IPAC

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

Executive Summary

Final Report - Part A

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JAMES COOK UNIVERSITY AUSTRALIA

NATIONAL ABORIGINAL COMMUNITY CONTROLLED HEALTH ORGANISATION NACCHO

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

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The authors also acknowledge members of the IPAC Evaluation Team, the Affiliates of the National Aboriginal Community Controlled Organisation, the participating ACCHSs, IPAC pharmacists, and the IPAC Steering Committee members. In presenting this document the authors would like to thank the Aboriginal and Torres Strait Islander people for their cooperation and assistance as consented patients for the research information that was essential for this project.

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Background

In Australia, Aboriginal peoples and Torres Strait Islanders are five times more likely to die from chronic disease before the age of 75 years (premature mortality) than other Australians (2011-15).[1] This profound health disparity has generated many policies and programs to encourage better chronic disease prevention and management within primary healthcare services. Yet, despite their higher burden of disease, medication underutilisation, and inappropriate use of medications by Aboriginal peoples and Torres Strait Islanders persists when assessed within primary health care settings.[2 3] There are many reasons for this including health system factors such as poorer access to primary health care services,[4] culturally unsafe pharmaceutical support,[5] lack of health service integration,[6] disease profiles inconsistent with medicines listed on the PBS,[7] and suboptimal prescribing quality.[8] Patient factors include insufficient health literacy for optimal self-management of disease,[9] distrust of health services,[10] family and community obligations,[11] and belief in traditional medicines,[12] whilst condition-related factors include disproportionately high multimorbidity.[13] Socioeconomic factors may also affect the personal management of medicines such as adherence and storage.[14]

A whole of health system response is needed to tackle these factors. One strategy has been to integrate pharmacists within primary health care multidisciplinary teams so that patients and teams can receive enhanced medication management support, direct care from a pharmacist, and a more joined-up experience of care. This builds upon the role that pharmacists have within community pharmacy settings. Increasingly, studies are reporting that the addition of pharmacists to healthcare teams enhances quality prescribing,[15] biomedical outcomes,[16 17] and reduces hospitalisation.[18 19] Co-location of pharmacists within general practice has been demonstrated to enable greater communication, collaboration and relationship building among health professionals.[20] However, the impact of integrated pharmacists on health outcomes for patients with chronic disease, in Aboriginal health settings, needs further investigation.

The Australian Government Department of Health, under the Pharmacy Trials Program (PTP, Tranche 2) funding as part of the Sixth Community Pharmacy Agreement (6CPA) sought to improve clinical outcomes for patients by utilizing the full scope of pharmacist's role in delivering primary health care services. This Program supported a project to investigate the potential gains in health outcomes arising from integrated models of care within Aboriginal health settings- the *Integrating Pharmacists within Aboriginal Community Controlled Health Services* (ACCHSs) *to improve Chronic Disease Management* (IPAC) Project.[21 22] The project explored if integrating a registered pharmacist as part of the primary health care (PHC) team within ACCHSs (the intervention) led to improvements in the quality of the care received by Aboriginal and Torres Strait Islander peoples with chronic diseases, when compared with prior (usual) care (Appendices 1 and 2). It was anticipated that pharmacists integrated within these settings would facilitate increased access to medication-related expertise and assessments, which when coupled with increased engagement with participants, staff and other stakeholders, would result in improved services and quality use of medicines as outlined in the proposed the theory of change for the IPAC Project (Appendix 3).

Methodology

The IPAC project was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study (Trial Registration Number and Register: ACTRN12618002002268) implemented in three jurisdictions: Victoria, Queensland and the Northern Territory. There were three project phases: Phase 1: Establishment (4-8 months); Phase 2: Implementation of the intervention (up to 15 months); Phase 3: Analysis and reporting (6 months).

The project adhered to community-based participatory research (CBPR) principles, adapted from the World Health Organization guiding principles[23] as described in a previous project involving Aboriginal peoples and Torres Strait Islanders.[24] This approach ensured clear benefits to project sites, acceptability and sustainability of the intervention within ACCHSs, and ultimately, transferability to other PHC services. For this reason, study outcomes were compared before and after the intervention without the use of control sites, for within-subject comparisons (with repeated measures). The project assessed any changes in study sites that occurred pre to post intervention through serial health systems assessments and qualitative methods.

ACCHSs in geographically diverse settings in the three jurisdictions that met the established site eligibility criteria were invited to participate in the project. Each service was offered an integrated pharmacist (aggregated 0.57 FTE across 22 sites each for 15 months duration) under a service agreement with the PSA. Service selection aimed 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. All participating ACCHSs received the intervention, with study measures referring to periods prior to and after implementation, activities within ACCHSs, and aggregated ACCHSs.

The pharmacist intervention involved delivery of ten core roles, which were classified as either patient-related roles or as systems and health practitioner-level roles. The Logic Model for the evaluation of the IPAC project outlines the roles and the expected outputs and outcomes from each role (Appendix 4). Activities targeting patients included the assessment of medication management through medication reviews, medication adherence and appropriateness, medication-related problems, improving patient medication knowledge and giving preventive health advice. Medication management reviews comprised either a Home Medicines Review (HMR) or a non-HMR which was defined as a comprehensive medication management review comprising some or all of the elements of a HMR, but not fulfilling all relevant HMR criteria stipulated by the Medicare Benefits Schedule (MBS). Pharmacists at each ACCHS undertook an audit of medication appropriateness and an assessment of underutilisation, for a sample of participants at the rate of 30 participants per one full time equivalent (FTE) pro rata. Pharmacists also provided patient education and preventive health activities.

Activities targeting health professionals and systems included conducting education sessions, responding to medication-related queries, reviewing prescribing and mentoring new prescribers, participating in case conferences, undertaking drug utilisation reviews, and liaising with community pharmacies and other stakeholders to ensure continuity of care and transitional care that supported patients discharged from hospital.

Outcome measures focused on Aboriginal and Torres Strait Islander patients with chronic disease aged 18 years or over, who were regular patients of the ACCHSs. Measures included indices to assess the quality of prescribing, intermediate clinical endpoints, health service utilisation measures, medication adherence, self-assessed health status, a qualitative evaluation, and a cost-effectiveness analysis to explore if the intervention was cost effective relative to usual care (at baseline).

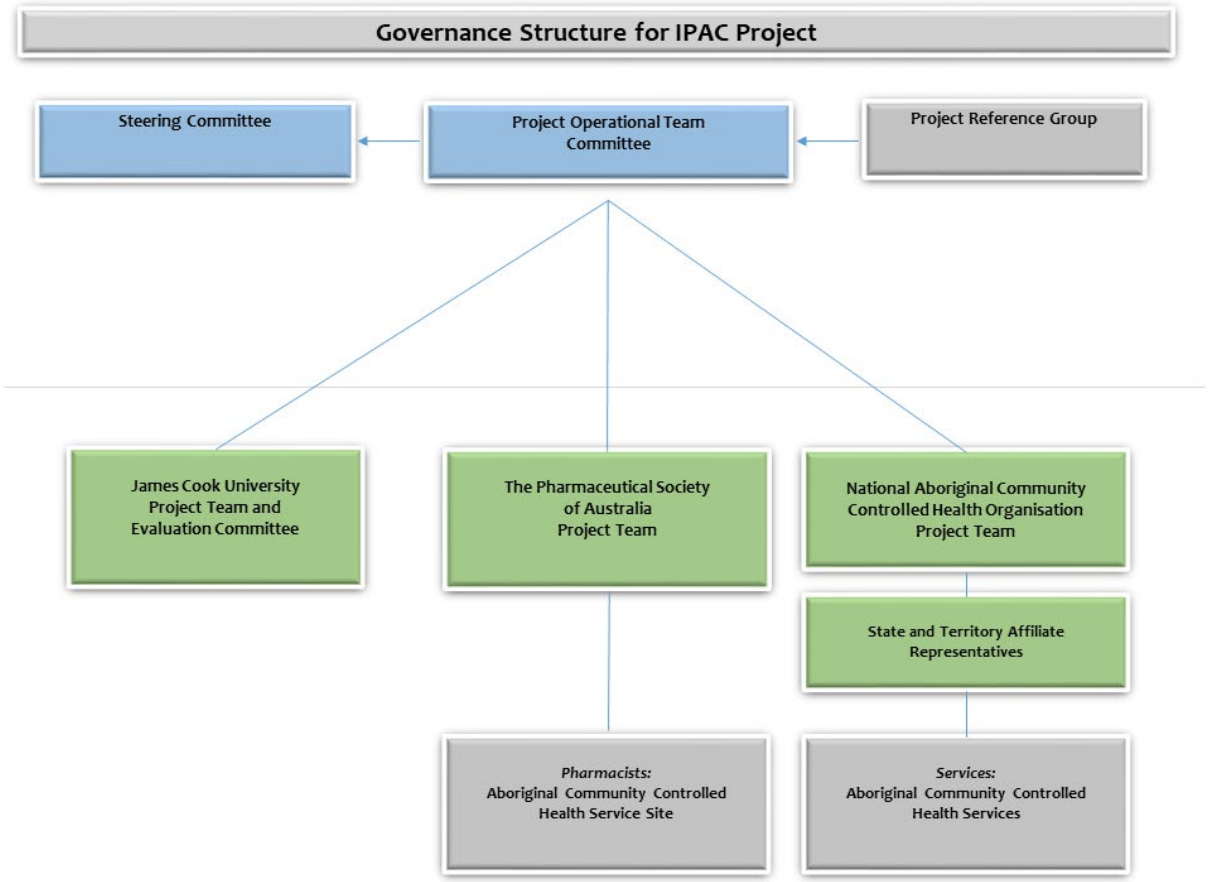
Project governance

The IPAC project was conducted through a partnership between the Pharmaceutical Society of Australia (PSA), the National Aboriginal Community Controlled Health Organisation (NACCHO), and James Cook University (JCU) College of Medicine and Dentistry, guided by a Memorandum of Understanding that outlined communication and governance processes which were grounded in Aboriginal and Torres Strait Islander leadership and self-determination.

All partners were involved in the conceptualisation and development of the project. The PSA, as the lead agency, had responsibility for managing the Head Agreement with the Australian Government Department of Health, and service agreements with partners and ACCHSs. PSA coordinated the appointment of pharmacists, their recruitment, training, placement, mentoring and performance. The NACCHO provided Aboriginal governance leadership for the project and coordinated communication with ACCHSs, Affiliates and the NACCHO Board. NACCHO recruited ACCHSs to participate in the project and provided induction and ongoing support. Affiliates of NACCHO are state and territory peak bodies who represent ACCHSs at this level and provided input into project design, governance and evaluation and additional support for participating ACCHSs where required. JCU designed the research study, methodology, data requirements, and built data collection platforms and study tools. JCU managed data management subcontractors, acted as data custodian, monitored and guided project progression through its phases to meet study timelines and sample size, and developed the project evaluation reports.

The project was coordinated by a Project Operational Team with members from the three partners (Figure 1). A Steering Committee with an independent Chair, oversaw the project with representatives from partner organisations, a representative from the Pharmacy Guild of Australia (PGA), an independent pharmacist and a representative from the Department of Health. A Project Reference Group, including representatives from all participating ACCHSs, NACCHO, and its Affiliates, provided Aboriginal and Torres Strait Islander oversight and input into the Project, and to advise on implementation issues. The Evaluation Team was led by JCU with representatives from the partners, the Affiliates, Aboriginal Academics and content experts. Members of the operational team, evaluation team and steering committee reviewed and provided feedback on all reports, led by JCU.

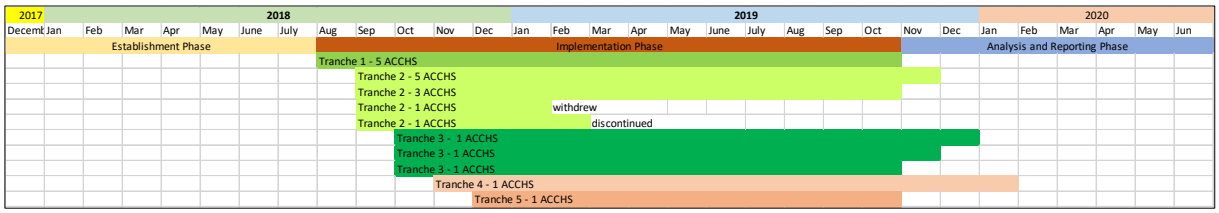
Figure 1. Governance structure for the IPAC project.



Timelines

The final timeline indicates the project phases and the commencement and end dates of integrated pharmacist activity delivered in the ACCHSs (Figure 2). The original timeline reflected the project implementation phase commencing in April 2018. However, delays in the establishment phase of the project meant the implementation phase did not commence until August 2018. The implementation phase was shortened due to the end of study date set for 31st October 2019. The first pharmacists commenced in ACCHSs on 2nd August 2018 and the first patient was recruited into the study that same day.

Figure 2. Project timeline with ACCHS/pharmacist commencement and end dates.



In some sites where pharmacists commenced in later tranches of the implementation phase, efforts to optimise project delivery within the data capture period were achieved by increasing the FTE allocation over a reduced period of time (e.g. 0.6 FTE over 15 months became a 0.8 FTE contract over 12 months). A small proportion of pharmacist hours could not be compressed to fit within the intervention phase (eg where the pharmacist was already working 1.0 FTE). In such circumstances, pharmacist hours continued into the analysis phase to honour the project's commitment to participating ACCHSs to provide access to an integrated non-dispensing pharmacist for a total period of 15 months.

ACCHS recruitment and support

NACCHO conducted a two-phase Expression of Interest (EOI) site recruitment strategy for the IPAC Project, which was overseen by the NACCHO executive and managed by the two NACCHO project coordinators. Service inclusion criteria were used to select sites in urban, regional and remote locations across three jurisdictions, the Northern Territory, Queensland and Victoria,[25] after reviewing the responses to the advertised EOI. ACCHSs selected were endorsed by the Steering Committee. ACCHS participation required a formal agreement between the ACCHS and the PSA as the head contractor, outlining the requirements of each party to the agreement, consent for ACCHS participation in the IPAC Project and consent to install the GRHANITE™ software to enable extraction of deidentified patient specific data.

Twenty ACCHSs commenced delivering the pharmacist intervention across 24 clinic sites. During the implementation phase one ACCHS withdrew due to the unexpected workload placed on other staff due to the pharmacist's recommendations and activities, in an already busy period where staff shortages were ongoing. Another ACCHS chose to discontinue with the intervention after 6 months of activity, when their pharmacist resigned for personal reasons. There were insufficient patient numbers at the ACCHS to warrant re-recruitment of a pharmacist for the remaining project duration. Eighteen ACCHSs completed the intervention and were well distributed across urban, regional and remote settings (Table 1).

Table 1. Distribution of ACCHSs by setting and jurisdiction.

	Urban	Regional	Remote	**Total**
Northern Territory	0	1	4	5
Queensland	3	2	2	7
Victoria	2	4	0	6
Total	**5**	**7**	**6**	**18**

NACCHO project coordinators visited each ACCHS at least twice in accordance with the project protocol. The initial visit was undertaken at the commencement of the Project and facilitated discussion of the ACCHSs preferred system for referring patients to the pharmacist and for seeking consent, conducted the ACCHS Pharmacist Needs Assessment, collected ACCHS data recorded on the health systems assessment, and discussed logistical issues including access to the clinical information system (CIS), consulting space and availability of a uniform. The NACCHO coordinators also worked to build a strong rapport with relevant ACCHSs staff and arranged a nominated ACCHS staff member to act as a 'go to' person for the integrated pharmacist to assist in the pharmacists' orientation to the service.

At the second site visit during the final three months of the implementation phase, the health system assessment was repeated to identify any changes that might impact upon the project results. The final visit also provided an opportunity for the project coordinator to seek feedback from ACCHS staff on the conduct of the project as well as their experience of having a pharmacist as part of the team. In response to significant ACCHS demand, information was provided by the project coordinator about possible sources of ad-hoc funding for ACCHSs to continue access to a pharmacist beyond the project.

Ongoing support was provided to the participating ACCHSs through communication with NACCHO project coordinators, provision of resources, promotional materials and information updates, and meetings of representatives from all participating sites, jurisdictional Affiliates and NACCHO (Project Reference Group). The report outlining the method used to select ACCHSs and support provided to participating services is included in Appendix 22.

Pharmacist recruitment

An overview of the pharmacist recruitment process for the project is depicted in Figure 3. This algorithm was derived by the project operational team, consistent with the project protocol. This guided the pharmacist recruitment process for each ACCHS.

As part of ACCHS selection, NACCHO also sought information from each service to identify the community pharmacy(ies) with whom they had an existing relationship. PSA engaged with these local community pharmacies and invited them to nominate suitable pharmacist candidates for all sites. In addition to approaching community pharmacy, an open call for expressions of interest was conducted by PSA Coordinators to generate a database of potential pharmacists interested in working within Aboriginal Community Controlled Health Services. This was done via PSA and AACP newsletters, social media channels, the NACCHO/PSA ACCHS Leadership group and throughout the ACCHS network via NACCHO. Where these avenues of recruitment were not successful, advertising through mainstream online job seeking platforms was utilised along with active, direct scoping of candidates through known networks, hospital departments and publicly available accredited pharmacist lists.

Figure 3. Pharmacist recruitment algorithm.

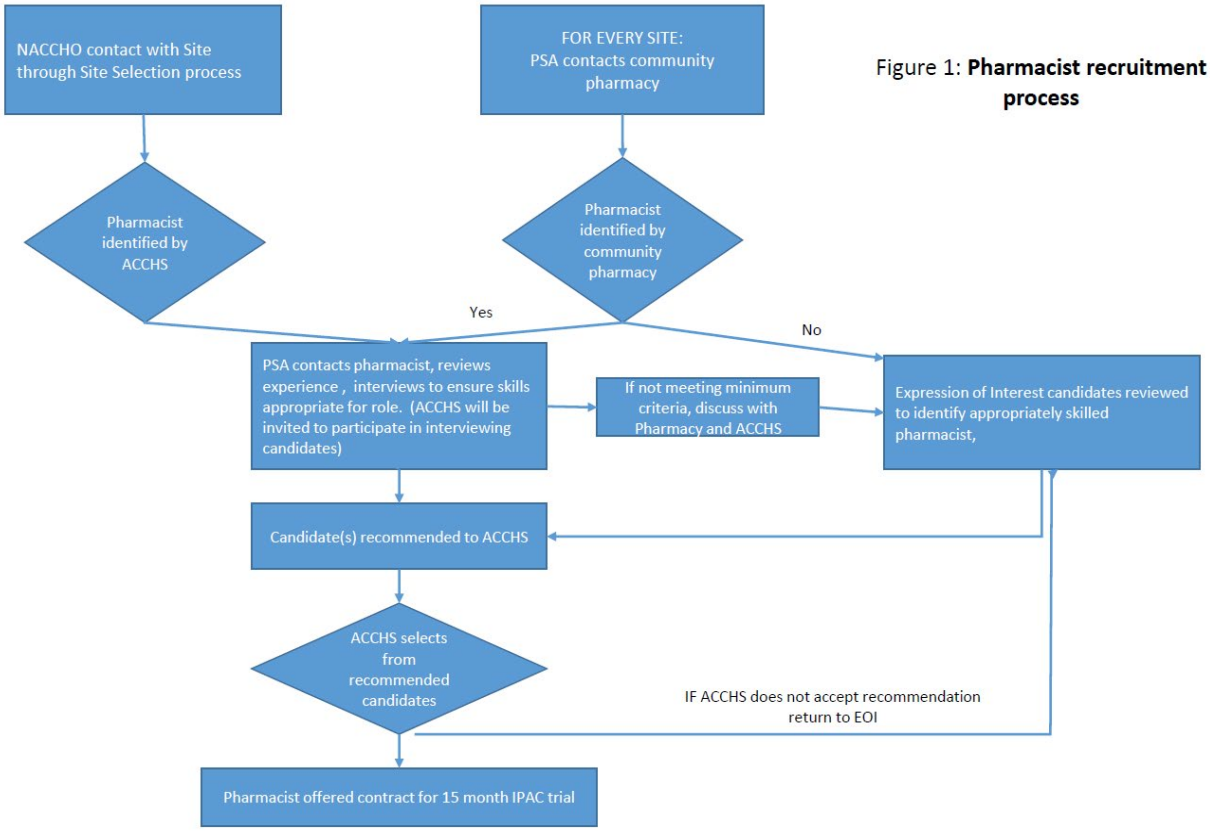
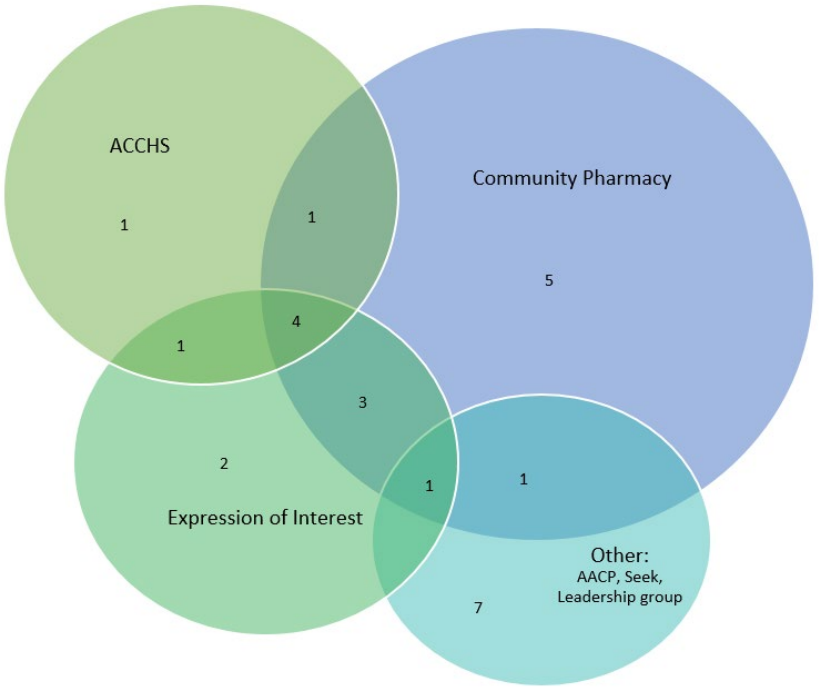


Figure 1: **Pharmacist recruitment process**

Figure 4 shows the source of nominations for the 26 pharmacists accepted to participate in the Project.

Applicants were screened by PSA Coordinators using a checklist to standardise the process to shortlist candidates for each ACCHS. Staff members from each ACCHS were invited to review applications, select candidates for interview and participate in the interviewing process. Respecting the principles of self-determination, each ACCHS was responsible for making the final decision on the appointment of the pharmacist. PSA undertook checks on pharmacists' registration status and ensured that appropriate police clearance or working with children checks (as per state specific requirements) were sighted. Pharmacists were engaged via a subcontract through community pharmacy or an employment contract with the PSA.

Figure 4. Integrated Pharmacist Nomination Sources



PSA was responsible for the performance management of the pharmacists directly employed by PSA, and was also responsible for overseeing the delivery of the subcontracting arrangements through community pharmacy. PSA utilised regular communication with pharmacists and community pharmacy owners via phone calls and emails to provide updates regarding their activity. Site visits conducted by PSA Coordinators provided an opportunity to undertake a face to face review of pharmacist performance and offer additional support to optimise project delivery.

Recruitment of 23 pharmacists enabled initial implementation of the project at all 20 participating ACCHSs with a total of 12.5 full time equivalent (FTE) pharmacist hours distributed across the services. Pharmacist time was apportioned between 0.2 and 1.4 FTE across the ACCHSs according to patient numbers and the capacity of both the pharmacists and health service. Pharmacist FTE was reallocated throughout the project following pharmacist turnover and ACCHSs not continuing with the intervention. Reallocation of pharmacist FTE aimed to maximise data capture with the implementation phase. A total of 26 pharmacists were involved in delivering integrated services in ACCHSs resulting in overall delivery of 12.3 FTE throughout the implementation phase (Table 2).

In all sites where community pharmacy nominated a candidate for the role, a community pharmacy nominated candidate was appointed to the role with the employment arrangement being either via a subcontract with the community pharmacy or directly with PSA as per the preference of the community pharmacy owner or, in keeping with principles of self-determination, at the request of the health service.

Seven pharmacists were employed under subcontract with community pharmacy, with the remaining 19 pharmacists employed directly by PSA. Of the 26 pharmacists employed over the duration of the IPAC project, 21 were female and 5 were male. At the time of being appointed to the role, 19 of the pharmacists were accredited to conduct medication management reviews, with another pharmacist gaining accreditation during the project. An additional two pharmacists have completed their accreditation since the end of the project, while a further two pharmacists who were not accredited have commenced studies to become Credentialed Diabetes Educators. For further information, see Appendix 19 - Pharmacist Recruitment Report (PSA).

Table 2. Number of ACCHSs and pharmacists via employment method throughout the implementation phase, by jurisdiction.

States	Final number of ACCHSs involved	FTE Allocated	Pharmacists	PSA employed	Community pharmacy subcontracted pharmacists
Northern Territory	5	4.6	8	3	5
Queensland	7	5.1	9	7	2
Victoria	6	2.6	9	9	0
Total	**18**	**12.3**	**26**	**19**	**7**

A comprehensive induction training program was facilitated by PSA Coordinators for pharmacists. It was tailored to ensure that participating integrated pharmacists would have the necessary skills to work within diverse ACCHS settings in a culturally-responsive manner to deliver the core roles and to capture relevant data for evaluation. The training involved preparatory pre-reading including components of the project protocol, learning about the 6th Community Pharmacy Agreement rules related to Aboriginal and Torres Strait Islander programs, and a series of online learning modules selected by PSA Coordinators for their relevance to chronic disease management services in Aboriginal and Torres Strait Islander primary healthcare settings and working in an integrated team environment.

Induction training was delivered through two day workshops as facilitated face to face group sessions in Sydney, Melbourne and Brisbane (Table 3). Elements of the program included cultural awareness training (delivered by experienced cultural trainers), project overview, consent process, integrated pharmacist core roles, activity work plans, use of the electronic logbook and clinical information systems, resources and lines of communication.

A small number of pharmacists who were recruited after completion of the workshops were given a full day of one-on-one project-specific training in a mutually agreed location followed by another day of pre-arranged experience alongside an ACCHS pharmacist at their place of work. For further information, see Appendix 20: Pharmacist Induction Training Report (PSA).

Table 3. Summary of IPAC Project Pharmacist Induction Training attendance.

Date of training delivery	Delivery method	Location	Number of pharmacists attending
July 2018	Workshop	Sydney	11
August 2018	Workshop	Melbourne	7
October 2018	Workshop	Brisbane	3
October 2018	Small group	Melbourne	2
September 2018	One to one	Cairns (Qld)	1
March 2019 (replacement)	One to one	Geelong (Vic)	1
April 2019 (replacement)	One to one	Gove (NT)	1
TOTAL			**26**

PSA project coordinators were primarily responsible for coordinating and managing the delivery of a multifaceted and tailored program of support for the integrated pharmacists throughout the project's implementation phase. Support methods included phone and email support from the Project Team

(comprising representatives from PSA, NACCHO and JCU), as well as formal and informal mentoring by experienced Aboriginal Health Services pharmacists. Further support was provided by means of site visits by PSA Coordinators, participation in regular monthly teleconferences, inclusion in an online discussion group and contact by closed-group social media. The integrated pharmacists were also given access to a contemporary online repository of resources related to medicines use and management of chronic disease in Aboriginal and Torres Strait Islander peoples, taking into account jurisdiction-specific differences in legislation and best-practice guidelines.

Throughout the project's implementation phase, significant uptake and consistent utilisation of the various platforms of support provided to the integrated pharmacists was demonstrated. PSA Coordinators conducted twenty site visits across 16 ACCHSs, eleven monthly teleconferences were held, 91 unique topic threads were raised in the online discussion form, and 530 individual messages were posted in the social media group (using WhatsApp®). Eleven pharmacists formally participated in the Mentor Program Support and a further three pharmacists received informal support. Regular communication by phone or email occurred between PSA project coordinators and integrated pharmacists. The integrated pharmacists contacted PSA project coordinators for support on at least a daily basis. For further information see Appendix 21: Support for Pharmacists Report (PSA).

Participant recruitment

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

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

Convenience sampling kept with the pragmatic project design. Patients attending sites were invited to see the integrated pharmacist after being referred by a doctor, health worker or other healthcare provider. In accordance with ACCHSs preferred processes, pharmacists in some ACCHSs approached potentially eligible patients directly. Written consent was required from patients to participate in the project and to provide permission for information and health data to be used for project evaluation. A Master Participant Information Brief informed participant of all aspects of the project (Appendix 24). Referral and consent processes were developed in consultation with each ACCHS to ensure they were culturally appropriate for the individual site. The integrated pharmacist recorded consent in the ACCHS' clinical information system (CIS). Participants were able to withdraw from the study at any time.

Ethics approval

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

Approval from each HREC was obtained prior to the commencement of the project in their respective

jurisdictions. As the project evolved and some changes were made, further approval of changes was received through the submission of amendments to each HREC. The tools used in the qualitative evaluation were approved by the HRECs prior to commencement of this component of the study. Project Information Briefs and Consent Forms for sites, pharmacists, participants and GPs are presented in Appendix 24.

Data collection

Deidentified data was extracted from the clinical information systems (CIS) of ACCHSs pertaining to consented participants through an electronic data extraction tool known as GRHANITE™. Data included participant demographics, biomedical measures and indices for contact, and measures of health service utilization (MBS items, eg home medicines reviews). Additional deidentified data on participant interactions (such as medication management reviews, assessments of medication adherence, appropriateness and underutilisation, self-assessed health status and education) and services related to health care staff and systems (such as team-based collaborations, education, stakeholder liaison plans, contact with community pharmacies, transitional care occasions, and drug utilisation reviews) were recorded by the integrated pharmacists in an electronic logbook.

Existing tools used included the medication appropriateness index and the first question (SF1) of the Short Form (SF)-36 health related quality of life instrument to measure self-assessed health status. Existing processes and rules for Home Medicines Reviews were observed. Other data collection tools were adapted from established tools or had to be developed to meet the specific requirements of the project. These included the health systems assessment form, assessment criteria for medication underutilization and medication-related problems, a medication adherence patient survey and processes for non-home medicines reviews.

Templates were designed to collect details about follow-up to a HMR or non-HMR, team-based collaborations, provision of medicines information services, education and training, implementation of stakeholder liaison plans, contact with community pharmacy, transition care occasions and drug utilization reviews.

Data collected through all assessments, tools and templates was entered into the logbook, with the exception of the health systems assessment. Qualitative evaluation was informed through focus groups, interviews and observations undertaken through three site visits, and online surveys with CEOs, managers, general practitioners and community pharmacists from all sites. Economic analyses used participant, health services, and intervention costs data.

GRHANITE™ data extraction software

GRHANITE™ software extracted demographic, biomedical and health service utilization indices from the ACCHSs CISs.[26] ACCHSs consented to have the software installed within their server environments (via remote connection) and for regular data extractions to occur for the term of the project. ACCHSs used either Communicare or Best Practice as their CIS. Participant consent was recorded in the CIS by the integrated pharmacists. GRHANITE™ data was copied to a JCU databank employing internationally recognised point-to-point encryption (P2PE) mechanisms to protect data in transit.

The scope of the data extractions was agreed based on IPAC-specific data requirements (approved by HRECs) and data definitions used within the Communicare and Best Practice systems, to develop an XML software interface to extract the data. Each ACCHS successfully completed 'site acceptance testing' after installation of the software that confirmed the data extracted was fit-for purpose. The integrity of the data extraction process was monitored through weekly data downloads. XML interface maintenance ensured that any

vendor software upgrades to the CIS were aligned with data extract definitions. The de-identified CIS participant identification numbers in the GRHANITE™ extractions linked with participant data recorded by pharmacists in the electronic logbook.

Pharmacist logbook

The integrated pharmacists recorded data on all ten core roles in a bespoke electronic pharmacist logbook. The logbook was a password protected, electronic database, accessible from any internet-connected device. It was designed specifically for the project and had dual functionality for data entry and reporting. Each core role had its own 'questionnaire' in the logbook to record all required data for that specific activity. An additional questionnaire recorded details of participants withdrawn from the study. The logbook design was optimised to make data collection and entry useful and efficient. The use of 'select-from' lists and multiple-choice questions was maximised were possible and free text fields only used where necessary. As part of certain core role questionnaires, pharmacists were able to upload a PDF document to support their activity entry.

Logbook system administration was managed by a JCU administrator and a data custodian. Security was paramount and all users of the logbook had to be approved by the administrator, who could manage the creation and deactivation of accounts. Pharmacists were only able to access the system when the PSA had advised JCU of their commencement and details. Individual accounts were set up and pharmacists set their own password to ensure security and integrity of the system. Using a permissions-based hierarchy meant that each pharmacist could only see their own data, whereas administrators were able to run overall data reports and view the activity of each pharmacist.

The JCU administrator, with the permission and support of the software developer, created a guidebook with step-by-step instructions and screenshots for pharmacists to help them navigate the system. Pharmacists were expected to enter data on their activity at the end of each IPAC project working day.

Raw data was downloaded from the logbook into Microsoft Excel. To facilitate the monitoring of pharmacist activity, the JCU Team analysed high level quantitative logbook data and provided monthly reports to the project operational team on the pharmacists' levels of activity for each of the 10 core roles, including selected project targets, during the implementation phase and for the duration of the project.

Qualitative evaluation

Three main strategies were used to collect data to inform the qualitative evaluation of the project including semi-structured interviews with integrated pharmacists; mixed methods online surveys with GPs, CEO and managers and community pharmacists; and three site-visits comprising focus groups and interviews with health services staff and patients, interviews with the integrated pharmacists, and shadowing and observation. Proformas were developed to guide each data collection activity:

1. Focus groups and interviews – ACCHS staff
2. Focus groups and interviews – Patients
3. Interviews with pharmacists
4. Online survey – ACCHS staff
5. Online survey – GPs
6. Online survey – Community pharmacists
7. Observation checklist for site visits

Proformas and the online surveys were developed and distributed to the project operational team, the steering committee and the evaluation team for comment. The Project Reference Group members provided

feedback on the proformas to be used with patients and ACCHS staff. All proformas were submitted and received approval from the HRECs in each jurisdiction.

The online surveys were implemented through Survey Monkey[R] and piloted by the project operational team members and relevant members from the evaluation team. The online surveys were a combination of yes/no responses, Likert-style and 'slider' rating scales and open-ended questions. Demographic questions collected data on gender, age group, role and experience working within (or with) ACCHSs (see Appendix 14).

Economic analysis

The economic analysis was trial-based, rather than model-based, with costs and outcomes compared in the post- and pre-intervention periods (MSAC Assessment Report, and Appendix 25). Data relating to resource use in implementing the IPAC intervention and changes in resource use were obtained directly from the trial, with unit costs also available from the trial with the exception of GP earnings (the latter obtained from official ABS data). The comparator was usual care in the pre-intervention period.

Outcome measures included biomedical indices from (i) those with T2DM with pre- and post-measures of HbA1c and (ii) the subset of participants for whom an assessment of underutilisation was conducted (the number of potential prescribing omissions). A cost-consequence analysis was undertaken for all participants, with costs presented alongside a range of biomedical outcomes to demonstrate the full impact of the intervention, given the intervention had multiple effects and is a public health intervention with a range of health and non-health benefits that are difficult to measure in a common unit.[27 28] For participants with a clinical diagnosis of T2DM, a cost-utility analysis was also conducted that derived lifetime quality of life changes from the decreases in HbA1c observed during the trial period and mapped the HbA1c changes to lifetime quality of life changes, based on the findings of a systematic review.[29] For further information see MSAC Assessment Report: Sections D and E.

Health systems assessment

Each ACCHS underwent repeated health systems assessments (HSA) to explore service characteristics and identify any systems change over the trial intervention period. There were 140 distinct items in the IPAC 140 HSA form which collected data on ACCHS details such as service size, local population, number and types of staff, access to local or visiting specialist and allied health services, budgets, services offered, quality improvement processes, medicines access information, systems for clinical management and chronic disease care, engagement with other health care providers and the quality of communication with the hospital and community pharmacies (Appendix 10 - Assessment of MAI report: Appendix B).[30] The HSA form assessed health services by exploring five (5) abbreviated domains of the chronic care model.[31]

The data was collected from ACCHSs by the NACCHO project coordinators prior to the commencement of pharmacists at each service. The collection was repeated in the final three months of the implementation phase by the respective NACCHO project coordinator who had conducted the initial HSA to ensure data collection consistency.

Medication Appropriateness Index (MAI) audit

Medication appropriateness was measured by assigning a Medication Appropriateness Index (MAI) weighted score to each participant's medicine based on an internationally validated tool[32 33] that assessed the potential for medicine-related risks that outweigh the benefits to the patient (prescribing quality, see Appendix 10). The MAI has 10 items investigating measures of medication appropriateness and included medication indication, effectiveness, correct dosage, correct direction, practical direction, drug–drug

interaction, drug–disease interaction, drug duplication, duration of therapy, and cost. Overuse of medications, defined as participants' medications deemed to be 'unnecessary', was measured by assigning a MAI score to three items. Pharmacists reviewed each participant's medical record containing their currently prescribed medications and assigned the 10 -item ratings to each medication. Pharmacists used this medication review and other assessments related to their core role to formulate recommendations for the prescriber. The assessed ratings were entered by pharmacists into the electronic logbook.

Assessment of underutilisation (AoU)

All MAI subset participants were also assessed for medication underuse using ten (10) evidence-based prescribing quality categories to define clinically relevant potential prescribing omissions (PPO) for cardiovascular disease (CVD), type II diabetes mellitus (T2DM), chronic kidney disease (CKD), pneumococcal vaccination, acute rheumatic fever (ARF) and/or rheumatic heart disease (RHD) (Appendix 11). These conditions were known to contribute significantly to the burden of disease and healthcare disparities in Aboriginal peoples and Torres Strait Islanders (especially in remote Australia).[34] The use of evidence-based guidelines applicable to Aboriginal and Torres-Strait Islander peoples informed the face and content validity of the underutilisation criteria. Data from the assessments was entered into the logbook by pharmacists.

Home medicines reviews (HMRs)

Participant data for the number of HMRs (based on the number of MBS item 900 claims) completed in the pre and post-intervention period was sourced from GRHANITETM extractions (Appendix 12). The number of HMRs completed during the study period, and related data was also recorded by pharmacists in the logbook (Appendix 16). Pharmacists were required to document the clinical indications for a HMR and if an MBS rebate claim for item 900 was generated by the health service as well as reasons for not claiming. Pharmacists were required to record if a HMR conducted during the project period was completed by an IPAC or external pharmacist. If the HMR was conducted by an accredited integrated pharmacist, the HMR was conducted either within IPAC hours or outside IPAC hours. Payment for HMRs completed by IPAC pharmacists within project hours was not claimed via the 6CPA.

Non-home medicines review

For the purposes of the IPAC project, a non-HMR was defined as comprising some or all the elements of a HMR but not fulfilling all relevant HMR criteria to be eligible to claim the MBS rebate. Integrated pharmacists' conducted non-HMRs for those at risk of medicines misadventure but did not fully meet the criteria for an HMR. For example, the interview could be undertaken outside the participant's home. Thus a non-HMR was defined by eight mandatory criteria that included:

1. an interactive face-to-face or telehealth interview with the patient;
2. the collection of patient-specific data;
3. the compilation of a comprehensive medication profile;
4. education of the patient about their medications;
5. the assessment of the medication profile to identify medication-related problems;
6. prioritizing a list of medication-related problems;
7. recommendations made and documented in the ACCHS clinical information system; and
8. recommendations were discussed with the prescriber.

All completed non-HMRs fulfilled all eight criteria and were entered into the logbook by pharmacists (Appendices 12 and 16).

A non-HMR was distinct from a HMR in that a non-HMR allowed for an opportunistic medication review by a pharmacist either within or outside the patient's home; without needing a formal referral from the patient's GP; and the absence of frequency restrictions for a non-HMR whereupon a patient may have a non-HMR following a HMR, or repeat non-HMRs as deemed clinically necessary.

Follow-up to an HMR or a non-HMR

The project protocol required that an integrated pharmacist should schedule a patient follow-up as per usual clinic processes after the completion of an HMR or a non-HMR. Information regarding pharmacist's follow-up activity was collected for patients who had a HMR or a non-HMR. Pharmacists undertaking a follow-up activity were required to fulfil three criteria for each activity:

1. reinforce the HMR and non-HMR advice and recommendations provided by the pharmacist (and the GP, if appropriate);
2. assess the impact of any actions recommended from the HMR or non-HMR; and
3. determine if another HMR or non-HMR, education session or preventive intervention was needed.

Pharmacists logging the completion of participant follow-up for the IPAC study were required to confirm the assessment of all three criteria with the encounter entered into the logbook (Appendices 12 and 16).

Medication-related problems

For every HMR or non-HMR during the intervention phase, pharmacists were required to report any medication-related problems (MRPs) identified (Appendix 12). The definition of MRPs was adapted from some of the criteria in the MAI used to assess drug-related problems, supplemented by additional problems commonly reported in other studies such as if any medicine was associated with an adverse drug reaction, and if the medication dosage was sub-therapeutic or if there was an overdosage. Pharmacists could also report 'other' MRPs not included in this list, or the complete absence of a MRP. All data was recorded by pharmacists in the logbook.

Medication adherence

The extent of participant adherence to medications and the reasons for non-adherence was assessed from each participant using indirect self-reported measures at baseline and then at the end of the study. Two methods were used as part of a single survey tool – a single-item question (SIQ), and an 11-item patient survey (NMARS, NACCHO Medication Adherence Response Scale) that was validated for the purpose of the IPAC study. The SIQ asked participants: '*How many days in the last week have you taken this medication?*' (asked for each medication the participant was taking). Pharmacists were trained to express the score as a proportion of the number of days the participant took the correct doses of the medication as prescribed in the preceding week. An 'adherent day' was defined as not missing any doses of prescribed medicines on that day. The mean number of adherent days in the preceding week ranged from 0-7 days, based on the mean score for all medications. This informed on the proportion of days with the correct number of doses taken, which is a frequent summary statistic used for reporting medication adherence.[35] If the mean number of adherent days for participants was least 6 of 7 days, this approximated medication adherence for at least 80% of the days indicated.

Content for the NMARS was based on literature review with face and content validity supported by a conceptual framework, expert panel, testing with scale and item-specific content validity indices (CVI), pre-testing with Aboriginal consumers, assessment of question properties, and initial pilot testing, that was then used with all IPAC participants. Construct validity and reliability testing was also undertaken. Scores from 8-

11 indicated adherence. Pharmacists entered participant responses to both measures of adherence into the logbook and were not required to determine scores (Appendix 13).

Self-assessed health status

Self-assessed health status was determined at baseline and at the end of the study using the first question of the Short Form (SF)-36 health related quality of life instrument 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. Pharmacists entered participant responses into the logbook (Appendix 13).

Team-based collaboration

The pharmacists were integrated within the ACCHS model of care as a member of the PHC team to improve the chronic disease management of participants. Integration meant that pharmacists had identified positions and core roles, shared access to clinical information systems, provided continuous clinical care to participants, received administrative and other supports from primary health care staff, and adhered to the governance, cultural, and clinical protocols within ACCHSs as part of their shared vision. Pharmacists recorded details of their involvement in team-based care activities in the logbook, such as the role of team members or stakeholders who were involved in the collaborative activity, the duration of the activity and whether or not it involved an IPAC consented participant (Appendix 16).

Medicines information service

Integrated pharmacists provided medicines-related information to clinicians and other staff within the ACCHSs including responding to PBS queries, information requests regarding dose titration, interactions, new and emerging drugs, drugs in stock and ad-hoc medicine queries. Data recorded in the logbook included the recipient of the information, how the request was received, the type of information provided and the clinical reference, and the time taken to complete the service. Evidence of an outcome was recorded in situations where the pharmacist was aware that the GP or other clinician had made a change to participant therapy based upon their advice or recommendations (Appendix 16).

Education and training

Medication-related education sessions were provided by the integrated pharmacists for both participants and healthcare providers. The pharmacists also participated in preventive health promotion and community events. Details recorded in the logbook included the type of activity, the format in which it was provided, duration and examples of materials or resources which could be uploaded (Appendix 16).

Stakeholder liaison plans

A written stakeholder liaison plan aimed to support the development of relationships and networks between the ACCHS and community pharmacies, and other relevant service providers (such as local hospitals or aged care facilities) in order to facilitate communication and collaboration. It was anticipated that enhancement of communication processes with stakeholders would continue to have benefit and relevance to the ACCHSs even after completion of the project. Pharmacists were expected to develop one written plan for communication between their ACCHS and each of their local community pharmacy/ies, and any other relevant stakeholders. Data collected in the logbook included the identification of staff involved in the co-design of the plan, the key stakeholders, whether the plan had approval of the ACCHS CEO and the time take

to develop the plan. A template was provided for the plan and when completed was uploaded into the logbook. Pharmacists were also able to note or upload documentation providing evidence of any outcomes (Appendix 16).

Contacts with community pharmacy

In addition to the development of the stakeholder liaison plans, integrated pharmacists recorded details of interactions with community pharmacy in the logbook including the reason for contact, whether contact was initiated by the IPAC or community pharmacist, and the method of contact used (Appendix 16).

Transitional care

The transitional care core role aimed to optimize medication management for participants across the continuum of care, by relaying relevant information and improving the communication of discharge summaries for medicines reconciliation. Integrated pharmacists reported details of each occasion of transitional care in which they participated including the agency they engaged with, the reason and mode of contact, and the duration of the activity (Appendix 16).

Drug utilisation reviews

Integrated pharmacists also completed one or more drug utilisation reviews (DUR) at their respective ACCHSs. The World Health Organisation defines a drug utilisation review (or drug utilisation evaluation) as 'a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately'.[36] Pharmacist training on DURs required reviews to be based on a priority issue nominated by the ACCHS. Best practice evidence or guidelines were to be used to support the DUR and a template was provided to pharmacists to assist the reporting process. Pharmacists uploaded the DUR report into the logbook, in addition to providing details about the initiator of the review, duration, and measures used to assess progress with this quality assurance activity within the ACCHS (Appendix 16).

Data management and intellectual property

Privacy and confidentiality

Individual patients participating in the project were not able to be identified. The GRHANITE™ software program provided an ethical and secure mechanism for the extraction of participant data that strictly conformed to variables approved by HRECs. Identifying details were not extracted and participants and were automatically allocated a unique patient identification (ID) code. When entering data in the logbook, pharmacists used the participants' ID number, and did not enter any identifying details. The participant ID numbers could be linked with those in the GRHANITE™ extracts to enable analysis. Individual ACCHSs, communities and participants were not identified in any reports, publications or conference presentations of data from this project, unless this was approved by the ACCHS. Project results were reported at an aggregate level.

Data security

As the leading research organisation, JCU was responsible for the protection of data from loss, misuse and unauthorised access. The Data Custodian at JCU was responsible for this role. No issues were raised in relation to data security during the project. Pharmacist, participant and site consent forms and all data collected via GRHANITE™ extractions and entered into the pharmacist logbook was held electronically in a

password protected computer by the Data Custodian at the JCU College of Medicine and Dentistry. Consent forms collected by project staff from sites were posted to the Data Custodian. Forms were stored in a locked filing cabinet, in a locked room at the JCU College of Medicine and Dentistry, with any other project-related paper-based data. All electronic files and paper-based data will be stored securely after the project under the control of the Data Custodian for a period of 7 years in line with ethical requirements. After this time, all files will be deleted and papers destroyed through JCUs secure waste management services.

Quantitative Data

Data was extracted from ACCHS clinical information systems via the GRHANITE™ data extraction tool, as well as data recorded by pharmacists in the logbook. Electronic data was stored on password-protected server at JCU. Data accessed during the analysis phase was stored only in JCU-supported database applications.

Qualitative data

Qualitative data collected via interviews and focus group discussions (including zoom and teleconferences) were recorded digitally. Photographs of signs and the clinic layout were taken on a password-protected mobile phone. All electronic files (digital recordings and photos) were removed from recording devices (recorder and mobile phone) immediately once transferred to the laptop. Field notes from site visits were recorded in a notebook or electronically. Identifying information was removed from data collected immediately after transcription of the interviews and focus group discussions. Consent forms and paper notes of any identifiable project data were stored in a locked filing cabinet, in a locked room.

Online survey data collected was stored in a password-protected 'Survey Monkey' account until the end of the data collection period. At this time, the data was downloaded and removed from the online account. All electronic files were stored on password-protected computers during the project.

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 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™), are vested in JCU. JCU has subsequently granted a license to the PSA. The raw (unanalysed) data extracted by GRHANITE™ and collected is acknowledged to be owned by the ACCHSs from which it was collected. ACCHSs granted the PSA (and in turn, NACCHO and 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 arose from participation in the IPAC Project in accordance with the Project Protocol.

Results

Registered pharmacists were integrated within the primary healthcare teams of 18 ACCHSs across 22 sites, for up to 15-months from 2nd August 2018 to 31st October 2019. Pharmacist positions were aggregated to the rate of 12.3 FTE in total.

A total of 1,733 patients were consented for the project, of which 1,456 had pre and post data and were included for analysis of participant outcomes. An overview of all pharmacist activity is presented in Table 4.

Table 4. Overview of pharmacist activity included in analysis from 02/08/2018 to 31/10/2019.

Pharmacist core role	Number of activities
Self-reported medication adherence survey (NMARS)	2,759
Medication Appropriateness Index (MAI) Audits / Assessments of Underutilisation (AoU)	789
Home Medicines Reviews (HMRs)	639
Non-HMRs	757
Follow-up to a HMR or Non-HMR	1,548
Team Based Collaboration (1,082 related directly to IPAC participants)	3,165
Medicines Information	1,715
Education and Training	358
Drug Utilisation Reviews	26
Stakeholder Liaison Plans	47
Stakeholder Liaison – Community Pharmacy Contact	3,233
Transitional Care	1,901

NMARS=NACCHO Medication Adherence Readiness Scale

Practice-based activity

Extensive collaboration and communication with other healthcare providers was evident through team-based collaboration, transitional care for participants, the development and implementation of stakeholder liaison plans and extensive contact with community pharmacy. Integrated pharmacists were pivotal as a point of contact for stakeholders with whom services worked such as community pharmacists, and staff in local hospitals, rehabilitation and dialysis units. Pharmacists also provided medicines-related information, education and advice. Drug utilisation reviews and medication management reviews facilitated improvements in prescribing quality and other supports for participants. Analysis of these activities in the IPAC project provided evidence that delivery of non-dispensing pharmacist services was feasible within ACCHS settings and contributed to the integration between the pharmacist and other health care staff, as

well as enhancing communication and collaboration with community pharmacy and other stakeholders. These activities contributed to other outcomes achieved in the project (outlined below).

For further details:

Appendix 16: Smith D, Couzos S, Biros E. Integrated pharmacists within ACCHSs: support for practice-based activities in the IPAC project. Final report to the Pharmaceutical Society of Australia for the IPAC Project, April 2020.

Clinical endpoints analysis

Integrated pharmacists embedded into usual care in ACCHSs provided clinically and statistically significant improvements in the control of cardiovascular disease (CVD) risk factors, glycaemic control in participants with T2DM, and reduced absolute CVD risk in Aboriginal and Torres Strait islander adults with chronic disease.[37] Analysis of 1,456 participants with pre and post data found:

- Mean age of participants ranged from 57- 58 years, most (91-94%) were Aboriginal and/or Torres Strait Islander, 65 to 76% attended health services located in inner and outer regional locations, 59% to 75.4% had T2DM, and 87.5% to 90.2% had co-morbidity.
- Statistically significant improvement in HbA1c results in participants with T2DM, with a 2.8 mmol/mol or 0.3% (unit) reduction (p=0.001, 95% CI -0.4% to -0.1%).
- Reductions in diastolic blood pressure (-0.8mmHg, p=0.008), total cholesterol (-0.15 mmol/L, p<0.001), LDL-C (-0.08 mmol/L, p=0.001), and triglyceride levels (-0.11 mmol/L, p=0.006) were significant for all participants.
- Mean calculated absolute 5-year CVD risk was significantly reduced by 1% (95% CI: -1.8% to -0.12%, p=0.027).
- Mean annual estimated glomerular filtration rate (eGFR) significantly improved with an increase of 1.9mL/min/1.73m^2 (95% CI: 0.1 to 3.7) from baseline, which is a significant slowing of eGFR decline (p<0.001). When participants with less than 6-months of follow-up were excluded, the mean annual eGFR decline was -0.2ml/min/1.73m^2 (95% CI:-2.99 to 2.7), significantly slower than the predicted and expected annual decline of -3ml/min/1.73m^2 (p=0.034, n=720) in the Aboriginal and Torres Strait Islander population.
- SBP significantly improved for younger participants (<57 years, -1.8 mmHg, SD: 12.5, p=0.004).

The observed net improvements in biomedical outcomes are clinically meaningful at a population level. Even a modest HbA1c drop may translate to a reduction in micro and macrovascular complications in people with T2DM if sustained population wide. According to the UK Prospective Diabetes Study (UKPDS) *any improvement* in HbA1c in those with T2DM reduced the risk of diabetes complications, with little evidence of a threshold of effect. [38] Moreover, the observed net improvement in glycaemic control of participants with T2DM from baseline values was consistent with the -0.18% to -2.1% HbA1c decrease (difference between intervention and control groups) observed over a mean of 9.4 months in 24 of 26 other studies that investigated pharmacist interventions in patients with T2DM.[39]

The small but significant average DBP and SBP reductions shown for IPAC participants may also attenuate the incidence of CVD events for Aboriginal and Torres Strait islander peoples if such reductions were population-wide, particularly for those with chronic disease. The net BP reduction was observed for the IPAC cohort as a whole, irrespective of whether participants had a clinical diagnosis of hypertension. Population-wide BP reduction strategies are recommended for the primary prevention of CVD events because the benefits that accrue from BP reduction are not just limited to those with hypertension.[40] A population-wide reduction in DBP of a mere 2mmHg has been estimated to reduce the prevalence of hypertension and CHD risk by 17%

and 6% respectively, and combined with BP reductions in those needing medical treatment, could double or triple the impact of medical treatment alone.[41] A mere 1 mmHg reduction in SBP may substantially reduce heart failure (with 20 fewer cases for every 100,000 African-Americans per year), as well as CHD, and stroke incidence.[42]

Any population-wide reduction in LDL-C, even if small in magnitude such as demonstrated in the IPAC study, may also have broader benefits in reducing major CVD events for Aboriginal and Torres Strait Islander peoples. For example, for those already on statins, reducing LDL-C levels by a further 0.51 mmol/l from the LDL-C at baseline over a year, can significantly reduce the residual risk for major CVD events by an additional 15% (on top of the existing 20% relative risk reduction per 1 mmol/L LDL-C reduction from statin therapy).[43] [44]

The progression of kidney disease significantly slowed as a result of the intervention for IPAC participants and this slowing may have delayed the onset of end-stage kidney disease (ESKD) and CVD events if the impact of the intervention was sustained. Moreover, without intervention, IPAC participants were at risk of a much higher rate of eGFR decline per year than the selected expected rate because their characteristics more closely matched those in the eGFR Follow-Up study who had an annual eGFR decline of -5 ml/min/1.73m^2. In an analysis from the USA involving participants from mixed ethnic groups, a decline in eGFR of -5ml/min/1.73m^2 over 2 years predicted a 1.5 and 1.2 times higher risk of ESKD and CVD events respectively.[45] The eGFR Follow-Up study involving Aboriginal Australians showed that those with a slower rate of kidney disease progression (a 5 ml/min/1.73m^2 higher eGFR) had an 18% risk reduction (hazard ratio 95% confidence interval 0.75-0.91) in combined renal endpoints over a median of 3 years (adjusted for aged, sex, and ACR) that included death from renal causes, and initiation of renal replacement therapy.[46]

The net biomedical improvements observed in the IPAC study most likely emanated from the observed targeted improvements to prescribing quality, participant medication adherence, and team-based care. Prescribing quality significantly improved following the IPAC intervention with reductions in inappropriate prescribing for BP lowering and diabetes medications,[47] a significant reduction in underprescribing of BP-lowering medications for those with T2DM and albuminuria,[48] and significant improvements in patient self-reported medication adherence.[49] Integrated pharmacists also delivered team-based care to optimise chronic disease management (such as case conferences) and attended patient group meetings to deliver preventive health messages such as advice on dietary and lifestyle improvements (Appendix 16).

The net absolute reduction in 5-year CVD risk of 1% for participants without pre-existing CVD indicates the clinically significant potential for primary CVD prevention arising from the IPAC intervention.

For further details:

Appendix 9: Couzos S, Smith D, Buttner P, Biros E. Integrated pharmacists in ACCHSs- Analysis of the assessment of clinical endpoints in Aboriginal and Torres Strait Islander patients with chronic disease (IPAC study) Report to the Pharmaceutical Society of Australia. Final Report. April 2020.

Medication Appropriateness Index (MAI) audits

Prescribing quality improved significantly for participants following the integrated pharmacist intervention within ACCHSs. Key results included:

- 357 participants had paired MAI data and were included for analysis (median follow-up of 270 days).

- Participants had CVD, T2DM, CKD, or other chronic disease, 93% were Aboriginal and/or Torres Strait Islander with a mean age of 57 years (SD 14.4). Chronic disease co-morbidity was present in 87.4%.
- A total of 2,804 and 2,963 medications were evaluated at baseline and at the end of the study respectively. At baseline, 67.8% (n=242/357) of participants were prescribed ≥1 medications rated as inappropriate in at least one MAI criterion; 23.1% of all medications had ≥1 inappropriateness rating; the mean MAI score per participant was 6.02 (SD±23.6); and the mean MAI score per medication was 0.76 (SD±8.5). The most common reason for medication inappropriateness was incorrect dosage.
- The intervention significantly reduced mean MAI scores per participant (to 3.20, SD ±11.7, p=0.003); the mean MAI score per individual medication (to 0.39, SD±-4.4, p=0.004); the proportion of participants receiving medications rated as inappropriate (to 44.5% n=159, p<0.001), and the proportion of medications with the following prescribing risks: incorrect dosage, impractical directions, unacceptable therapy duration, drug-disease interactions; and unnecessary medications due to absent clinical indications, or lack of clinical effectiveness (all p <0.05).
- There was a 34.1% relative reduction in the number of participants with medications meeting ≥1 medication overuse criteria. Significant reductions in participant numbers prescribed medications with an inappropriateness rating was observed for: cardiovascular (-19.9% absolute reduction, p<0.001), endocrine (-11.2%, p<0.001), and respiratory conditions (-4.5%, p=0.019).
- Prescribing quality improved for participants with medications for hypertension, diabetes and/or dyslipidaemia (absolute reductions of -5.3%, p=0.01; -9.5%, p<0.001 and -9.8%, p<0.001 respectively).

For further details:

Appendix 10: Couzos, S, Smith D, Buttner P, Biros E. Assessment of medication appropriateness using the Medication Appropriateness Index (MAI) in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community Controlled Health Services (IPAC project). Final Report to the PSA, February 2020.

Assessment of underutilisation

Potential Prescribing Omissions (PPOs) were common in the IPAC cohort. Improvements in prescribing quality arising from pharmacists integrated within ACCHSs significantly averted PPOs to high-value pharmacotherapies. Key results were:

- 353 participants (from the MAI subset) had paired AoU data and were included in analysis (median follow-up of 266 days).
- Participants had CVD, T2DM, CKD, or other chronic disease (87.5% had co-morbidity); 93.2% were Aboriginal and/or Torres Strait Islander with a mean age of 57.2 years (SD±15.4) and a mean of 7.2 (SD±8.0) medications each.
- At baseline, 51.2% (181/353) of participants had at least one PPO from explicit and implicit criteria, totalling 256 PPOs or 0.73 (SD± 1.3) PPOs per participant. The most common PPO of the 10 criteria was for 23vPPV and blood pressure (BP) and/or lipid lowering therapy for those at high primary CVD risk. No chemoprophylactic PPOs for participants with ARF/RHD were identified. Other PPOs included symptomatic therapy for a range of chronic conditions.

- At follow-up (mean 267 days post-baseline), there was a significant (58%, p<0.001) reduction in the number of participants with potential prescription-based medication underutilisation, and a significant relative reduction in the mean number of PPOs per participant (60.3%, p<0.001).
- The PPOs that were averted were for pneumococcal vaccination, BP and/or lipid lowering medication in those clinically at high primary CVD risk, ACEI or ARB for participants with T2DM and albuminuria, and metformin for those with T2DM.

For further details:

Appendix 11: Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilization in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community Controlled Health Services (IPAC project). Report to the Pharmaceutical Society of Australia. Final report. February 2020.

Medication management reviews

Within ACCHS, integrated pharmacists significantly increased access to medication management reviews (HMRs and non-HMRs), and follow-up to these reviews for Aboriginal and Torres Strait Islander adults with chronic disease. Key results were:

- There were 609 (41.8%) HMR, and 719 (49.4%) non-HMR recipients after a mean of 284 days (SD ±11.5) following study enrolment. Some recipients had multiple reviews undertaken throughout the Project.
- HMR recipients had a mean age of 58.7 years (SD ±21.9), a mean of 8 prescribed medications each, and 89% had comorbidity.
- Participants (n=1,456) had a 3.9 times (p<0.001) significant increase in HMR access (based on MBS claims) compared with usual care, whilst the number of HMRs (MBS claims) increased 4.1 times (p<0.001).
- Of non-HMRs, 91% (n=689) were conducted within the ACCHS; whilst the majority of recipients were from remote (19.8%) or very remote ACCHSs (21.4%); and had the non-HMR commonly completed for opportunistic reasons being at risk of forgoing a HMR (48.1%, n=364).
- Pharmacists delivered 1,548 follow-up assessments to HMR or non-HMR- recipients.
- Of HMR recipients, 87.9% (n=535) compared with 70.0% (n=503) of non-HMR recipients had at least one medication-related problem (MRP) (p=0.035).
- Non-HMR eligibility criteria, participant need for a medication review, pharmacist recommendations, and identified types of MRPs in recipients were similar to a HMR.

For further details:

Appendix 12: Couzos S, Smith D, Buttner P, Biros E. Assessment of Home Medicines Review (HMR) and non-HMR in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated support within Aboriginal Community Controlled Health Services (IPAC project). Report to the Pharmaceutical Society of Australia. Final report. February 2020.

Medication adherence and self-reported health status

By the end of the study, integrated pharmacists significantly increased the number of participants' adherent to their medications from baseline. There were significant improvements in participant self-assessed health status during the same period.

- There were 1,103 participants with paired SIQ and NMARS data and 975 participants with paired SF1 data.
- Almost all participants were Aboriginal and/or Torres Strait Islander with a mean age at baseline of 58 (SD 29.8) years.
- Based on SIQ cut-scores, 70.8% (781/1103) of participants were adherent at baseline, 73.3% (808/1103) were adherent according to NMARS (scores 8 to 11), and 18% (175/975) had 'excellent to very good' health status according to SF1.
- There was a 12.8% (142/1103) and 10.3% (114/1103) net absolute increase in the number of participants adherent to medications at the end of the study compared with baseline (p<0.001) using NMARS and SIQ measures respectively.
- There was a 23.9% (233/975) net absolute increase in the number of participants with improved self-assessed health status (p<0.001).

For further details:

Appendix 13: Couzos S, Smith D, Buttner P, Biros E. Assessment of change in medication adherence and self-assessed health status in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community Controlled Health Services (IPAC project). Report to the Pharmaceutical Society of Australia. Final report. May 2020.

Economic analysis

The result of the cost-consequence analysis, comparing the cost of the IPAC intervention with changes in biomedical indices for which statistically significant differences were observed, was $1,493 per participant. This cost was associated with statistically significant improvements in the following biomedical indices for participants with pre and post-intervention measures: glycated haemoglobin (HbA1c) for participants with a clinical diagnosis of T2DM, diastolic blood pressure (DBP), total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), triglycerides (TG), cardiovascular risk 5-year risk (CVD 5-year risk) and estimated glomerular filtration rate (eGFR) (Table 5).

Table 5. Statistically significant improvements in biomedical indices related to cost-consequence analysis.[1]

Variable	Mean difference in biomedical indices mean (SD, 95% CI)	p-value
HbA1c mmol/mol *[% units]* (n=539 in T2DM)	-2.8 (19.5, -4.5 to -1.0) *[-0.3% (3.9%, -0.4% to -0.1%)]*	0.001
DBP, mmHg (n=1045)	-0.8 (9.4, -1.4 to -0.2)	0.008
TC, mmol/L (n=660)	-0.15 (0.77, -0.22 to -0.09)	<0.001
LDL-C mmol/L (n=575)	-0.08 (0.48, -0.13 to -0.03)	0.001
TG mmol/L (n=730)	-0.11 (1.08, -0.20 to -0.01)	0.006
CVD 5-year risk % units (n=38)	-1.0 (2.6, -1.8 to -0.12)	0.027
eGFR (no minimum follow-up time) ml/min/1.73m^2 (n=895)	1.9 (25.7, 0.1 to 3.7)	<0.001
eGFR (6-month follow-up time) ml/min/1.73m^2 (n=895)	-0.2 (36.0, -2.99 to 2.7)	0.034

1. Data pertains to biomedical indices with mean difference that was statistically significant at the 0.05 level, as sourced from clinical endpoint report (Appendix 9) and MSAC Assessment Report.

CVD= cardiovascular disease.

DBP= diastolic blood pressure

eGFR= estimated glomerular filtration rate

HbA1C= glycated haemoglobin

LDL-C= low density lipoprotein cholesterol

TC= total cholesterol

TG= triglycerides

T2DM= type 2 diabetes mellitus

The cost-effectiveness analysis was undertaken for: (i) participants with a clinical diagnosis of T2DM with pre- and post-measures of HbA1c and (ii) participants selected for MAI assessments at baseline and at the end of the study, with potential prescribing omissions used as the relevant outcome measure.[50] For participants with a clinical diagnosis of T2DM, and with pre and post-measures of HbA1c, costs and outcomes for the IPAC intervention compared with no IPAC intervention (the comparator) found the incremental cost effectiveness ratio (ICER) of the IPAC intervention, versus no IPAC intervention was $3,769 ($753,774/200) per participant with a clinically meaningful reduction in HbA1c of at least 0.5%.[51]

For the sample of participants assessed for the underutilisation of medications (AOU), the ICER of the IPAC intervention versus no IPAC intervention was $6,809 per reduction in the number of participants with a potential prescribing omission.

A cost-utility analysis was undertaken for participants with a clinical diagnosis of T2DM, and with pre and post-measures of HbA1c, with changes in HbA1c during the trial period being mapped to lifetime quality of life changes based on the findings of a systematic review.[52] Findings of the systematic review based on multivariable regression indicated a linear relationship of every 1% decrease in HbA1c resulting in a 0.371 (95% CI 0.282-0.456) increase in quality-adjusted life years (QALYs). However, studies did not appear to include a decrease in HbA1c exceeding 3%. To be conservative, participants in the IPAC trial that were recorded to have HbA1c reductions of greater than 3% were assumed to have QALY gains corresponding to a 3% decrease. Percentage reductions in HbA1c refer to the change in measured HbA1c. For example, a change from 9% to 8% reflects a decrease of 1%.
The increase in lifetime QALYs for participants with T2DM were calculated based on the following assumptions:

1. Participants with a decrease in HbA1c of less than 1% were assigned no lifetime QALYs.
2. Participants with a decrease in HbA1c of between 1% and 3% were assigned lifetime QALY gains calculated as 0.371 multiplied by the corresponding decrease.
3. Participants with a decrease in HbA1c of more than 3% were assigned lifetime QALY gains calculated as 0.371 multiplied by 3.

Mapping changes in HbA1c over the trial period to a gain in lifetime QALYs resulted in a projected increase of 101 QALYs (95% CI 78-125) (Table 6).

Table 6 Distribution of lifetime QALY gains by changes in HbA1c for participants with T2DM

Change in HbA1c (%)	No. of participants	Lifetime QALY gains
<1%	401	0
1% to 3%	111	71.27
>3%	27	30.05
Total	**539**	**101.32**

Based on an incremental cost of the IPAC intervention of $753,774 for participants (n=539) with a clinical diagnosis of T2DM , and with pre and post-measures of HbA1c, this suggested an ICER of $7,463 (95% CI $6,030-$9,664) per QALY, assuming no lifetime costs additional to usual care are required to maintain the reduction in HbA1c.

For further details:

IPAC Project: MSAC Assessment Report. June 2020

Qualitative evaluation

Data to inform the qualitative evaluation was collected between June and August 2019, when pharmacists had been integrated within ACCHSs for at least six months. Twenty-four (24) integrated pharmacists provided feedback on their experiences in the role and how well the project was able to be implemented within their ACCHS. The integrated pharmacists represented all health services recruited in the project (n=20). Thirteen general practitioners, 12 managers and 10 community pharmacists responded to the online survey. Three ACCHSs were visited for an in-depth assessment of implementation. One service was located in an urban area, another in a regional area, and one in a remote setting. Seven focus groups or group interviews were conducted with 17 service staff and 17 participants (patients/carers). Individual interviews were held with eight (8) health service staff and three (3) participants (patients/carers). Fieldwork included a day observing the work of the integrated pharmacist (or shadowing) and the service in general at each site, as well as observation of the community context (e.g. a visit to community pharmacies).

The qualitative evaluation of the IPAC study identified many benefits resulting from the project and demonstrated overwhelming support for non-dispensing pharmacist services integrated within the primary health care team of participating IPAC sites and in ACCHSs more broadly.[53] Participants reported numerous benefits with having a pharmacist delivering services within ACCHSs and appreciated their medications being assessed and receiving alternative or different combinations of medications or treatment regimes. Participants reported *'feeling better',* being more involved in decisions about their care, and felt empowered to better manage their health. They better understood their conditions and why they needed to take their medications and how they worked, after receiving education from the pharmacists. Many participants indicated they were more adherent to their medications.

For health services staff, the main benefit with having a pharmacist integrated in their team was access to an *'in-house medicines expert'* who provided support and advice informally through *'corridor conversations'* as well as formally through team based collaboration and medication management reviews. Recommendations made following medication reviews were perceived to be of high quality and prescriber up-take was reported to be high. Education sessions for health services staff were perceived as valuable and staff also benefited

from the pharmacists having input into their clinical team meetings and case conferences. Pharmacists contributed to medicines safety and quality assurance activities by conducting drug utilisation reviews and assisting in reviewing ACCHS medication-related policies.

Benefits from the pharmacists' perspective were the opportunity "*to sit down with the patient"* and *"spend a bit more time"* with them, and being available to see patients opportunistically. Integrated pharmacists developed meaningful relationships with participants and empowered them by developing their health literacy and knowledge about their medicines. The pharmacists' roles were designed to be predominantly patient-centred and the majority of pharmacists enjoyed this aspect of the role. Of the pharmacists asked, all indicated they would continue their employment if their IPAC role was continued as they enjoyed their role and experienced personal and professional satisfaction in the services they were providing.

Community pharmacists reported benefits from the IPAC project that included increased referrals for them to undertake HMRs and improved engagement by participants in HMRs. Community pharmacists felt that participants were more interested in their medicines and that patient knowledge of their medicines and adherence to medicines had improved since the integrated pharmacists had commenced in the ACCHSs. Integrated pharmacists worked together with community pharmacists to problem solve, access discharge summaries, confirm the patient's medication history, undertake medication reconciliation by correcting errors and creating current medication lists, and facilitate provision of dose administration aids for health service patients. Community pharmacists reported that the integrated pharmacist role was very helpful and useful to them and it facilitated communication between the community pharmacy and GPs within the ACCHS. All seven community pharmacists who responded to the question believed that there was a role for an IPAC-type (non-dispensing) integrated pharmacist within ACCHSs.

<u>Enablers and challenges</u>

Various enablers and challenges to implementing the project were identified in the qualitative evaluation. Having a pharmacist with the right *'organizational fit'* and personality was just as important as possessing good clinical skills, while the ability to communicate, collaborate with internal and external stakeholders and practice in a culturally responsive way was essential for effective integration. ACCHSs provided access to clinical information systems, uniforms and consulting room space, as well as assistance with promotion of the pharmacist services, which were reported as enablers to effective service delivery. Aboriginal Health Workers and Practitioners supported pharmacists' integration into the services and the local community. Referrals from GPs enabled pharmacists to consult with patients and undertake recruitment for the project.

Service readiness for the project was a challenge for some ACCHSs. Whilst some services were well prepared for the pharmacist and understood the nature of the role and its potential value, staff in other services needed time to further understand the role and learn how to best utilise the pharmacists' expertise. Initially this impacted upon the rate of referrals and recruitment. The majority of the pharmacists felt accepted and well-integrated within the PHC team at the time of their interview (after approximately six months of practice in their service). Other challenges reported included the irregular attendance of participants, those with chronic diseases being overwhelmed with appointments, transience, language barriers and 'sorry business'. Other project-related challenges were the complexity of the participant consent process and the need for written consent from the patient. This was particularly challenging where participants had low health literacy or where English was not their first language. Another challenge within the project was the time it took for pharmacists to enter research data for the quantitative analysis.

For further details:

Appendix 14: Preston R, Smith D, Drovandi A, Morris L, Page P, Swain L, Couzos S. Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHSs) to improve Chronic Disease Management (IPAC) Project: Qualitative Evaluation Report to the PSA. Final report. February 2020

Health systems assessment

There was little change in health systems within participating sites from baseline to the end of the study that might otherwise explain improvements (such as from non-IPAC related service activity). Moreover, the health system changes that were observed were most likely explained by improvements generated by integrated pharmacist activity. For example, ACCHSs had more accessible on-site pharmacists at the end of the trial than at baseline, which is explained by integrated pharmacists working within sites. By the end of the trial, six services received community pharmacy support for educational sessions, but no services reported this activity at baseline. The local community pharmacy employed the integrated pharmacists in five of these six services which likely explains this increased activity. The remaining service reported increased collaborative activity with community pharmacy as a result of the project. Other perceptions of community pharmacy support to ACCHSs did not change during the study.

For further details:

Appendix 10: Couzos, S, Smith D, Buttner P, Biros E. Assessment of medication appropriateness using the Medication Appropriateness Index (MAI) in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community Controlled Health Services (IPAC project). Final Report to the PSA, February 2020.

Discussion

Analysis of participant data and integrated pharmacist activities collected through the IPAC project demonstrated that integrated pharmacists significantly improved a range of intermediate clinical outcomes for adult Aboriginal and Torres Strait Islander participants with chronic disease attending ACCHSs. Participants had significantly improved control of CVD risk factors, glycaemic control in participants with T2DM, and reduced absolute CVD risk. Moreover, the observed net improvements in biomedical outcomes are clinically meaningful at a population level. A nearly four-fold increase in HMRs indicates that pharmacists integrated within ACCHSs are well placed to deliver medication management reviews to participants who experience substantial barriers in accessing HMRs under current program rules, especially for participants who would otherwise forgo a medication review. Prescribing quality improved significantly for participants following assessments of medication appropriateness and underutilisation. Medication adherence and self-assessed health status improved significantly indicating that integrated pharmacists can help to overcome some of the many difficulties this population faces with taking medications.

Economic analysis has revealed that the total cost of implementing the IPAC intervention was $1,493 per participant in order to achieve all outcomes for participants including statistically significant improvements in biomedical measures mentioned above. The IPAC intervention represented good value for money. Included in this cost of implementing the IPAC intervention, participants, health service staff and internal and external stakeholders also received numerous other benefits from the pharmacists' provision of education and training, medicines information and advice, and contribution to chronic disease care through case conferences, care planning, and other team-based activity. Integrated pharmacists were well placed to minimize medication errors whilst facilitating transitions of care. Stakeholder liaison plans were developed and implemented, and integrated pharmacists were the key point of contact for communication and contact with community pharmacies and other stakeholders. Communication and collaboration were important functions for integrated pharmacists. As the project progressed and the pharmacists' capabilities were recognised, professional relationships grew and trust developed. Pharmacists became integrated and respected members of primary health care teams and the services more broadly.

Qualitative evaluation of the IPAC project facilitated feedback from participants, GPs, other health services staff, community pharmacists, and the integrated pharmacists themselves and provides context around the core roles and their the impact.[54] Health services staff identified that the pharmacists built and maintained relationships and integrated with the primary health care team and more broadly within ACCHSs. Education sessions and medicines information provided by the pharmacist was found valuable and knowledge levels of staff had increased as a result. ACCHS staff felt communication and services from external stakeholders had been enhanced by integrating a pharmacist into the ACCHS, such as relationships with community pharmacists. Benefits for patients from interactions with the pharmacists resulted in them feeling better. Patients reported being more adherent to taking their medicines as a result of having a better understanding of their conditions, including what their medicines were for, how they worked, and why they needed to take them, which was explained to them by the integrated pharmacist. The significant improvement in participant self-assessed health status supports the overall improvements in health status reported by participants themselves in qualitative analysis.

The qualitative evaluation of the IPAC project demonstrated there was overwhelming support from the vast majority of participants including patients, health services staff, community pharmacists and the integrated pharmacists, for non-dispensing pharmacist services to be integrated within the PHC team of participating IPAC sites and in ACCHSs more broadly.

While the IPAC project did not monitor utilisation of health care and other services beyond its focus on primary medical services (including medications), the improvement in biomedical indices is expected to be associated with a reduction in the utilisation and corresponding costs of other government funded health services including emergency department presentations and hospital admissions. For example, preliminary analysis of the outcomes of the Western Sydney integrated care program targeting patients with chronic disease, including people with type 2 diabetes, chronic obstructive pulmonary disease and coronary artery disease or congestive cardiac failure found statistically significant reductions as follows: 34% in the number of hospital admissions, 37% in potentially preventable hospitalisations; 32% in emergency department presentations; and 25% in unplanned admission length of stay.[55] The IPAC model shares the main objective of integrated care programs, namely to improve overall care for patients and achieve a better coordinated journey. An umbrella review of systematic reviews of integrated care programs found that more than half of reviews found a statistically significant improvement in at least one outcome measure, with improvements of the following order of magnitude: reductions in emergency admissions, 15-50%; all-cause readmissions, 10-30%; condition-specific readmissions, 15-50%; reported length of stay of 1 to 7 days; and lower emergency department presentations, 30-40%.[56]

Pharmacists are increasingly becoming integrated into general practices internationally and in Australia.[57] [58] There is evidence that the delivery of multifaceted interventions and interprofessional collaboration through face-to-face communication is most effective.[59] [60] A recent study undertaken in Australia found the role of practice pharmacists (defined as those integrated within mainstream general practices), included undertaking HMRs and medication reconciliation, providing medicines information, patient counselling, monitoring medication adherence, and providing advice on complementary and alternative medicines. In addition, education for staff and patients was provided, as well as medication use evaluations (internal audits of prescribing patterns of specific medications), support for clinical audits and the transition of patients from hospital back into the community, and for a small number of sites, the supply of medication in remote Aboriginal Health services.[61] The study found that medication reviews by the practice pharmacists were highly valued and led to better outcomes in relation to addressing inappropriate prescribing and patient adherence. The Indigenous Medication Review Service (IMeRSe) study currently being conducted in Australia also recognises the value of medication reviews and aims to evaluate the feasibility of a culturally appropriate medication management service delivered by community pharmacists in collaboration with Aboriginal health workers.[62]

Benson et al describes seven GP pharmacist role sub-categories including medication management, patient examination and screening, chronic disease management, drug information and education, collaboration and liaison, audit and quality assurance and research.[63] Other studies have also reported that pharmacists in general practices conduct a variety of clinical and non-clinical roles related to medicines, notably excluding dispensing.[64] [65] In comparison to the seven roles described by Benson et al,[66] in the IPAC project, medication adherence was identified as a distinct function or core role of the integrated pharmacist so that integrated pharmacists could assess adherence to medications and support all patients they were encountering whilst focusing on a comprehensive medication management review (like a HMR) for those that needed it most. The activity of transitional care was also identified to be a different function to stakeholder liaison which was defined in the IPAC project as pertaining to communication and partnerships with community pharmacy as well as other stakeholders.

The generalizability of the 10 core IPAC roles for integrated pharmacists in Australian settings is further corroborated by other and emerging studies. The Integrating Models of Pharmacists across Care Teams (IMPACT) Framework identifies six domains to guide PHC services in readiness for the integration of pharmacists.[67] The six domains identify enabling factors and include the characteristics, skills and experience of the pharmacist; relationships; scopes of practice; connectivity; localisation; and sustainability. The

framework's domains have similarities with the protocol for the IPAC project.[68] Medication management reviews (i.e. HMRs and non-HMRs), medicines information and education; liaison with stakeholders; and drug audits are also common features of integrated pharmacist roles in other Australian studies undertaken predominantly in mainstream settings. [69,70,71] As observed in the IPAC project, the services provided by integrated pharmacists were also highly valued by health service staff, external stakeholders and also patients in these other Australian studies. The IPAC project provided evidence that the implementation of similar non-dispensing pharmacy services were well received and valuable for Aboriginal peoples and Torres Strait Islanders attending ACCHSs in urban, regional and remote settings.[72] This evidence supports the generalisability of implementation of the integrated pharmacist core roles more broadly, and future expansion of non-dispensing pharmacists working in Aboriginal primary health care settings. While the scope of practice of an integrated pharmacist working in these settings may have similarities to the general practice pharmacist, the roles have unique features such as working in ways that are culturally acceptable and consistent with a holistic model of care.

An international pilot study of pharmacists working within general practices recommended that pharmacists be employed at least 2 days a week, with a preference for 3 days or more, to assist with successful integration[73]. A minimum FTE allocation was suggested acknowledging smaller practices may take a longer time to realise the benefits of a pharmacist within a general practice. Given that seven of the ACCHSs participating in the IPAC project had a pharmacist allocation of 0.4 FTE or less, a 15-month timeframe may not have allowed sufficient time to demonstrate the full benefit that can be achieved by having an integrated pharmacist as part of the team. This suggests that the statistically significant and clinically meaningful clinical endpoint and other quality outcomes improvements reported from the IPAC trial may underestimate these benefits to the target population. Ultimately, the acceptability and effectiveness of this model and the delivery of the key activities was supported empirically by extremely low patient attrition, low site attrition, positive findings in the qualitative evaluation, feedback provided to the PSA project coordinators[74], and feedback from the participating services through the PRG and from Affiliates.

The recommendation for the broader expansion of integrated pharmacists within ACCHSs arising from this evaluation has an existing policy context. In principle, the Pharmacy Guild of Australia (PGA) supports the non-dispensing role of pharmacists in general practice however have emphasized that communication with community pharmacy is critical to the role. In particular the relationship between community pharmacies and GPs, and that between patients, community pharmacies and GPs must be maintained and strengthened.[75] Evaluation findings from the IPAC trial support the PGA as findings clearly demonstrated the strengthened relationship between community pharmacies and ACCHSs arising from integrated pharmacist roles. Community pharmacists involved in the qualitative evaluation affirmed that relationships between ACCHSs and community pharmacies were further strengthened as a result of the IPAC project, referrals for HMRs had increased and there was improved participation by patients in HMRs. They felt that patients were more interested in their medicines and that patient knowledge of their medicines and adherence had improved since the integrated pharmacists had commenced in the ACCHSs. Integrated pharmacists worked together with community pharmacists to problem solve, access discharge summaries, confirm the patient's medication history, undertake medication reconciliation by correcting errors and medication lists, and facilitate provision of dose administration aids for health service patients. Community pharmacists concluded that the integrated pharmacist role was very helpful and useful to them and it facilitated communication between the community pharmacy and GPs. Integrated pharmacists were found to have interacted with community pharmacists on a daily basis with more occasions logged for such interactions than any other IPAC activity undertaken by integrated pharmacists.[76]

Several leading Australian leading bodies including the PGA, RACGP, AMA support pharmacists in general practices.[77] [78] [79] The PSA promotes pharmacists working in Aboriginal settings[80] [81] and in 2017 the Federal

Health Minister committed to supporting a trial of integrated pharmacists into Aboriginal Health Services that led to the IPAC trial.[82] Whilst eligible Aboriginal and Torres Strait Islanders living with or at risk of chronic disease can access free or low cost medicines through the Section 100 Remote Area Aboriginal Health Services program and Closing the Gap PBS Co-payment measure,[83] support from an integrated pharmacist can complement such schemes and go further to address a multitude of barriers to the quality use of medicines experienced by Aboriginal and Torres Strait Islanders. The IPAC trial has demonstrated significant positive impacts of pharmacists being integrated into primary health care teams of ACCHSs on health services staff and internal and external stakeholders.

Ultimately, funding mechanisms may drive the employment structure of pharmacists and the integration model to provide services to ACCHS. Underpinning any program rules for the expansion of integrated pharmacists is the acknowledgement of the needs and preferences of individual ACCHSs and their representative bodies to guide the integration model. ACCHSs are founded on the principle of 'Aboriginal Health in Aboriginal Hands'.[84] Upholding the principle of self-determination is necessary to enable a culturally acceptable mode of delivering effective and sustainable primary health care services to Aboriginal peoples and Torres Strait Islanders. Having a pharmacist with the right *'organizational fit'* and personality was just as important as their skills and experience according to qualitative evaluation findings from the IPAC trial. ACCHS staff made the ultimate decision on pharmacist selection for their service and it was acknowledged that some participating services had a preference for a particular employment model, highlighting the necessity for this consideration in future programs.

Based on the experiences in the IPAC trial, this evaluation recommends that future programs should consider adapting the support activities, resources and tools developed from the IPAC trial, which contributed to its effective execution. The NACCHO in collaboration with its Affiliates demonstrated that they are well placed to support ACCHSs to introduce the integrated pharmacist role within their services. This is evidenced by low site and participant attrition and positive ACCHS feedback in qualitative evaluation. While service readiness for the role was a challenge for some ACCHSs as they'd had little or no experience with non-dispensing pharmacists prior to the project, this was ultimately not a barrier as NACCHO supported ACCHSs to understand the nature of the role and its potential value. Ongoing support was also provided by Affiliates who worked closely with ACCHSs within their jurisdictions. In addition to direct NACCHO facilitated ongoing communication through a peer support network and support from project staff. The PSA have developed processes for recruitment of pharmacists interested in working in ACCHSs and developed/sourced resources for training pharmacists to prepare for working in Aboriginal health settings and to upskill them in topics relevant to a non-dispensing clinical role and medication management for those with chronic diseases. Furthermore the PSA developed a comprehensive and multimodal program of support for pharmacists integrated within ACCHSs, acknowledging that placing pharmacists into ACCHSs without adequate support may limit the uptake and effectiveness of this service. JCU have developed or sourced numerous tools to evaluate the IPAC project which can be used or adapted to monitor the implementation and progress of future programs. The electronic logbook was a research tool that effectively collected data for the project from participating pharmacists in one central database. The ongoing monitoring and assessment of a broader integrated pharmacist roll-out within ACCHSs may utilize this type of tool to ensure that the program is meeting its stated objectives, identify any issues affecting implementation, and address these in a timely manner. However, administration time for data entry or reporting, should be included in roles, if required.

A fundamental premise of the pragmatic, community-based and participatory IPAC trial was that the IPAC intervention would be generalisable to all ACCHSs. The IPAC trial has delivered significant benefits to the 18 participating ACCHSs and it is proposed that this model be extended to all ACCHSs across Australia. A model outlining anticipated costs for 140 ACCHSs across Australia based on the integrated model of care for pharmacists investigated in the IPAC Trial is presented in the MSAC Assessment Report – Section E. The

program cost incorporates pharmacist training and salary, support for ACCHSs and pharmacists to ensure successful expansion of the intervention, and ongoing program monitoring and evaluation. The cost per annum for five years is estimated to be $13,846,142 for the first year reducing to approximately $13 million per year for the following years, is comparable with other federally funded Aboriginal and Torres Strait Islander medicines initiatives and will help to close the gap in Aboriginal and Torres Strait Islander underutilization of nation-wide Australian pharmaceutical measures, such as the PBS and other Community Pharmacy Agreement related programs. Furthermore, this is a timely and impactful intervention to improve medication use for this under-served population, considering the Health Minister's national prioritization of medicines safety.[85]

Any challenges related to implementation of the IPAC trial were not insurmountable, and considering the overwhelming support for the integrated pharmacist role, successful implementation of the trial in urban, regional and remote settings, the very low patient withdrawal rate and low site attrition observed, the trial demonstrates the feasibility of expansion in Aboriginal health service settings across Australia.

Highlights

Support for the integrated pharmacist role

The key highlight from the trial was the overwhelming support from nearly every participant involved in the qualitative evaluation of the trial for integrated pharmacist roles to continue, and for further expansion into other Aboriginal health services. The majority of participants in the qualitative evaluation strongly supported the intervention and it's continuation, which was corroborated by feedback received by the NACCHO project coordinators (Appendix 22) and unsolicited comments received by PSA project coordinators (Appendix 18). Upon hearing the integrated pharmacist trial was concluding one patient stated: *"you get a program and it works and bugger me dead if they don't pull the plug on it."* (focus group, case study 2, Appendix 14)

Patients reported numerous benefits from their interactions with the integrated pharmacists. The majority of patients reported that the integrated pharmacist had been able to look at their medications and suggest alternative or different combinations of medications, or regimes that resulted in them *'feeling better'*. Integrated pharmacists took a holistic approach to patient care, listened to patients and better understood their lives. Some patients reported being more involved in decisions about their care with the support they received from the pharmacists. Pharmacists sometimes sat in on consultations with the patient and their GP. Patients felt they were empowered to better manage their health conditions through better understanding their condition, why they needed to take their medications and how these medications worked. Many patients indicated they were more adherent to their medications. In addition to feeling better, patients also reported other benefits as a result of medication changes such as losing weight, being motivated to do more exercise and engaging with other support groups in the community.

The integrated pharmacists and other health services staff concurred that patients' management of the health conditions (and adherence to medications) had improved, as had their biomedical test results, particularly the HbA1c level. This matched the findings of the analysis of patients' biomedical data where a range of intermediate clinical outcomes for adult Aboriginal and Torres Strait Islander participants with chronic disease had improved. Participants had significantly improved control of CVD risk factors, glycaemic control in participants with T2DM, and reduced absolute CVD risk. One patient explained how the integrated pharmacist had helped them improve their glycaemic control:

> *"Before I was on different medications that was just not working at all. And then she [IPAC pharmacist] recommended some medications and I've recently just started the insulin and it's already been life changing. I've gone from having continuous hypers to normal sugar levels for once in my life and*

everything is just starting to go back on track for me since she's been here, so it's been absolutely helpful.

"She's basically explained everything to me. She will even show me diagrams and she will print out the information and highlight everything, circle what I need to know and any questions that I have she'll answer them spot on, and she explains it so damn well, that I am just like 'Oh wow, I did not know this before'. And the insulin that I was first put on I was actually allergic to and I did not know that because I was injecting myself and I would get, it was burning sensations, severe bruising and like my stomach would go purple and whatnot and she's like 'you're allergic to it'. I'm like 'oh am I?'. She's like 'yes, we need to start you on something else.' So she's helped me so much with changing the medications and adjusting their units to what it needs to be. And I've gone from having high sugar levels from like 30 to 29 every single day, down to ten to eight … It's brilliant." (patient, focus group, case study 3, Appendix 14)

Health services staff benefited from having access to an *'in-house medicines expert'*. Integrated pharmacists provided support and advice to health services staff informally such as through *'corridor conversations'* as well as formally through team based collaborations and medication management reviews. Both the integrated pharmacists and GPs reported that recommendations were commonly made by the integrated pharmacists following medication reviews that were perceived to be of high quality with reportedly high prescriber up-take of the recommendations. Provision of education sessions for health services staff, including GPs, nurses and Aboriginal Health Workers and Practitioners were perceived as valuable, as was pharmacists input into their clinical team meetings and case conferences. GPs reported having the integrated pharmacist as part of the PHC team saved them time as medication queries were answered quickly, and they could refer patients to the pharmacist for education about their clinical conditions where it was thought the pharmacists could better explain to the patient how their medications worked. Time was also saved for some GPs as they could make referrals for medication reviews to the integrated pharmacist.

One general practitioner commented:

"As a locum, I feel this service has improved safety for patients around medication management, compliance, and avoidance of medication errors. I feel quite supported in my clinical work with this team holistic approach. [integrated pharmacist] is an awesome resource with tricky pharmacological queries and medication interaction[s] particularly in an AMS service with so much chronic disease, where patients are on multiple medications, with much potential for interactions. In addition, [integrated pharmacist] has been able to spend time with the patients fully explaining their medication, and reasons for this, this improves compliance, and clients do seem more interested in the reasons they are taking medications. It saves the doctor so much time too. I really hope this service will continue in the future." (general practitioner, testimonial 10, Appendix 18)

The pharmacists also contributed to medicines safety and quality assurance activities by conducting drug utilisation reviews and assisting in reviewing ACCHS medication-related policies.

Community pharmacists reported the integrated IPAC pharmacist role was very helpful and useful to them and it facilitated communication between the community pharmacy and GPs. Participating community pharmacists believed that there was a role for an IPAC-type (non-dispensing) pharmacists within ACCHSs.

Support from ACCHSs

ACCHSs supported the integrated pharmacists by allowing them to access their clinical information systems, which enabled the pharmacist to conduct clinical assessments of patients and medication reviews using comprehensive patient information about medications history, disease conditions, pathology results and

other information regarding the patient's social history. Integrated pharmacists documented their recommendations and interactions with the patient into the CIS which enabled their integration into the primary health care team.

Most integrated pharmacists had a 'go-to person' or project champion within their ACCHS who assisted with their integration. Support from GPs and Aboriginal Health Workers were enablers to the integration of the IPAC pharmacist and the referral of patients. ACCHSs also supported the integrated pharmacists through provision of a uniform if available and space with a consulting room, as well as assisting the pharmacist to promote their services.

Financial in-kind contributions

ACCHSs and sub-contracted community pharmacies strongly supported the trial and some were prepared, where required, to contribute their own funds to support the work of the integrated pharmacist. Costs covered included travel to and from the IPAC site; local travel (air and land) within the IPAC site service area; accommodation; resources and equipment such as computers; other staff members' time (salary), to work with the pharmacist; and other expenses.

These financial in-kind contributions were tracked, collected through the health system assessment and incorporated into the economic analysis of the trial.

Working with community pharmacy

The health systems assessment of participating ACCHSs found that many already had strong relationships with their local community pharmacies at the commencement of the project, particularly through the Section 100 arrangements for remote-area Aboriginal Health Services and the Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) program. Relationships between ACCHSs and community pharmacies were further strengthened as a result of the IPAC project.

While there are documented concerns that general practice pharmacists may reduce the supply of dispensing pharmacists in regional and remote areas,[86] the experience within the IPAC Project suggests this is not necessarily the case. The project identified a cohort of pharmacists who were seeking alternate career pathways and willing to relocate to regional and remote locations for these positions. Therefore rather than perceiving these roles as a drain on stretched staffing models, opportunities could be created for more pharmacists to be employed within discrete geographical locations, thereby increasing opportunities for professional support, collaboration and additional workforce capacity to staff community pharmacies 'after hours' on evenings and weekends. Some of the pharmacists who worked full time hours within the IPAC project elected to work additional hours within community pharmacies where they were located. In multiple locations, community pharmacies that did not have capacity to provide pharmacists to undertake the roles advised PSA project coordinators that they could offer hours of employment to supplement the integrated pharmacist's role. Where integrated pharmacists worked part-time in the IPAC project, the remaining time could be used to support community pharmacy.

Community pharmacists reported many benefits from working with the integrated pharmacist and commented that the role was very helpful and useful to them. All participating community pharmacists felt there was a role for an IPAC-type (non-dispensing) integrated pharmacist within ACCHSs.

Proportion of patient-level activities

A core requirement from the funding body was that integrated pharmacists spend 75% of their time directed towards patient-level activities (defined in the funding agreement as medication management reviews and assessments of adherence and appropriateness).[87] Patient-level activities in this project comprised 62.5% of activities recorded including medication reviews and assessments, but also included direct service delivery to patients through education and preventive health care, and team-based collaborations identified as being patient-related as defined in the Logic Model for Evaluation (Appendix 4). This approximates the expected division of pharmacist roles, especially given that significant underreporting of actual patient-related activity occurred as consequence of project requirements for data collection. For example, patient education and team-based collaboration activities (such as case conferences) although categorised for the purpose of the evaluation as practice-based activities, were critical to direct patient care as well as to the practice. Furthermore, transitional care occasions and a proportion of contacts with community pharmacy were also expected to have been related to the care of individual patients. However, the categorisation of this activity as purely practice-based also underestimated the proportion of time that pharmacists spent delivering patient-based care. In addition, time taken for patient-based activities may have been underestimated as the time able to be recorded in the logbook for these activities was limited to 180 minutes. In all, the activities undertaken by integrated pharmacists during the IPAC project closely approximated the division of core roles that were expected by the funding body.

It is important to note that whilst the project protocol defined 10 core roles for pharmacists which formed the foundation for the project and the evaluation, in line with community-based participatory research principles, each participating ACCHS also had the flexibility to utilise the services of the pharmacist according to service and client priorities at the local level.

Involvement of Aboriginal people and Torres Strait Islanders

The project adopted a community-based participatory research (CBPR) design, to ensure clear benefits to project sites and ensure acceptability and sustainability of the intervention within ACCHSs and ultimately, transferability to other PHC services. The CBPR model 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*".[88]

Aboriginal people and Torres Strait Islanders and their representative bodies were involved throughout the design, establishment, implementation and analysis stages of the IPAC Project. The project protocol was developed through input from project partners including the NACCHO who were a key partner in the project and provided Aboriginal governance, leadership, and coordinated communication with the NACCHO Board, Affiliates and ACCHSs.

The NACCHO project coordinators facilitated a Project Reference Group (PRG), which was the primary governance body representing participating Aboriginal and Torres Strait Islander organisations, leaders and patients. The PRG comprised representatives from NACCHO, the Affiliates, representatives from all participating ACCHSs, and the project coordinators. The PRG provided oversight and feedback to the project operation team. PRG teleconferences were held approximately three-monthly; forums were convened at the 2018 and 2019 NACCHO national conferences; electronic updates were circulated; and numerous instances of ad hoc communication occurred between NACCHO project coordinators and PRG members via phone or email.

The evaluation team led by JCU, comprised project partners, researchers, expert advisors, Aboriginal Academics and representatives from the 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 Northern Territory (AMSANT), and a representative from an ACCHS.

An example of a change grounded in community-based participatory research principles was the simplification of the four-page Patient Information Brief. Following the commencement of the integrated pharmacists, feedback was provided that ACCHS staff felt the 4-page brief was too long and needed to be simplified so that patients could better understand it. The JCU Team acted upon this feedback and simplified the document, reducing its length to 2-pages. The edited document was approved by the HRECs. In addition, tools and questionnaires developed for collecting quantitative and qualitative data for the IPAC project were reviewed by members of the operational and evaluation teams. The interview and focus group proformas for patient participants and ACCHS staff as part of the qualitative evaluation were also distributed to PRG members to ensure they were appropriate for research with Aboriginal patients and staff. PRG members provided comments and endorsed these tools.

For the qualitative evaluation the JCU Team liaised with ACCHS site staff (after introduction from the NACCHO project coordinators) and the integrated pharmacists to plan and conduct the site visits. Staff advised on the timing of the visits, recruitment of participants and scheduling of activities to minimise disruption to the health service. Through the site visits, Aboriginal and Torres Strait Islander staff and participants have provided feedback on the project and interactions with the integrated pharmacist.

All reports were sent to members of the operational and evaluation teams for feedback. A plain language summary of the results from the trial will be available to participants, with the permission of the funding body.

Difficulties

ACCHS challenges

In the initial project stages, ACCHS staff experienced some confusion regarding who would manage the integrated pharmacists, as they were not their employees. This issue was largely overcome by regular communication between ACCHS representatives and project coordinators from NACCHO and PSA. For a broader program roll-out pharmacist recruitment to integrated roles within ACCHSs will be influenced by the financing models. The employment of pharmacists by the PSA (which was the dominant model used in the IPAC trial) will not be applicable for future program expansion.

The qualitative evaluation found staff turnover was a challenge faced by ACCHSs, and consequently the integrated pharmacists. NACCHO project coordinators were dedicated to supporting the continuity of the project in services and assisted to inform new ACCHS staff about the project and the role. A PRG was established to facilitate communication with participating ACCHSs at key times in the project (at the request of members, rather than regularly) through information updates by email and meetings of project participants at conferences. Participation by ACCHS staff in PRG meetings was infrequent, although there were no specific criticisms of the meeting format or methods.

Pharmacist service delivery

Community pharmacy challenges

Some challenges were experienced by community pharmacy in delivering their subcontracted hours due to competing interests in ensuring community pharmacies remained adequately staffed including at times of ill health. In recognition of the need for pharmacists to build rapport and trust with ACCHS patients and to integrate effectively into the primary health care team, the subcontracts specified participation by individual pharmacists rather than a service that could be delivered by any pharmacist employed within the community pharmacy. This restricted the community pharmacy from covering times of pharmacist absence with another staff member. Some of the participating pharmacists were long term employees of community pharmacy, and as such backfilling these staff members with replacement staff required additional effort from the community pharmacy owner to maintain their core operation. Despite these challenges, community pharmacy participants were able to deliver 89% of their contracted hours, demonstrating their ongoing commitment to the project. Community pharmacies who have well developed and respectful relationships with ACCHSs are well placed to identify pharmacists to perform integrated roles.

Remoteness

To accommodate challenges involved in delivering part time roles in remote locations in the IPAC Project, blocks of activity were conducted in six ACCHSs. At one ACCHS, a pharmacist appointed to a 0.4 FTE position delivered a 2-week block of activity at regular intervals, rather than 2 days per week, while in another setting the pharmacist spent 2 week blocks at one of the clinics that involved charter flights for access. Based upon this experience, blocks of activity should be considered in future programs as an appropriate method of delivering integrated pharmacist services to ensure that smaller and more remote ACCHS are not excluded. Another challenge due to the location of a few ACCHSs was road conditions and difficulty travelling to clinic sites during the wet season.

Salary

Pharmacist salary for the IPAC project was budgeted at $50 per hour based on the study design and project budget. For some pharmacists this rate was an increase on what they had been receiving prior to IPAC, while for others the rate was lower than the pay rate in their role immediately prior to IPAC. Hourly rates for employment within community pharmacy vary significantly depending on the market forces in place for specific roles and geographic areas, while salary rates within public health systems can influence pay conditions within ACCHSs in the same jurisdictions. For example, comparative rates within the NT public hospital system NT at the time of the project were $45 - $59/hour with 6 weeks' annual leave provisions[89]. These comparative rates highlight that participating pharmacists were committed to supporting the project's aims and objectives and was primary motivation for participating in IPAC, rather than seeking high levels of remuneration.

Patient population size and remoteness are factors that also need to be considered with pharmacist FTE allocation and salary. Studies have demonstrated that health costs increase with decreasing population size.[90] For this reason, the proposed methodology for future expansion of the IPAC model provides a baseline 0.2FTE for all ACCHSs, regardless of their size, before allowing for the estimated patient population. The Workforce Incentive Program (WIP) Practice Scheme incorporates rural loadings of between 20-50% to incentive payments to practices located in MMM 3-7, with the greater loading skewed to more remote locations.[91] In the IPAC Project, integrated pharmacists were supported in some remote ACCHSs with

additional funding sourced from the project budget, ACCHSs in-kind support, and community pharmacy contributions towards travel, housing and allowances.

Scope of practice

Pharmacists' ability to work to their full scope of practice within an ACCHS can be limited by legislative barriers at a State or Territory level. An example of these legislative barriers identified through the IPAC project included pharmacists in the Northern Territory being able to provide an immunisation service when working within the community pharmacy, however they were unable to immunise when working as a pharmacist (employed by the community pharmacy) within the ACCHS. Ongoing efforts need to be undertaken by peak bodies such as PSA, to identify and advocate for changes to legislation to enable pharmacists to work to their full scope of practice within an ACCHS.

Role implementation challenges

Practical challenges to integrating a pharmacist within the PHC team were identified through the qualitative evaluation. Prior to the IPAC project there were few pharmacists working in general practices or ACCHSs nationally, and there was very little understanding of the role of an integrated pharmacist in the primary health care practice setting. At commencement, an initial lack of understanding of the integrated pharmacist role led to some pharmacists being underutilised, with referrals to the pharmacists from other ACCHS health professionals being low.

A few ACCHSs in the project had worked closely with pharmacists providing HMRs for their patients, and staff at these services had a slightly better understanding of the value a pharmacist could add to patient care. However, service readiness for the project was a challenge for some services. All ACCHSs received support and a site visit by NACCHO project coordinators as part of the recruitment process. Some services were well prepared for the pharmacist and understood the nature of the role and its potential value. However, staff in other services needed time to fully understand the role and learn how to utilise the pharmacists' expertise. More discussion and education with ACCHS staff may have assisted with preparation of services before the pharmacist commenced. It is expected that over time, with increased awareness of what the role can achieve, the need for this education and support will diminish.

Some services needed to develop policies and procedures in order to guide ACCHS medicine-related activity so that the integrated pharmacist could assist with these activities and establish their role within the service. This was burdensome for some ACCHSs. In addition, the need for pharmacist induction into the service, the reality of staff turnover, and other service priorities were challenges.

At the time of their qualitative interview (after approximately six months of practice in their service) the majority of the integrated pharmacists felt accepted and well-integrated within the PHC team. The provision of education to staff on how an integrated pharmacist could contribute to the PHC team and their ability to improve health outcomes for participants' facilitated better understanding of their role, developed relationships, and helped the pharmacist to integrate into the team. Over time, these factors contributed to more patients being referred to the pharmacist.

Many of the pharmacists and health services staff reported that the irregular attendance of participants at ACCHSs presented challenges. When participants did present, this often resulted in them being seen by many health professionals within the one visit in order to deliver opportunistic care. Participants with chronic disease, especially those with kidney disease also had many appointments with clinical staff and were often overwhelmed, meaning they may not have wanted to spend additional time for a pharmacist consultation. Other issues that presented challenges for the pharmacists to organise follow-up appointments with

participants included transience, difficulty contacting patients, language barriers and 'sorry business'. Several integrated pharmacists commented that participants often visited their homelands or family, meaning they were not readily available for follow up.

Research-related challenges

The NACCHO reported that a few ACCHSs expressed concern about data extraction processes. Other research-related challenges included the complexity of the participant consent process and the need for written consent from the patient which was an issue where patients had low health literacy or where English was not their first language. Some pharmacists reported entering research data for the quantitative analysis was quite time-consuming.

Generally, ACCHSs were accepting that research projects have inherent additional requirements beyond a health care program or intervention, and ACCHSs and the integrated pharmacists were accommodating of these challenges. In an expansion of the integrated pharmacist role more broadly research challenges would be eliminated, with reporting limited to the monitoring requirements of the funding body.

The majority of participants in the qualitative evaluation strongly supported the intervention and its continuation, which was corroborated by feedback received by the NACCHO and PSA project coordinators. Upon hearing the integrated pharmacist trial was concluding one patient stated: *"you get a program and it works and bugger me dead if they don't pull the plug on it."* (focus group, case study 2, Appendix 14). Research projects such as the IPAC trial which are considered by participating ACCHSs and patients to be acceptable, culturally safe and effective, but which are completed without ongoing funding to maintain the new service throughout analysis and evaluation phase, contribute to the existing research fatigue reported by Aboriginal people and Torres Strait Islanders.[92] Future trials involving Aboriginal people and Torres Strait Islanders should consider inclusion of a contingency for continuance of successful services and programs.

Conclusion and recommendations

The IPAC trial provided evidence that integrated pharmacists in ACCHSs significantly improved quality of care outcomes for adult Aboriginal and Torres Strait Islander patients with chronic disease through the provision of superior quality of care when compared to pre-intervention. The trial demonstrated that appropriate funding for integrated pharmacist services within ACCHSs leads to superior health service utilisation (towards equity) compared to utilisation pre-intervention. This report has summarized the outcomes of the IPAC trial and clearly demonstrates that both clinical claims were achieved.

Analysis of participant data and integrated pharmacist activities collected through the IPAC trial demonstrated that integrated pharmacists significantly improved a range of intermediate clinical outcomes for adult Aboriginal and Torres Strait Islander participants with chronic disease. Significant improvements in the control of CVD risk factors, glycaemic control in participants with T2DM, and reduced absolute CVD risk were observed in participants attending ACCHSs. Medication adherence and self-assessed health status improved significantly indicating that integrated pharmacists can help to overcome the barriers Aboriginal patients face with taking medications.

Prescribing quality improved significantly for participants following assessments of medication appropriateness and underutilisation, in particular for participants taking medications for hypertension, diabetes and/or dyslipidaemia. At the end of the study there was a significant reduction in the number of participants with potential prescription-based medication underutilisation, and a significant relative reduction in the mean number of PPOs per participant. Potential omissions prevented were for pneumococcal vaccination, BP and/or lipid lowering medication in those clinically at high primary CVD risk, ACEI or ARB for participants with T2DM and albuminuria, and metformin for those with T2DM.

A nearly four-fold increase in HMRs and significant uptake of the non-HMR model by both accredited and non-accredited pharmacists indicates that pharmacists integrated within ACCHSs are well placed to deliver medication management reviews to participants who experience substantial barriers in accessing HMRs under current program rules, especially for participants who would otherwise forgo a medication review if not conducted opportunistically.

The IPAC trial has demonstrated improved quality of care outcomes for patients and more equitable health service utilisation through the successful implementation of integrated pharmacists in 18 ACCHSs located in urban, regional and remote settings across three jurisdictions within Australia. Data collected through the health systems assessment found there were few other changes within health services during the implementation phase, which supports attribution of trial results to the integrated pharmacist intervention.

The outcomes from the intervention are generalisable to the broader adult Aboriginal and Torres Strait Islander patient population with chronic disease who are at risk of developing medication related problems and attending ACCHSs in urban, rural and remote geographical locations. The evidence for generalisability was demonstrated for all outcome measure investigated in the project (see Appendices 9-14, and the MSAC Assessment Report - Section C). The IPAC participants were usual patients accessing ACCHSs, and the intervention was tested within usual clinical settings involving the ACCHS sector. IPAC participants were identified using methods identical to those that would be used under usual conditions within the proposed health services, which is consistent with the pragmatic study design.[93] The delivery of the intervention was also flexible, and follow-up reflected the usual mechanisms in healthcare settings which are also hallmarks of pragmatic study design.

Given the relative novelty of the integrated pharmacist role in Aboriginal health settings in Australia, future roll-out or expansion of programs should be supported with strategies similar to those used in the IPAC trial.

Sector-specific training is important for integrated pharmacists to understand the nature of holistic care delivered by ACCHSs and how the pharmacist can best integrate into the primary health care team to improve chronic disease management and optimise quality of care outcomes for Aboriginal Australians and Torres Strait Islanders. As evidenced in the IPAC Project, training must be comprehensive and include integrated pharmacist core roles as well as an understanding of contributors to the disparity in health outcomes experienced by Aboriginal Australians and Torres Strait Islanders, including social determinants of health.

Ongoing support for integrated pharmacists is essential and should involve multi-modal strategies to take into account accessibility, ease of utilisation and responsiveness of available platforms. Provision of adequate training and support, along with the creation of a community of practice for pharmacists working with Aboriginal people and Torres Strait Islanders will enable sharing of sector knowledge and expertise with the aim of increased uptake, up-skilling and retention of pharmacists working in the ACCHS sector.

NACCHO and their Affiliates are well placed to support ACCHSs to promote readiness for the integrated pharmacist role, to ensure staff fully understand the value of the role and learn how to utilise the pharmacists' expertise to best suit the needs of the service and their patients. Based on experiences in the IPAC trial, substantive and considered program support is needed for ACCHS staff to undertake a change management process to introduce the role, develop work plans, and adapt workflow to incorporate the new integrated pharmacist services. There is a risk that integrating pharmacists into ACCHSs without adequate support may limit uptake and effectiveness of an integrated pharmacist program.

Principles of self-determination must enable ACCHSs to lead, or be actively involved, in the design of the integrated pharmacist model of care for their service, to ensure a culturally acceptable mode of delivering effective and sustainable services to Aboriginal peoples and Torres Strait Islanders is achieved. ACCHSs must also make the ultimate decision on pharmacist selection for their service and consider preferences for employment models.

Ongoing monitoring and assessment is essential for any future expansion of an integrated pharmacist program more broadly to ensure that the program is meeting its stated objectives, identify any issues affecting implementation, and address these in a timely manner. As JCU led the evaluation of the IPAC trial, it would be well placed to collaborate with the Australian Department of Health, NACCHO, the PSA and other stakeholders to design and implement an evaluation framework for broader program rollout. The pharmacist logbook used in the trial could be adapted and tailored to report on key pharmacist activity measures (such as medication reviews, follow-up assessments, contact with community pharmacy, etc), as agreed to by the business rules for the program.

The IPAC Project has delivered significant benefits to patients, health services staff, community pharmacists and other stakeholders across the 18 ACCHSs participating in the IPAC trial. The economic cost of implementing the program across 140 ACCHSs is comparable with other federally funded Aboriginal and Torres Strait Islander medicines initiatives and may help to close the gap in Aboriginal and Torres Strait Islander underutilization of nation-wide Australian pharmaceutical measures, such as the PBS and other Community Pharmacy Agreement related programs. It is therefore proposed that this model be extended to all ACCHSs across Australia.

Table 7 summarises recommendations for future policy and implementation of integrated pharmacists in ACCHSs.

Table 7. Recommendations for future policy and implementation of integrated pharmacists in ACCHSs.

Suggested actions for sector development	Owner and key partners	Potential pathways to implementation	Intended industry impacts Implementing the recommendation will lead to:
1. **Support policy to integrate the role of an integrated pharmacist within ACCHSs across Australia.**	**Federal Government**	1.1 Funding to enable ACCHSs to implement the integrated pharmacist role within their service is recommended. 1.2 The program must be patient-focused to synergise with other pharmacy activities and medicines programs such as relevant community pharmacy programs, Home Medicines Reviews, QUMAX and s100 Support Allowance. 1.3 The specific challenges related to remoteness must be considered in a national program, e.g. remote ACCHSs require a higher level of funding for additional implementation costs such as salary loading, travel and accommodation. 1.4 Legislative barriers (i.e. immunization) that inhibit an integrated pharmacist from practicing to their full scope of practice within an ACCHS should be identified and overcome.	• Enhanced quality of care outcomes for Aboriginal Australians and Torres Strait Islanders with chronic disease • Continuity of care provided by pharmacists integrated into the team • Improved prescribing quality • Improved cost effectiveness • Improved medication adherence • Increased Home Medicines Reviews • Improved self-assessed health status
2. Advocacy and support to ACCHSs to facilitate processes for integrating pharmacists	**NACCHO and Affiliates**	2.1 NACCHO and Affiliates should be supported to assist ACCHSs and staff to be informed of the value of having a pharmacist as part of their primary health care team, support change management processes to introduce and embed the pharmacist within the service, develop referral processes, and adapt workflow to incorporate the new service. 2.2 NACCHO and Affiliates should be supported to develop processes and resources for ACCHSs considering the ten core roles of the IPAC project and the six domains of the Integrating Models of Pharmacists across Care Teams (IMPACT) Framework[55] to assist ACCHSs prepare for the integrated pharmacist role.	• Improved staff awareness of value and benefits of the role to facilitate the integration of the pharmacist into the primary health care team • ACCHSs are prepared for the integrated pharmacist role
3. ACCHSs lead co-design of the integrated pharmacist role to ensure it meets the needs of the their patients	**ACCHSs,** NACCHO and PSA, PGA	3.1 Policy guiding the implementation of the integrated pharmacist role should allow ACCHSs the flexibility to use the role to best meet the needs of the health service. 3.2 ACCHSs should be actively involved in the co-design of the integrated pharmacist role to ensure it suits their needs and seek support from NACCHO and their Affiliate where necessary. 3.3 Integrated pharmacist recruitment should be flexible and be led by	• Integrated pharmacist services are tailored to meet the needs of the local ACCHS and their patients

Suggested actions for sector development	Owner and key partners	Potential pathways to implementation	Intended industry impacts Implementing the recommendation will lead to:
		ACCHSs so that pharmacists have the 'right organisational fit'. 3.4 ACCHSs should be supported to provide pharmacists with induction to the service and the local community including introduction to staff members in key roles and cultural orientation to the local population. 3.5 ACCHSs should be supported to develop the capacity of Aboriginal Health Workers, Practitioners and Outreach Workers to facilitate referral for patients needing support from the integrated pharmacist.	
4. Training and support to prepare pharmacists for a non-dispensing, integrated role within ACCHSs	**PSA,** NACCHO, and ACCHS, pharmacist training providers, PGA	4.1 Pharmacists should be supported to develop career pathways for integrated pharmacist roles. 4.2 Strategies are required to assist with the recruitment of integrated pharmacists that includes the maintenance of a register of pharmacists interested in working within the ACCHS sector and generic templates for position descriptions including the ten core roles from the IPAC trial. 4.3 Prepare pharmacists for integrative roles within ACCHSs through the development of a tailored induction training program. 4.4 Facilitate opportunities for pharmacists to undertake cultural safety training responsive to their place of practice prior to commencing activity within ACCHSs. 4.5 Facilitate relevant continuing professional development for pharmacists working in the ACCHS sector. 4.6 Facilitate a program of ongoing support and a community of practice network to enable knowledge sharing and peer support amongst integrated pharmacists. Mentors can assist with clinical and/or cultural aspects of integrated practice and development of career pathways.	• Pharmacists are prepared and effectively deliver patient-centred care to Aboriginal peoples and Torres Strait Islanders • Pharmacists receive ongoing support from mentors, professional development and peer support through a community of practice network
5. Funding for evaluation of integrated pharmacist programs to enhance roll-out across Australia	**Federal Government,** Academic Institutions, NACCHO, and affiliates, ACCHSs, PGA	5.1 Funding of a program is needed to monitor the implementation of integrated pharmacist programs to facilitate the continuous quality improvement of prescribing quality and the quality use of medicines within ACCHSs. 5.2 Quality improvement programs involving integrated pharmacists need to allow a lead-in time to enable	• Monitoring of the quality of the integrated pharmacist role within ACCHSs • Improved evidence base around the integrated pharmacist role in Aboriginal health settings

Suggested actions for sector development	Owner and key partners	Potential pathways to implementation	Intended industry impacts Implementing the recommendation will lead to:
		integrated pharmacists to develop relationships with staff and patients and develop a deeper understanding of the local community and health service culture. 5.3 Some tools and resources created from the IPAC project such as the PSA templates used to guide stakeholder liaison plan development and promotional materials commissioned by NACCHO may be adapted for use by program developers to support future roll-out.	

ACCHS – Aboriginal Community Controlled Health Services

NACCHO – National Aboriginal Community Controlled Health Organisation

PGA – Pharmacy Guild of Australia

PSA – Pharmaceutical Society of Australia

QUMAX - Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) program

Media, conference or promotional material

- IPAC Poster for use within ACCHS
- IPAC Brochure for use within ACCHS
- IPAC Promotional Video's for use within ACCHS (Feb 2019)
- Conference Presentation – PSA July 18 Conference
- Conference Presentation - Are You Remotely Interested (July 18)
- Conference Presentation – Community Pharmacy Stakeholder Forum (Sept 2018)
- Conference Presentation – NACCHO Annual Conference (Nov 18)
- Conference Presentation – Hot North Workshop (13 June 2019)
- Conference Presentation – PSA 19 Conference (26 July 2019)
- Conference Presentation – NACCHO Annual Conference (Nov 19) (video link provided at the time)
- Conference Presentation – PSA/SHPA Collaborative Research Showcase (15 Feb 2020)
- *Media Release* – Enlisting pharmacists to Close the Gap (5 Sept 2018)
- *Media Release* – Pharmacists can help to Close the Gap (9 Feb 2018)
- Annual Report – PSA 17/18
- Annual Report – PSA 18/19
- Annual Report – NACCHO 17/18
- Annual Report – NACCHO 18/19
- ABC Interview – RN Interview Medicines Week 22/8/2019 – Angela Madden Danila Dilba *Available at:* https://www.abc.net.au/radionational/programs/lifematters/tackling-aboriginal-chronic-disease-through-grass-roots-pharmacy/11435412
- Australian Pharmacist article – June 2019. Available at: https://www.australianpharmacist.com.au/rural-health-pharmacist/

The presentations given during the trial period were small in number in keeping with the contractual obligations of the project.

Publications

Couzos S, Smith D, Stephens M, Preston R, Hendrie D, Loller H, Tremlett M, Nugent A, Vaughan F, Crowther S, Boyle D, Buettner P, Biros E. Integrating pharmacists into Aboriginal community controlled health services (IPAC Project): Protocol for an interventional, non-randomised study to improve chronic disease outcomes. Research into Social and Administrative Pharmacy, 2020. In Press. https://doi.org/10.1016/j.sapharm.2019.12.022

Appendices

Appendix 1 **Published IPAC Protocol**

Appendix 2 **Full IPAC Protocol**

Appendix 3 **IPAC Trial Theory of Change**

Appendix 4 **IPAC Trial Logic Model**

Appendix 5 **Clinical Algorithm 1 - Proposed Service**

Appendix 6 **Clinical Algorithm 2 - Usual Care Service**

Appendix 7 **Literature Review- Cost Effectiveness Analysis**

Appendix 8 **Umbrella Review- Integrated Pharmacists (Primary Health Care)**

Appendix 9 **Assessment of clinical endpoints report**

Appendix 10 **Assessment of Medication Appropriateness Index Report**

Appendix 11 **Assessment of Medication Underutilisation Report**

Appendix 12 **Assessment of Home Medicines Review and Non-Home Medicines Reviews**

Appendix 13 **Assessment of Medication Adherence and Self-Reported Health Status Report**

Appendix 14a **Qualitative Evaluation Report**

Appendix 14b **Qualitative Evaluation Report Appendices**

Appendix 15 **Net Cost to the PBS of Medication Changes from the IPAC Trial**

Appendix 16 **Support for practice-based activities report**

Appendix 17 **Methodology for a model for extending a program**

Appendix 18 **Feedback received by PSA coordinators (PSA)**

Appendix 19 **Pharmacist recruitment report (PSA)**

Appendix 20a **Pharmacist induction training (PSA)**

Appendix 20b **Pharmacist induction training (PSA) Appendices**

Appendix 21 **Support for pharmacists report (PSA)**

Appendix 22 ACCHS Support (NACCHO)

Appendix 23 List of People Involved in the Assessment Report

Appendix 24 Information Briefs and Consent Forms

Appendix 25 Economic Analysis (Stand-alone) Report

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