 'expression of interest' process will explain to ACCHS the process that will be used for site selection. See also Figure 11 (p83) for a map outlining the recruitment process.

Health service inclusion criteria will be used to select sites. The Project Operational Team, Chaired by the NACCHO Deputy CEO will review the expressions of interest and decide if a temporary Panel made up of Affiliate representatives is necessary to select the most suitable sites to participate in the project. As the recruitment process for sites will be staggered (see 5.2), this process will be repeated.

The proposed site distribution plan reflects the diversity in geographical location required for this project and is shown in Figure 1. Service location will be defined by the ASGS- Modified Monash Method classification or the Australian Statistical Geography Standard-Remoteness Area (ASGS-RA, 2016).⁴⁵ The site distribution plan will influence and limit the selection of sites.

Figure 1. Proposed site distribution plan*

	Urban	regional	remote	total
NT		1	5	6
Qld	3	3	2	8
Vic	5	3		8
	8	7	7	22

**May be modified after further consultation with Affiliates.*

ACCHSs that are not selected to be part of the project will be informed in writing as to the outcome of the selection process, together with the reasons for not being selected.

4.2.3 Formalisation of participation

When NACCHO receives an expression of interest from an ACCHS, and the ACCHS is agreed to being a suitable site, the NACCHO Project Coordinator will contact the

ACCHS and explain the project further to provide instructions on the process required to establish the site participation.

After this consultation, a *Site Agreement*, *Site Consent form*, and *Site Participation Brief* will be provided to the ACCHS (see 11.3, and see draft *Site Consent Form* in the Appendix). Once this is signed and agreed, the project officers will institute a process for practice pharmacist recruitment and placement within the ACCHS.

A site visit will be arranged to undertake a Site Needs Assessment and a Health Systems Assessment (see 13.3, and 8.8 respectively) at the time that the practice pharmacist commences. At least two (2) face-to-face ACCHS site visits will be conducted by the NACCHO Project Coordinator during the Implementation Phase of the project (see 13.3).

Participating ACCHSs will also be invited to be members of the Project Reference Group managed by NACCHO (*see earlier*).

4.3 Patients attending ACCHSs as participants

Patient participants will be patients who have visited selected ACCHS sites ≥ 3 times in the past 2 years (relative to the beginning of this study) with chronic disease (known as 'active' or 'regular' patients).

This is consistent with the definition of a regular client that has been agreed nationally for reporting against the national key performance indicators (nKPIs) required by the Australian Government. This definition is also consistent with that of the Royal Australian College of General Practitioners of someone with an active medical record.⁴⁶ An adult is a person aged 18 years and older.

This project will target patients with certain chronic diseases to optimize the pharmacological management of their condition. This is based on an AIHW analysis that showed that most of the mortality gap due to chronic disease can be attributed to certain diseases including:

- Coronary heart disease (explains 22% of the mortality gap due to chronic disease)
- Diabetes (explains 12%)
- Chronic lower respiratory disease such as chronic obstructive pulmonary disease (explains 6%), and
- Cerebrovascular diseases, such as stroke (explains 5%).⁴⁷

As most of the patients attending ACCHSs are of Aboriginal and Torres Strait Islander origin (81%),⁴⁸ this group will comprise most of the patients recruited in this project.

These patients are well known to the services that generally rely on self –identification consistent with the national standard identification question “*are you of Aboriginal or Torres Strait Islander origin?*”.⁴⁹ This is generally supplemented by additional evidence of Indigeneity such as evidence of Aboriginal descent. The clinical information systems (CIS) of ACCHS contain identifiers for the patient’s Indigeneity.

4.3.1 Individual participant inclusion criteria

Participant inclusion criteria include those:

Aged 18 years of age and over with:

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

Patient consent will be required to participate in this project, which will require the patient's progress to be monitored based on deidentified data extraction from clinical information systems within each ACCHS (see 11.3).

4.3.2 Individual participant recruitment

Convenience sampling of individual participants is a characteristic of the pragmatic project design. Patients attending the ACCHSs will be invited to be seen by a practice pharmacist after being referred by a doctor, health worker or other healthcare provider. However, some guidance for participant selection is necessary to ensure that patients who are most in need are offered the services of the pharmacist. These are defined by the participant inclusion criteria.

The practice pharmacists (with assistance from trained ACCHS staff) may also approach patients attending the clinic who meet the individual participant criteria.

These patients will be asked if they wish to be attended to by the practice pharmacist. The process for participant recruitment will be flexible according to the preferred process recommended by the ACCHS.

A process that may be used to refer patients to the practice pharmacist will be suggested to ACCHSs as shown in Figure 8 (see 11.7).

As the pharmacist will be on-site in the clinic for up to 15 months, patients can consider participation in this Project during this time. Early participation will be encouraged to ensure patients can benefit most from the services of the pharmacist during this time.

4.3.3. Participant follow-up

Practice Pharmacists will follow-up participants as per usual clinic processes (pragmatic study design). These follow-up mechanisms may vary from service to service. Participants will be reviewed according to clinical needs and Medicare rules, and may include 3-monthly, 6-monthly or an annual review by the pharmacist.

The pharmacist will use the CIS within the ACCHS to record follow-up clinical details like other healthcare staff. The pharmacist will also record follow-up details in the pharmacist log-book as is appropriate for the type of review being conducted (such as medication appropriateness index measurements).

The pharmacist log-book (like the data extraction from the CIS) will use the unique patient ID extracted from the CIS. No identifying information will be collected in the log-book. This will also ensure the log-book data can be matched with the CIS data for that participant whilst maintaining confidentiality through de-identification (see 8.2, and 10.5).

4.4 The practice pharmacists as participants

Practice pharmacists will be appointed within participating ACCHSs at an aggregated 0.57 FTE for up to a 15-month period (per site) at 22 ACCHS sites.

4.4.1 Practice Pharmacist inclusion criteria

Pharmacists' eligibility criteria for the project will include:

- current registration with the Australian Health Practitioners Regulation Agency (AHPRA) as a pharmacist;
- more than 2 years post-registration experience;
- post-graduate clinical qualifications or demonstrated clinical experience (e.g. hospital or HMRs).

The need for post-graduate qualifications will be dependent on ACCHSs preference regarding the applicant and an adequate supply of accredited and experienced pharmacist applicants.

The PSA confirms that the proposed activities are consistent with the existing scope of practice of pharmacists as defined by the PSA Competency Standards endorsed by the Australian Health Practitioner Registration Agency.

4.4.2 Pharmacist recruitment

Pharmacist recruitment will be influenced by the needs of ACCHSs. The PSA will work with ACCHSs and the NACCHO Coordinator to undertake a Needs-Assessment of ACCHSs with regard to placing a pharmacist in that service (see 13.3). By considering ACCHSs needs, the availability of local pharmacist services and project inclusion criteria, suitable pharmacist candidates will be identified.

Local community pharmacies will be first approached 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 to or this is not accepted by the ACCHS in line with principles of self-determination, then the ACCHS may employ a pharmacist directly. The PSA operate a list of pharmacists who are interested in being employed within ACCHSs.

PSA will manage all aspects of employment for the pharmacists; including payroll, superannuation and leave.

4.5 NACCHO Affiliates as participants

State and Territory Affiliates of NACCHO (QAIHC, VACCHO and AMSANT) will represent ACCHSs in respective jurisdictions as members of the Evaluation Team and Project Reference Group. Affiliates have already nominated appropriate staff members to represent them in the Evaluation Team (*see earlier*).

Letters of support from Affiliates for the development of this project have been acquired (*see Appendix*).

Service Agreements will be developed with Affiliates to support their role in this project, and to provide salary support for a 0.2-0.4 FTE project officer for the duration of the

project. These part-time appointments may likely back-fill staff within Affiliates to support the roll-out of the project.

The participating Affiliates will support ACCHSs in this project through this project officer and/or through nominated public health medical officer support (see *Evaluation Team members*). ACCHSs are members of Affiliates and therefore already receive regular support to deliver their services.

Affiliate staff will be able to support agreements, answer queries and solve problems at the local level. Affiliates will be able to communicate with Evaluation Team members and PSA, NACCHO, and JCU project officers and/or the Project Operational Team (which will meet fortnightly).

Affiliates will assist ACCHSs to nominate a 'go-to' person as a contact point if the service agrees to participate in the project. This person can also contact Affiliates and any of the project officers, at any time, to discuss progress with the project on site. Project officers will maintain regular contact with 'go to' persons and ACCHSs during the project.

5. Timelines and Project Phases

The project will take 29 months over three phases with staggered recruitment of pharmacists and sites to achieve an average of 0.57 FTE pharmacists /site over a period of 15 months (equivalent to 15 months/site).

The project period is from December 2017- 30 April 2020. The project timeline is shown in Figure 2. The project timeline may be amended to accommodate delays in the project start time.

Figure 2. IPAC Project Timeline.

	2018						2019												2020					
	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June
							IMPLEMENTATION PHASE												ANALYSIS AND REPORTING PHASE					
Tranche 1		Tranche 1															15 months data							
Tranche 2			Tranche 2														14 months data							
Tranche 3				Tranche 3													13 months data							
Tranche 4					Tranche 4												12 months data							
Preliminary Eval Report Due																			01/02/20					
Final Eval Report Due																							09/05/20	

5.1 Project phases

There are three project phases over a 29-month project duration:

Phase 1: Establishment (4-8 months);

Phase 2: Implementation/intervention (up to 15 months);

Phase 3: Analysis and Reporting (6 months).

In *phase one* of the project (month 1 to 8), the project partners will commence pharmacist recruitment, prepare pharmacist training, finalise consent forms and service agreements (patients and services), prepare additional ethics applications (and amendments) for all jurisdictions, register eligible ACCHSs following an expression of interest and selection process, and upload service software (GRHANITE) into agreed/consented sites.

In *phase two* (month 9 to 23), pharmacists will be trained off-site and on-site (core roles) and appointed to commence work within ACCHSs (see 6.6). Patients referred to the pharmacist will be asked to participate in the project (see 11.3).

Baseline study measures for each consented participant will be extracted from the existing ACCHS clinical information systems (CIS) using the GRHANITE data extraction tool (see 8.1). *Qualitative data* will be collected from three site-visits towards the end of the practice pharmacist tenure within the ACCHSs. These sites will be selected after consultation with the Project Reference Group (see 8.10).

Pharmacists will record practice, patient and systems-related activity in an online log-book (see 8.2).

In *phase 3* (month 24-29), the project-related data will be cleaned and analysed. Concurrent facilitated discussions within the team and with partners will also be occurring during this period. The community-based participatory research methodology of the trial will be recorded and documented. A draft final report will be produced after 3 months (January-February 2020) with final report by April 2020.

5.2 Staggered commencement of ACCHSs (Tranches)

As 22 ACCHSs will be invited to take part in the project, the commencement time will be staggered into 4 'tranches'. This means that Tranche 1 ACCHSs will start in August 2018, then Tranche 2 will start one month later, and so on. Depending on site recruitment rates, there may be a need for additional tranches of ACCHSs. The Project Reference Group will be comprised to suit the participating Tranches of ACCHSs.

Time frames for the project have been developed with NACCHO to be workable, and ensure as little impost on participating ACCHSs. Staggered recruitment and commencement of ACCHS sites allows services time to prepare and consider the project. Staggered commencement will ease introduction to the project and enable sufficient time for other ACCHSs to opt-into the project if they feel it is workable for them and based on feedback from earlier Tranche sites.

6. Practice Pharmacists Roles and Training

6.1 Core practice pharmacist roles within ACCHSs

Practice pharmacists will aim to augment current practice within primary health care services, and introduce new services not currently delivered within ACCHS settings. The practice pharmacist will undertake core roles and additional roles as specified by services and the service agreement which will reflect the pragmatic approach to the intervention and evaluation of 'real-life' health service roles.

There are 10 core roles that are non-dispensing, for which practice pharmacists are registered to deliver. These include activities targeted *towards patients*, and *health professionals and health systems*.

These 10 core roles include:

- Activity targeted towards patients includes: the assessment of medication management, optimization of medicines, in the home or out-of-home settings (such as the clinic), resolution of medication related problems, arrangements for multiple follow-up encounters with patients. (Core roles 1-5).
- Activity targeted towards health professionals and systems includes: recommendations to clinicians, adhoc and specific education sessions/training and support, liaison with community pharmacy and other healthcare service providers. (Core roles 6-10).

The pharmacist 10 core roles include:

1. Medication Management Reviews
2. Team-based collaboration
3. Medication adherence assessment & support
4. Medication appropriateness audit, and Assessment of Underutilisation
5. Preventative health care
6. Drug Utilisation Review
7. Education and training
8. Medicines information service
9. Medicines stakeholder liaison
10. Transitional care

These are expanded in Table 1. *The Logic Model for Evaluation that maps the pharmacists roles is also included in the Appendix).*

Table 1. Ten (10) Core Pharmacists roles in the IPAC project

SUMMARY OF PRACTICE PHARMACISTS CORE ROLES

Core Role #	Focus	Theme	Core activity	Process*	Output/Outcome
1 (a)	Patient	Medication Management Reviews	Pharmacist reviews the medication the patient is taking. The pharmacist initiates and facilitates a medication management review- which may be a Home Medicines Review (HMR) or a non-HMR (medication management review not conducted in the patient's home)	Targets HMR and Non-HMR for participants (<i>as per patient inclusion criteria</i>).	Medication optimisation, Direct improvement in biometric data, Reduction in inappropriate polypharmacy, Number and type of pharmacist recommendations made in the medication management plans.
1 (b)	Patient		Pharmacist reviews the patient who had a HMR after 12 months and a Non-HMR after 3-6 months.	Undertakes participant-follow up	Outcomes as above
1 (c)	Patient		Pharmacist ensures the MMR is claimed by the practice when completed (as a DMMR item 900)	Pharmacist will work with the practice staff to support MBS claims.	Increased claims for DMMR
2	Patient and practice	Team-based collaboration	Pharmacist participates in clinic activities that support team-based chronic disease care plans, and cardiovascular (CV) risk assessment	Contributes to clinic efforts to undertake GP Management care plans (GPMP), and efforts to measure and stratify CV risk	Improved chronic disease management (GPMP, case conferencing, etc), Improved CV risk assessment, Team-based care is enhanced.
3 (a)	Patient	Medication adherence assessment & support	Pharmacist assesses the medication adherence of the patient being seen	Conducted at first and subsequent consultations of participants (eg those having an HMR/non-HMR, and/or those being assessed for other reasons)	Improved participant adherence; direct improvements in biometric data
3 (b)	Patient		Pharmacist improves the patient's experience with their medicines	Uses appropriate strategies to support chronic disease self-management (self-care) and medication adherence	Improved participant experience and adherence; new resources to Improve patient health literacy about self-care and/or medicines use
4	Patient and Practice	Medication appropriateness audit	Pharmacist assesses 'medication appropriateness, overuse of medicines and underutilisation of medicines' <u>as an audit of a sample</u> of patients with chronic disease.	A sample of 30 participants are audited using MAI tool and are assessed for the underuse of medicines.	Improvements in prescribing (medication appropriateness) and reduction in suboptimal prescribing.

5	Patient and practice	Preventative health care	Pharmacist provides preventive interventions to patients	Pharmacist uses the opportunity to promote preventive interventions with every participant contact.	Reduction in pneumococcal vaccine underuse; change in item 715 claims; qualitative perceptions of interactions participants have with other healthcare providers and the practice pharmacist.
6	Practice	Drug Utilisation Review	Pharmacist conducts a DUR to audit and improve a priority issue at the service	A DUR (ie a quality assurance activity) is conducted after identifying a priority issue within the ACCHS. Interventions are recommended in collaboration with the practice staff.	Pharmacist perceptions if the DUR improves the standard of care at the practice.
7	Practice	Education and training	Pharmacist conducts education sessions at the service	Co-designed with ACCHS	Description of this specific activity. Additional information from focus groups with staff can elicit if staff felt their learning had improved.
8	Practitioner	Medicines information service	Pharmacist provides medicines related information to staff within the service and responds to clinician medicines enquiries.	Ad hoc provision of advice to clinical staff about medications. E.g. PBS queries, dose titration, interactions, new and emerging drugs, out of stock, etc	Description of this specific activity. Pharmacist may describe evidence of an outcome in the logbook. Additional information from focus groups with staff can elicit if staff felt they were supported.
9	System	Medicines stakeholder liaison	Pharmacist develops a written <u>stakeholder liaison plan</u> supporting engagement with community pharmacies.	A written plan will support the provision of referrals and communication of all relevant patient information (such as for HMRs) with community pharmacy	Descriptive. Pharmacist may describe evidence of an outcome in the logbook.
10	System	Transitional care	Pharmacist facilitates care coordination with relevant hospitals; residential aged care facilities, etc.	Adhoc care coordination to ensure seamless care across community and hospital settings by relaying all relevant information including contact details, current medications list, management plan, monitoring requirements	Perceptions of improved transitional care communication through qualitative data.

*** References to the term 'patient' refers to general interactions and activities with those patients attending the ACCHS. The Practice Pharmacist will be attending to 'patients' as well as 'participants'. The term 'participant' refers specifically to patients who have consented to participate in this Project. Deidentified data will only be collected with regard to 'participants'.*

The ACCHS pharmacist will deliver clinical pharmacy services from or within an ACCHS through a coordinated, collaborative and integrated approach with an overall goal to improve the quality of care of patients.⁵⁰

The pharmacist employed within the ACCHS would deliver medication advice and education to consumers and staff, and work with both consumers and other health professionals to improve medication adherence and reduce medication misadventure through tailoring medication regimens and overseeing medication management processes.

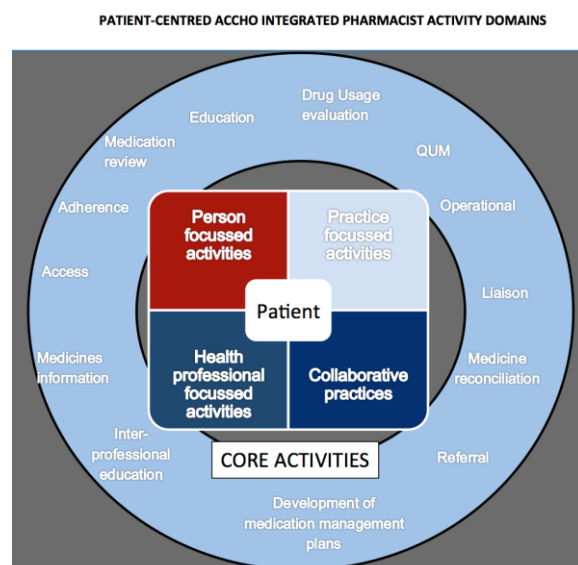
Other activities that pharmacists would deliver within an ACCHS include health promotion, disease prevention initiatives, and assistance with self- management and judicious use of medicines.

As a core role, the pharmacist will be required to respond to medication enquiries from patients and health professionals such as general practitioners and Aboriginal and Torres Strait Islander Health Workers/Practitioners, conduct staff education, review prescribing, mentor new prescribers, participate in case conferences, liaise across health sectors, undertake medication management reviews, and evaluate drug utilisation to ensure optimal therapy.⁵¹

As part of their collaborative work, an important element of the practice pharmacist's role is liaison with local community pharmacists to ensure continuity of care, and assist in transitions of care.

The practice pharmacist's core roles have also been shown diagrammatically as Figure 3.

Figure 3. Pharmacist core roles within primary healthcare services.



6.2 Examples of practice pharmacists activities

The terminology used to describe the activities a practice pharmacist undertakes have been explained in Table 2, with examples.

Table 2: Examples of practice pharmacist activities.

Activities	Examples of activities
<i>Inter-professional education</i>	Professional development of ACCHS staff on new evidence and guidelines
<i>Medicines Information</i>	Responding to adhoc medicine queries, PBS queries, specific medication concerns from GPs e.g. switching antihypertensives, anticoagulants, opioid equivalence
<i>Access</i>	Private consultations for medication-based concerns for patients
<i>Adherence</i>	Optimising medication regimens and supporting patient needs
<i>Medication management reviews</i>	Providing in-practice referral based medicine reviews, prompt medication reviews and advice, monitoring and advising on prescribing behaviour, providing home medication reviews
<i>Patient education</i>	Counselling, patient education sessions
<i>Quality use of medicines</i>	Assessing judicious medication choices, safety, and appropriateness with documentation and patient follow-up on adverse drug events, and making recommendations to prescribers about suboptimal prescribing (polypharmacy and underutilisation)
<i>Operation</i>	Increasing practice efficiency and freeing up GP time, sourcing medications, storage, supply.
<i>Liaison</i>	Facilitating seamless care with community pharmacists and hospitals
<i>Medicines reconciliation</i>	Assisting patients navigate the health system and medication changes between health settings
<i>Referral</i>	Referral to community pharmacy and other health care providers
<i>Continuing Quality Improvement</i>	Auditing medication management reviews, auditing and updating practitioners' medicines-related clinical records entries e.g. medicines allergy status, correct cancellation of ceased drugs, correct inclusion of current medications
<i>Development of medication management plans</i>	Recommendations to prescribers, collaborative care arrangements, case conferencing
<i>Shared medical appointments</i>	Organising and attending disease-specific shared appointments

6.3 Flexibility with core practice pharmacist roles

Whilst the project has developed 10 core pharmacists roles which form the foundation for the impact and outcome evaluation, each participating ACCHS has the flexibility to utilise the services of the pharmacist according to service and client priorities at the local level.

Practice pharmacists will be supported to adapt to cultural ways of delivering primary health care within each service. Each ACCHS will be different and reflect the unique ways of providing culturally appropriate healthcare.

This is vital to respect Aboriginal staff and services expertise on what may work best in each particular community setting. However, it also provides a pragmatic evaluation opportunity to document the diversity in pharmacist core roles and in the patient journey. This will be possible through qualitative evaluation, but also through pre-post Health Systems Assessments (see 8.8, 8.10).

The practice pharmacist will be supported to adapt to their role as directed by the staff and CEO. For example, some ACCHSs may require pharmacists to work specifically with chronic care coordinators, whilst others may be more flexible. Other roles pharmacists could undertake include point-of-care testing (e.g. blood pressure, blood glucose, INR) and monitoring, clinical audits, health assessments, immunisation, transitional care and facilitation of shared medical appointments.^{52,53}

Culturally mediated differences in the model of care for pharmacists roles are important outcomes of this project and will be captured in the qualitative evaluation (see 8.10).

6.4 Pharmacists access to clinical information systems

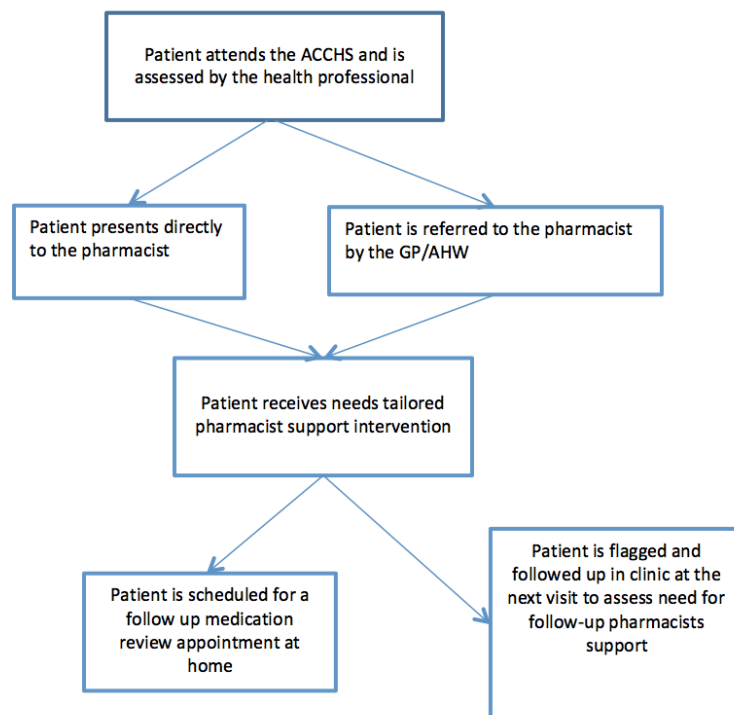
Pharmacists will require access to the patient's medical file to assess the patients history and enable meaningful, informed clinical interventions and enhances pharmacist–GP communication and collaboration.^{54,55} Full access by the pharmacist to the patient's medical records is a necessity in order to provide optimal patient care.⁵⁶

ACCHSs will be supported to configure their CIS so that the practice pharmacist has access to and can enter clinical information when assessing patients. Depending on the type of CIS used by the ACCHS, practice pharmacists may be allocated a 'job role' or 'user group' on the CIS to identify them as a practice pharmacist. This will require set-up prior to the patient seeing any patients, and will be managed during Needs Assessment and Health System Assessment site visits (see 13.3, and 8.8).

6.5 The patient journey with the practice pharmacist

ACCHSs will identify workplans and systems that will best suit the role of the practice pharmacist. Referral pathways for patients to be seen by the practice pharmacist will be established by ACCHSs depending on how patients are referred within sites. For example, patients in some ACCHSs may be first seen by an Aboriginal Health Worker (AHW) or Aboriginal and Torres Strait Islander Health Practitioner (ATSIHP) before being seen by a general practitioner. An example of the expected patient journey is shown in Figure 4. (See also 11.3).

Figure 4. Example of the patient journey.



6.6 Training of practice pharmacists

Practice pharmacists will be required to work with complex patients, sometimes with multiple chronic diseases, and to understand how their needs fit into the cultural and social environment of the community. ACCHS pharmacists will require an understanding of the social determinants of health, health promotion and

general public health challenges relating to Aboriginal and Torres Strait Islander people. Continuity of care will require an understanding of ACCHSs recall and reminder systems and how healthcare and wellbeing services are coordinated within the entire community. Practice pharmacists will need to be familiar with and use clinical information systems (electronic health records) within ACCHSs.

Work within a culturally responsive health care setting will assist practice pharmacists to understand the reasons for a client's non-attendance and help them to build solutions to address the underlying cause. The practice pharmacist must be flexible, adaptive and receptive to the advice provided by experienced staff within ACCHSs, and they must adapt to being a team member. Pharmacists may also spend time in remote and outreach services and must be willing to adapt their style and practice to an environment that suits the client. This may be outside, in a patient's home, from an outreach vehicle or caravan, via teleconference and with family members, and external staff such as interpreters or hospital-based Aboriginal Health Liaison Officers.

6.6.1 Process for training of pharmacists

The PSA will deliver the training to practice pharmacists. Training will be a three-step process.

Step 1: Cultural training.

This training will be provided at the foundation workshop by experienced facilitators, to provide an overview of practicing as a pharmacist in a culturally safe manner. Pharmacists will also be provided health specific cultural safety training from a trainer local to the ACCHS, if available. Pharmacists who commence after the foundation workshop will undertake locally specific cultural safety training and an online cultural safety course approved by NACCHO.

Step 2: Foundation Training.

All pharmacists will be required to complete pre-reading, quiz questions, and online modules, and this will contribute up to 15 hours of learning time. The majority of pharmacists will then participate in foundation training through facilitated 2-day group workshops (an additional 15 hours), making up 30 hours of training per pharmacist.

Pharmacists recruited after this time will be provided with 7.5 hours of face-face individual project-specific training in mutually agreed locations followed by another 7.5 hours of pre-arranged on-site training with a pharmacist who has workplace skills within ACCHSs.

This training will introduce the skills required to undertake the 10 core roles. This will include an introduction to the project protocol, CIS and other software used by ACCHSs, introduction to the Pharmacists log-book software, processes for recording of data, obtaining patient consent, and use of the evaluation tools (medication adherence and MAI), and developing a work plan to undertake core roles and to record data.

Step 3: On-site training within the ACCHSs.

ACCHSs will provide the pharmacists with site specific training, e.g. local team process.

Training will be consistent with the PSA *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people*.⁵⁷

6.6.2 Approval of training materials

The training materials to be developed and the training plan will be finalised during the establishment phase of the project. The materials will be approved by the Project Operational Team and Steering Committee.

6.7 Mentor and peer support for Pharmacists

The PSA will manage a network of mentors (subject matter experts who are pharmacists) and the pharmacist support and training process. Each pharmacist will be offered one expert mentor to be appointed mutually between PSA and NACCHO. NACCHO will provide support to practice pharmacists through the *NACCHO-PSA ACCHO Pharmacist Leadership Group*. This group meets via teleconference quarterly and will meet as needed.

Peer support for all participating pharmacists will be provided through the *PSA Mentoring Program* in collaboration with NACCHO. The program will source mentor pharmacists from the joint *NACCHO-PSA ACCHO Pharmacist Leadership Group* and other pharmacists with relevant experience in the ACCH sector. The structured PSA Mentoring Program platform consists of several validated mentoring components, including:

- Applications – made on a set format by prospective mentors and mentees online, at a dedicated PSA web page.
- Enrolment – intake will be aligned between NACCHO-PSA ACCHO Pharmacist Leadership Group mentor application and mentee applications
- Matching – mentees will be matched with appropriate mentors by NACCHO and PSA. A mentor or mentee can reject the first matching if needed.
- Meetings – a minimum of four meetings (including the initial meeting) form the interaction for the program. A personal learning plan, including the core pharmacist roles, will be discussed and drafted during this initial meeting. Meetings will be held over the telephone or same time electronic communication devices or face to face if convenient.
- Online training and peer interaction – provided through the Mentoring Hub and available to mentors and mentees. Mentors and mentees can confer, provide support and share resources, as a group or one-on-one.
- Counselling – mentors will not provide advice on areas that are personal or health related for the mentee.

6.8 Reports of Practice Pharmacist misconduct

Complaints or allegations of professional misconduct relating to the conduct of a practice pharmacist can be relayed by ACCHSs or Affiliates to NACCHO, or the Project Partners or the Project Operational Team. Any such notices will be initially referred to the PSA. The PSA may discuss with the Project Operational Team or may recommend reporting to AHPRA where applicable. See also section 10.10.

7. Study design and measures

The IPAC project is a pragmatic, non-randomized, prospective, pre and post quasi-experimental study with a cost-effectiveness analysis, where the practice pharmacist intervention will be added to standard primary health care practice within ACCHSs.

The project will adhere to community-based participatory research (CBPR) principles, to ensure clear benefits to project sites, to ensure acceptability and sustainability of the intervention within ACCHSs, and ultimately, transferability to other PHC services.

All eligible ACCHS sites will receive the intervention, with study measures referring to periods prior to and after implementation.

7.1 Community-based participatory research study design

The CBPR principles to be adopted in this project are summarised in Box 1. This has been adapted from the WHO guiding principles for CBPR.⁵⁸

Box 1. Community-based participatory research guiding principles for this PTP trial⁵⁹

2 Condensed framework: guiding principles for participatory health research involving research institutions, Indigenous peoples and their representative bodies*		
Theme	Subsection	The guiding principles refer to:
1. Consultation and approval	1.1–1.3	Initiation of research and making contact
	1.4–1.5	Approval for the research to proceed
2. Partnerships and research agreements	2.1–2.4	Equality of research relationships, joint preparation of a research agreement and research proposal
	2.5–2.6	Development of agreed research processes
	2.7–2.8	Joint obligations towards the research
3. Communication	3.1	Clarification of, and respect for, the lines of authority of the partners
	3.2	Committee selection by Indigenous peoples (for communication, facilitation and promotion); the committee should represent all relevant community-controlled organisations
	3.3–3.4	Maintenance of communication, including progress reports, results and implications of the research
4. Funding	4.1–4.2	A joint commitment to fund seeking, and agreement of sources in advance
	4.3	Research institutions' obligation to ensure Indigenous peoples are involved where resources or capacity are lacking
5. Ethics and consent	5.1–5.2	Respect for ethical guidelines, approval from human research ethics committees and Indigenous-controlled ethics committees
	5.3	Research commencing only after ethics approval is received and signed agreements are finalised
	5.4	Research conforming to additional protocols of the Indigenous peoples involved
	5.5	Consent for research at various levels: individual (study participants), representatives of Indigenous peoples, and the umbrella Indigenous organisation
	5.6	A jointly agreed consent-seeking process
	5.7	Umbrella Indigenous organisation demonstrating the collective consent of Indigenous peoples
6. Data	6.1–6.2	Intellectual property rights, benefit sharing and boundaries pertaining to information use
	6.3	Confidentiality and limiting access to research data
	6.4	Joint review and interpretation of data before publication
	6.5	Authorship or acknowledgement of participants in joint research
	6.6	Formatting data and reports for independent use by Indigenous peoples
	6.7	Indigenous ownership of data and authorisation for further use
7. Benefits of the research	7.1	Obligation for research to provide short-term and long-term benefits for Indigenous peoples, including provision of health care where lacking
	7.2	Disclosure of potential economic benefits of the research
	7.3	Research benefits including training, employment, general capacity building and improved health status or services (or prospects for such improvement)

* Adapted from the World Health Organization, 2003.⁷ See Appendix 1 for the full framework. ♦

7.2 Pragmatic study design

Pragmatic trials seek to determine if interventions work under usual conditions rather than under ideal conditions.⁶⁰ ACCHSs will integrate the practice pharmacist within their existing and usual service delivery systems. These systems and patient needs will vary considerably from practice to practice, which will create variability in the role of the practice pharmacist (see section 6). This permits practice pharmacists to flexibly meet the priorities of health services and the needs of patients without enforcing activities for the sole purpose of data collection.

Data will be collected from ACCHSs in ways that are feasible and within scope to source. Mixed methods of analysis will be used to elicit the variability of health service processes and outcomes. This will inform on the practicalities of the role of practice pharmacists, their daily activities, how their work is integrated within the primary health care team, and the acceptability of their role to Aboriginal and Torres Strait Islander peoples and ACCHS staff.

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 that recognises that the benefits of the research should be clearly articulated, negotiated and implemented in such a way that it will build community capacity.

The pragmatic features of this project are summarised in the Table 3.

Table 3. Adapted⁶¹ pragmatic methodology for this PTP program.

Domain	Evaluation plan
Service eligibility	Eligibility criteria for participating ACCHSs are defined to reflect the conditions required for usual activity.
Participant eligibility criteria	Practice pharmacists will integrate within the primary health care team delivering services according to patient needs and clinician requests. Certain patients will be targeted as high priority (inclusion criteria), but other patients may receive services. Patient eligibility for data analysis pertains to 'regular patients' of the ACCHS, and describe baseline and outcome measures for patients specifically seen by the practice pharmacist.
Intervention flexibility	Practice pharmacist activities will include core tasks and duties but will remain flexible.
Intervention flexibility practitioner expertise	Practice pharmacists must hold specific qualifications and accreditation status.
Comparison intervention	Usual practice will be considered the comparator that will comprise baseline measures (pre-intervention) within each ACCHS, and aggregated measures for all ACCHSs.
Follow-up intensity	Patients in receipt of medication management reviews will be followed up for repeat review at usual intervals specified by

	Medicare, plus at intervals necessary for quality care. Data collection will be minimally intrusive to ensure usual practice. Existing clinical information systems will extract de-identified patient data, and using an installed data extraction tool (DET) software. This is minimally intrusive and will not impact on any staff activity.
Primary trial outcome	The primary outcome is clinically meaningful, and can be assessed under usual conditions, without the need for special tests or training beyond what is currently provided to staff within ACCHSs. The DET will be installed through telephone support externally.
Practitioner adherence to study protocol	Training will be provided to practice pharmacists prior to starting. There may be no need for additional strategies to maintain or improve practice pharmacist adherence to their core roles.
Analysis of primary outcome	The analysis will explore if the intervention works under usual conditions.

7.3 Study measures

In order to meet the project objective, a number of study measures will be collected. These include clinical, demographic, prescribing, and economic characteristics related to the primary health care of patients with the specified eligibility criteria.

The list of selected study measures, and the source of the data is shown in Table 4.

Data will be extracted for consented patients only (see 11.7). Additional economic measures will be sourced with Site Consent (see 11.3).

Table 4: Clinical, demographic, pharmaceutical, health system, and economical measures assessed in this study.

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 utilisation: <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 utilisation: <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	Medication Appropriateness Index (MAI)	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: Education and training, medicines information, team-based collaboration.	Activities undertaken	Logbook
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

7.4 Relationship between study measures and the project objective

All the study measures relate to ‘*quality of care*’ outcomes (the project objective). They include indices to assess change:

- in the quality of prescribing,
- the quality of medicines support through indicators of health service utilization,
- the quality of the patient, service and stakeholder experience, and
- ultimately an effect of these improvements on biometric indices as a measure of health outcome.

7.5 Relationship between the study measures and pharmacists core roles

The study measures are related to the pharmacist's core roles (see 6.1). Table 5 provides a summary of these measures linked to core roles.

Table 5: Data sources to evaluate the pharmacist core roles.

Data source	Description:
GRHANITE DET	Used to evaluate core roles #1-2.

PHARMACIST LOGBOOK & MAI AUDIT LOG	The data collected from this logbook will inform the evaluation for core roles # 1-10. The collection of Non-HMR data (medication management reviews not conducted in the patient's home) will also inform the evaluation of core roles #1-2.
ACCHS HEALTH SYSTEMS ASSESSMENT DATA	The data collected from participating ACCHS enables comparisons between sites and cost-effectiveness analysis.

DET= Data Extraction Tool; MAI= medication appropriateness Index

8. Data collection

8.1 GRHANITE Data Extraction Tool

Only the study measures as shown in Table 4 will be extracted from the CIS used by ACCHSs for each consented patient who has been attended to by a practice pharmacist.

These include: unique patient ID, patient characteristics, indices for contact/demographics, biomedical, prescribing, and measures of health service utilization (MBS items, eg home medicines reviews, and out-of-home medicines reviews).

Data will only be extracted for the 15-month duration of the project, and 12-month pre-intervention period.

This data will be extracted from the CIS using the GRHANITE data extraction tool (DET). This is a minimally intrusive preprogrammed extraction of deidentified electronic data comprising only items that have been ethics approved. The tool was developed by the University of Melbourne, Health and Biomedical Informatics Centre. Over 1000 health services across Australia have used/are using this tool for quality improvement and research activity.

8.1.1 Deidentified and ethical data extraction

GRHANITE™ strictly conforms to extract only data that has been approved by ethics committees. It provides ethical and secure mechanisms for the provision of data from the CIS.

If an individual gives their permission to be involved in a project, GRHANITE can read this consent information if it is recorded in the clinical notes. Patients who have not consented will not have their data interrogated, even if deidentified. This is an 'opt-in' consent process.

The CIS at sites can be interrogated for unique 'strings' that can be added by practice pharmacists in various locations in the CIS. Examples include codes for non-HMRs, medication adherence, and other indicators of pharmacist activity. This ensures linkage between the intervention and outcome indicators, and more efficient use of pharmacist time with regard to data entry.

All data extracted by GHRANITE is deidentified. No identified patient data will be received by the evaluation team. Patient names, dates of birth, address or other identifying information are not extracted.

Data items will be allocated a unique patient ID code in order to enable deidentified linkage with the medication appropriateness index, and assessment of underutilisation measures recorded in the pharmacist logbook (see 8.2).

8.1.2 Support with the use of GRHANITE

ACCHSs participating in this project will be supported to upload the GRHANITE DET into their computers. The tool can be uploaded electronically or by installing software received in the post. Telephone support will be provided to ACCHSs to enable this.

The project Evaluation Team includes the developer of the GRHANITE DET as a co-investigator. This will ensure that the ACCHSs receive the optimal support they need with installation and any problem solving.

8.1.3 Patient consent for electronic data extraction

Patient consent will be required from all patients in all jurisdictions to permit the extraction of deidentified data using the DET. GRHANITE will include only consented patients in the data transfer (see 11.7)

8.1.4 Transfer of GRHANITE data

GRHANITE employs a number of internationally-recognised encryption mechanisms to protect data in transit. The extracted study measures from the ACCHS CIS (baseline and intervention) will be extracted and electronically transferred from the ACCHSs CIS and curated at the central facility (James Cook University) in a secure data repository. The JCU repository runs GRHANITE software for importation and only this machine holds the decryption keys to the data. Because the decryption keys are only present on the JCU repository, the data is secure in transit.

GRHANITE will enable weekly data extracts from the CIS during the 15-month intervention phase. File transfer from all ACCHSs with GHRANITE installed will be automatic.

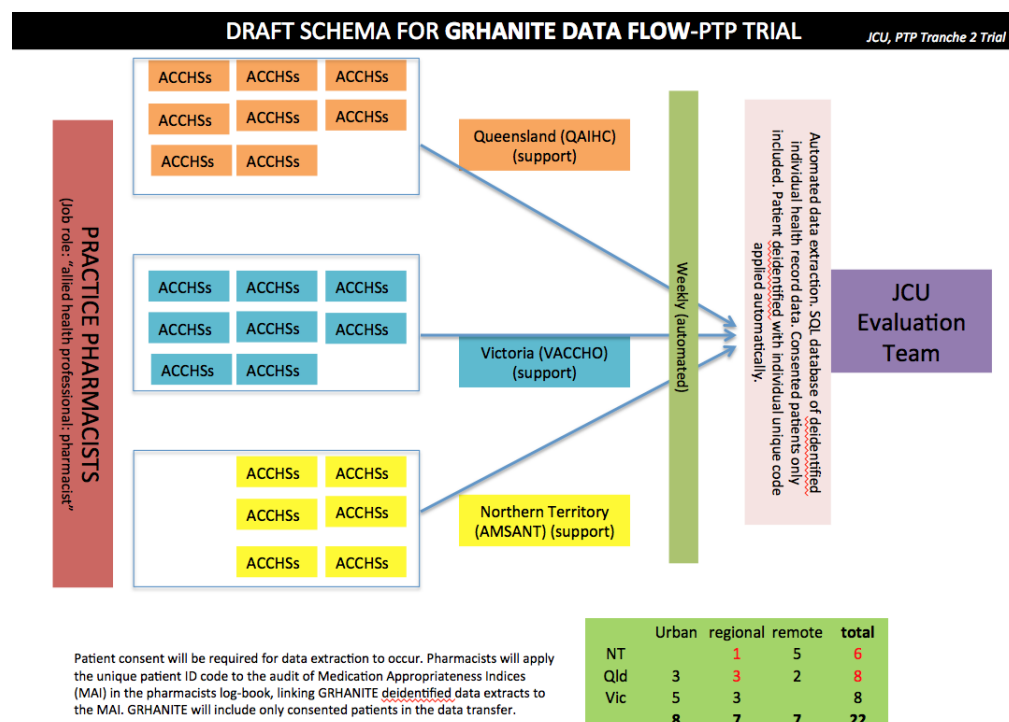
GRHANITE software will not operate if copied or moved from one computer to another.

All installations require a unique authorizing license. This license is secured for the project through a subcontracting arrangement between JCU and the University of Melbourne. Access to the data collected for this project will be managed as outlined in 10.9.

8.1.5 Schema for GRHANITE data flow

A schema to illustrate how data will flow from ACCHSs to the data repository is shown as Figure 5.

Figure 5. Schema for data flow (GRHANITE)



8.2 Pharmacists Log-book data

Additional deidentified data on patients and health systems interactions will be collected by practice pharmacists through an electronic log-book. This system will be an online secure database requiring practice pharmacist secure log-in. It will be used by practice pharmacists to record deidentified daily activity. Each electronic log-book entry will be able to be interrogated by the JCU data custodian.

The daily-recorded activity will refer to 10 core pharmacists' roles and comprise qualitative and quantitative data measures. An outline of the measures is shown in Table 6. The logbook will record if any education sessions were delivered for staff within the ACCHS, if a quality assurance activity at the practice (drug utilization review) was undertaken, and examples of liaison with community pharmacy or hospitals.

The electronic interface will be user-friendly to minimise the reporting burden of practice pharmacists.

Table 6. Measures to be collected by practice pharmacists in the electronic pharmacist log-book

Core roles #1: Medication Management Reviews	Details of HMR and non-HMRs and follow-ups Date of HMR and data entry Reasons for choosing to do the particular medication review If HMR, conducted by the IPAC pharmacist or an external pharmacist? Details of AoU
Core roles #2: Team-based collaboration	Date of activity Did activity relate to specific patients Staff involved Duration
Core roles #3: Medication adherence assessment & support	Date of activity Responses to patient survey questions SF1 responses
Core role #4: Medication Appropriateness Index (MAI) Audit, and Assessment of Underutilisation (AOU)	The unique patient ID (extracted from the CIS) for 30 patients. <i>[This ensures the patient is deidentified and the MAI score, and AOU results can be linked to GRHANITE data extraction. See 8.1 for more detail]</i>
	Date the MAI and AOU were undertaken
	The MAI measurement questions answered for each medicine and their scoring and comments (see Table 7)
	The results of the AOU ('no prescribing omission' or 'prescribing omission')
	Description of any medication omissions (list of underused medications)
	Prescribing recommendations accepted (ye/no) upon review of MAI and AOU
	Time spent to complete MAI and AOU
Core role #5: Preventative health care	Recorded under #2 'Team-based collaboration' or #5 'Education and Training'
Core role #6: Drug Utilisation Review (DUR) (a QA activity)	date of development of DUR
	description of the DUR;
	summarise the plan of action;
	proposed changes to be made to the standard of care;
	evidence of change in the practice (over time) as a result of the DUR. <i>[A pdf of the plan could also be emailed with the monthly upload]</i>
	Time taken to conduct the DUR
	date of the education session held and time taken;

Core role #7: Education and training	Topic/s covered;
	number and job roles of staff in attendance.
Core role #8: Medicines information service	description of the event (options to include: <i>PBS query, query about drug interactions, advice about new and emerging drugs, etc</i>);
	job role of the staff the information was provided to;
	evidence this event led to an outcome.
	Time spent for medicines information service
Core role #9: Medicines stakeholder liaison	date of development of the plan;
	what is the plan for?;
	expected outcome from the plan;
	name of community pharmacy/pharmacist involved in the plan;
	number of ACCHS interactions with community pharmacy (in the reporting period);
	evidence this plan led to an outcome (if available).
	Time spent to develop the plan
Core role #10. Transitional care liaison	Type of hospital/organisation engaged;
	number of transitional care activities with the organisation (eg medicines reconciliations; discharge medication discussions, etc)
	Total time spent for transitional care activity; and other evidence of engagement

8.3 Measures of suboptimal prescribing

Suboptimal prescribing will be evaluated in the following ways:

- *Overuse* (polypharmacy, defined as ≥ 5 medications per patient, and as measured in the Medication Appropriateness Index)
- *Inappropriate use* (prescribing that does not agree with accepted medical standards, or poses more risks than benefits, as measured in the Medication Appropriateness Index)
- *Underuse* (missing drugs that the patient needs, termed 'potential prescribing omissions', as measured by an assessment of underutilisation)

The project will assess measures in all three categories using data from clinical information systems at sites, as well as from data collected by pharmacists.

Inappropriate use will be measured using the Medication Appropriateness Index (MAI). Three (3) items in the MAI will be used to measure overuse of medicines, as well as measures of polypharmacy (the number of medicines per patient) from the prescribing indices as extracted by the DET. An assessment of the underutilisation of medicines will be determined at the time the audit for the MAI is conducted.

8.4 Medication Appropriateness Index data

The pharmacists log-book will enable practice pharmacists to record the results of the measurement of the 'medication appropriateness index' (MAI) for each of 30

participants. A MAI is a more detailed and comprehensive assessment of the appropriateness of a patient's medication.⁶²

Of the participants seen by a practice pharmacist, 30 participants per site (per FTE pharmacist) will have their medications intensively appraised as part of this type of medication management review.

The MAI will be measured in the first three months of the intervention phase (baseline) and recorded in the pharmacists' logbook. These audited participants will have their MAI assessed again 12 months later (within the implementation phase).

8.4.1 Measuring the MAI

The medication appropriateness index (MAI)⁶³ is a scoring method to assess medication appropriateness at baseline and follow-up. The index has been internationally validated and widely used to assess the potential for improvement in prescribing quality due to a clinical pharmacist intervention.⁶⁴ Instructions for the use of the index and how pharmacists can be trained to undertake scoring have been sourced from the author in Canada.⁶⁵

For each medicine taken by the participants, the pharmacist will assign a score with the scores weighted as shown in Table 7. The total score is then added. A score of 18 represents maximal inappropriateness with regard to the medication. The mean score can then be calculated for all the drugs the patient is taking, and an overall score noted.

Practice pharmacists do not need to do the calculation. This will be measured by the evaluators.

The pharmacists' log-book will facilitate the electronic scoring for the MAI for each medicine. This will be measured for each of the 30 patients being audited, at two points in time:

- at baseline (month 1-3), and
- at 12-months later.

Table 7. How the MAI will be scored

*1. Is there an indication for the drug?	A_____	B_____	C_____3
	Indicated		Not Indicated
*2. Is the medication effective for the condition?	A_____	B_____	C_____3
	Effective		Ineffective
3. Is the dosage correct?	A_____	B_____	C + or C - 2
	Correct		Incorrect
4. Are the directions correct?	A_____	B_____	C_____2
	Correct		Incorrect
5. Are the directions practical?	A_____	B_____	C_____1
	Practical		Impractical
6. Are there clinically significant drug-drug interactions?	A_____	B_____	C_____2
	Insignificant		Significant
7. Are there clinically significant drug-disease/condition interactions?	A_____	B_____	C_____2
	Insignificant		Significant
*8. Is there unnecessary duplication with other drug(s)?	A_____	B_____	C_____1
	Necessary		Unnecessary
9. Is the duration of therapy acceptable?	A_____	B_____	C_____1
	Acceptable		Not acceptable
10. Is this drug the least expensive alternative compared to others of equal utility?	A_____	B_____	C_____1
	Least expensive		Most expensive

Red score is aggregated (per medicine) to determine the total MAI score for the patient (the total result can range from 0-infinity). Scores in columns A and B are weighted zero.

* Rows represent the MAI ratings for medication overuse (combined MAI scores for question, 1, 2, 8)⁶⁶

8.4.2 Undertaking and reporting the MAI result within the ACCHS

- The MAI assessment does not require the participant to be present. No personal information about participants is contained in the log-book.
- The medications of 30 participants (per FTE pharmacist) will need to be assessed within the first 3 months of the implementation phase in the service, and reassessed 12 months later.
- The date of the MAI measurement will be recorded in the pharmacists log-book.
- Practice pharmacists will enter the unique patient ID code for each of the participants who have had an MAI measured into the pharmacists log-book. This will link the GRHANITE deidentified data extracts to the MAI scores. (This step is necessary as clinical information systems do not easily facilitate pharmacists to measure and record scores for medication appropriateness, so a pharmacist logbook is necessary to collect and record this data referring only to the unique patient ID).
- Practice pharmacists will ensure that the participants clinical record notes that an MAI was conducted.
- Practice Pharmacists will follow-up participants as per usual clinic processes.
- Practice pharmacists will ensure that the MAI assessment takes account of additional clinical information such as an assessment of the participant's *absolute cardiovascular risk* when assessing medications for the AOU.
- It is expected that the practice pharmacist will communicate the findings of the MAI to the prescribing team within the ACCHS for each participant, so that appropriate clinical action is taken.

8.5 Assessment of underutilization (AOU)

An Assessment of Underutilization (AOU) will be determined at the time of the audit for the MAI. The same participant's being audited for the MAI will be assessed for the underutilization of medicines.

The MAI does not measure underuse of medicines. However, pharmacist evaluation of underuse of medicines (medicines that have been omitted despite being indicated and potentially beneficial) is also possible during this audit.

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 recommendation.^{67 68 69 70}

Ratings for individual items will be dichotomised into 'no prescribing omission' or 'omission of an indicated drug'. The outcome measure will be the "proportion of patients with at least one medication omission detected".

8.5.1 Measuring the AOU

The project will define evidence-based indicators of common prescribing omissions for the conditions listed in the patient inclusion criteria for this project. This list will be influenced by the validated indicators developed in European START randomized controlled trials.^{71 72} These indicators are organized into physiological systems to

assist with use. An extract of the current version of sample START indicators to determine potential prescribing omissions is shown in Table 8.

Table 8. Extract of evidence-based criteria checklist for prescribing omissions (updated Version 2 START criteria).

<p>Section A: Cardiovascular System</p> <ol style="list-style-type: none">2. Aspirin (75 mg – 160 mg once daily) in the presence of chronic atrial fibrillation, where Vitamin K antagonists or direct thrombin inhibitors or factor Xa inhibitors are contraindicated.3. Antiplatelet therapy (aspirin or clopidogrel or prasugrel or ticagrelor) with a documented history of coronary, cerebral or peripheral vascular disease.4. Antihypertensive therapy where systolic blood pressure consistently > 160 mmHg and/or diastolic blood pressure consistently >90 mmHg; if systolic blood pressure > 140 mmHg and /or diastolic blood pressure > 90 mmHg, if diabetic.5. Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, unless the patient's status is end-of-life or age is > 85 years.6. Angiotensin Converting Enzyme (ACE) inhibitor with systolic heart failure and/or documented coronary artery disease.7. Beta-blocker with ischaemic heart disease.8. Appropriate beta-blocker (bisoprolol, nebivolol, metoprolol or carvedilol) with stable systolic heart failure. <p>Section F: Endocrine System</p> <ol style="list-style-type: none">1. ACE inhibitor or Angiotensin Receptor Blocker (if intolerant of ACE inhibitor) in diabetes with evidence of renal disease i.e. dipstick proteinuria or microalbuminuria (>30mg/24 hours) with or without serum biochemical renal impairment. <p>Section I: Vaccines</p> <ol style="list-style-type: none">1. Seasonal trivalent influenza vaccine annually2. Pneumococcal vaccine at least once after age 65 according to national guidelines
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However, the START criteria are not applicable to the Australian Aboriginal and Torres Strait Islander context and exclusively refer to pharmacotherapy for the elderly. For this reason, a list will be created drawing from current high-value prescribing recommendations from Australian best practice guidelines to be appropriate to the health context involving Aboriginal and Torres Strait Islander peoples who have chronic disease at younger ages.

Prescribing recommendations relevant to the target population will be compiled and sourced from evidence-based guidelines (including the CARPA Standard Treatment Manual,⁷³ National Guide to a Preventive Health Assessment for Aboriginal and Torres Strait Islander People (3rd Edition),⁷⁴ Australian Medicines Handbook,⁷⁵ and the Australian Immunisation Handbook⁷⁶). Each medication management review will assess for PPOs. Drug types will include cardiovascular and anti-hyperglycaemic medications for primary and secondary CVD prevention and optimal management of T2DM and CKD, pneumococcal vaccination, chemoprophylaxis for rheumatic heart disease, and other omissions.

Recommendations from clinical practice guidelines will be selected if they were unambiguous and represent high-value interventions known to be underused.⁷⁷ The recommendations will be arranged into pharmacotherapeutic criteria to benefit Indigenous Australians with the listed conditions, and the selection will be kept small in order to minimise the reporting burden on pharmacists. These criteria have now been compiled and are shown in the Appendix.

Pharmacists will need to be aware of the clinical condition of the participant, their medications and medication history in order to identify a PPO.

The pharmacists log-book will facilitate the electronic reporting of the AOU of the participant's medicines. The AOU will be measured for each of the participant's being audited for an MAI, at two points in time:

- at baseline (month 1-3), and
- at 12-months later.

The log-book will facilitate data entry for each participant as:

- no prescribing omission, or
- omission of an indicated drug.

8.5.2 Undertaking and reporting the AOU result within the ACCHS

- The AOU assessment does not require the participant to be present.
- The date of the AOU measurement be recorded in the pharmacists log-book.
- Practice pharmacists will enter the unique patient ID code for each of the 30 participant's who have had an AOU measured, into the pharmacists log-book. (These should be the same participant's as those who are being assessed for the MAI).
- Practice pharmacists will ensure that the participants clinical record notes that an AOU was conducted.
- It is expected that the practice pharmacist will communicate the findings of the AOU to the prescribing team within the ACCHS for each participant, so that appropriate clinical action is taken.

8.6 Measures of health service utilisation

Measures of health service utilization will include Medicare claims data for Home Medicine Reviews and other Medicare items.

8.6.1 Medicare data

Medicare claims data will be extracted from the CIS using the GRHANITE DET. The data will include claims for completed Home Medication Reviews (HMR), and chronic disease management plans, as well as other markers of health service use. (See Table 4).

The data extractions only pertain to participants.

Descriptive information about HMRs will be collected in the pharmacist logbook.

8.6.2 Non-HMR data

As there is no Medicare rebate for a medication management review that is not conducted as a Home Medicines Review, this project will document this service as a 'non-HMR'. A non-HMR is defined as:

- comprising some or all the elements of a HMR, but not fulfilling all relevant MBS HMR criteria.

For many Aboriginal and Torres Strait Islander patients, the offer of a HMR may be inappropriate.⁷⁸ A number of barriers have been identified to undertaking HMRs. These have been summarized in Table 9.

Table 9. The offer of a HMR may be inappropriate in these situations.

- a) If the patient has no fixed address;
- b) If the patient is at risk of forgoing a HMR if it is not conducted opportunistically (e.g. unlikely to keep an appointment);
- c) If conducting a home visit is culturally inappropriate (even with an AHW);
- d) If the patient lives far away or travel poses a risk for staff due to distance or unsafe and difficult road conditions;
- e) If there is a language communication barrier in the home setting (i.e. No-one at home to help translate);
- f) If there is a need for visual or learning resources that are not accessible in a home visit situation.

Practice pharmacists will be encouraged to undertake a medication management review in more appropriate settings such as the clinic according to the wishes and circumstances of the participants.

8.6.3 Documenting a non-HMR in the CIS of the ACCHS

Medication management reviews not conducted in the participant's home will be documented as a 'non-HMR' in the clinical information system for that participant within the ACCHS. This will indicate the participant has had a 'non-HMR'.

Descriptive information about the non-HMR will be collected in the pharmacist logbook.

8.7 Measures of medication adherence

8.7.1 Self-report of Medication Adherence

Medication adherence will be measured at least twice for each participant, at baseline and study end using self-reported, indirect methods of assessment. Pharmacists will ask patients questions about missed doses and if they have difficulty taking their medicines. This will help prescribers and pharmacists to identify modifiable factors that affect patient adherence and to assist individual patients to overcome any difficulties they report.

The practice pharmacist will record the responses in a designated place in the Pharmacist Log Book. Participants will be asked these questions when they have a repeat medication review or any subsequent consult with the pharmacist. Pharmacists will record that they have assessed for adherence in the CIS using a code.

8.7.2 Measures of medication adherence

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 0-7 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.⁷⁹ This single question and its variations have been used in the Kanyini study involving Aboriginal and Torres Strait Islander peoples in Australia⁸⁰ and internationally.^{81 82 83}

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,⁸⁴ 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 of change (see Appendix). 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 survey has now been compiled and is shown in the Appendix.

8.8 Health systems assessment data

To identify health system-related covariates, every participating ACCHS site will be visited twice to conduct a health systems assessment (HSA):

- at the time of, or just prior to the appointment of the pharmacist, and
- repeated towards the end of the implementation phase (month 12-15).

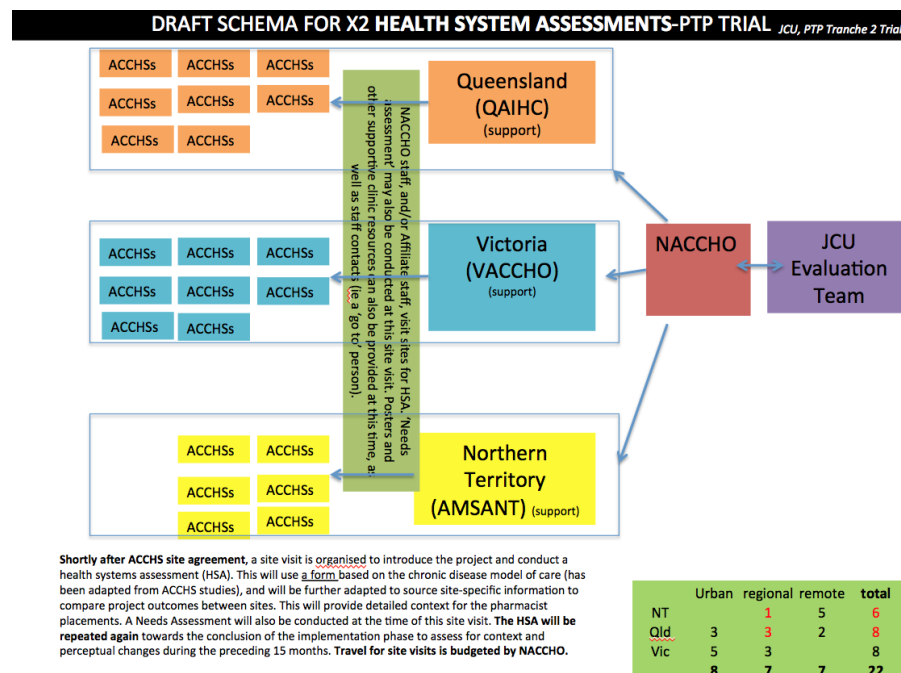
The 'health systems assessment' will source information about service size and function within the ACCHS. Each ACCHS is different in many ways. The project needs to understand how many staff (and types) are employed within the ACCHS, the total service population, the total service budget, Aboriginal governance structures, health services on offer, CQI processes, models of care such as outreach, if home medicines reviews are conducted and how, type of CIS used, recall systems in place, the adequacy of existing communication with the hospital, and community pharmacy/ies, medicines access information, use of point of care testing, regional services available such as specialist and allied health visits, and how the ACCHS will implement and define the core roles of practice pharmacists.

A site visit for this assessment will be conducted by the NACCHO Project Coordinator with assistance from Affiliate staff. This may comprise the first visit to the ACCHS, and coincide with the Needs Assessment (see 13.3.3). A meeting with key informant staff in a focus group setting within the ACCHS may be needed.

The health systems assessment will adapt the Kanyini Health Assessment Form⁸⁵ (which itself has been adapted from the Wagners Chronic Disease Model for health systems assessment),⁸⁶ Permission to adapt and use the form has been provided by Prof Alex Brown from SAHMRI.⁸⁷ The HSA form has now been compiled and is shown in the Appendix.

An outline of the process to conduct the HSA is shown in Figure 6.

Figure 6. Process for conducting a health systems assessment within each ACCHS.



The HSA will also inform service location (which will inform the ASGS- Modified Monash Method classification⁸⁸ and Index of relative socioeconomic disadvantage by postcode, and the index for Indigenous Relative Socioeconomic Outcomes). See also Section 11 regarding site visits.

8.9 Patient experience measures and self-assessed health status

The IPAC project will explore the overall 'quality of care' experience from the participants perspective after receiving care from the IPAC pharmacist. The 'patient experience' will be elicited through qualitative data collection through focus group discussion at three Sites (see 8.10).

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.⁸⁹

Responses to this single-item (SF-1) question have been shown to correlate well with multi-item tools measuring the same construct,⁹⁰ and are used in the National Aboriginal and Torres Strait Islander Social Survey.⁹¹

8.10 Qualitative data

There are three main sources of qualitative data for the evaluation of the intervention:

- General sources of data (Pharmacists Logbook analysis, qualitative data from Health Systems Assessment, and 'patient experience' survey data (see relevant Sections))
- Site-visit fieldwork
- Remote data collection.

8.10.1 Site-visit fieldwork for qualitative evaluation

Three (3) ACCHSs, one in each jurisdiction, will be visited as ‘case study’ sites for qualitative data collection. ACCHSs will be invited after being purposively selected for on-site field visits in partnership with NACCHO and the Affiliates. The Project Operational Team and Project Reference Group will assist with site selection. ACCHSs can also nominate to be considered for these site visits.

These services will be urban, rural or remote to ensure an understanding of the phenomenon (an in-service Pharmacist) in different settings.

Site-visit field-work will be undertaken over a three-day period at each service by three researchers experienced in health services research, in partnership with the ACCHS and with the assistance of Pharmacist and clinic staff. They 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). 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.

It is expected that this fieldwork will anytime from June- October 2019.

A summary of the site-visit fieldwork data collection process is shown in Table 10.

Table 10: Summary of the qualitative analysis to be undertaken in three ‘case-study’ sites.

Time	Data collection method	Example:
Day 1	In-depth semi-structured interview with the Practice Pharmacist	<p>To elicit perceptions of:</p> <ul style="list-style-type: none"> • Team-based care and their clinical role • The degree of integration • The effectiveness of the role <p>To describe:</p> <ul style="list-style-type: none"> • What and why certain processes were adopted • Why new resources were needed <p>To map:</p> <ul style="list-style-type: none"> • The patient journey and the interactions they had with patients, other healthcare providers and community pharmacies. • To describe case studies
Day 2	Non-participant observation of Pharmacist for one work day (Shadowing)	<ul style="list-style-type: none"> • The qualitative researcher will “shadow” the Pharmacist for one day taking detailed field notes and recording observations of workflow and patient interactions. • Observation will be guided by an observation guide (developed by the Evaluation Team) and the interview with the Pharmacist.
Day 3	Focus Group Discussion with patients	<ul style="list-style-type: none"> • 6 to 8 participants • Purposively selected (those who have experience with Pharmacist) • Semi-structured with an interview guide (developed by the Evaluation Team) and the interview with the Pharmacist.

	In-depth semi-structured interview with one patient	<ul style="list-style-type: none"> Purposively selected having experience with Pharmacist Semi-structured with an interview guide (developed by the Evaluation Team) and the interview with the Pharmacist.
Day 4	Focus Group Discussion or individual interview/s with Aboriginal Health Workers/Practitioners/CEOs/ Practice Managers / GPs	<ul style="list-style-type: none"> 6 to 8 participants Purposively selected for knowledge of role of the pharmacist and patient journey Will aim to elicit 'a map' of the interactions patients have and other healthcare providers have with the practice pharmacist, and with community pharmacies. To elicit case studies.
During the 4 days	Photographs, collection of relevant documents	Photographs will be taken of any signs and posters, outlining the role of the Pharmacists. Examples of documents, and patient health promotion materials outlining the role of the pharmacist; newsletter articles and other documents will also be collected

8.10.2 Qualitative data collected remotely

Other qualitative data will be collected remotely through one-hour sessions held using webinar, skype, video conferencing or phone discussion. The same qualitative evaluation team will conduct individual interviews and focus groups to ensure consistency and data quality.

It is expected this data collection will occur during June- August 2019 once all ACCHSs have had a Pharmacist in their service for at least 6 months.

Participants will be recruited upon invitation by NACCHO, during this period.

A summary of the process for collecting qualitative data remotely is shown in Table 11.

Table 11. Summary of the process for collecting qualitative data remotely

Data collection method	Example:
Individual Interviews with all participating pharmacists	<p>To elicit perceptions of:</p> <ul style="list-style-type: none"> Team-based care and their clinical role The degree of integration The effectiveness of the role <p>To describe:</p> <ul style="list-style-type: none"> What and why certain processes were adopted Why new resources were needed <p>To map:</p> <ul style="list-style-type: none"> The patient journey and the interactions they had with patients, other healthcare providers and community pharmacies. <p>To describe case studies.</p>
Online questionnaire with GPs within ACCHS sites	As above with specific GP focus.
Online questionnaire of Community Pharmacists	To elicit perceptions of:

	<ul style="list-style-type: none"> Transitional care arrangements, stakeholder engagement and collaboration
Online questionnaire of CEOs and Managers	<p>To elicit perceptions of:</p> <ul style="list-style-type: none"> Team-based care and their clinical role The degree of integration The effectiveness of the role Overall satisfaction

8.11 Cost-effectiveness data

The cost-effectiveness analysis will determine if the intervention is cost effective relative to standard practice (at baseline).

The two comparison groups will include:

- Group 1: Standard care (defined as care received at baseline, prior to receiving care from a Practice Pharmacist)
- Group 2: Patients receiving care from a Practice Pharmacist

The direct costs of providing the pharmacist intervention in each practice will be estimated. As Group 1 care is defined as standard practice, it will be assumed that no additional costs were incurred. The pharmacist intervention costs will consist of pharmacist salaries, on-costs associated with the pharmacists' employment, overheads associated with employing the pharmacists, training of the pharmacists, time of other professionals within the ACCHS meeting with the pharmacists (if available), costs of pharmacist travel and equipment and consumable purchases related to delivering the pharmacist service.

8.11.1 Outcome measures of economic analysis

The primary outcome measures for the economic evaluation will be biomedical indices for (i) all IPAC participants (using generic biomedical indices) and (ii) subgroups of participants with specific chronic diseases (using condition-specific outcomes) .

The secondary outcome for the economic evaluation will be the number of patients in each practice at baseline and post-intervention with medication underutilisation. Medication underutilisation will be reported as change in the number of participants with at least one PPO.

8.11.2 Source of cost-related data

The sources of cost will be obtained as follows (Table 12):

Table 12: Source of information for economic analysis

Cost	Source
Pharmacist salary, on-costs and overheads	PSA (project accounting data)

Training of the pharmacists	PSA (project accounting data)
Time of other professionals within the ACCHS meeting with the pharmacists	Pharmacist logbook
Costs of pharmacist travel	Pharmacist logbook and PSA (project accounting data)
Equipment and consumable purchases related to delivering the pharmacist service	Pharmacist logbook and PSA (trial accounting data)

8.11.3 Sources of effectiveness-related data

This will be sourced from the GRHANITE data extraction (see 8.1), and Health Systems Assessment data (see 8.8).

9. Data Analysis

9.1 Quantitative data analysis

Biometric indices will inform on improvements arising from the intervention compared with baseline as outlined in the Theory of Change and Logic Model (see Appendix).

The effect of the pharmacist intervention will be investigated by comparing study measures 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 CIs in a 12-month period preceding patient enrolment into the study. 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 relevant subgroups of participants with chronic disease. The change in these measures over time will be examined for participants with chronic disease and for participants with T2DM.

Absolute CVD risk will be calculated based on the 1991 Framingham Risk Equation (FRE)⁹² 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.^{93 94} 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)^{95 96} 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.⁹⁷ 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.⁹⁸ Estimated GFR as reported in CIs will be used without derivation from serum creatinine measures.

An analysis of differences in summated 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 unnecessary⁹⁹ will be measured by assigning a MAI score to three items.¹⁰⁰ 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.

Self-assessed health status (SF1) and indices of health service utilisation (Medicare) and measures of medication adherence will be analysed for change from baseline.

The number of claims for relevant MBS services 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. The frequency and characteristics of non-HMRs will be described in the logbook including the reasons for undertaking a non-HMR over a HMR.

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.

A Statistical Analysis Plan will outline more detail of these analyses.

9.2 Qualitative data analysis

For qualitative trial outcomes, the discussions will be transcribed verbatim. Themes will be developed and finalized through the constant comparison method. Initial similar themes will be inductively developed from data immersion and refined through coder triangulation. Data will be stored, and analysed with NVivo 12 (QRS International) software.

9.3 Cost-effectiveness analysis

The cost-effectiveness analysis will compare costs and outcomes in the pre- and post-trial periods using paired data.

For the primary economic evaluation, outcomes will comprise relevant biomedical indices and will be compared for (i) all IPAC participants (e.g. using systolic blood pressure as an outcome measure that is available for all participants) and (ii) subgroups of participants (e.g. using HbA1c for participants with diabetes).

For these analyses, the numerator of the incremental cost-effectiveness ratio (ICER) will reflect total costs for the relevant participant group and the denominator will be the appropriate biomedical index for that group.

$$\text{ICER} = \frac{\text{Total costs of pharmacy intervention} - \text{Total costs at baseline}}{\text{Change in biomedical index}}$$

For the secondary economic evaluation (i.e. based on the subgroup of enrolled participants who had a complete assessment of medicines underutilisation), the outcome measure of potential prescribing omissions (PPOs) will be compared for three groups of participants if possible: (i) those with a baseline and final MAI review (ii) those with a baseline and final HMR review and (iii) those with a baseline and final non-HMR review. The outcome measure will be calculated based on the proportion of participants who changed from having at least one PPO to no medication omission.

This ICER will show the incremental cost to have one less person with a PPO. The numerator will reflect total costs for participants with both baseline and final medication reviews. The denominator will be calculated from the proportion of participants who changed from at least one PPO to no omission, multiplied by the corresponding number of participants.

$$\text{ICER} = \frac{\text{Total costs of pharmacy intervention} - \text{Total costs at baseline}}{\text{Proportion of patients who changed from a PPO to no PPO times no. of participants}}$$

Unadjusted and adjusted comparisons of costs and outcomes for each target group will be conducted using appropriate statistical tests.

The incremental cost effectiveness ratios will be estimated both excluding and including health system costs using the adjusted cost and outcome data.

The sensitivity of the results to different assumptions, such as changes in pharmacist salary, training costs or time spent conducting medication reviews, will be tested with one-way sensitivity analysis.

Cost-effectiveness acceptability curves will be constructed to demonstrate the probability that the incremental costs and outcomes gained from the pharmacy intervention is cost-effective within an acceptable cost effectiveness range in the context of improving specific health outcomes amongst Aboriginal and Torres Strait Islander people.

9.4 Policy analyses

Analyses will also include reporting of the CBPR methodology, and health policy implications for the pharmacist workforce as well as national nKPIs and quality improvement.

9.5 Sample size for the study

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 1% (1-point difference) from baseline if a standard deviation (SD) of 2.7% was assumed^{101 102}; (2) a clinically relevant reduction of 10mmHg (SD 20 mmHg) in systolic blood pressure and (3) 5 mmHg (SD 10 mmHg) in diastolic blood pressure;^{103 104} (4) a reduction in total cholesterol (-0.3mmol/L; SD 1 mmol/l),^{105 106} (5) an increase in high-density lipoproteins (0.1 mmol/L; SD 0.4 mmol/l),^{107 108} and (6) a reduction in low-density lipoproteins (-0.3 mmol/L; SD 0.9 mmol/l);¹⁰⁹ (7) a reduction in triglycerides (-0.9mmol/L; SD 1.5 mmol/l);^{110 111} and (8) a 30% decrease in ACR (SD: 23 mg/mmol);^{112 113} 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%¹¹⁴ 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^{115 116} 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).

10. Data Storage and Management

10.1 Guiding documents and legislation

Processes related to data ownership and management is consistent with the policies and guidelines of the lead evaluation organisation (JCU) and ACCHS related policies.

The policies that this project adheres to include:

- *The Code for the Responsible Conduct of Research* (JCU) [This Code has been adapted from the Australian Code for the Responsible Conduct of Research [“the National Code”], developed jointly by the National Health and Medical Research Council, Australian Research Council and Universities Australia, and published in 2007]. <https://www.jcu.edu.au/policy/research-management/code-for-the-responsible-conduct-of-research>
- The *Intellectual Property Policy and Procedure* (JCU). <https://www.jcu.edu.au/policy/research-management/intellectual-property-policy-and-procedure>
- *National Aboriginal and Torres Strait Islander Health Data principles*, endorsed by Australian Health Ministers Advisory Council (AHMAC) in 2006 (see *Appendix*)
- *Primary Health Networks and Aboriginal Community Controlled Health Organisations – Guiding Principles*. <http://www.health.gov.au/internet/main/publishing.nsf/Content/PHN-Accho>
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, endorsed by NHMRC in 2003. <https://www.nhmrc.gov.au/guidelines-publications/e52>
- *National Statement on Ethical Conduct in Human Research (2007)* - Updated May 2015. <https://www.nhmrc.gov.au/guidelines-publications/e72>

10.2 Intellectual Property

Intellectual property as outlined in the Funding Agreement with the Australian Government Department of Health means all copyright and rights resulting from intellectual activity but does not include moral rights (the right of attribution and/or integrity of authorship of copyright material and the right not to have authorship falsely attributed) or rights in relation to confidential material.

The ownership of data and materials that are produced from this project is subject to the clauses in the Funding Agreement. Intellectual property rights in materials created as arising from activity in this project (but not raw unanalysed data extracted using GRHANITE), will be vested in respective organisations: JCU, the PSA, and NACCHO with license granted to PSA.

10.3 ACCHS ownership of data

Data collected in each Project site is acknowledged to be the property of the specific ACCHS. The raw (unanalysed) data extracted by GRHANITE and collected is acknowledged to be owned by the ACCHSs from which it was collected.

This is in keeping with the guiding documents in 10.1. For example Primary Health Network Guiding Principles state: *“recognize that data generated by ACCHOs is owned by ACCHOs.”*

The ACCHS will be asked to grant the PSA (and in turn, NACCHO and the JCU) a perpetual, irrevocable, royalty-free and licence fee-free, non-exclusive licence (including a right of sub-licence) to use and analyse the raw (unanalysed) extracted data that arises from participation in the IPAC Project in accordance with this Project Protocol.

The PSA will grant the ACCHS a perpetual, irrevocable, royalty-free and licence fee-free, non-exclusive licence (including a right of sub-licence) to use, reproduce, modify, adapt, analyse, publish, perform, broadcast, communicate and exploit (but not commercialise) the local feedback provided by the Project Partners to the ACCHS (if requested) in accordance with ACCHS Site Agreements once the Australian Government Department of Health have approved public releases of results or information arising from activity in the IPAC Project.

10.4 Confidentiality of ACCHS data extracted from GRHANITE

Individual patients participating in this project will not be able to be identified. This is secured through the use of the GRHANITE data extraction tool and because deidentified GRHANITE data will only be extracted from consented patients. GRHANITE data received by the evaluation team will not be able to be reidentified.

All data collected by GHRANITE and forwarded to the evaluation team is deidentified. Data items are allocated a unique patient identification (ID) code. The tool provides ethical and secure mechanisms for the provision of data. Patient names, dates of birth, address or other identifying information are not extracted. The number of fields and the types of data extracted for this project have been described earlier (Table 4, section 8.1). GRHANITE strictly conforms to what is approved by ethics committees.

10.5 Confidentiality of ACCHS data extracted from Pharmacists log-book

With regard to the Medication Appropriateness Indices (MAI) in the pharmacists log-book, pharmacists will apply the unique patient ID code to the audit of 30 participants, thereby linking GRHANITE deidentified data extracts to the MAI scores. This step is necessary as clinical information systems do not easily facilitate pharmacists to measure and record scores for medication appropriateness, so a pharmacist logbook is necessary to collect and record this data referring only to the unique patient ID.

GRHANITE will include only participants in the data transfer. GRHANITE employs a number of internationally-recognised encryption mechanisms to protect data in transit. GRHANITE software will not operate if copied or moved from one computer to another. All installations require a unique authorising license. Over 1000 health services across Australia have used/are using this tool for quality improvement and research activity.

10.6 Confidentiality from pharmacists and in reports

Practice Pharmacists participating in this project will sign a *Practice Pharmacist Participant Consent Form* prior to participating in the project stating: *“I will have access to the clinical information system and will utilise the information contained within to undertake my clinical duties, and to support the data collection required for this Project.”*

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Individual ACCHSs and communities will not to be identified in any reports, publications or conference presentations of data from this project, unless this has been requested/approved by the ACCHS.

Project results will be reported at an aggregate level, and will not identify individual participants, communities, or ACCHSs, without their consent.

10.7 Security of ACCHS data

As the leading research organisation, JCU (the Repository Body) will be responsible for the protection of data from loss, misuse and unauthorised access. The following position from within the JCU Evaluation Team will be responsible for this role:

- Data Custodian: Biostatistician (Erik Biros)

Further, the Project Operational Team, Chaired by the Deputy CEO of NACCHO, will be consulted in all matters brought to its attention with regard to concerns about data security. Mechanisms for these communications are explained in section 10.10.

10.8 Data storage and transportation

10.8.1 Consent Forms

Completed Participant and Site Consent Forms will scanned by the practice pharmacist and electronically transmitted to the data custodian (Biostatistician: Erik Biros). The forms will be stored electronically in a secure computer under the management of the data custodian on the property of College of Medicine and Dentistry, James Cook University.

10.8.2 GRHANITE data and Pharmacist Log-book data

Electronic data extracted from CIS and the Pharmacist log-book 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.

10.8.3 Health systems assessment data, Needs Assessment information

Health Systems Assessment (HSA) data, and Needs Assessment information collected from site visits will be collected on paper-based forms, (or in electronic format for the HSA). Any electronic forms will be stored in a password-protected computer.

Paper-based forms collected by project staff from sites will be transported in a locked briefcase, scanned and stored in electronic format in a secure computer under the management of the data custodian on the property of College of Medicine and Dentistry, James Cook University.

Paper-based patient experience surveys (if collected) will be scanned to JCU Data Custodian, or posted in registered mail, and similarly stored in a secure computer under the management of the data custodian.

10.8.4 Qualitative data

Qualitative data will be collected in 2019 (see Section 8.10), and stored and transported as follows:

- Qualitative interviews and focus group discussions (including webinar or electronic interviews) will be recorded on a digital recorder and stored in a password-protected file.
- Photographs will be taken on a password-protected mobile phone.
- Field notes will be recorded on a digital recorder and in a notebook (non-participant observation/pharmacist shadowing).
- During field work all digital files (recorded interviews, field notes and photographs) will be downloaded to a password-protected laptop and stored on a password-protected file immediately after interviews or field work.
- All electronic files (digital recordings and photos) will be removed from recording devices (recorder and mobile phone) immediately once transferred to the laptop.
- All electronic files will be stored on password-protected computers during and after the project (under the control of the data custodian).
- Identifying information will be removed from data collected immediately after the interviews and focus group discussions have been transcribed.
- Paper copies of any identifiable project data will be stored in a locked filing cabinet, in a lockable room (ie. Field notes, paper-based forms, and photographs).
- Electronic questionnaire data collected will be stored in a password-protected 'Survey Monkey' account until the end of the data collection period. At this time, the data will be downloaded and stored on a password-protected computer, in a file accessible only by the data custodian.

10.9 Access to Data

10.9.1 Evaluation Team access to data

Data access will be granted to Project Partners and writing teams established for the purpose of this Project who will comprise members of the Evaluation Team. Approval for data access will be given for reasons meeting the specific objectives of this project, and consistent with the Funding and Service Agreements with the Australian Government Department of Health. Requests for access to data will need to be submitted to the Data Custodian (Biostatistician: Erik Biros).

Additional requests for access to data from within the Evaluation Team or Project Partners *that may not meet the specific objectives of this project*, must be made to the Project Operational Team for approval prior to the release of the data, and must be approved by a relevant HREC.

10.9.2 ACCHS request to access data

ACCHS sites that request access to data arising from their participation in this project will be able to access data related to their ACCHS, in acknowledgment of the ACCHS's ownership of the raw, unanalysed data extracted from CIs using GRHANITE.

These requests can be made to the Project Operational Team or its members, or directly through the NACCHO Affiliate or Project Officers involved in this project. The

request must also include documentation of intended data use and must align with project objectives. Requests to access the data that *does not align* with the project objectives will need HREC approval.

10.9.3 Affiliates request to access data

As per 10.9.2, Affiliates will be able to request access to data at their jurisdictional level (State/Territory). This request must be in writing and align with the project objectives. Data will only be able to be provided as it pertains to the deidentified data extracted from GRHANITE, and specific to the jurisdiction. Requests for access to data will need to be submitted to the Data Custodian (Biostatistician: Erik Biros). This data is de-identified, is not reidentifiable, and will be aggregated.^[1] Any other requests for access to data that may not meet the specific objectives of this project, must be made to the Project Operational Team for their consideration, and must be approved by a relevant HREC.

10.9.4 External requests to access data

External requests comprise requests from other organizations and research agencies not participating in this project. External requests to access data from this project will need to be submitted to the Project Operational Team.

NACCHO will recommend that external agencies seek approval from Affiliates and from participating ACCHSs relevant to the request. Approval will not be granted for the release of data if it is not approved by NACCHO. There may be a need to seek approval from the Australian Government Department of Health if this is a condition in the Funding Agreement for this project.

All external requests will need to have HREC approval prior to the release of this data.

10.10 Reporting breaches in data security, research misconduct or complaints

Project partners, project staff, and project participants can report any breaches in data security or research misconduct or complaints. Reports can be made to:

- project partners/staff,
- Affiliates,
- NACCHO directly, and/or
- Designated HREC representative.

Reports will be forwarded to the Project Operational Team and forwarded to the Deputy CEO of NACCHO.

The JCU *Code for the Responsible Conduct of Research* outlines a framework for receiving and investigating allegations of research misconduct and data security breaches. The data custodian (Biostatistician- Erik Biros) will be notified of any such reports and manage them in accordance with this Code.

10.11 Data Retention, Storage and Disposal

Consistent with the JCU *Code for the Responsible Conduct of Research*, data will be retained for a minimum period of 7 years from the end of the year of publication of the last refereed publication or other form of public release to an audience external to JCU.

Electronic data will be stored on password-secured databases only. Paper-based documents will be scanned and stored electronically, and the paper documents labeled with the data custodians name, date, and 'IPAC project', stored in a locked cabinet in a secure room not generally accessible, and marked as 'confidential'. The data custodian (Biostatistician- Erik Biros) will be responsible for data storage consistent with the JCU *Code for the Responsible Conduct of Research*.

After the minimum period of storage, the data may be considered for disposal if there is a written request to the Evaluation Lead, from both the NACCHO and the PSA for the disposal of the data. As the raw unanalyzed data extracted by GHRANITE is owned by the ACCHSs, JCU will seek instruction from NACCHO and each ACCHS as to the ongoing use or destruction of this data. The Evaluation Lead will authorize the data custodian to delete the data if this is instructed by NACCHO, in accordance with the JCU *Code for the Responsible Conduct of Research*.

10.12 Data Dissemination

Data dissemination refers to knowledge transfer and communication regarding the project. Project partners have a responsibility to the project participants, funders, and the wider community to disseminate a full account of the process and findings of the study as broadly as possible. This account should be complete, and where applicable, include negative findings and results contrary to the clinical claims. Data dissemination activities will take account of any intellectual property restrictions and culturally sensitive data.

Project results will be presented at an aggregate level, exploring regional and/or jurisdictional level variations, as well as national findings. No participants or communities will be identifiable from any results that are publicly released.

10.12.1 Approval for the release of information

10.12.1.1 Approval from the Steering Committee

Subject to the contractual obligations in the Funding Agreement (A2. 1.2), the Australian Government Departments "prior written approval to any public disclosure of the results or findings" arising from this project is required. Accordingly, project partners will seek the approval of the Steering Committee for public disclosure of the results or findings of this project.

10.12.1.2 Approval of project partners

Project partners will seek each other's approval before requesting permission from the Steering Committee for the release of project related information. This may occur at Project Operational Team meetings or out-of-session through email and other forms of communication.

Approval of project partners will be assumed when no feedback to the request for approval is received in 14 days.

Subject to the contractual obligations in Annexure A (Supplementary Conditions) in the Funding Agreement (A2. 1.4), once research "is published (with the Australian Government Department's approval)," the partners "do not need to seek the Department's approval for further publication of that research".

The partners will not unreasonably withhold permission for the release of project related information.

10.12.1.3 Approval of ACCHSs and Affiliates

The approval of the Chief Executive Officer (CEO) of the relevant ACCHS will be sought for the release of any information that identifies that ACCHS (such as qualitative information as approved by the CEO).

The approval of the CEO of the relevant Affiliate will be sought for the release of any aggregated information that identifies the Affiliate and jurisdiction.

These representative bodies have the right to veto, refuse permission for publication, or suggest changes to the public release of information containing their aggregated data, if the information is considered sensitive.

The project partners will ensure representative bodies have sufficient time for the approval for release of public information. ACCHSs and Affiliates will be encouraged (where feasible) to participate in conference presentations where they occur in their locality.

10.12.2 To ACCHSs and Affiliates

Subject to conditions of approval for reporting, examples of knowledge transfer include:

- The Project Reference Group will be provided with updates on progress with the project and extracts of reports arising from the project.
- Summary results to individual ACCHSs (pertaining to their own data) may be provided upon request to the Project Operational Team if this is possible.
- Extracts of reports arising from this project will be summarized in plain language and disseminated according to usual NACCHO communication mechanisms, such as email, the *NACCHO News*, and NACCHO website, including communication with any relevant special interest groups supported by NACCHO.
- Presentations detailing progress and results will be communicated at NACCHO and/or Affiliate Conferences and Annual Meetings.

10.12.3 To Practice Pharmacists

Subject to conditions of approval for reporting, examples of knowledge transfer include:

- Extracts of reports arising from this project will be summarized and be provided to a support network - the *ACCHO Pharmacist Leadership Group* managed by NACCHO and the PSA.

10.12.4 To the general public

Subject to conditions of approval for reporting, examples of knowledge transfer include:

- Presentation at conferences and workshops
- Submission of journal articles for publication
- Opportunistic use of unpaid media, such as radio, television, and print media interviews
- Generation of media releases to communicate broad, national aggregated results.

10.12.5 To respective project partner organisations

Extracts of reports arising from this project, and full reports will be presented at NACCHO Board of Directors meetings, PSA meetings, and Evaluation Team, and relevant College of Medicine and Dentistry (JCU) meetings.

10.12.6 To the funding body (Australian Government Department of Health)

Reports prepared for the Australian Government Department of Health will be in accordance with the contractual obligations in the Funding Agreement.

10.13 Authorship

All authors of publications must meet the criteria for authorship, disclosure, scientific integrity, and other requirements of peer-reviewed scientific journals.¹¹⁷ The *International Committee of Medical Journal Editors* (ICMJE) recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Contributors who meet fewer than all 4 of the above criteria for authorship will not be listed as authors, but they will be acknowledged. These activities include: general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.

Authorship will be invited to all those who meet the criteria for authorship. The corresponding author will obtain written permission from authors who will be included as an author and from those individuals to be acknowledged.

11. Ethics approval and consent processes

11.1 Ethics approval

The Project Partners will seek ethics approval from four Human Research Ethics Committees (HREC):

- St Vincent's Public Hospital HREC (*participates in the National Mutual Acceptance of Human Research Ethics Applications- HREA, and also requires a Victorian Specific Module to be completed*)
- James Cook University HREC
- Menzies School of Health Research HREC
- Central Australian HREC

11.2 Tiers of consent

The project partners participant consent process respecting Aboriginal community control principles includes four tiers:

- Aboriginal collective consent at the national level through NACCHO (NACCHO is a project partner),
- NACCHO Affiliate consent at a jurisdictional level (Affiliates are project participants),
- local community collective consent from individual ACCHSs (services are project participants), and
- informed consent from individual patients being attended to by practice pharmacists (patients are project participants).

These tiers of consent are consistent with the NHMRC Values and Ethics Guidelines (2003) and WHO principles for CBPR involving Indigenous peoples (2003).¹¹⁸

11.3 Site Agreements, Site Consent, and Site Brief

Participation of each Affiliate and ACCHS will proceed through:

- A Site (Service) Agreement
- Written informed consent (Site Consent).

The Service Agreement will comprise a legal contractual agreement pertaining to the delivery of project support and funding for a project officer. It will be signed by each CEO of each participating ACCHS and Affiliate. The PSA will issue the Site Agreements with the assistance of NACCHO.

The Consent form (for Site Consent) outlines the conditions of participation as negotiated with each ACCHS site. It will be accompanied by a Site Participation Brief that includes a summary of the project, purpose and aims; data collection methods, data use, and other relevant issues pertaining to the participation of the ACCHS, as recommended by the NHMRC.

Data collection will not commence until these Agreements with Affiliates and each ACCHS project site have been agreed. This protocol includes a potential Site Consent Form (Appendix).

11.4 Site support

Each Affiliate that participates in the project will receive:

- Remuneration to participate in the project (see section 4.4). This can be used to employ a part-time project officer (or to back-fill existing staff).
- Involvement of nominated staff as members of the Evaluation Team in the project (see preamble to this Protocol).
- An opportunity to review project findings and provide feedback (see section 8).
- Customised reports specific to the jurisdiction (if requested).

Each ACCHS that participates in the project will receive:

- The services of an on-site accredited practice pharmacist (see section 6) for a 15-month duration.
- The opportunity to select their preferred practice pharmacist.
- A 'Needs Assessment' site visit to ascertain any specific needs of ACCHS. (see 13.3)
- A facilitated 'training' site visit to support and prepare the practice pharmacist within the primary healthcare team (see section 6).
- Resources to support the practice pharmacist, such as medication management guides.
- A supportive mentor for the practice pharmacist (see 6.7).
- Installation of the GRHANITE data extraction tool in the CIS and licence for its use for 15 months (see 8.1).
- Two site visits to explore Health Systems Assessment (see 8.8).
- A Health Systems Assessment Report for CQI use.
- Involvement of a nominated staff member to be a member of the Project Reference Group in the project (see Preamble to this Protocol).
- An opportunity to review project findings and provide feedback (see 13.1).
- Customised reports specific to the participating ACCHS (if requested).

11.5 Complaints mechanism for sites

A process for complaints about the project is outlined in section 10.10.

11.6 Withdrawal of site participation

ACCHSs and Affiliates that are participants reserve the right to withdraw their participation in the project in accordance with their service agreements. If an ACCHS site withdraws, the ACCHS will be asked to provide a written reason for the withdrawal, to the PSA (for the contract) and the Project Operational Team. The ACCHS will be asked whether they agree to the continued use of the data collected in this Project prior to their withdrawal of Site Consent.

The withdrawal of the Site from the project will mean the withdrawal of the site support specified in section 11.4.

The withdrawal of the Site will be reported to all relevant HRECs when the Project's annual report is due.

11.7 Individual consent

Individuals will only participate following their informed consent. Written consent will be sought from each individual who agrees to receive the services of the practice

pharmacist and be part of this Project. The information about the project will be provided in written and verbal formats. This will include a clear explanation as to what participation involves, and how the information arising from their participation will be used. It will not be possible to provide results that relate to a specific participant, as data collection will be completely deidentified.

Informed consent will include the provision of verbal and written information about the purpose and aims of the project, who is funding and running the project, what participation involves (including any risks and benefits), ownership and storage of information, use and release of information and confidentiality. This is in the form of a *Participant Information Brief*.

If the individual elects to participate they will be asked to indicate in writing their understanding of each piece of information, and sign their name to having:

- (1) Understood the information provided, and asked any questions concerning this;
- (2) Agree to have their deidentified health information extracted from the clinical information system and provided for the purposes of the evaluation;
- (3) Agree to the information being stored, used and published; and
- (4) Freely give consent to participate in this project.

The participant information sheet will refer to the use of deidentified data extraction from ACCHS clinical information systems. Data extraction will cover the 15-month duration of the project as well as the period 12 months prior to first pharmacist contact.

The draft Participant Consent Form, and Participant Information Brief is shown in the Appendix.

11.7.1 Process for seeking Individual consent

The process for seeking individual consent is shown in Figure 8. The proposed process for seeking individual client consent has been developed in consultation with NACCHO Affiliates on the Evaluation Team. The process respects the systems that ACCHSs may wish and choose to adopt.

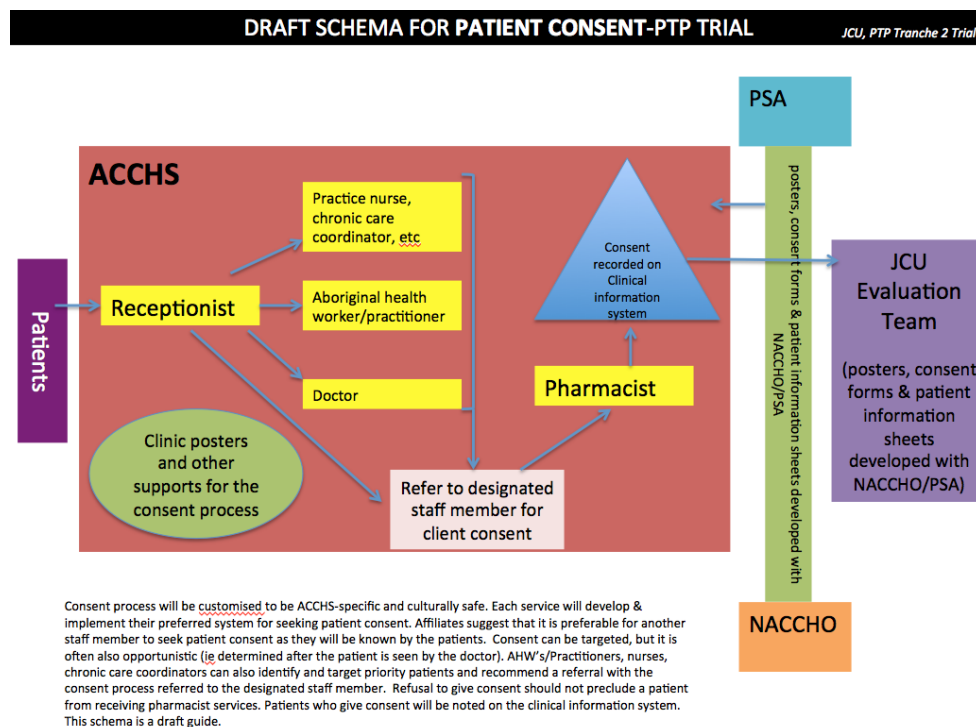
The process involves the practice pharmacist who will be trained to seek the participant's consent. Training for seeking participant consent will also be provided to other staff that may be designated by the ACCHS to seek the participant's consent for cultural appropriateness reasons.

This consent form will then be signed and dated by the patient, a witness, and the designated staff member seeking patient consent. The consent form will be stored in a locked briefcase by the practice pharmacist.

A written copy of the verbal information will be provided to the patient, including details to raise questions or complaints arising from participation in the project.

Consent will then be recorded on the clinical information system and GRHANITE will extract information only from consented patients.

Figure 8. Proposed process for seeking individual consent within ACCHSs



11.8 Individual consent for qualitative evaluation

Consent from patients/participants participating in the qualitative parts of the evaluation (see 8.10) will be obtained specific to this part of the evaluation. The qualitative evaluation will be undertaken during 2019.

Consent forms and information sheets will be developed for:

- Pharmacist interviews (case study visit and participants interviewed through webinars, skype, videoconferencing or phone contact)
- Focus-group participants (patients who are participants, Aboriginal Health Workers/Practitioners)
- Online survey with GPs within ACCHS sites
- Online survey with CEOs and Managers
- Online survey of community pharmacists.

HREC approval will be sought for this part of the project evaluation when these consent forms and Information Sheets are completed.

11.9 Individual withdrawal

Individual participants will also be informed at the time of consent, that if they choose to participate, they may withdraw at any stage without consequence. Individual participants reserve the right to withdraw their participation in the project at any stage. If an individual withdraws, they will be asked to provide a reason for the withdrawal. This discussion may be had with a designated staff member within the ACCHS or the practice pharmacist. The individual will be asked whether they agree to the continued use of the data collected prior to their withdrawal of their Consent.

All patients who wish to see the practice pharmacist will not have these services withheld if they refuse to participate in this Project. Aggregated information about

participants who withdrew their consent will be reported to all relevant HRECs when the Project's annual report is due.

12. Governance process

12.1 Memorandum of Understanding

Core principles, recitals and a commitment to communication between project partners (PSA, NACCHO and JCU) have been incorporated into a signed Memorandum of Understanding (MOU). See Appendix.

The project partners are committed to undertaking the Project as a community-based participatory research (CBPR) model. This is defined as:

*“a partnership approach to research that equitably involves, for example, community members, organizational representatives, and researchers in all aspects of the research process and in which all partners contribute expertise and share decision making and ownership”.*¹¹⁹

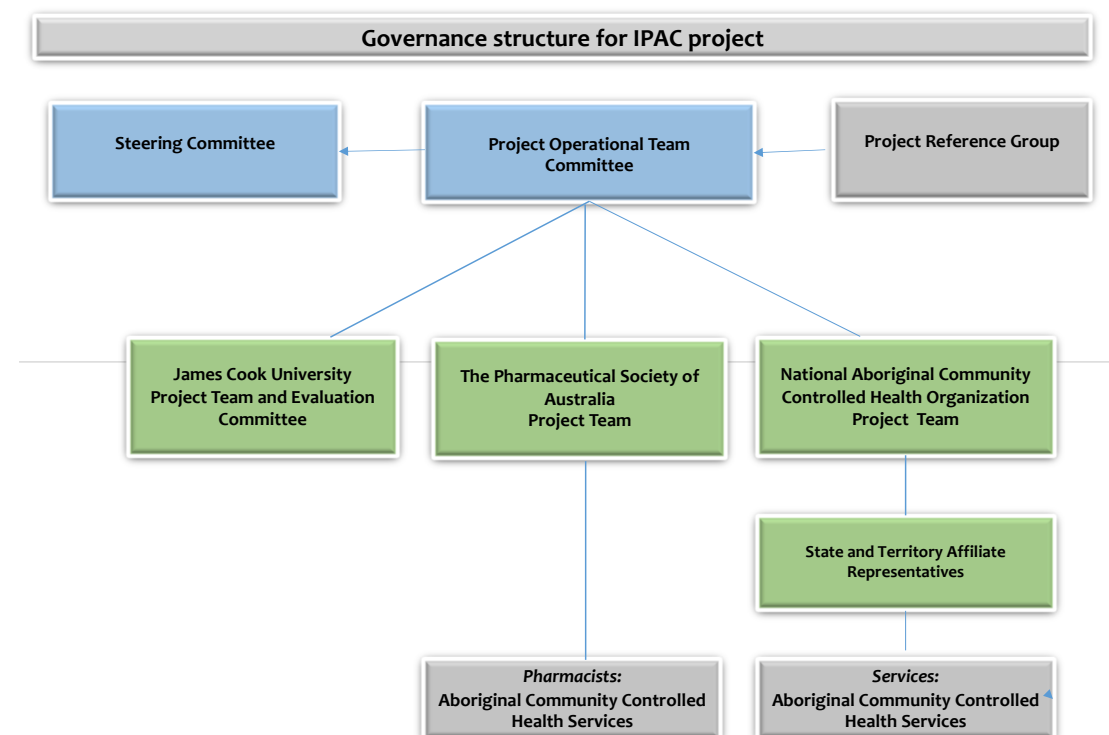
12.2 Project partners

An overview of the project partners, project leaders, staff and structures providing oversight in the project is shown as Figure 9.

The Chair of the Project Operational Team is the NACCHO Project Lead (NACCHO Deputy CEO, Ms Dawn Casey).

The Chair of the Project Reference Group will be a nominated member of the NACCHO Board of Directors.

Figure 9. Governance and partnership structure of the IPAC project



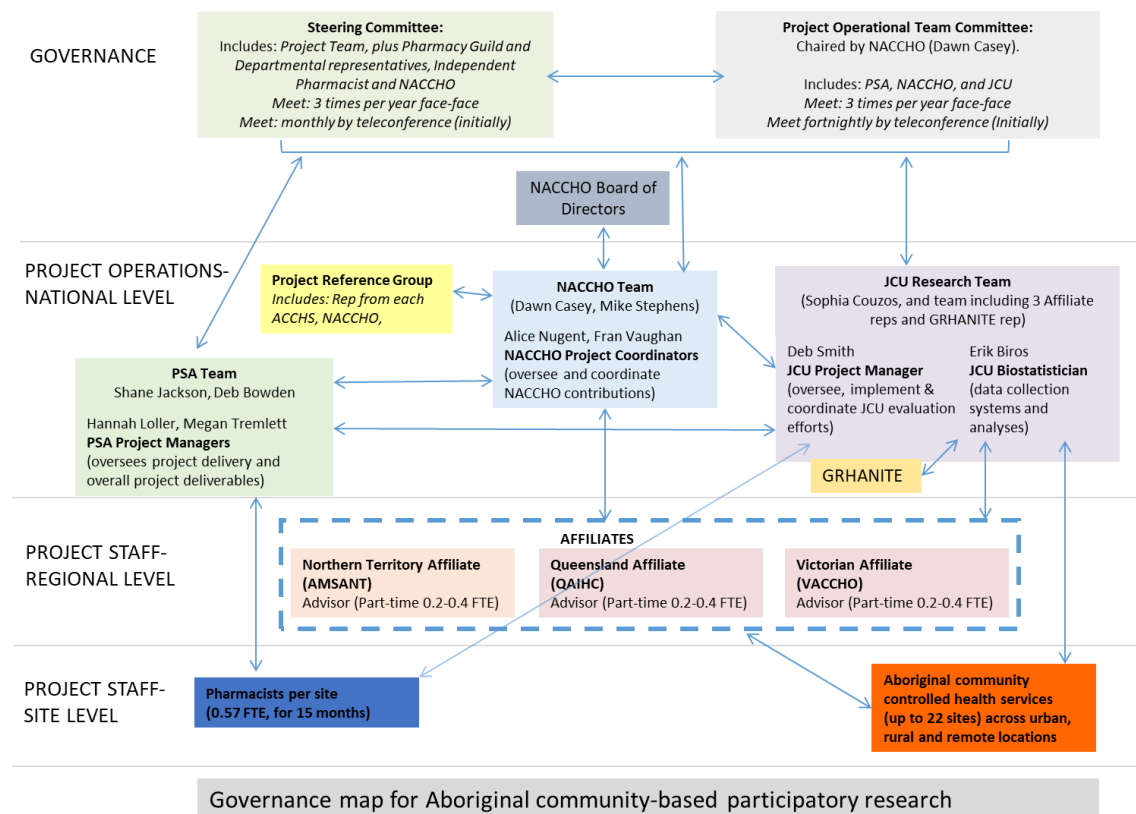
12.3 Governance map

The project teams, groups, and committees have been described in the Preamble to this Protocol and section 13.1.

The IPAC project governance process is consistent with ACCHS governance models. It respects the lines of authority for communication within the Aboriginal health service sector. The tripartite project staff will facilitate engagement between the evaluation team and sites using existing ACCHS sector networks such as through NACCHO and through Affiliates. Regular reports to Affiliates and the NACCHO Board leadership will occur through NACCHO personnel involvement in this project as co-investigators’.

The governance map for this project is shown in Figure 10.

Figure 10. Governance map for the IPAC project.



13. Communication systems

The IPAC Project Partners will respect the commitment for effective communication as agreed in the Memorandum of Understanding (See *Appendix*). Mechanisms of communication with the parties indicated in the project governance map (see 12.3) are outlined as follows:

13.1 Meetings and teleconferences

Phone and email communication will be the main mode for day-to-day communication between project partners, project staff and all committees. The committee meetings are summarised as follows:

- *Steering Committee*: face-face meetings as required, teleconference quarterly and final face-face meeting;
- *Project Operational Team*: face-face meetings as required, monthly teleconference meetings, and final face-face meeting;
- *Project Reference Group*: Meet at least quarterly by teleconference or other web-based platforms of communication;
- *Evaluation Team*: Meet as required, and face-face meetings as required during the evaluation phase of the project.

13.2 Communications with ACCHSs and Affiliates

All communications with ACCHSs will be coordinated through the NACCHO team, except if otherwise indicated (for example, if the ACCHS prefers direct contact with any other project partner).

The NACCHO Project Coordinator will be responsible for ensuring timely and effective communication between ACCHSs and other project parties including: the contractor (PSA), Evaluation Team, Affiliates, project partners and other project groups and committees referenced in 13.1. This position will involve liaising closely between ACCHSs and PSA in the development and signing of Site Agreements. The NACCHO Project Coordinator will visit each ACCHS on at least two occasions throughout the project and maintain regular communication with all sites throughout the establishment and implementation phases.

Affiliates are members of the Evaluation Team and will be contacted directly by the Project Partners.

NACCHO will provide support to practice pharmacists through the *NACCHO-PSA ACCHO Pharmacist Leadership Group* as referenced in section 4.4. This group meets via teleconference quarterly and as needed.

The PSA will communicate regularly with practice pharmacists during their placement within ACCHS by email and phone (see also 4.4, 6.6, and 6.7).

13.3 Site visits to ACCHSs

Most communication between project staff and project sites will occur using phone or email or web-based systems. In addition, ACCHSs will be visited at least three (3) times by project staff.

13.3.1 Site visit for on-site training of the practice pharmacist

The PSA Project Officer will provide a facilitated site visit to the ACCHS as required to assist with the orientation and preparation of the practice pharmacist. This visit may also need to be supported by the NACCHO Project Coordinator.

13.3.2 Baseline Health Systems Assessment visit with project initiation (0-3 month)

The NACCHO project coordinators will visit all sites to undertake a health systems assessment prior to or at the commencement of the practice pharmacist. This is to establish baseline health system characteristics of the service (see 8.8).

13.3.3 Needs Assessment site visits

The 'needs assessment' visit to the ACCHS will elicit the type of support needed by the ACCHS so that the practice pharmacist may best be integrated within the service. The visit will also assist the ACCHS to establish their preferred system to seek patient consent, and ensure the pharmacist can use the CIS, has a space to consult with patients, and the CIS is set to accept the 'job-role' for the pharmacist (this is necessary for the GRHANITE data extraction).

This visit may occur at the same time as the baseline Health Systems Assessment visit. The NACCHO Project Coordinator will visit sites (with the assistance of Affiliates) for the needs assessment and ascertain if any further supports to the ACCHS may be needed.

At the time of this visit, the NACCHO Project Coordinator will make contact with a nominated ACCHS staff member who will act as a 'go to' person. A second 'go to' person may need to be identified by the ACCHS and Coordinator as contingency for leave, resignation or movement between clinics or roles.

The NACCHO Project Coordinator will liaise directly with the nominated 'go to' person/s and relevant ACCHS staff to develop a project consent pathway and process that is consistent with the Draft Schema for Patient Consent (see 11.7 and Figure 8) and is also responsive to the local ACCHS' model of care.

A template poster aimed at clients for distribution and use within the ACCHSs' clinics and community will be provided by NACCHO (See Appendix).

The NACCHO Project Coordinator will work with each ACCHS to ensure that the service has adequate promotional material and strategies to engage both ACCHS staff and clients. (See also section 13.4 and *health service inclusion criteria*- see 4.2.1).

13.3.4 Repeat Health Systems Assessment visit (12-15 month)

The NACCHO project coordinators will undertake a repeat health systems assessment at the near conclusion of the tenure of the practice pharmacist in order to document changes in health systems.

13.3.5 An ACCHS may request an additional site visit

If there is a need to resolve any concerns or difficulties that arise from participation in the Project, and where it is not possible (or preferable) to address these concerns remotely, the most appropriate project officer may conduct this site visit.

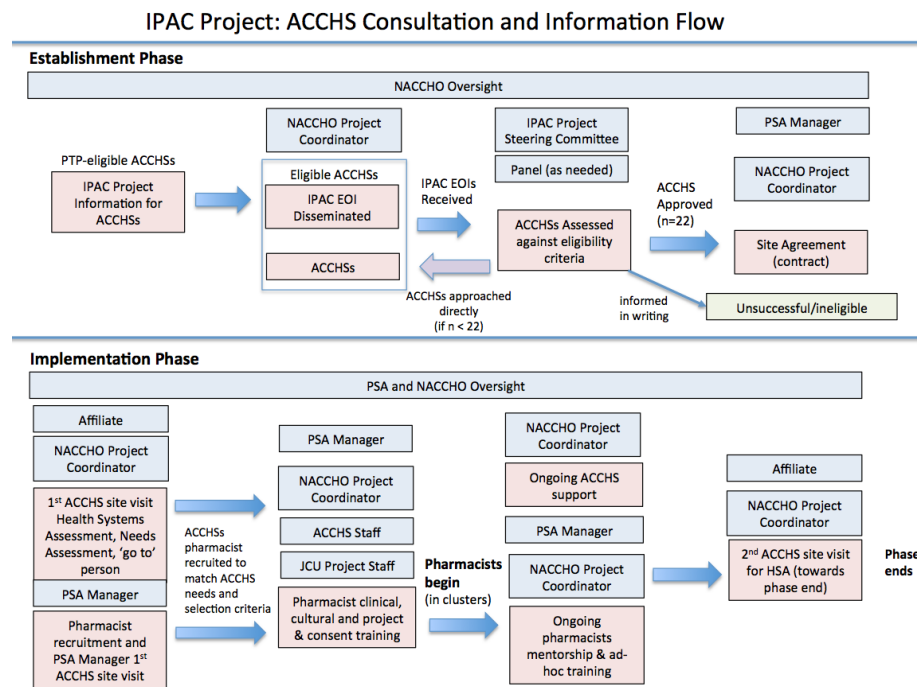
13.3.6 Site visit for qualitative data collection

Three (3) participant ACCHSs will be invited to act as case study sites for a qualitative evaluation of the integrated role of the practice pharmacist. (see section 8.10)

13.4 ACCHS site visit and information flow map by project phase

A map of the site visits to ACCHSs showing the process for site selection, support and project oversight is shown in Figure 11.

Figure 11. ACCHSs site visit and information flow map by project phase



13.4 Newsletters

A newsletter will be developed for participating ACCHSs and Affiliates for the purpose of updating progress with the Project, and communicating any results (subject to approval processes- see 10.12).

The newsletter will be distributed to participant sites using usual NACCHO lines of communication. If there is interest in more broader member communication, and subject to approval, NACCHO may communicate with members more broadly. Communication through public release of reports and other use of media have been described elsewhere (see 10.12).

14. Benefits, feasibility, acceptability and generalisability

14.1 Expected benefits from the project

This project has the potential to deliver:

- better medication management to improve medication adherence, enhance quality prescribing and deprescribing (reducing risks with polypharmacy and potentially harm from adverse drug reactions arising from inappropriate medicines);
- improved quality of care outcomes for chronic disease (which by inference can avoid or reduce unnecessary hospital admissions);
- early interventions for health promotion/disease prevention and any required social support systems;
- improved continuity of care between hospital and home and between GPs and specialists (inferred from patient interview and qualitative studies in this project);
- improvements in the patient experience; and
- address gaps in service delivery through a more integrated workforce operating within their scope of practice.

14.1.1 Expected benefits to individual participants and other patients

Aboriginal and Torres Strait Islander patients of ACCHSs attended to by the accredited practice pharmacist serve to benefit from the interaction. They will benefit because this project will facilitate their immediate access to an on-site pharmacist.

This on-site and timely access to the healthcare skills of a pharmacist is consistent with the ACCHS model of care. The staff with ACCHSs deliver opportunistic, holistic, culturally appropriate, and comprehensive primary health care services to Aboriginal peoples and Torres Strait Islanders. This model of care has been called a 'one stop shop'. It is this model of care that delivers the best health outcomes for peoples who are marginalised and have poorer access to primary health care than other Australians.¹²⁰

Patients will receive tailored and appropriate medication reviews to optimise their use of medicines. A review of medications will lead to improved prescribing by clinicians, and improvements in access to and interactions with community pharmacy. The patient's medications can be checked in the home (called home medications reviews or HMRs) or places like the clinic (called 'non-HMRs'). The pharmacist will assess if the patient has difficulty taking their medicines (a check for medication adherence) and depending on the barriers identified, the pharmacist will provide tailored personal supports plus link with other members of the primary healthcare team.

Patients seen by the practice pharmacist will be followed up to check on progress and to provide on-going support.

14.1.2 Expected benefits to ACCHSs

This project may significantly benefit the ACCHS sector by providing the evidence-base to better support quality use of medicines through integrated care models. Having

a culturally responsive pharmacist integrated into ACCHSs will facilitate building of relationship and trust between pharmacists and patients, ACCHS staff and the community.

The project may:

1. Benefit ACCHSs in the short-term by enhancing their medicines-related workforce capacity through the employment of practice pharmacists within the primary healthcare team for 15 months. The ACCHS sector have been advocating for such a workforce for many years. Practice pharmacist appointments will be non-dispensing, and registered to work within their scope of practice. The appointments will include salary, training, and the provision of supportive resources.
2. Benefit ACCHSs in the short-term by enhancing their medications-related, preventive care and chronic disease care-related service claims through Medicare.
3. Benefit the clinic staff within the ACCHS as the practice pharmacist can support other staff with quality prescribing and medicines use, though adhoc medication advice, as well as more intensive education and training sessions.
4. Benefit the ACCHS by improving the quality use of medicines within the ACCHS by enabling a quality improvement activity called a 'drug utilisation review'.
5. Benefit the ACCHS by improving the relationship with community pharmacies in the local area. This may help pharmacies to provide more appropriate services to the local community.
6. Benefit the relationship the ACCHS has with local hospitals and other care providers by improving communication between care providers when it pertains to the medicines that patients are taking.
7. Benefit all ACCHSs in the long-term as the project aim is to develop a sustainable model of pharmacist service within ACCHSs anywhere in Australia. The project will provide the Australian Government with the evidence-base (biomedical, process, and economic evaluations) for the development of national health policies to potentially support on-going resourcing for practice pharmacists integrated within ACCHSs. This is consistent with the purpose of the Australian Government PTP Tranche 2 funding. This is also consistent with NACCHO Board of Directors recommendation for the development of this project from March 2016.

14.1.3 Expected benefits to the Australian healthcare system

Healthcare reform is a key priority for the Australian Government looking for ways to improve productivity and ensure the triple aim of: clinically effective healthcare, improved patient experience, and cost-effectiveness. The Government of Western Australia Department of Health refer to this as: 'better health, better health care, and better value'.¹²¹

This project provides the evidence-base for an integrated care model to improve the quality use of medicines within settings that target Aboriginal peoples and Torres Strait Islanders. This Project will provide evidence of biomedical, qualitative, and economic outcomes arising from the integration of a practice pharmacist within ACCHSs targeting Aboriginal and/or Torres Strait Islander patients with chronic disease.

The Project will provide a potential framework for workforce reform into the future. The findings will be used by the *Medical Services Advisory Committee (MSAC)* to develop submissions to the Australian Government for potential funding of practice pharmacists in primary health care settings in the future. The MSAC is an independent non-statutory committee established by the Australian Government Minister for Health to appraise proposals for public funding, and advise on whether a new service should be publicly funded.

The findings of the study may inform priorities for Health Care Home (HCH) sites. Optimising the quality of care for patients with chronic disease is a key objective of HCHs. Blended payments through the HCH model to facilitate improvements in chronic disease care may also provide a funding stream for integrated practice pharmacist roles in sites that opt-in to the HCH financing model.

The project may assist Primary Health Networks with implementation and workforce financing decisions within network boundaries. PHNs have an important role in supporting CQI within their boundaries, and in particular, focusing on enhancing health outcomes for the Aboriginal and Torres Strait Islander population in partnership with ACCHSs.¹²² Workforce investments that enhance quality of care outcomes for patients with chronic disease are very important to PHNs. See also section 11.2 (generalizability).

14.2 Feasibility and acceptability

The project has been designed to be acceptable and feasible to ACCHSs, health staff within those services, the Aboriginal governing structures of those services (Chief Executive Officers and Directors of Boards), and practice pharmacists. This is evident though the community-based participatory research design, and the pre-post pragmatic approach to the evaluation (see 7.1, 7.2).

The governance structure outlines the process to ensure support to, and the participation of ACCHSs (see 12.3). The project is built around the existing professional networks with ACCHSs and with Affiliates and NACCHO. The project remunerates Affiliates for the support they provide in this project. Members of the Evaluation Team also have extensive experience in CBPR methods and experience working with ACCHSs. NACCHO and Affiliates have provided letters of support for the project (see Appendix).

The project supports ACCHSs to integrate practice pharmacists within the primary health care team, and to improve the patient journey, with education, learning resources and other products created by practice pharmacists, and stakeholder relationships with community pharmacy to benefit ACCHSs and to continue to have relevance to ACCHSs even after the project.

The collection of data using a data extraction tool from CIS is consistent with data collected by ACCHSs when undertaking core CQI activity (see 8.1).

14.3 Generalisability

The project will 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. Beneficial outcomes of the trial may ensure that all ACCHSs can benefit into the future and not just those participating. The acceptability of the intervention to Aboriginal and

Torres Strait Islander peoples across 22 ACCHS sites suggests the intervention would be acceptable and implementable in other services across Australia.

The generalisability of trial outcomes is supported by a methodology accounting for variability in the intervention (practice pharmacist activities), integrated within health services delivering 'usual care', and data collection mechanisms adapted to minimise disruption of services (real-life and pragmatic).

15. Potential dependencies, limitations and mitigation strategies

15.1 Potential dependencies

ACCHSs may develop a dependency on the skills and contribution of the practice pharmacist that will not be able to be remunerated from this project beyond the 15-month implementation phase.

However, when the project concludes, ACCHSs will be empowered to fill these positions with identified roles, as this becomes feasible for each service. The cost-effectiveness analysis and Medicare utilization outcomes from the project may inform ACCHSs on the potential returns of financing models.

In addition, relationships with community pharmacies may be enhanced from this project, ensuring continuity of service provision in a particular or similar form.

Many of the proposed benefits of this project (see section 14) to ACCHSs will continue beyond this project. The long-term benefits to ACCHSs are dependent on the development of future financing models by the Australian Government for practice pharmacists within ACCHSs, which this project may enable.

15.2 Study limitations and mitigation strategies

A summary of potential study limitations and mitigating strategies are included in Table 13.

Table 13. Summary of potential study limitations and mitigating strategies

Data	Potential limitations	Mitigating strategies
Recruitment of ACCHSs into the project	Under-recruitment of ACCHSs to the project	This is unlikely. ACCHSs have been very supportive of this project, and representatives from NACCHO Affiliates are project participants. Site eligibility criteria have been devised to be consistent with the majority of ACCHSs (particularly in Qld and Victoria). If under-recruitment occurs, the project site eligibility criteria will be reviewed.
Recruitment of patients	Under-recruitment of patients to the project	There may be a risk that patients will not consent to be participants in this project in view of their right to access pharmacists services regardless of participation. Affiliates have indicated that patients are likely to consent, in view of the trust they place in the ACCHS. In order to minimise the risk of patients declining to participate in this project, promotional material will be developed by NACCHO and the ACCHS to provide supportive information to patients attending the practice. A culturally appropriate process for seeking consent has also been outlined. See Figure 8 of

		the Protocol.
Recruitment of practice pharmacists	Under-recruitment of pharmacists to the project, and delays in recruitment	This is unlikely given the lead agency in the trial is the PSA. There are a substantial number of pharmacists who have already registered their interest in appointments within ACCHSs including in remote locations. If under-recruitment occurs, sharing of roles between ACCHSs of close proximity is an option. The staggered recruitment of sites enables more time for pharmacist recruitment. Analysis of staggered data collection will take into account recruitment delays.
Quality of care measures	Patients within ACCHSs may not consent for CIS data extraction for the project	Patients already provide permission for ACCHSs to interrogate CIS data for the purposes of CQI activity within ACCHSs and to share de-identified data for analysis with Affiliates. The Participant consent forms and Information Brief provides detail on how extracted data is completely de-identified. The proposed flexible schema for seeking patient consent ensures this process can be optimised to best suit ACCHS systems. GRHANITE will extract data weekly, so the Project Operational Team can monitor this outcome. The Project Reference Group will advise on mitigation strategies if necessary. The group may recommend the development of promotional materials to encourage patient participation. Draft materials are currently under development.
	CIS data may be unreliable	<p>Site inclusion criteria specify that ACCHSs must have been participating in CQI activity using data extraction tools for at least 24 months. The AIHW have been collecting extracted data from CIS from ACCHSs and reporting to the Australian Government since 2012-13. ACCHSs are familiar with the nKPI reporting system, having improved their systems and processes over the years. Several AIHW and independent analyses have confirmed that high performing services are identified by the duration of CQI reporting.^{123 124 125}</p> <p>An independent review of ACCHSs CQI data quality commissioned by the Australian Government Department of Health found in 2015 that the data set is of high quality and fidelity, and confirmed the value of publishing and disseminating the findings in AIHW reports. It did not find any evidence of system-wide technical problems affecting</p>

		nKPI data quality. ¹²⁶ A further independent review in 2017 confirmed data validation of nKPIs from ACCHSs CIS's – Medical Director and Communicare. ¹²⁷ An independent review in 2013 explored the validity of pathology data from CISs using a DET and found that it accurately extracted data. ¹²⁸
	Patient inclusion criteria refer to regular patients. This may underestimate the impact of the intervention as outcomes may be evident for non-regular patients who are seen during the project period.	The ACCHSs will target regular patients with chronic disease and polypharmacy, but any other patient who consents will be a participant in the project. The study measures extracted from the CIS will inform if the participants are regular (active) or not. This is appropriate to explore the variability in types of interventions provided to patients, as well as covariates about patients. The inclusion of secondary outcome measures such as medication adherence and MAI will also specifically refer to the impact on participants. Provided the follow-up occurs, whether a participant is regular or not won't impact on outcomes related to this assessment. Variations in the characteristics of regular patients will be compared across ACCHSs (there may be differences in remote versus urban populations).
	Unrandomised patient selection for medication review (patients will be referred from health workers and doctors)	Being unrandomised means that referrals to the practice pharmacists from doctors or other healthcare staff might lead to patient selection bias (such as patients who are more health literate). This project will assess the characteristics of the patients that benefit the most. However, because this project is conducted within ACCHSs, and ACCHSs provide support to the most needy people in the community, the degree to which certain patients above others are selected may be minimised. It is anticipated that health staff would act on the recommendations of the practice pharmacist.

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