IPAC Project

Integrating Pharmacists within Aboriginal Community Controlled Health Services to Improve Chronic Disease Management

Final Report to the Australian Government

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Assessment Report

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee which has been established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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ACRONYMS AND ABBREVIATIONS

ACCHS	Aboriginal community-controlled health service
ACR	Albumin-creatinine ratio
AHW/Ps	Aboriginal Health Workers/Practitioners
AIHW	Australian Institute of Health and Welfare
CI	confidence interval
CVD	cardiovascular disease
FFS	fee-for-service
HDL-C	high density lipoprotein cholesterol
HMR	Home Medicines Review
ICER	incremental cost-effectiveness ratio
JCU	James Cook University
LDL-C	low density lipoprotein cholesterol
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NACCHO	National Aboriginal Community Controlled Health Organisation
NHMRC	National Health and Medical Research Council
NMARS	NACCHO Medication Adherence Response Survey
PASC	PICO Confirmation Advisory Sub-Committee of the MSAC
PHC	Primary health care
PICO	Population, Intervention, Comparator, Outcomes
PSA	Pharmaceutical Society of Australia
QALY	Quality adjusted life year
SIQ	Single-item question
TC	Total cholesterol
TG	Triglycerides
T2DM	Type 2 diabetes mellitus

EXECUTIVE SUMMARY

MAIN ISSUES FOR MSAC CONSIDERATION

- *Aboriginal and Torres Strait Islander people with chronic diseases are particularly prone to medication-related problems and associated health complications. The Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHSs) to improve Chronic Disease Management (IPAC) trial demonstrated that integrating a registered pharmacist as part of the primary health care (PHC) team within ACCHSs led to significant improvements in health outcomes, access to medication-related services, and the quality of the care received by Aboriginal and Torres Strait Islander adults with chronic diseases.*
- *The IPAC trial found relatively low costs to be associated with increases in the utilisation of medications and primary health care services. The observed 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.*
- *This proposal recommends funding for the Australia-wide integration of registered pharmacists within ACCHS settings (the proposed service) given that these settings facilitate unique, accessible, culturally safe and holistic care provision to people who are Aboriginal and/or Torres Strait Islander. For Aboriginal and Torres Strait Islander people (proposed population), implementation of such a program would lead to significant benefits from improvements in biomedical and pharmacological indices such as better glycaemic control of those with diabetes, improvements in the control of cardiovascular disease risk factors, slowing of decline in kidney function, marked improvements in prescribing quality with the reduction in inappropriate prescribing and medication underutilisation, markedly improved access to medication management reviews (such as Home Medicines Review and other types of review), and improvements in patient adherence to medications, as well as their self-assessed health status.*
- *The IPAC Trial was the largest clinical, non-randomised, interventional study conducted to date to investigate the impact of integrated pharmacists with regard to Aboriginal and Torres Strait Islander adults with chronic diseases. The Trial was supported by the Pharmaceutical Society of Australia (PSA), the National Aboriginal Community Controlled Health Organisation (NACCHO), in conjunction with James Cook University (JCU) undertaking the evaluation.*
- *The proposed service would reduce the disparity in access to the PBS, whilst enhancing the Quality Use of Medicines for Aboriginal people and Torres Strait Islanders within ACCHSs and lead to superior health service utilisation (towards equity).*

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

This submission-based assessment outlines the findings of the evaluation of the IPAC Trial. The project was a non-randomised, prospective, pre and post quasi-experimental community-based, participatory, and pragmatic trial that integrated a registered pharmacist within Aboriginal Community Controlled Health Services (ACCHSs) in Queensland, the Northern Territory and Victoria for a period of up to 15 months. This assessment provides evidence to support public funding for the integration of non-dispensing pharmacists within Aboriginal Community Controlled Health Services (ACCHSs).

The IPAC 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. Integration within ACCHSs meant that pharmacists had identified positions and core roles, shared access to clinical information systems, provided continuous clinical care to patients, 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 acted within 10 core roles that included patient-related activities and staff and service-level activities. Through these 10 roles, pharmacists supported study participants by conducting medication management reviews (to resolve identified medication-related problems and optimise prescribing quality), assessed adherence and medication appropriateness, provided medicines information and education and training, collaborated with health care teams, delivered preventive care, liaised with stakeholders such as community pharmacy, provided transitional care, and undertook a drug utilisation review to support quality improvement within the ACCHS. 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 did not dispense medication.

Based on the evidence presented in this submission, the proposed population for integrated pharmacist support are Aboriginal and Torres Strait Islander patients attending ACCHSs, who have a clinical need for pharmacist support (irrespective of age) either because of chronic disease and/or being at high risk of developing medication related problems. This proposal also recommends that the proposed service should not preclude other Aboriginal and Torres

Strait Islander patients of ACCHSs in need of medication management support from having access to the proposed integrated pharmacist services, given the holistic nature of primary health care service delivery.

This proposal recommends funding the integration of registered pharmacists within ACCHS settings Australia-wide as this will lead to significant improvements in the quality of care received by the proposed population. In particular, the proposed population will significantly benefit from improvements in biomedical indices that are known cardiovascular disease risk factors, significant improvements in the glycaemic control of those with diabetes, significant slowing of decline in kidney function, significant improvements in prescribing quality with the reduction in inappropriate prescribing and medication underutilisation, significantly improved access to medication management reviews (such as Home Medicines Review and other types of review), and significant improvement in adherence to medications and self-assessed health status. Economic analysis has reported the cost-effectiveness of the intervention. The intervention was also considered acceptable and implementable by participants, ACCHSs and stakeholders. These benefits have been summarised in this report with full technical analyses included as appendices. The protocol for the IPAC Trial was published (Appendix 1), and the full protocol is included (Appendix 2).

ALIGNMENT WITH AGREED PICO CONFIRMATION

This submission-based assessment of the integration of pharmacists within ACCHSs addresses all of the PICO[1] elements that were pre-specified. The reference standard was the test as set out in the approved Trial Protocol and the case for the economic evaluation is based on a trial-based evaluation.

A minor change from the original PICO proposed at the time of the PTP Trial funding application was accepted by the Department of Health and incorporated in the funding contract and project protocol. The change altered the target population from patients 'of any age' to adults ≥ 18 years. This change was made prior to PTP Trial funding and was agreed at the time contracts were finalised (see section A).

PROPOSED MEDICAL SERVICE

The proposed service is the integration of a non-dispensing pharmacist as part of the primary health care team of ACCHSs to provide care to Aboriginal and/or Torres Strait Islander

[1] Population, Intervention, Comparator, Outcomes

patients (considered 'regular' clients) with chronic disease, irrespective of age. The services to be delivered by the integrated pharmacist include both patient-related and practice-related activities through the following **core roles:** providing medication management reviews, assessing and supporting medication adherence, providing medicines information and education and training, collaborating with health care teams, delivering preventive care, liaising with stakeholders such as community pharmacy including developing stakeholder liaison plans, providing transitional care, and undertaking quality improvement activity such as a drug utilisation review.

The integration of a non-dispensing pharmacist within ACCHSs means the following (based on the key features of pharmacists working to deliver IPAC services):

- Pharmacists supported as team members within ACCHSs with identified positions;
- with shared access to clinical information systems;
- providing rational and continuous clinical care to patients;
- receiving administrative and other supports from primary health care staff within ACCHSs, and
- adhering to governance, cultural, and clinical protocols within ACCHSs as part of their shared vision.

These features are consistent with the dimensions of 'integration' reported by other studies investigating the integration of pharmacists within primary health care settings.[2] The integration processes listed above are described as the 'IPAC integration model' in this submission.

The integration of non-dispensing registered pharmacists within ACCHSs is not currently funded nor reimbursed within private or public settings in Australia for the proposed patient population to deliver the proposed core roles. Some public funding can be sourced by ACCHSs through the Workforce Incentive Program (WIP, Practice Stream), but this funding is mostly utilised by ACCHSs Australia-wide for nursing or Aboriginal health worker/practitioner or other allied health supports (see below and also Section A7).

[2] Hazen ACM, de Bont AA, Boelman L, et al. The degree of integration of non-dispensing pharmacists in primary care practice and the impact on health outcomes: A systematic review. Res Social Adm Pharm. 2018; 14(3):228-240. doi: 10.1016/j.sapharm.2017.04.014. Epub 2017 Apr 22.

PROPOSAL FOR PUBLIC FUNDING

This proposal is for baseline plus pro-rata public funding (depending on the health service client load and episodes of care) of a non-dispensing pharmacist within ACCHSs to provide the services outlined in this proposal within an integrated model of care.

While a mixed model encompassing baseline funding plus a fee-for-service (FFS) methodology may be considered for future program rollout, block funding is likely to be more appropriate to enable integrated pharmacists to most effectively meet the unique needs of Aboriginal and Torres Strait Islander peoples. A block funding approach aligns with other Commonwealth funding approaches for ACCHSs (such as the Indigenous Australians' Health Programme); accommodates patient non-attendance at scheduled clinic appointments that occurred in some ACCHSs during the IPAC Trial; and allows for the significant variation in preference for pharmacist services (including clinical governance, education and training, and patient-directed care) observed across ACCHSs in the IPAC Trial. On this basis an MBS item descriptor is not being suggested as it would encourage a FFS funding arrangement for pharmacists' services which is inconsistent with the integration model being proposed. An MBS item descriptor may not deliver the necessary integration of pharmacists required for them to provide services consistent with the proposed core roles within ACCHSs.

Currently, pharmacists are not supported to deliver integrated and non-dispensing services within these primary health care service settings through existing Australian Government of State and territory programs, except notionally through the WIP. The WIP is intended for rural and remote Australia and provides financial incentives to support general practices to engage the services of nurses and other allied health staff. Many ACCHSs are currently already accessing the WIP to employ practice nurses and/or Aboriginal health practitioners/workers. This means there are no remaining WIP program funds to support the proposed medical service. The quantum of funding from the WIP is insufficient to also support the integration of a non-dispensing pharmacist within ACCHSs, especially for services with a large chronic disease subpopulation. Furthermore, non-dispensing pharmacists remain unable to claim MBS item fees for chronic disease management (CDM) services provided in a primary care setting, and therefore cannot supplement the maximum incentive payment available under the WIP.

POPULATION

The IPAC trial delivered integrated pharmacist services to adult Aboriginal and Torres Strait Islander patients attending ACCHSs as regular clients. The conditions for the receipt of

pharmacist services were for patients with chronic disease who had visited a participating ACCHS site at least three times in the past two years (known as 'active' or 'regular' patients). Patients 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
- Other chronic conditions and at high risk of developing medication-related problems (e.g. polypharmacy).

The proposed patient population for the broader translation of the integrated pharmacist intervention are Aboriginal and Torres Strait Islander patients (irrespective of age) who have a clinical need for pharmacist support because of chronic disease and/or being at high risk of developing medication related problems. The recommendation to extend the proposed service to patients irrespective of age is outlined in Section C of this submission.

Aboriginal peoples and Torres Strait Islander people experience a significantly higher burden of chronic disease than non-Indigenous Australians.[3] For example, 80% of the mortality gap between Indigenous and other Australians aged 35–74 years is due to chronic diseases. Of the gap due to chronic disease, the main contributors are: ischaemic heart diseases (22%) diabetes mellitus (12%); chronic lower respiratory diseases (mainly chronic obstructive pulmonary disease); and (6%) cerebrovascular diseases (5%).[4] In the 2012-13 Aboriginal and Torres Strait Islander Health Survey, 35% of Aboriginal and Torres Strait Islander adults had cardiovascular disease (CVD), diabetes or chronic kidney disease (CKD). Of all Indigenous adults with these conditions, 38% had 2 or more conditions together, 11% had all 3 conditions together.[5]

These chronic conditions are more prevalent in the Aboriginal and Torres Strait Islander population than other Australians and rely heavily on medications to manage them and to reduce potential hospitalisations and premature mortality. For example, diabetes was recorded as the principal and/or additional diagnosis in around 1 million hospitalisations of

[3] Bainbridge R, McCalman J, Clifford A, Tsey K. Cultural competency in the delivery of health services for Indigenous people. Issues paper no. 13. Produced for the Closing the Gap Clearinghouse. In. Edited by Welfare AIoHa, vol. 13. Canberra: Australian 2015.

[4] Australian Institute of Health and Welfare 2010.Contribution of chronic disease to the gap in adult mortality between Aboriginal and Torres Strait Islander and other Australians. Cat. No. IHW 48. Canberra: AIHW.

[5] Merone L, Burns J, Poynton M, McDermott, R. Review of cardiovascular health among Aboriginal and Torres Strait Islander people. Perth, WA: Australian Indigenous HealthBulletin 19(4), 2019.

Australians in 2015–16 and accounted for 10% of all hospitalisations in Australia. The prevalence of diabetes is 3-6 times higher in the Aboriginal and Torres Strait Islander population than non-Indigenous Australians.[6]

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).[7] The rate of potentially avoidable hospitalisations for Aboriginal and Torres Strait Islander people is almost 5 times the rate for other Australians with over half of these related to chronic conditions.[8] This profound health disparity has generated many policies and programs to encourage better chronic disease prevention and management within primary healthcare services. Yet, despite these programs, 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.[9] [10] [11] There are many reasons for this including health system factors such as poorer access to primary health care services,[12] culturally unsafe pharmaceutical support,[13] lack of health service integration,[14] disease profiles inconsistent with medicines listed on the PBS,[15] and suboptimal prescribing quality.[16] Patient factors include insufficient health literacy for optimal self-management of

[6] Australian Institute of Health and Welfare 2018. Australia's health 2018. Australia's health series no. 16. AUS 221. Canberra: AIHW.

[7] Australian Health Ministers' Advisory Council. Aboriginal and Torres Strait Islander Health Performance Framework 2017 Report, AHMAC, Canberra, 2017.

[8] Australian Institute of Health and Welfare 2011. Access to health services for Aboriginal and Torres Strait Islander people. Cat. No. IHW 46. Canberra: AIHW https://www.aihw.gov.au/reports/indigenous-australians/access-to-health-and-services-for-aboriginal-and-t/contents/table-of-contents

[9] Page A, Hyde Z, Smith K, et al. Potentially suboptimal prescribing of medicines for older Aboriginal Australians in remote areas. Med J Aust. 2019 211(3):119-125. doi: 10.5694/mja2.50226.

[10] Heeley, E. L., Peiris, D. P., Patel, A. A., Cass, A. , Weekes, A. , Morgan, C. , Anderson, C. S. and Chalmers, J. P. (2010), Cardiovascular risk perception and evidence–practice gaps in Australian general practice (the AusHEART study). Medical Journal of Australia, 192: 254-259. doi:10.5694/j.1326-5377.2010.tb03502.x

[11] Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people.* Jul 2014. http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf

[12] Australian Health Ministers' Advisory Council. Op. Cit.

[13] Swain L, Barclay L. Medication reviews are useful, but the model needs to be changed: Perspectives of Aboriginal Health Service health professionals on Home Medicines Reviews. BMC Health Serv Res. 2015;15:366-.

[14] Thompson SC, Haynes E, Woods JA, et al. Improving cardiovascular outcomes among Aboriginal Australians: Lessons from research for primary care. SAGE Open Med. 2016;4:2050312116681224. Published 2016 Nov 29. doi:10.1177/2050312116681224

[15] Couzos S. PBS medications. Improving access for Aboriginal and Torres Strait Islander peoples. Aust Fam Physician. 2005; 34 (10):841-4.

[16] Peiris DP, Patel AA, Cass A,et al. Cardiovascular disease risk management for Aboriginal and Torres Strait Islander peoples in primary health care settings: findings from the Kanyini Audit. Med J Aust. 2009 21;191(6):304-9.

disease,[17] distrust of health services,[18] family and community obligations,[19] and belief in traditional medicines,[20] whilst condition-related factors include disproportionately high multimorbidity.[21] Socioeconomic factors may also affect the personal management of medicines such as adherence and storage.[22]

It is worth emphasising that Aboriginal and Torres Strait Islander people's access to primary health services remains disproportionately low particularly when considering their higher burden of chronic disease[23] and PBS medicines continue to be underutilised compared with non-Indigenous Australians.[24] Less is spent on medications and medical services for Indigenous Australians than for non-Indigenous Australians.[25] For years, the Indigenous Australians per person expenditure for medicines through the Pharmaceutical Benefits Scheme (PBS) has been a fraction (33% in 2013-14) of the expenditure for non-Indigenous Australians.[26] This problem is often compounded by more complex medicine regimens and more co-morbidities seen in Aboriginal and Torres Strait Islander patients.[27]

Together with changes to lifestyle factors, long term treatment with medications is usually needed to prevent or reduce disease progression and thereby mitigate outcomes of ill health. Social determinants of health and population-based disparities in this regard, impact on medication adherence to prescribed medicines and this is associated with adverse health outcomes in all population groups.[28] Social circumstances, deficiencies in health services and systems mean Aboriginal people often experience even greater challenges in medication

[17] Rheault H, Coyer F, Jones L, Bonner A. Health literacy in Indigenous people with chronic disease living in remote Australia [published correction appears in BMC Health Serv Res. 2019 Aug 14;19(1):566]. BMC Health Serv Res. 2019;19(1):523. Published 2019 Jul 26. doi:10.1186/s12913-019-4335-3

[18] Hamrosi K, Taylor S, Aslani P. Issues with prescribed medications in Aboriginal communities: Aboriginal Health Workers' perspectives. Rural and Remote Health 2006; 6: 557. Available: www.rrh.org.au/journal/article/557

[19] Kingsley J, Townsend M, Henderson-Wilson C, Bolam B. Developing an exploratory framework linking Australian Aboriginal peoples' connection to country and concepts of wellbeing. Int J Environ Res Public Health. 2013;10(2):678-98. Published 2013 Feb 7. doi:10.3390/ijerph10020678

[20] Senior K, Chenhall R. Health Beliefs and Behavior. Medical Anthropology Quarterly 2013 27: 155-174. doi:10.1111/maq.12021

[21] Randall DA, Lujic S, Havard A, Eades SJ, Jorm L. Multimorbidity among Aboriginal people in New South Wales contributes significantly to their higher mortality. Medical Journal of Australia, 2018 209: 19-23. doi:10.5694/mja17.00878

[22] de Dassel JL, Ralph AP, Cass AA. systematic review of adherence in Indigenous Australians: an opportunity to improve chronic condition management. BMC Health Serv Res. 2017 Dec 27;17(1):845. doi: 10.1186/s12913-017-2794-y.

[23] Australian Institute of Health and Welfare: Australia's health 2014. Australia's health series no.14. In., vol. Cat.no.AUS178. Canberra: AIHW; 2014.

[24] Australian Health Ministers' Advisory Council. Aboriginal and Torres Strait Islander Health Performance Framework 2017 Report. AHMAC, Canberra, 2017.

[25] Australian Institute of Health and Welfare 2018. Op. Cit.

[26] Australian Health Ministers' Advisory Council. Op. Cit.

[27] Swain L: Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people. In. Canberra, ACT, Australia: Pharmaceutical Society of Australia, 2014

[28] World Health Organisation. Adherence to long term therapies; evidence for action. WHO, Switzerland, 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf?ua=1 {accessed 8 October 2018].

management than non-Indigenous Australians. Social and emotional wellbeing issues may deeply pervade the lives of many Aboriginal people and may diminish the value that individuals place upon medications and the potential for these to improve their quality of life.[29] It has been said that "Australia's mainstream medical model focuses on compliance with medical advice and often ignores the complex historical and sociocultural influences that shape patients' responses to their health and health care."[30]

A whole of health system response is needed to tackle these factors which is why the IPAC trial explored the potential for integrated pharmacists within primary health care multidisciplinary teams for patients and teams to receive better medication management support, direct care from a pharmacist, and a more joined-up experience of care. This strategy was intended to compliment and extend the services provided as usual care by community pharmacists.

Increasingly, studies are reporting that the addition of pharmacists to healthcare teams enhances quality prescribing,[31] biomedical outcomes,[32] [33] and reduces hospitalisation.[34] [35] Co-location of pharmacists within general practice appears to enable greater communication, collaboration and relationship building among health professionals.[36] [37] However, the impact of integrated pharmacists on health outcomes for Aboriginal and Torres Strait Islander patients with chronic disease has never been evaluated in general practice or Aboriginal health settings.

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[29] Emden C, Kowanko I, De Crespigny C, et al. *Better medication management for Indigenous Australian: findings from the field*. Aust J Prim Health 2005;11:80–90.

[30] Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people.* Jul 2014. http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf

[31] Clyne B, Fitzgerald C, Quinlan A, Hardy C, Galvin R, Fahey T, et al. Interventions to address potentially inappropriate prescribing in community dwelling older adults: a systematic review of randomized controlled trials. J Am Geriatr Soc. 2016, 64: 1210–1222. doi: 10.1111/jgs.14133

[32] Martínez-Mardones F, Fernandez-Llimos F, Benrimoj SI, et al. Systematic Review and Meta-Analysis of Medication Reviews Conducted by Pharmacists on Cardiovascular Diseases Risk Factors in Ambulatory Care. *J Am Heart Assoc*. 2019;8(22):e013627. doi:10.1161/JAHA.119.013627

[33] Pousinho S, Morgado M, Falcão A, Alves G. Pharmacist Interventions in the Management of Type 2 Diabetes Mellitus: A Systematic Review of Randomized Controlled Trials. J Manag Care Spec Pharm. 2016 22:5: 493-515

[34] Gillespie U, Alassaad A, Hammarlund-Udenaes M, et al. Effects of pharmacists' interventions on appropriateness of prescribing and evaluation of the instruments' (MAI, STOPP and STARTs') ability to predict hospitalization--analyses from a randomized controlled trial. *PLoS One*. 2013;8(5):e62401. Published 2013 May 17. doi:10.1371/journal.pone.0062401

[35] Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. *Int J Pharm Pract*. 2018; 26: 387-397. doi:10.1111/ijpp.12462.

[36] Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. Int J Pharm Pract 2014;22(1):28–37.

[37] Shaw C. Integration of general practice pharmacists into primary healthcare settings for chronic disease management. Issues Brief for the Deeble Institute for Health Policy Research. Australian Healthcare & Hospitals Association, May 2020. https://ahha.asn.au/system/files/docs/publications/deeble_issues_brief_no._35_integration_of_general_practice_pharmacists_into_primary_healthcare_settings.pdf

The IPAC trial targeted Aboriginal and Torres Strait Islander adults with chronic disease, within settings that were culturally appropriate such as Aboriginal community-controlled health services (ACCHSs), in order to evaluate the impact of integrated pharmacists on quality use of medicine outcomes.

COMPARATOR DETAILS

The proposed service will supplement the usual care provided to Aboriginal and Torres Strait Islander patients of existing ACCHSs.

The comparator used for the evaluation of the IPAC trial was 'usual care' provided to the enrolled participants within participating ACCHSs in the 12 months preceding their enrolment into the study. Usual care was defined as usual primary healthcare service provision to Aboriginal and Torres Strait Islander patients *without* the presence of an integrated pharmacist within the health service.

Usual care varies across ACCHS contexts. In the absence of integrated pharmacists' services, usual care provides limited medication adherence support to Aboriginal and Torres Strait Islander patients of ACCHSs. Access to this support is often ad hoc and if it is sourced by the target population, it is accessed via community pharmacy which may not be integrated into the ACCHS model of care or adequately responsive to the specific needs of the ACCHS. Medication management reviews (if sourced) are accessed via community pharmacies, or independent accredited pharmacists, with delivery and content strictly guided by Program Rules.[38] Education and training is currently provided to ACCHS staff (and some patients in the target population) by community pharmacy such as from the S100 Support Allowance for Remote Area Aboriginal Health Services, and some arrangements with ACCHSs have contracted community pharmacy to provide this support through the QUMAX Program. However, the following services which were provided by integrated pharmacists in the IPAC trial, have not been generally and routinely available as part of usual care to healthcare providers and the target population within ACCHSs:

- Opportunistic patient follow up
- Team-based collaboration activity

[38] Pharmacy Programs Administrator. Program Rules. Home Medicines Review. Australian Government, Department of Health, Canberra, July 2019.

- Preventive health care delivery specifically targeting the Aboriginal and Torres Strait Islander population
- Medicines information service on-site, including opportunistic advice
- Stakeholder liaison services
- Transitional care support
- Quality improvement activity (such as a drug utilisation review).

CLINICAL MANAGEMENT ALGORITHM(S)

The theory of change model for the IPAC Trial (Appendix 3) proposed that if pharmacists were integrated within ACCHSs that provide comprehensive primary health care to Aboriginal peoples and Torres Strait Islanders, pharmacists would support prescribers and other members of the primary healthcare team to better access medication-related expertise at the clinical point of care, compared with usual care. When that access is coupled with more direct pharmacist to patient engagement within the clinic, and more collaboration with stakeholders such as community pharmacy and hospitals, it was proposed that this would result in improved patient access to medication management reviews, reduced suboptimal prescribing, increased medicines utilisation, enhanced communication for transitional care, and improvements in chronic disease outcomes for the target population. This model was tested in the IPAC Trial and all technical analyses support these associations and outcomes as having been achieved.

The theory of change model outlined factors influencing the impact of an integrated pharmacist and the underpinning assumptions, such as conditions outside the control of individual healthcare professionals, and also to some extent, outside the control of healthcare services. These assumptions included: that prescribers are supportive and receptive to pharmacists' recommendations; the recognition that many barriers to optimal medication use are socially determined and outside the control of the patient and healthcare team; and that community pharmacy is sufficiently engaged, adequately remunerated and has the capacity to support change.

The logic model developed for evaluation of the IPAC Trial acts as a clinical management algorithm for the purpose of this submission-based assessment. It depicts the context of the proposed service where a non-dispensing pharmacist integrated within an ACCHS functions to deliver clinical care to individual Aboriginal and Torres Strait Islander patients and to improve the overall integration of care for the patient. Pharmacists integrated within the ACCHS can themselves facilitate a 'joined-up' and more coordinated journey for the patient. This is achieved through medicines reconciliation when patients are hospitalised or

discharged and supporting their transition in care; through liaison with community pharmacy to support the patient and general practitioner; through consultations at time and place that suit the patient; and through improved record-keeping and team-based care. Integrated pharmacists can enhance health systems by supporting quality prescribing and quality improvement within the ACCHS context.

The proposed clinical management algorithm that depicts the context of the intended use of the proposed medical service following public funding for the service is shown in **section A6**. This is identical to Appendix 4 (IPAC logic model). The proposed clinical management algorithm (Appendix 5) is formatted to be comparable to the usual care algorithm (without an integrated pharmacist within ACCHSs) (Appendix 6).

KEY DIFFERENCES IN THE DELIVERY OF THE PROPOSED MEDICAL SERVICE AND THE MAIN COMPARATOR

The main differences between the proposed service and the main comparator (usual care) are summarised in **section A7**. The main differences pertain to a more integrated, coordinated, collaborative, and expansive set of medication- related services being introduced than is able to be currently provided through usual care systems within primary health care settings. This means that with the proposed medical service, Aboriginal and Torres Strait Islander patients with chronic disease (who are particularly vulnerable to disjointed care), will have a more 'joined-up' experience of care with regard to medication management within the ACCHS setting than is currently available or possible. Integration into the ACCHSs' model of care allows the pharmacist to be more culturally responsive and their activities to be aligned with ACCHSs' core priorities based on self-determination.

The proposed medical service was evaluated in the IPAC trial and demonstrated superior health outcomes for Aboriginal and Torres Strait Islander patients with chronic disease, compared with usual care arrangements (**Section B**). Study participants benefited from the service in ways they would not have otherwise benefited through usual care mechanisms.

CLINICAL CLAIM

As set out in the PICO for this project, the clinical claim was as follows:

- Aboriginal and/or Torres Strait Islander adult patients with chronic disease receiving pharmacist services that are integrated within ACCHSs, will experience superior quality of care outcomes compared to usual care.

- Services provided by pharmacists within ACCHSs are likely to lead to superior health care service utilization (towards equity) by patients with chronic disease compared to usual care.

B1.1 APPROACH TAKEN TO THE EVIDENCE ASSESSMENT

Primary research

The IPAC Trial investigated the effectiveness of non-dispensing pharmacists integrated within ACCHSs during 2018-2019. The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental interventional study that was community-based and participatory (*Trial Registration Number and Register: ACTRN12618002002268*). The intervention was the integration of a registered pharmacist within the ACCHS primary healthcare team for up to a 15-month period. There were 22 ACCHS sites (18 ACCHSs) that participated in the project until the end, across three jurisdictions: Victoria, Queensland and the Northern Territory to ensure a sampling frame that best informed external validity of the outcomes across varied services and patient populations. Pharmacist positions were aggregated to represent approximately 12.3 full time equivalent (FTE) positions. All eligible ACCHS sites that participated received the intervention, and a total of 26 pharmacists were trained and integrated within the ACCHSs.

The primary expected clinical endpoint outcomes were an improvement in quality of care indicators (including systolic and diastolic blood pressure, glycated haemoglobin (HbA1c), lipids, estimated absolute cardiovascular disease (CVD) risk, and albumin-creatinine ratio (ACR) in patients with chronic disease. Secondary outcomes included improvements in:

- estimated glomerular filtration rate (eGFR);
- prescribing indices (medication appropriateness, overuse, underuse, and medication-related problems);
- patient use of medicines (medication adherence, self-assessed health status, and patient experience);
- health service utilization indices (Medicare Benefits Schedule claims for: home medicines reviews, and other MBS items likely to be related to pharmacist activities), and other comprehensive medication management reviews (non-HMRs); and
- stakeholder perceptions (ACCHSs staff; community pharmacies; pharmacists).

An economic evaluation of the IPAC Trial also undertook a cost- consequence analysis, estimation of the incremental cost-effectiveness ratio, and a cost-utility analysis

(extrapolated for participants with T2DM) of the integrated pharmacist intervention in relation to usual practice (at baseline) to assess whether the IPAC Trial represents value for money from a health system perspective.

Secondary research

Two systematic reviews were undertaken or sourced:

1) A systematic review of published literature was undertaken as part of the IPAC Trial to explore cost-effectiveness analyses of integrated models of care involving pharmacists (Appendix 7) in the absence of existing reviews;
2) A recently completed umbrella review of systematic reviews was sourced and included in this report, with permission granted from the authors[39] (Copyright James Cook University, in- confidence, Appendix 8). This umbrella review synthesised several systematic reviews that have been published exploring patient-related outcomes from integrated pharmacist interventions within primary health care settings. **Please note that permission to release this report in the public domain has not been granted.**

B1.2 CHARACTERISTICS OF THE EVIDENCE BASE (LITERATURE REVIEW AND PRIMARY RESEARCH)

For the results of the IPAC Trial (primary research evidence) - please see Section B (and Appendices 9 to 16). The key features of the studies that were explored in the two literature reviews (secondary research) is shown in Table 1.

[39] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.

Table 1 Key features of the included studies sourced in the literature reviews (secondary research)

Type of evidence	Description	Number
Literature review of cost-effectiveness studies[40]	Synthesis of published literature on cost-effectiveness studies exploring pharmacist services integrated or co-located within general practices/primary health care services for adults with chronic disease.	n=13 studies
Umbrella review of systematic reviews[41]	Synthesis of published literature exploring outcomes from pharmacist services integrated or co-located within general practices/primary health care services for adults with chronic disease.	n=5 studies

The main findings of these literature reviews are presented as Appendices 7 and 8 and in Section B. The evidence presented in the review of cost-effectiveness studies is not directly applicable to the context of the proposed medical service due to the absence of relevant published studies. The evidence presented in the umbrella review of systematic reviews has some application to the context of the proposed medical service.

B1.3 RESULTS

The results of the IPAC trial (primary research evidence) are summarised here as well as the literature reviews.

Effectiveness (secondary research outcomes from literature reviews, and primary research outcomes)

The secondary research outcomes are presented first in accordance with the submission template as literature reviews (a) and (b). The effectiveness outcomes from the two systematic reviews of the literature are summarised in Table 2 and Table 3. This section also outlines the primary research outcomes from the conduct of the IPAC Trial.

a) Literature review for economic analyses

The economic analyses literature review (Appendix 7)[42] did not reveal any studies that had analysed the cost-effectiveness of interventions involving a pharmacist integrated within primary health care services such as ACCHSs in Australia. Furthermore, no cost-effectiveness

[40] Johnstone K, Smith D, Couzos S. Literature review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care. James Cook University, February 2020.
[41] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.
[42] Johnstone K, Smith D, Couzos S. Literature review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care. James Cook University, February 2020.

studies were identified involving clinical pharmacist services to Indigenous peoples through Indigenous health services or any other type of primary health care service from any country in the world. Only one study, set in the United States, commented on the participation of minority populations.

Given the lack of cost-effectiveness studies that were directly relevant to the IPAC Trial, the cost-effectiveness studies included in the review had a broader focus involving general practice or other primary health care settings and involving collaborative care between a pharmacist and a general practitioner (GP).

Direct effectiveness

Table 2 shows a narrative synthesis of the findings of this literature review.

The literature review for studies assessing the cost-effectiveness of integrated pharmacist interventions within primary health care settings found only two studies that explicitly mentioned the co-location of the pharmacist within the primary health care facility. However, it was not clear if the pharmacists in these studies were co-located solely for the purposes of the intervention or if they were existing staff at the facility.[43] [44] The remaining studies involved community pharmacists, clinical pharmacists or research pharmacists and again it was unclear if they were co-located at the primary health care facility for the intervention period (Table 2).

Table 2 Summary of systematic literature review findings of cost-effectiveness analyses from randomised controlled trials that explored pharmacist interventions within primary health care settings

Author, year, setting, study design	Participants	Pharmacist intervention	Follow-up duration	Control	Outcome measure	Cost-effectiveness outcome
Avery et al, 2012. UK, general practice, Pragmatic Cluster randomised trial e.g. Quality of life	General practices	Simple computerised feedback plus pharmacist-led interventions with practice team	12 months	Simple computerised feedback	Patients identified with potential medication error. Cost per additional medication error avoided due to the intervention at 12 months.	95% probability is cost effective if the decision-maker's ceiling willingness to pay reached £85 per error avoided (at 12 months).

[43] Kulchaitanaroaj, P., Brooks, J. M., Ardery, G., Newman, D. & Carter, B. L. (2012). Incremental costs associated with physician and pharmacist collaboration to improve blood pressure control. Pharmacotherapy, 32(8):772-780.

[44] Kulchaitanaroaj, P., Brooks, J. M., Chaiyakunapruk, N., Goedken, A. M., Chrischilles, E. A., & Carter, B. L. (2017). Cost-utility analysis of physician-pharmacist collaborative intervention for treating hypertension compared with usual care. Journal of Hypertension, 35(1), 178-187.

Author, year, setting, study design	Participants	Pharmacist intervention	Follow-up duration	Control	Outcome measure	Cost-effectiveness outcome
Bojke et al, 2010. UK General practice. Randomised multiple interrupted timeseries.	>=75 years with polypharmacy	Pharmacist moderated drug management in collaboration with doctor, patient and carer.	12 months	Usual care	Mean incremental cost per additional QALY	78%-81% probability that pharmaceutical care is cost-effective at a threshold between £20,000 and £30,000 per QALY.
Cowper et al, 1998. USA Randomised control trial	>=65 years (males) with polypharmacy	Pharmacist medication review for prescribing appropriateness (MAI)	12 months	Nurse review of prescriptions.	Cost per 1 unit change in MAI	Cost was $7.50 per 1-unit change in MAI. Excluding drug costs, the ratio was $30/1 unit change in MAI.
Elliott et al, 2014, UK. General Practice Pragmatic cluster randomised trial	General practices	Simple computerised feedback plus pharmacist-led interventions with practice team	12 months	Simple computerised feedback	Cost per additional QALY	59% probability of being cost-effective at a threshold ceiling willingness-to-pay for a QALY of £20,000.
Kulchaitanaroaj et al, 2012, and 2017, USA Community-based clinics. Combined data from two prospective cluster-randomised controlled clinical trials	>=21 years with hypertension	Pharmacists co-located with physicians. In-person recommendations to address suboptimal drug regimens and educate physicians as needed.	6 months	Physician management only.	Cost for one additional patient to achieve blood pressure control Cost per QALY gained	Cost for one additional patient to achieve blood pressure control was $1338.05. $36.25 per additional 1mmHg reduction in systolic blood pressure and $94.32 per additional 1mmHg reduction in diastolic blood pressure. $26,807.83 per QALY gained
Obreli-Neto et al, 2015. Brazil Primary health care unit. Randomised controlled trial	>= 60 years, diagnosed with diabetes or hypertension receiving medications	Pharmacist follow-up of patients every 6 months, compliance checks; patient and family education; and physician recommendations	36 months	Usual care (3 monthly physician visits without a pharmacist)	Incremental cost-effectiveness ratio per QALY, based on patients reaching clinical outcome goals.	Incremental cost-effectiveness ratio per QALY was estimated at $53.50. The intervention did not significantly increase health care cost and significantly improved health outcomes.
Polgreen et al, 2015. USA. Primary care Offices. Cluster randomised controlled trial	>= 18 years with uncontrolled hypertension defined as SBP>140mmHg or DBP >90 mmHg or SBP >130 mmHg and DBP >80 mmHg in diabetes and chronic kidney disease	Pharmacist collaboration with physicians with pharmacist care plans and regular patient visits.	9 months	Usual care – no pharmacist involvement	Cost to lower blood pressure by 1mmHg.	Cost to lower BP by 1mmHg was $33.27 for systolic and $69.98 for diastolic. Comparing rates in the intervention and control groups, the cost to increase BP control by 1 percentage point was $22.55.
Simpson et al, 2015. USA. Primary care clinic Randomised controlled trial	Patients with Type 2 diabetes	Pharmacist visits with patients with medication review and physical examination including blood	12 months	Usual care – no pharmacist involvement	Cost to reduce annualised cardiovascular 10-year risk by 1%	95% probability that intervention is cost-effective at level of about $4,000 per 1% reduction in annualised cardiovascular risk.

Author, year, setting, study design	Participants	Pharmacist intervention	Follow-up duration	Control	Outcome measure	Cost-effectiveness outcome
		pressure measurement; pharmacist recommendations to the physician; and patient follow-up by pharmacist.				
Sorensen et al, 2004. Australia. General practice, Randomised controlled trial	Patients at risk of medication misadventure	GPs coordinated linking up of pharmacists. Patient home visit by the pharmacist for medication review, with prescriber recommendations	6 months	Usual care	Cost-saving per intervention patient	There was a net cost saving per intervention patient (marginal cost benefit) of AUS$54 per patient relative to controls. No significant difference was demonstrated in health-related quality of life, patient satisfaction, or clinical outcomes.

In summary, this review did not identify cost-effectiveness evaluations of pharmacist's interventions that were directly relevant to the proposed service (consistent with the IPAC Trial). There was considerable heterogeneity in health systems and the measurement of health gains between the included studies. The cost-effectiveness of the interventions could only be interpreted by considering and understanding the context of each individual setting. Nevertheless, most authors concluded that the pharmacist intervention was cost-effective. These findings therefore highlight the importance of the IPAC Trial to inform on the cost-effectiveness of integrated pharmacist interventions as regards the health of Indigenous Australians.

b) Umbrella review- Integrated pharmacists within primary health care settings

This umbrella review[45] (Appendix 8) aimed to determine the effectiveness of integrated non-dispensing pharmacists within primary health care settings on patient outcomes such as biomedical markers, prescribing quality, and patient-reported outcomes. Integration was defined broadly as any intervention that involved co-location of pharmacists within PHC

[45] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.

settings, and/or pharmacists who worked as part of multidisciplinary healthcare teams using a range of integrative processes.

The umbrella review of systematic reviews did not reveal any systematic reviews nor any primary research studies that had investigated quantitative outcomes from pharmacist integration within Aboriginal health settings. The review revealed five systematic reviews- one of which was conducted in Australia exploring pharmacist integration within general practice.[46] None of the included studies identified if participants were from marginalised groups such as Indigenous peoples or peoples residing in remote geographical locations.

Direct effectiveness

Table 3 provides a narrative synthesis of the findings of this Umbrella Review.

Eligible publications were assessed for methodological quality using the critical appraisal tool for systematic reviews and research syntheses developed by The Joanna Briggs Institute.[47] A total of 161 studies were assessed across the five reviews, and included randomised controlled trials (RCTs), non-randomised controlled trials (non-RCTs), quasi RCTs, cohort studies, controlled before and after studies and pretest-posttest studies. Approximately 60% (97 of 161) of the studies were conducted in the USA. The studies were heterogenous in regard to 'integration' of non-dispensing pharmacists into primary health care teams. All studies primarily examined interprofessional collaboration between pharmacists and GPs. Across the included studies patients were either categorised according to a particular chronic disease; or were considered more broadly as patients prescribed multiple medications, those at risk of an adverse health issue or those at risk of a medication-related adverse event. All reviews except one stipulated that the comparison group was usual care or no intervention. Outcomes examined across the included studies were also heterogenous.

Outcomes assessed in reviews were classified broadly as changes in biomedical markers (blood pressure, HbA1c, cholesterol, lipids, Framingham risk score), changes in prescribing practices or appropriateness (prescribing quality, reduction of inappropriate prescribing), and patient-reported outcomes (quality of life, patient satisfaction).

[46] Tan ECK, Stewart K, Elliot RA, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. *Res Social Adm Pharm*. 2014;10: 608-622.

[47] Aromataris E, Fernandez R, Godfrey C et al. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthc. 2015;(13)3:132-140.

In summary, the aggregated results from the included reviews suggest that the integration of a non-dispensing pharmacist in PHC settings can improve patient outcomes and the quality of care relative to usual care. Biomedical markers, such as HbA1c, blood pressure and cholesterol improved with pharmacist intervention across a number of trials. Pharmacist intervention also improved the quality use of medications and reduced inappropriate prescribing. There was no effect on the quality of life of patients. There were no published studies to inform on the impact of this intervention on the Aboriginal and Torres Strait Islander population with chronic disease. These findings therefore highlight the importance of the IPAC Trial to inform on clinical endpoint and quality use of medicines outcomes from services provided by pharmacists when they are integrated within ACCHS or other relevant primary healthcare settings.

Table 3 Characteristics of included studies – Umbrella Review of integration of non-dispensing pharmacists into primary health care services (copyright: James Cook University, 2020) [48]

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
Fish et al. 2002 **The International Journal of Pharmacy Practice**	Effect and cost of practice-based pharmaceutical services	Changes in prescribing practices Prescribing quality Cholesterol BP Medication compliance QoL	Systematic review	Physicians/GPs Pharmacists/ Pharmaceutical prescribing advisors	Adults with chronic disease (hypercholesterolaemia, hypertension, polypharmacy, COPD) Patients at risk of medication-related errors	GP practice Community health centre	5	Jan 1980-March 2001	1983-2000	16 studies RCTs UK Australia Sweden Canada US	Educational outreach visits, medication reviews and patient specific prescribing advice were effective in achieving desired outcomes There is insufficient evidence to generalise about cost-effectiveness of the interventions
Tan et al. 2014 **Research in Social and Administrative Pharmacy**	Effectiveness of clinical pharmacist services delivered in primary care general practice clinics	HbA1c BP Cholesterol Framingham risk score	Systematic review and meta-analysis	GPs Pharmacists	Adults with chronic disease (CVD, diabetes, depression, metabolic syndrome, pain, COPD, menopause) or polypharmacy	GP practice	4	1966-2013	1996-2013	38 studies RCTs US UK Canada Brazil Chile Japan Thailand Jordan	Pharmacist co-location in GP clinics delivered a range of interventions with favourable results in chronic disease management and quality use of medications

[48] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
					Patients at risk of medication-related errors Patients at risk of adverse health problem						
Riordan et al. 2016 **SAGE Open Medicine**	Effect of pharmacist-led interventions in optimising prescribing	Change in prescribing appropriateness: Beers criteria STOPP/START MAI Clinical or patient-reported outcomes eg QoL or patient satisfaction	Systematic review	Pharmacists Physicians Nurses	Community-dwelling older adults (>65 years) with polypharmacy, drug-related problems	GP practice Family medicine clinic Veterans Affairs medical centre	11	Inception-Dec 2015	1996-2010	5 studies RCTs Quasi-RCTs Controlled before and after studies Interrupted time series US UK New Zealand	Pharmacist-led interventions involving access to medical notes and medication reviews conducted in physician practices with feedback to physicians may improve prescribing appropriateness
Fazel et al. 2017 **Annals of Pharmacotherapy**	Impact of pharmacist interventions as part of the health care team on diabetes therapeutic outcomes in ambulatory care settings	HbA1c Systolic BP LDL-C	Systematic review and meta-analysis	Pharmacists	Adults with Type 1 or Type 2 diabetes mellitus	Hospital-based outpatient clinics Community pharmacies Primary care physician offices Community clinics	9	1995-Feb 2017	1996-2016	42 studies (Systematic review = 42 studies Meta-analysis = 35 studies) RCTs Non-RCTs Pretest-posttest studies US	Pharmacists' interventions as part of the patient's health care team improved diabetic therapeutic outcomes by significantly reducing HbA1c, SBP, LDL-C

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
										Australia Iran Jordan Thailand	
Hazen et al. 2018 **Research in Social and Administrative Pharmacy**	Impact of degree of integration of a non-dispensing pharmacist on medication related health outcomes in primary care	Real clinical health outcomes eg mortality Surrogate clinical health outcomes eg HbA1c, lipids, BP Patient reported outcomes eg QoL Proxies of health outcomes eg quality of care performance indicators	Systematic review	Pharmacists GPs	Adults with chronic disease (diabetes, hypertension, dyslipidaemia, metabolic syndrome, heart failure, depression, cardiovascular disease, osteoporosis)	Primary care practice	2	1966-June 2016	1996-2015	60 studies RCTs Two group cohort studies One group cohort study US UK Brazil Canada Hong Kong Jordan Australia Sweden	Full integration of a non-dispensing pharmacist into a primary health care setting adds value to patient-centred (heterogeneous patients such as those with multimorbidity and polypharmacy), but not disease-specific (patients with specific chronic conditions), clinical pharmacy services

BP = blood pressure, SBP = systolic blood pressure, LDL-C = low-density lipoprotein C, HbA1c = haemoglobin A1c, CVD = cardiovascular disease, COPD = chronic obstructive pulmonary disease, QoL = quality of life, GPs= general practitioners, RCT = randomised controlled trial, STOPP/START = Screening Tool for Older Persons Prescriptions/Screening Tool to Alert doctors to Right Treatment, MAI = Medication Appropriateness Index

Primary research outcomes – the IPAC Trial

The IPAC Trial was the first interventional study to investigate the impact of integrating a non-dispensing pharmacist within Aboriginal community-controlled health services (ACCHSs) on the health of Indigenous Australians. The primary and secondary outcomes from the trial are summarised in Table 4, Table 5 and Appendices 9 to 14.

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. A brief summary of outcomes and activities is given below**.**

Clinical endpoints

Integrated pharmacists embedded into usual care in ACCHSs, significantly improved the control of cardiovascular disease (CVD) risk factors, glycaemic control in patients with T2DM, and reduced absolute CVD risk in Aboriginal and Torres Strait islander adults with chronic disease.[49] The following was reported:

- 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/1.73m2 (95% CI:-2.99 to 2.7), significantly slower than the predicted and annual decline of -3.0 ml/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).

[49] Couzos S, Smith D, 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). Draft Report to the PSA, April 2020.

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.[50] 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.[51]

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.[52] 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.[53] 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.[54]

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

[50] Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ 2000; 321:7258: 405-412.

[51] Pousinho S, Morgado M, Falcão A, Alves G. Pharmacist Interventions in the Management of Type 2 Diabetes Mellitus: A Systematic Review of Randomized Controlled Trials. J Manag Care Spec Pharm. 2016 22:5: 493-515

[52] Hardy ST, Loehr LR, Butler KR, et al. Reducing the Blood Pressure-Related Burden of Cardiovascular Disease: Impact of Achievable Improvements in Blood Pressure Prevention and Control. *J Am Heart Assoc*. 2015;4(10):e002276. Published 2015 Oct 27. doi:10.1161/JAHA.115.002276

[53] Cook NR, Cohen J, Hebert PR, Taylor JO, Hennekens CH. Implications of small reductions in diastolic blood pressure for primary prevention. Arch Intern Med. 1995;155:701–709.

[54] Hardy ST, Loehr LR, Butler KR, et al. Op. Cit.

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).[55] [56]

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.[57] 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.[58]

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,[59] a significant reduction in underprescribing of BP-lowering medications for those with T2DM and albuminuria,[60] and significant improvements in patient self-reported medication adherence.[61] Integrated pharmacists also delivered team-based care to optimise chronic disease management (such as case conferences) and attended patient group

[55] Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170 000 participants in 26 randomised trials. Lancet 2010; 376: 1670–81.
[56] Collins R, Reith C, Emberson J, et al. Interpretation of the evidence for the efficacy and safety of statin therapy. Lancet 2016; 388: 2532–2561.
[57] Ku E, Xie D, Shlipak M, et al. Change in Measured GFR Versus eGFR and CKD Outcomes. J Am Soc Nephrol. 2016;27(7):2196–2204. doi:10.1681/ASN.2015040341
[58] Maple-Brown LJ, Hughes JT, Ritte R, Barzi F, et al. Op. cit.
[59] Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilisation in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project). Op. Cit.
[60] Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilisation in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project). Op. Cit.
[61] 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. Draft Report, May 2020.

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.

Medication management reviews

Within ACCHSs, integrated pharmacists significantly increased access to medication management reviews (HMRs and non-HMRs), and provided follow-up to these reviews for Aboriginal and Torres Strait Islander adults with chronic disease.[62] Key results were:

- Participants (n=1,456) had 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 ($p<0.001$). 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.
- HMR recipients had a mean age of 58.7 years (SD ±21.9), a mean of 8 prescribed medications each, and 89% had comorbidity.
- 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.

[62] 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 pharmacist support within Aboriginal Community -Controlled Health Services (IPAC Project). Final report to the Pharmaceutical Society of Australia. February 2020.

Medication Appropriateness Index (MAI) audits

Prescribing quality improved significantly for participants following the integrated pharmacist intervention within ACCHSs.[63] Nearly two-thirds of participants were prescribed a medication that was rated as inappropriate pre-intervention. Key results included:

- 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 who were 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).
- Quality prescribing 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).

Assessment of underutilisation results

Potential Prescribing Omissions (PPOs) were common in this cohort.[64] Improvements in prescribing quality arising from non-dispensing pharmacists integrated within ACCHSs significantly averted PPOs to high-value pharmacotherapies. Key results included:

[63] Couzos, S, Smith D, Buttner P, Biros E. Assessment of medication appropriateness using the Medication Appropriate 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, Feb 2020.

[64] Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilisation 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 Pharmaceutical Society of Australia. February 2020.

- 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.

Medication adherence patient survey and self-reported health status

Integrated pharmacists embedded into ACCHSs significantly improved the medication adherence of participants, as well as their self-assessed health status.[65] The NACCHO Medication Adherence Response Scale (NMARS) tool was developed for the project and was a valid and reliable research tool when used to evaluate the extent of medication adherence and reasons for medication non-adherence in the context of this study. Results included:

- Participants with paired single-item (SIQ) and NMARS data (n= 1,103) and paired SF1 data (n=975) had a median of 213 (IQR: 134-303) and 201 (IQR: 126-279) days between assessments, respectively.
- Almost all participants were Aboriginal and/or Torres Strait Islander with a mean age at baseline of 58 (SD 29.8) years.
- At baseline, 70.8% (781/1103) of participants were adherent according to SIQ (scores 6 or 7), 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, and a 23.9% (233/975) net absolute increase in the number of participants with improved self-assessed health status (p<0.001).

[65] 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 for the IPAC project. Final Report, May 2020.

- NMARS content and construct validation procedures affirmed acceptable validity for the newly developed tool. Cronbach's alpha was 0.66 indicating the upper limit for validity and acceptable internal consistency for the purpose of the study. PCA analysis supported unidimensionality of the tool. Pharmacists reported the NMARS and single-item question (SIQ) self-reporting tools for assessing the extent of adherence and the reasons for non-adherence were useful to stimulate conversation relating to adherence.

Economic evaluation

The IPAC intervention found relatively low costs to be associated with increases in the utilisation of medications and primary health care services, the latter having the potential to contribute to more equitable, needs-based health care expenditure for the Aboriginal and Torres Strait Islander population.[66] Results included:

- In the cost-consequence analysis, the net costs of delivering the intervention of $1,493 per person 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).
- In the cost-effectiveness analysis, for participants with a clinical diagnosis of T2DM, the ICER of the IPAC intervention versus no intervention was $3,769 per participant with a clinically meaningful reduction in HbA1c of at least 0.5%.
- For the subset of participants selected for MAI assessments, the corresponding ICER was $6,809 per reduction in the number of participants with a PPO.
- For participants with a clinical diagnosis of T2DM, the cost-utility analysis yielded an ICER of $7,463 (95% CI $6,030–9,664) per gain in quality adjusted life years (QALYs), assuming no lifetime costs additional to usual care were required to maintain the reduction in HbA1c.
- On an annual basis, the extended IPAC intervention was estimated to cost $13.2 million.
- The corresponding annual increase in utilisation of medications and primary health care services associated with better medication management support was $5.1

[66] Hendrie D, Smith D, Couzos S. Economic evaluation of the Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHSs) to improve Chronic Disease Management (IPAC Project). Final Report, May 2020.

million. However, cost savings were also likely to be achieved from the improvement in health outcomes, for example, from a reduction in the utilisation and corresponding costs of emergency department presentations and hospital admissions. Under different scenarios, these cost savings were assessed as falling between $0.6 and $1.9 million per annum, varying according to the expected decrease in utilisation achieved.

In summary, integrating a non-dispensing pharmacist within ACCHSs led to significant and clinically relevant improvements (relative to usual care) in a range of primary and secondary clinical endpoints and quality of care outcomes for Aboriginal and Torres Strait Islander peoples with chronic disease attending ACCHSs. The intervention significantly improved glycaemic control in participants with T2DM and also brought about improvements in diastolic BP, total cholesterol, LDL-C, triglycerides, mean annual eGFR, and mean calculated absolute 5-year CVD risk in all study participants. Systolic BP significantly improved in those younger than 57 years of age. These improvements were clinically meaningful and evident in a population with a substantial chronic disease burden that occurred at a relatively younger age than other Australians.

Improvements were evident for prescribing quality indicators reflective of significant reductions in suboptimal prescribing, reductions in the use of medications that were unnecessary, and reductions in underprescribing of high-value pharmacotherapies. There were significant and substantial increases in participant access to HMRs (based on item 900 MBS claims), and other medication management reviews indicating that services provided by pharmacists within ACCHSs relative to usual care, led to superior health care service utilization (towards equity) by Aboriginal and Torres Strait Islander participants with chronic disease. There were significant improvements in adherence to medications for participants who enrolled to receive pharmacist services, as well as significant improvements in their self-assessed health status. Qualitative evaluation indicated that patients, integrated pharmacists, community pharmacists, and ACCHS staff reported that the intervention had improved quality of care outcomes and found the intervention to be acceptable and feasible.

Economic analysis reported relatively low costs to be associated with increases in the utilisation of medications and primary health care services, the latter having the potential to contribute to more equitable, needs-based health care expenditure for the Aboriginal and Torres Strait Islander population. Additionally, the modelled cost-utility analysis conducted for patients with T2DM found that, based on commonly used reference ICERs for the Australian health system, the ICER of $7,463 represented good value for money.

Table 4 Summary of the IPAC Trial findings- primary and secondary outcomes.

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
Clinical endpoints (Appendix 9), (SD, 95% CI)							
Participants with a clinical diagnosis of T2DM	HbA1c*, mmol/mol [%units]	539	284	66.8 (37.2) *[8.3% (5.5%)]*	64.0 (39.5) *[8.0% (5.8%)]*	-2.8 (19.5, -4.5 to -1.0) *[-0.3% (3.9%, - 0.4% to - 0.1%]*	0.001
All participants	SBP, mmHg	1103	266	132.7 (33.2)	132.0 (29.9)	-0.7 (16.6, -1.7 to 0.4)	0.16
	DBP, mmHg	1045	268	80.0 (35.6)	79.2 (29.1)	-0.8 (9.4, -1.4 to -0.2)	**0.008**
	TC, mmol/L	660	314	4.51 (1.80)	4.35 (2.06)	-0.15 (0.77, -0.22 to -0.09)	**<0.001**
	LDL-C, mmol/L	575	295	2.35 (1.20)	2.27 (1.20)	-0.08 (0.48, -0.13 to -0.03)	**0.001**
	HDL-C, mmol/L	622	294	1.05 (0.5)	1.06 (0.5)	0.01 (0.25, -0.02 to 0.03)	0.32
	TG, mmol/L	730	296	2.39 (2.43)	2.29 (2.21)	-0.11 (1.08, -0.20 to -0.01)	**0.006**
	ACR, mg/mmol*	475	301	57.9 (183.1)	61.7 (224.5)	3.8 (102.4, -6.32 to 13.83)	0.42
	CVD 5-year risk, %units	38	255	11.9 (7.2)	10.9 (5.4)	-1.0 (2.6, -1.8 to -0.12)	**0.027**
	eGFR* (no minimum follow-up time), ml/min/1.73m^2	895	296	49.1 (159.2)	48.4 (160.4)	1.9 (25.7, 0.1 to 3.7)**	**<0.001**
	eGFR* (6-month minimum follow-up time), ml/min/1.73m^2	720	317	49.6 (140.6)	48.1 (145.4)	-0.2 (36.0, -2.99 to 2.7)**	**0.034**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- appropriateness of medications							
MAI subset of participants	Mean MAI score per participant	357	329	6.02 (SD 23.6)	3.20 (SD 11.7)	↓46.8%	**0.003**
	Mean MAI score per medication	357	329	0.76 (SD 8.5)	0.39 (SD 4.4)	↓48.7%	**0.004**
	Number of medications with ≥1 inappropriateness rating (n, %)	357	329	647/2804 (23.1%)	357/2963 (12.1%)	-11.0%	**0.008**
	Mean number of medications per participant with ≥1 inappropriateness rating (n, %)	357	329	1.8 (SD 5.3)	1.0 (SD3.6)	↓44.4%	**0.001**
	Number of participants with at least one inappropriate medication rating (n, %)	357	329	242 (67.8%)	159 (44.5%)	-23.3%	**<0.001**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- overuse of medications (n,%)							
MAI subset of participants	Number of participants with any medications that met ≥1 overuse criterion	357	329	132 (37.0%)	87/377 (24.4%)	-12.6%	**<0.001**

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
	Number of medications that met ≥1 overuse criterion	357	329	249/2804 (8.9%)	147/2963 (5.0%)	-3.9%	**0.017**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- medications meeting MAI risk criteria (n,%)							
MAI subset of participants	Drug not indicated	357	329	156/2804 (5.6%)	97/2963 (3.3%)	-2.29%	**0.033**
	Medication is ineffective for the condition	357	329	103/2804 (3.7%)	51/2963 (1.7%)	-1.95%	**0.010**
	Dosage incorrect	357	329	194/2804 (7.0%)	92/2963 (3.1%)	-3.81%	**<0.001**
	Directions incorrect	357	329	88/2804 (3.1%)	65/2963 (2.2%)	-0.94%	0.107
	Directions Impractical	357	329	89/2804 (3.2%)	16/2963 (0.5%)	-2.63%	**0.001**
	Significant drug-drug interactions	357	329	144/2804 (5.1%)	58/2963 (2.0%)	-3.18%	0.059
	Significant drug-disease interactions	357	329	72/2804 (2.6%)	38/2963 (1.3%)	-1.29%	**0.008**
	Unnecessary duplication of drugs	357	329	83/2804 (3.0%)	46/2963 (1.6%)	-1.41%	0.066
	Unacceptable therapy duration	357	329	164/2804 (5.9%)	98/2963 (3.3%)	-2.54%	**0.029**
	Most expensive drug	357	329	41/2804 (1.5%)	33/2963 (1.1%)	-0.35%	0.447
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10) - medications with an inappropriateness rating by medication type (n,%)							
MAI subset of participants	Cardiovascular medications [a]	357	329	164/1014 (16.2%)	77/1056 (7.3%)	-8.9%	**0.013**
	Endocrine medications [b]	357	329	136/593 (22.9%)	64/615 (10.4%)	-12.5%	**0.002**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10) - participants with medications with an inappropriateness rating by medication type (n,%)							
MAI subset of participants	Cardiovascular medications [a]	357	329	117/357 (32.8%)	46/357 (12.9%)	-19.9%	**<0.001**
	Endocrine medications [b]	357	329	91/357 (25.5%)	51/357 (14.3%)	-11.2%	**<0.001**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 11)- underuse of medications							
AoU subset of participants	Number of participants assessed with AoU, who had at least one potential prescribing omission (PPO) (n,%)	353	330	181/353 (51.3%)	76/353 (21.5%)	-29.7%	**<0.001**
	Number of PPOs/participant	353	330	0.73 (SD 1.3)	0.29 (SD 0.9)	↓60.3%	**<0.001**
Home Medicines Reviews by MBS item 900 (Appendix 12) (n/100 person years, 95%CI)							
All participants	Number of participants with ≥1 Home Medicines Reviews (HMR) based on MBS item 900 claims	1456	285	10.0 (5.2-18.0)	38.7 (29.6-49.3)	↑3.9 times (rate ratio)	**<0.001**
	Number of MBS item 900 rebate claims	1456	285	10.2 (5.5-18.0)]	41.6 (32.2-52.3)	↑4.1 times (rate ratio)	**<0.001**
Medication management reviews (Appendix 12) (n,%)							

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
All participants	Number of participants with HMR (from the logbook)	1456	285	na	609/1456 (41.8%)	↑639 reviews	na
	Number of participants with ≥1 'medication related problems' that were identified following a HMR	1456	285	na	535/609 (87.9%)	na	na
	Number of participants with a non-HMR[c]	1456	269	na	719/1456 (49.4%)	↑757 reviews	na
	Number of participants with ≥1 'medication related problems' that were identified following a non-HMR	1456	269	na	503/719 (70.0%)	na	na
	Number of assessments that were a follow-up to a HMR or non-HMR[d]	1456	285/269	na	na	↑1,548 reviews	na
Medication adherence and self-assessed health status (Appendix 13) (n,%)							
All participants	Number of participants adherent to medications (NMARS)	1103	294	808/1103 (73.3%)	950/1103 (86.1%)	12.8%	**<0.001**
	Number of participants adherent to medications (SIQ)	1103	294	781/1103 (70.8%)	895/1103 (81.1%)	10.3%	**<0.001**
	Number of participants with 'very good to excellent' self-assessed health status	975	281	175/975 (18.0%)	303/975 (31.1%)	23.9%	**<0.001**
Qualitative analysis -the patient experience and stakeholder perceptions (See **Appendix** 14)							

Bold p-values imply statistically significant change at the 0.05 level. SD = cluster-adjusted standard deviation (ACCHS cluster). 'na' refers to 'not applicable'.
^p-values are cluster adjusted (ACCHS), however the adjustment may have also been conducted at the patient level – see analyses described in each individual report for the method used for each outcome measure.
↑Refers to a relative increase in the outcome measure (baseline compared with end of study).
↓Refers to a relative reduction in the outcome measure (baseline compared with end of study).
*Refers to last observation pre-enrolment and at follow-up. Unit conversion from IFCC (International Federation of Clinical Chemistry, mmol/mol) to DCCT (Diabetes Control and Complications Trial, %) units using the https://www.diabetes.co.uk/hba1c-units-converter.html units converter. eGFR reference range: Normal or Stage 1: CKD >89, Stage 2: 60-89 Stage 3A: 45-59, Stage 3B: 30-44, Stage 4: 15-29, Stage 5:<15. (Units in ml/min/1.73m^2), sourced from the National Guide (3rd Edn).[67] Albumin:creatinine ratio normal reference range: >2.5 mg/mmol for males and >3.5mg/mmol for females. Macroalbuminuria is defined as >25mg/mmol in males and >35 mg/mmol in females. Absolute CVD 5-year risk sourced from the National Guide (3rd Edn).[68]

[67] NACCHO and RACGP. National Guide to a preventive health assessment for Aboriginal and Torres Strait Islander people. 3rd Edn. RACGP, Melbourne, 2018
[68] NACCHO and RACGP. Op. Cit.

Mean annualised difference. P-value (paired data) were derived from the cluster-adjusted (ACCHS cluster) comparison of annualised differences against -3, as this is equivalent to a paired t-test. The value of -3 is the expected mean annual eGFR (ml/min/1.73m2) linear decline in Aboriginal and Torres Strait Islander adults (*see* ***Appendix 9*).

[a] Medications for: heart failure, angina, hypertension, arrhythmia, dyslipidaemia, pulmonary hypertension, other.

[b] Medications for: adrenal insufficiency, bone, diabetes, thyroid disorders, other.

[c] Based on logbook entries. A non-HMR was defined as a comprehensive medication management review comprising some or all the elements of a HMR, but not fulfilling all relevant MBS HMR criteria. The most common reason given by pharmacists for a non-HMR was to opportunistically provide a medication management review because the patient was at risk of forgoing a HMR. The other most common reasons for a non-HMR were because of limited patient access to an accredited pharmacist, and patient preference.

[d] A follow-up to a HMR or non-HMR was defined as a participant follow-up 3-6 months after the completion of an HMR or a non-HMR. Each activity involved reminder about the HMR and non-HMR advice and recommendations provided by the pharmacist (and the GP, if appropriate), assessment of the impact of any actions recommended from the HMR or non-HMR, and if another HMR or non-HMR or education session or preventive intervention was needed.

ACR= albumin-creatine ratio
AoU= Assessment of underutilisation
BP= blood pressure;
CVD= cardiovascular disease.
DBP= diastolic blood pressure
eGFR= estimated glomerular filtration rate
HbA1C= glycated haemoglobin
HDL-C= high density lipoprotein cholesterol
HMR= Home Medicines Review
LDL-C= low density lipoprotein cholesterol
MAI= Medication Appropriateness Index. The MAI score increases with increasing medication inappropriateness.
MBS = Medicare Benefits Schedule
NMARS = NACCHO medication adherence response scale for the reasons for non-adherence
PPO= potential prescribing omission
SBP= systolic blood pressure
SIQ = Single-item question for the extent of medication adherence
TC= total cholesterol
TG= triglycerides
T2DM= type 2 diabetes mellitus

Table 5 Summary of the IPAC Trial findings- economic analysis.

Economic Analysis (Section D)							
Type of economic evaluation	**Population**	**Outcome measure**	**Number of participants (n)**	**Mean length of stay in the study (days)**	**Incremental cost**	**Incremental outcomes**	**ICER**
Cost-consequence analysis	All participants	Various biomedical indices	1,456	284	$2,173,981	Various[1]	$1,493 per participant to achieve improvements in multiple biomedical indices[1]
Cost-effectiveness analysis	Participants with a clinical diagnosis ofT2DM	Number of participants with a clinically meaningful reduction in HbA1c	539	287	**$753,774**	**200**	$3,769 per participant with a clinically meaningful reduction in HbA1c of at least 0.5%
Cost-effectiveness analysis	Participants assessed for the underutilisation of medications	Number of potentially preventable omissions (PPO)	353	326	$714,959[2]	105	$6,809 per reduction in the number of participants with a PPO
Cost-utility analysis	Participants with a clinical diagnosis of T2DM	QALYs	539	287	$753,774	101	$7,463 per QALY

[1] 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).

[2] Includes (i) cost of PBS medicines and (ii) participants in trial for an average of 326 days.

Economic Analysis (Section E)						
Cost item	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total – 5 years**
Total intervention costs to extend IPAC model to all ACCHSs	$13,846,142	$13,273,542	$13,141,042	12,876,292	$12,851,292	$66.0 million
Total costs of additional health services from extending IPAC model to achieve more equitable use of PBS medicines and HMRs	$5,139,777	$5,139,777	$5,139,777	$5,139,777	$5,139,777	$26.0 million
Potential reduction in costs from fewer ED presentations and hospital admissions[1]	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$3.17 million – $9.5 million

[1] Range based on assumption as to potential reduction in ED presentations and hospital admissions.

B1.4 TRANSLATION ISSUES

The IPAC trial investigated the integration of a non-dispensing pharmacist within ACCHS settings delivering services expected within their current scope of practice. The pragmatic study design enabled the evaluation of real-world outcomes expected in this setting for Aboriginal and Torres Strait Islander adults with chronic disease. The study involved a large sampling frame of 18 services of varying sizes and geographic locations (across 22 sites in Queensland, Victoria, and the Northern Territory), as the goal was to evaluate real-life outcomes affecting an unselected population with chronic disease to enhance the external validity of the quality improvements expected from the intervention.[69] The IPAC trial had a large sample and analysed data from 1,456 enrolled Aboriginal and/or Torres Strait Islander participants. This suggests that the trial enrolled and evaluated the impact of the intervention using a sample large enough to adequately represent the population for whom the broader roll-out of the intervention is proposed.

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 has been demonstrated for every outcome measure investigated in the project (see Appendices 9-14**, and Section C**). The IPAC participants were representative of the proposed population, and 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.[70] 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. Where prescribing outcomes from subsets of the population were investigated, analysis subsequently showed that the characteristics of this subset (n=357) was similar to the remaining broader IPAC cohort that did not have MAI assessments (n=1099, Appendix 10). Similarities were observed in age, sex, Aboriginality, geographical location, pensioner status, number of medications, CTG script eligibility, Health Care Homes enrolment, prior HMR, self-assessed health status, clinical diagnoses, type of chronic disease, degree of comorbidity or

[69] Øvretveit J, Leviton L, Parry G. Increasing the generalisability of improvement research with an improvement replication programme *BMJ Quality & Safety* 2011;20:i87-i91

[70] Ford I, Norrie J. Pragmatic Trials. N Engl J Med 2016; 375:454-463.

multimorbidity, obesity, glycaemic control, or prevalence of eGFR levels. The proportion of participants who self-reported as adherent to medications was also similar between cohorts (**Appendix 13).**

Table 6 provides a summary of the factors relevant to the translation of the IPAC intervention to ACCHSs and the proposed population more broadly. The proposed population for integrated pharmacist services delivered within ACCHSs are Aboriginal and Torres Strait Islander patients (irrespective of age) who have a clinical need for pharmacist support because of chronic disease and/or being at high risk of developing medication related problems because of their chronic disease. It is recommended that the intervention also target the broader ACCHS population including children who are also at high risk of developing medication related problems (irrespective of chronic disease).

The evaluation of pharmacist services as part of the IPAC Trial was restricted to adults over 18 years, mainly because of the ethics requirements for research associated with children providing informed consent. Chronic disease such as T2DM emerges at younger ages in the Aboriginal and Torres Strait Islander population than the general Australian population which means that arbitrary age-based criteria (set for evaluation purposes) is logistically restrictive in real-world settings for others who need medication support. There is a clear clinical need for services to support medication use in children, which is within the scope of practice of pharmacists to provide.

Table 6 Summary of factors relevant to the translation of the IPAC intervention to Aboriginal community-controlled health services more broadly

Factor	Translation issues	Implications for translation
General (implementation)	The IPAC trial used data from 1,456 participants making it one of the largest interventional studies involving individually consented Aboriginal and Torres Strait Islander adults with chronic disease ever conducted in Australia. The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study that was community-based and participatory.	The large sample size, the broad geographical distribution of involved ACCHSs, and the study design supports the transferability of the study findings to other ACCHS settings and the proposed population. The IPAC study evaluated real-life outcomes within ACCHS settings arising from the intervention (integrated pharmacists within ACCHSs).

Factor	Translation issues	Implications for translation
Proposed population	IPAC participant criteria were: adult (18 years and over) patients with chronic disease who had visited a participating ACCHS site at least three times in the past two years relative to the recruitment date into the study (known as 'active' or 'regular' patients). Patients 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).	The proposed patient population for the broader translation of the integrated pharmacist intervention includes all adult Aboriginal and Torres Strait Islander patients who have a clinical need for pharmacist support because of chronic disease and/or being at high risk of developing medication related problems. The economic evaluation has been outlined the financial implications for this roll-out (**Section D and E**). The intervention is likely to benefit a broader ACCHS population including children (who would only make up a very small portion of pharmacist patients). Broader roll-out of the intervention needs to meet the needs of all ACCHS patients using medication, and this more flexible approach aligns with the principle of ACCHS self-determination.
Consumer impact	Qualitative evaluation involved twenty-four (24) integrated pharmacists who provided feedback on their experiences in the role and how well the project was able to be implemented within their ACCHS. Thirteen general practitioners, 12 managers and 10 community pharmacists responded to an online survey. Three ACCHSs were visited for an in-depth assessment of implementation.	Consumer impact reports from the qualitative evaluation (**Appendix 14)** support transferability of the intervention to the broader ACCHS sector.
Participant satisfaction	Several focus groups with participants revealed the benefits and challenges of the intervention and were overwhelmingly positive. There was increased knowledge and engagement of participants in their own health care through increased engagement with the health service. (Appendix 14).	Qualitative evaluation (**Appendix 14**) support transferability of the intervention to the broader ACCHS sector.
ACCHS inclusion criteria	Each ACCHS underwent a health systems assessment (HSA) to explore service characteristics and identify any systems change over the trial intervention period. There was little change in health systems assessment within participating sites from baseline to the end of the study that might	The intervention (integrated pharmacist) is transferable to ACCHSs that meet site inclusion criteria consistent with the core success factors of the IPAC trial. The

Factor	Translation issues	Implications for translation
	otherwise explain prescribing improvements (such as from non-IPAC related service activity). ACCHSs were also required to meet site inclusion criteria for the project and are reported in the published protocol (Appendix 1). For example, making sure that ACCHS have the physical space to support clinical consultations between the patient and pharmacist, to have a GP prescriber employed within the service, and pharmacist access to patient medical records (clinical information systems) and team-based care, are essential. (Appendix 14)	proposed health service criteria that have been modified for transferability are shown in Table 10.
	ACCHSs involved in the IPAC Trial were representative of other ACCHSs within their jurisdiction (reported by *NACCHO Affiliates*).	The intervention (integrated pharmacist) is transferable to ACCHSs that meet site inclusion criteria shown in Table 10.
Integration model within ACCHSs	Pharmacists were integrated within ACCHSs with: identified positions and core roles; had shared access to clinical information systems; provided continuous clinical care to patients, particularly on-site within the clinic setting; 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.	Transferability will require and depend on fidelity to the integration model that was evaluated in the IPAC Trial.
Pharmacist registration	Integrated pharmacists fulfilled the following eligibility criteria: registration with the Australian Health Practitioners Regulation Agency (Ahpra); more than 2 years' post-registration experience; and post-graduate clinical qualifications or demonstrated clinical experience. Accreditation to conduct an HMR was preferred, however it was not mandatory for integrated pharmacists.	Transferability will require fidelity to the eligibility criteria for registered pharmacists as was evaluated in the IPAC Trial.
Pharmacists core roles	Integrated pharmacists functioned within existing and usual primary health care service delivery systems and focused on pre-determined core roles that included providing medication management reviews; assessing participant adherence and medication appropriateness; providing medicines information and education and training; collaborating with healthcare teams; delivering preventive care; liaising with stakeholders and developing stakeholder liaison plans; providing transitional care; and undertaking a drug utilisation review. Pharmacists' worked with ACCHSs to apply the roles to their individual setting to ensure the intervention was most impactful.	Transferability will require and depend on fidelity to the core pharmacist roles within the integration model that was evaluated in the IPAC Trial, with allowances for each health service to prioritise pharmacist activity to meet the individual needs of the proposed population.

Factor	Translation issues	Implications for translation
Pharmacist training	Pharmacists were trained by the Pharmaceutical Society of Australia (PSA) to deliver core roles (all within their existing scope of practice). Pharmacists were also provided with ongoing support through regular online communications and mentoring support.	Transferability of the intervention to broader ACCHSs will require additional resource commitments, such as the development of training materials and resources, to train registered pharmacists prior to commencing integrated pharmacist roles within ACCHSs. The PSA and PGA are well placed to provide a program of training and ongoing support for pharmacists.
	Patient follow-up to medication management reviews as undertaken by integrated pharmacists, was substantial. There were 1,548 follow-up assessments of patients who had a review (mean time for follow-up was 30 mins), over a mean period of 284 days of participant involvement in the study. Patient follow-up is complicated as the target population is burdened by many chronic diseases and healthcare providers face many important demands. Clinical algorithms to streamline patient referral systems so that integrated pharmacists within the ACCHS model of care can follow-up patients will be valuable (Appendix 14, and Appendix 16).	Opportunistic pharmacists' assessments of the target patient population are particularly important in enhancing patient access to medication-related services. NACCHO, the Affiliates and PSA are well placed to develop generic clinical algorithms and resources to support ACCHSs to implement processes for opportunistic and patient follow-up regarding medication management.
Cultural protocols	Pharmacists integrated within ACCHSs were required to adhere to cultural and team-based principles relevant to ACCHS settings, so that study participants could benefit from the community trust this supported. Only ACCHSs were involved in the IPAC study (n=18).	Translation of the impact of the intervention is relevant only to primary healthcare settings within the ACCHS sector.
ACCHSs being service-ready	All ACCHSs received support and a site visit to be involved in the IPAC Trial. Some services were well prepared for the pharmacist and understood the value of the role. Staff in other services needed time to fully understand the role and learn how to utilise the pharmacists' expertise. Support from GPs and Aboriginal Health Workers and Practitioners (AHW/P) were enablers to the integration of the integrated pharmacist within the ACCHS. In particular, AHW/Ps played a vital role in assisting with patient follow-up. (Appendix 14)	Support will need to be provided to clinic staff and managers (for flow-on effect to healthcare staff) to ensure ACCHSs are ready for the integrated pharmacist role. The adaption and development of policies and procedures to guide ACCHS medicine-related activity with an integrated pharmacist will be valuable. NACCHO and the Affiliates are well placed to develop these policies, support staff, and

Factor	Translation issues	Implications for translation
		procedures, in partnership with the PSA, to support ACCHSs.
Integrated pharmacist recruitment	Integrated pharmacists were selected for the IPAC Trial with skills aligned to the expected scope of practice and core roles. Placements within ACCHS were influenced by the needs, capacity, and preparedness of ACCHSs that was assessed by NACCHO. Local community pharmacies were approached first to see if they are able to provide a pharmacist to work within the ACCHS according to service requirements of the ACCHS. If community pharmacies were unable to nominate a pharmacist, or if this nomination was not accepted by the ACCHS in line with principles of self-determination, the integrated pharmacist was employed directly by the PSA for the purposes of the Trial. Analysis was not undertaken to compare outcomes arising from differential models of integrated pharmacist employment.	Pharmacist recruitment to integrated non-dispensing roles within ACCHSs will be influenced by the financing models for broader program roll-out. Respecting the principles of self-determination means that ACCHSs have control of pharmacist recruitment to ensure their 'fitness for the service' with respect to suitable skills and cultural safety. The employment of pharmacists by the PSA (which was the dominant model used in the IPAC trial) will not be applicable for broader program roll-out. Ensuring similar selection criteria and community pharmacy involvement will help with recruitment of suitable similar candidates.
Community pharmacy	Many ACCHSs already had strong existing relationships with their local community pharmacies. 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 dose administration aids for 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. Community pharmacists also perceived that patient knowledge of their medicines and adherence to medicines had improved since the integrated pharmacists had commenced in the ACCHSs. (Appendix 14). Integrated pharmacists completed 49 stakeholder liaison plans (median time taken for each plan was up to 5 hours) and 82% were completed with community pharmacies.	Pharmacists integrated within ACCHSs had substantial engagement with community pharmacy and pharmacists. Although engagement with community pharmacy is core to model of care for integrated pharmacist activity, resources to facilitate this stakeholder liaison will further encourage this activity. The PSA and the PGA are well placed to develop these resources or other supports.

Factor	Translation issues	Implications for translation
	Integrated pharmacists recorded 3,233 contacts with community pharmacy with nearly 70% being initiated by the integrated pharmacist [Appendix 16]	
Transferability of all IPAC outcomes	The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study that was community-based and participatory. Generalisability was explored in all evaluation reports for primary and secondary outcomes (Appendices 9-13).	Improvements to clinical endpoints, prescribing quality improvements, improvements in access to medication management reviews, and improvements to adherence and self-assessed health status are generalisable to the proposed population (Appendices 9-13).
Business rules for HMRs	Pharmacists within ACCHSs operated within existing and usual business rules for Home Medicines Review MBS item 900 rebate claim and pharmacist fee for HMR under the 6CPA.	Existing business rules for medication management reviews can be utilised by integrated pharmacists within ACCHSs.

ACCHS= Aboriginal community-controlled health service
GP= general practitioner
HCH= Health Care Homes
HMR= Home Medicines Review
IPAC= Integrated pharmacists within ACCHSs to improve chronic disease management Project
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
RAICCHO= Regional Aboriginal and Islander community-controlled health organisations

B1.5 ECONOMIC EVALUATION

A trial-based economic evaluation was undertaken (interventional pre-post quasi experimental study conducted within ACCHSs as presented in **Section B**). Three types of economic analysis were conducted:

(i) a cost-consequence analysis that included all participants with changes in biomedical indices for whom pre- and post-measures of outcomes were recorded;

(ii) a cost-effectiveness analysis for two sub-groups of participants: those with T2DM with pre- and post-measures of HbA1c and those selected for MAI assessments at baseline and at the end of the study, with potential prescribing omissions (PPOs) used as the relevant outcome measure; and

(iii) for participants with a clinical diagnosis of T2DM, a cost-utility analysis that derived lifetime quality of life changes from the decreases in HbA1c observed during the trial period based on T2DM simulation models.

A summary of the economic evaluation that was undertaken is included in Table 7.

Table 7 Summary of the economic evaluation

Perspective	Health system (excludes private)
Comparator	Usual care pre-intervention
Type of economic evaluation	Cost-effectiveness analysis (CEA) and cost-consequence analysis (CCA)
Sources of evidence	Clinical trial
Time horizon	284 days
Outcomes	Biomedical indices, HbA1c, number of potential prescribing omissions
Methods used to generate results	Trial-based
Discount rate	Not necessary due to time horizon
Software packages used	SPSS and MSExcel

1. A cost-utility analysis was included by deriving lifetime quality of life changes from a systematic review of published studies that modelled the relationship between decreases in HbA1c and lifetime gain in QALYs.

This economic evaluation compared the costs and outcomes of the IPAC intervention versus usual care prior to the addition of an integrated non-dispensing pharmacist within ACCHSs to promote the quality use of medicines. The perspective adopted was the publicly funded health system. Discounting was not applied as the mean participant enrolment period was less than one year.

The cost of implementing the IPAC intervention was $1,946,876 (Table 8). As a result of the intervention, the net cost of health services (HMRs) increased by $132,899 ($179,012-$46,113) and the net cost of PBS medicines (i.e. medicines started less medicines stopped) increased by $553,849 ($132,899+$418,049). Participants for whom information on medicine use was not collected, were allocated the average cost of PBS medicines per participant, as calculated for participants with a medicine cost. Cost offsets from time saved by GPs and integrated pharmacists conducting HMRs (within trial hours) and non-HMRs during the trial period amounted to $459,643.

The net total cost of implementing the IPAC trial was $2,173,981 (calculated as [$1,946,876+($132,899+$553,849)-$459,643]). **On a per participant basis, this cost was equivalent to $1,493 per person.**

The results of the economic analysis are outlined in Section D.

Table 8 Resource use, costs and cost offsets in delivering the IPAC intervention (n=1,456)

Item	Resource use (units)	Costs ($)	
		During-trial period	Pre-trial period ("comparator")
Integrated pharmacist salary	27,478 hours	$1,621,079	
Integrated pharmacist allowances	-	$136,658	
Pharmacist out-of-pocket payment	-	$9,741	
Integrated pharmacist training	-	$64,820	
ACCHS contribution[1]	-	$52,158	
General Practitioner time spent	719 hours	$62,420	
Total: Intervention costs	**-**	**$1,946,876**	
Home Medicines Review based on item 900 claims (HMR)	149 pre-intervention; 471 during intervention[2]	$179,012 [2]	$46,113[3]
Net cost of PBS medicines (participants for whom medicines was measured)		$135,800[4]	
- (PBS medicines started)	-	($514,467)[4]	
- (PBS medicines stopped)	-	($378,667)[4]	
Net cost of medicines (participants for whom medicines were not directly measured)	-	$418,049[5]	-
Cost of utilisation health services		**$732,861**	**$46,113[3]**
Time saved by General Practitioners	1366 hours	$118,528	
Cost offsets HMRs	-	$53,402[6]	
Non-HMRs	757	$287,713	
Cost offsets		**$459,643**	
Net total costs		**$2,220,094**	**$46,113[4]**

HMR= Home Medicines Review. A completed HMR represents a comprehensive medication management review that fulfils the criteria for a Medicare Benefits Scheme (MBS) claim for item 900, as sourced from the integrated pharmacist's logbook.
Non-HMR= a comprehensive medication management review that was not an HMR, as sourced from the integrated pharmacist's logbook.
PBS= Pharmaceutical Benefit Scheme.

[1]Excludes overheads and infrastructure costs (e.g. office space, computers, etc)

[2]Data from HMR report (Appendix 12).[71] A cost offset of $380.07 per HMR was applied.

[3]A cost offset of $380.07 per HMR was applied but was adjusted for each participant to reflect equivalent number of days in pre-trial period as during trial period.

[4]Derived from: *Couzos S, Drovandi A, Smith D, Hendrie D, Biros E. Net cost to the PBS of medication changes arising from the IPAC intervention: Method used to assess health system costs for economic analysis. Supplement to the Economic Evaluation for the IPAC Project. Report to the PSA, December 2019.* The costs differ slightly from this report as the costs here also include the cost of medicines for four participants who were not in the AoU group, totalling $2593.69 ($135,800 - $133,206). This cost relates to the subset of participants who had an AoU conducted.

[5]Participants for whom information on medicine use was not collected were allocated the average cost of PBS medicines per participant as calculated for participants with a medicine cost.

[6]Derived from 471 HMRs X $113.39. The majority (96.4%) of HMRs conducted during the trial period were completed by the integrated pharmacists, with approximately half (52.8%) conducted within IPAC hours and for which no 6CPA claim was submitted. Given the fee of $222.77 per HMR, this amounts to a cost offset to the system of $113.39 per HMR (0.964 x 0.528 x $222.77).

[71] 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 pharmacist support within Aboriginal community - controlled health services (IPAC Project). Final Report to the PSA, Feb 2020.

B1.6 ESTIMATED EXTENT OF USE AND FINANCIAL IMPLICATIONS

Section E outlines the financial implications of the broader roll-out of the proposed service to Aboriginal and Torres Strait Islander patients with chronic disease (irrespective of age) attending ACCHSs.

The financial implications have been determined based on the integrated model of care for pharmacists investigated in the IPAC Trial. **Section B and Appendices** outline the methods, main results, findings, limitations and generalisability of the findings. **Section C** outlines translation issues.

The approach used to estimate the financial implications of the introduction of an integrated pharmacist within ACCHSs has been based on costings for recruitment, employment, training, taking into account the proposed settings and the proposed population and extrapolated to the proposed ACCHS services. Information is also drawn from the economic evaluation presented in Section D.

Financial implications include the cost of (i) delivering the proposed service and (ii) additional utilisation of health services resulting from integrated pharmacists being part of the primary health care team. Costs presented are a maximum figure that assumes all ACCHSs across Australia will participate in the extended IPAC program and be able to access suitable pharmacists.

Cost offsets from implementing the IPAC model of care will be generated as the integrated pharmacists assume tasks previously undertaken by GPs, thus freeing up time for GPs. Additionally, improvement in biomedical indices for clients is likely to lead to a reduction in the need for acute health care services over time.

Over the projected 5-year period, total costs of implementing the extended IPAC intervention average $13.2 million per annum (Table 9).

Table 9 Financial implications of extending the IPAC intervention to all ACCHSs

Item	Year 1 ($)	Year 2 ($)	Year 3 ($)	Year 4 ($)	Year 5 ($)
Pharmacists salary	11,735,262	11,735,262	11,735,262	11,735,262	**11,735,262**
Training and support for pharmacists	1,151,000	621,000	621,000	488,750	488,750
Program support for ACCHSs	647,500	622,500	490,000	357,500	332,500
Program monitoring and evaluation	312,380	294,780	294,780	294,780	294,780
TOTAL COSTS	13,846,142	13,273,542	13,141,042	12,876,292	12,851,292

The corresponding annual increase in utilisation of medications and primary health care services associated with better medication management support and for more equitable use of health systems by the Aboriginal and Torres Strait Islander population was $5.1 million. However, cost savings were also likely to be achieved from the improvement in health outcomes, for example, from a reduction in the utilisation and corresponding costs of emergency department presentations and hospital admissions. Under different scenarios, these cost savings were assessed as falling between $0.6 and $1.9 million per annum, varying according to the expected decrease in utilisation achieved (see **Section E**).

B1.7 CONSUMER IMPACT SUMMARY

The impact of the intervention on consumers is detailed in a qualitative analysis that was undertaken to investigate participant, health service staff, pharmacist and general practitioner perspectives of the intervention (see Appendix 14). Twenty-four (24) integrated pharmacists representing all 20 health services involved in the project provided feedback on their experiences in the role and how well the project was able to be implemented within their ACCHS. Thirteen general practitioners, 12 managers and 10 community pharmacists responded to an online survey. Three ACCHSs were visited for an in-depth assessment of implementation.

The majority of patients, managers, GPs, other health services staff, and integrated pharmacists overwhelmingly supported the integration of pharmacists within ACCHSs.

Patients and health services staff benefited from having a pharmacist delivering services within the ACCHS. 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'. Patients felt empowered to better manage their health conditions through better understanding why they needed to take their medications and how they worked. Many patients indicated they were more adherent to their medications. In addition to feeling better, patients 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 pharmacist and other health services staff concurred that patients' management of the health conditions (such as adherence) had improved, as had their biomedical test results, particularly their HbA1c levels for patients with diabetes.

The main benefit for health services staff was having access to an 'in-house medicines expert'. The integrated pharmacists provided support and advice to health services staff informally

such as through 'corridor conversations' as well as formally through medication reviews. Integrated pharmacists and GPs reported that recommendations were commonly made by the integrated pharmacists following medication reviews. Recommendations were perceived to be of high quality and prescriber up-take of the recommendations was said to be high. Education sessions delivered for health services staff, including GPs, nurses and Aboriginal Health Workers were perceived as valuable. Health services staff also benefited from the pharmacists having input into their clinical team meetings and case conferences. The pharmacists contributed to medicines safety and quality assurance activities by conducting drug utilisation reviews and assisting in reviewing ACCHS medication-related policies.

Many ACCHSs had strong existing relationships with their local community pharmacies, particularly through supports for the Section 100 Remote Area Aboriginal Health Services program, and the Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) program arrangements. 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 access to dose administration aids (DAAs) for health service patients. Community pharmacists reported that the integrated pharmacist role was very helpful and useful to them and it facilitated communication between themselves and general practitioners. Relationships between ACCHSs and community pharmacies were further strengthened as a result of significant contact through the project. Participating community pharmacists believed there was a role for an IPAC-type (non-dispensing) pharmacists within ACCHSs

B1.8 OTHER RELEVANT CONSIDERATIONS- ACCESS AND EQUITY, AND WORKFORCE TRAINING

The integrated pharmacist intervention is likely to result in additional costs to the Australian Government through increased PBS medications, access to HMRs and health service utilisation. However, this is consistent with achieving equity for Aboriginal and Torres Strait Islander peoples who currently receive much less of these services. The integrated pharmacist intervention enhances access for Aboriginal and Torres Strait Islander peoples to these services.

Please see transferability issues in **Section C** and detailed considerations in **Section F**. For the intervention to be delivered to ACCHSs, issues needing further consideration include the additional resource commitments necessary to prepare and support pharmacists, such as through the PSA, and other ACCHS supports to deliver the integrated model of care

effectively. The qualitative analysis of the IPAC trial (Appendix 14) outlines some challenges that warrant consideration in the planning and support of program expansion.

Readiness for the pharmacist services delivered through the project was a challenge for some ACCHSs. All ACCHSs received support and a site visit as part of the recruitment process, and some services were well prepared for the pharmacist and understood the scope and roles in which integrated pharmacists can work. However, staff in other services needed time to further understand the role and learn how to best utilise the pharmacists' expertise. Addressing this issue if there is a broader roll-out of this program will require support to be provided to clinical staff and managers to ensure they are prepared for the integrated pharmacist role. A lead-in period enabling the pharmacist and services to familiarise themselves with the proposed model and role would be beneficial prior to requiring any outcome data related to program deliverables. Supporting ACCHSs to develop policies and procedures to guide medicine-related activity will be valuable and could assist pharmacists to establish their role within the service. Making sure that ACCHS have the physical space to support clinical consultations between the patient and pharmacist and have a GP prescriber employed within the service are essential.

Support for ACCHSs in a broader roll-out of this program should be based on the six ACCHS support strategies provided throughout the IPAC trial (Appendix 22). This involved support from NACCHO and its Affiliates with some collaboration and technical and pharmacy-related involvement from PSA. Affiliates of NACCHO can leverage from their public health and clinical expertise and local knowledge based on their proximity and involvement in daily ACCHS activity to ensure local needs are optimally met and include pharmacist induction into the service, as well as health care staff induction to the role of the integrated pharmacist. For example, most pharmacists had project 'go to' people or 'champions' who assisted with their integration in services. Support from GPs and AHW/Ps were enablers to the integration of the integrated pharmacist and patient referral process. This was particularly the case with AHW/Ps who played a vital role in assisting with patient follow-up. Clinical algorithms to support patient referral to the pharmacists within the ACCHS model of care may also be valuable. Coordinating referral processes is complicated as the target population is burdened by many chronic diseases and other important health care provider demands. This means opportunistic assessments are particularly important to close the gap in access to medication-related services. NACCHO is well placed to lead the development of generic clinical algorithms and referral resources in collaboration with Affiliates and the PSA, if there is a broader roll-out of the integrated pharmacist model of care within ACCHSs.

Pharmacist recruitment to integrated non-dispensing roles within ACCHSs will be influenced by the financing models for broader program roll-out. The selection criteria and processes undertaken throughout the IPAC trial can inform future models of recruitment (Appendix 19). Pharmacists would not need to be employed by the PSA. Principles to be considered are:

- Respecting the principles of self-determination, ACCHSs have a role in pharmacist recruitment to ensure their 'fitness for the service' with respect to suitable skills and cultural safety.
- Pharmacists are selected with skills aligned to the expected scope of practice and core roles;
- Placements within ACCHSs will be influenced by the ACCHSs' needs, capacity, and preparedness;
- Community pharmacies who have well developed and respectful relationships with ACCHSs are well placed to provide or identify pharmacists to perform integrated roles to build on and enhance existing connections.

Induction to the integrated pharmacist role and ongoing support was provided throughout the trial by the PSA project coordinators. Pharmacists providing an integrated service within ACCHSs would benefit from a coordinated induction to the role and ongoing support to enable them to work effectively within their respective health services.

SECTION A – CONTEXT

This submission-based assessment of the *Integrating Pharmacists within Aboriginal Community Controlled Health Services* (ACCHSs) *to improve Chronic Disease Management* (IPAC) Trial for the integration of non-dispensing pharmacists within Aboriginal Community-Controlled Health Services (ACCHSs) is intended for the Medical Services Advisory Committee (MSAC). MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

James Cook University, has provided systematic and umbrella review evidence and the results of the IPAC Trial including economic evaluation on behalf of the broader IPAC program team, in order to inform MSAC's decision-making regarding whether the proposed medical service should be publicly funded.

The Pharmaceutical Society of Australia (PSA) was commissioned by the Australian Government Department of Health to conduct the IPAC Trial and economic evaluation of the IPAC Trial which was then undertaken in partnership with James Cook University and the National Aboriginal Community Controlled Health Organisation (NACCHO).

Appendix 23 provides a list of the people involved in the development of this assessment report.

A1 ITEMS IN THE AGREED PICO CONFIRMATION

This submission-based assessment of the integration of pharmacists within ACCHSs addresses all of the PICO elements that were pre-specified. The reference standard was the test as set out in the approved Trial Protocol and the case for the economic evaluation is based on a trial-based evaluation.

The summary PICO for the IPAC trial was as follows:

P: Aboriginal and/or Torres Strait Islander patients (adults ≥18 years of age and considered 'regular' clients) with chronic disease in receipt of care from eligible ACCHSs.

I: The addition of an integrated pharmacist as part of the primary health care team of ACCHSs providing evidence-based core support services and responsive needs-based services.

C: Usual care prior to the addition of an integrated non-dispensing pharmacist.

O: To improve quality of care outcomes (primary biomedical outcome measures, secondary outcome measures, and economic cost-effectiveness analysis).

A minor change from the original PICO proposed at the time of the PTP Trial funding application was accepted by the Department of Health and incorporated in the funding contract and project protocol. The change altered the target population from patients 'of any age' to adults ≥ 18 years. This change was made prior to PTP Trial funding and was agreed at the time contracts were finalised. Primary and secondary outcome measures were also refined to reflect improvements to the research methodology, and this was done and accepted prior to contracts being finalised. Iterations to the Project Protocol were made over time to refine the research methods, so that the current version 1.6, 18 November 2019 (Appendix 2) reflects the final version of the protocol that was ratified by the Steering Committee and the Department of Health.

A2 PROPOSED MEDICAL SERVICE

The proposed service is the addition of an integrated non-dispensing pharmacist as part of the primary health care team of ACCHSs to provide care to Aboriginal and/or Torres Strait Islander patients (considered 'regular' clients) with chronic disease. The services to be delivered by the integrated pharmacist include both patient-related and practice-related activities through the following core roles: providing medication management reviews, assessing and supporting medication adherence, providing medicines information and education and training, collaborating with healthcare teams, delivering preventive care, liaising with stakeholders such as community pharmacy, providing transitional care, and undertaking quality improvement activity such as a drug utilisation review.

The integration of a non-dispensing pharmacist within ACCHSs means the following (based on the key features of pharmacists working to deliver IPAC services):

- Pharmacists supported as team members within ACCHSs with identified positions;
- with shared access to clinical information systems;
- providing rational and continuous clinical care to patients;

- receiving administrative and other supports from primary health care staff within ACCHSs, and
- adhering to governance, cultural, and clinical protocols within ACCHSs as part of their shared vision.

These roles are consistent with the dimensions of 'integration' reported by other studies investigating the integration of pharmacists within primary health care (PHC) settings,[72] and the Integrating Models of Pharmacists across Care Teams (IMPACT) Framework that identified six domains to guide PHC services in readiness for the integration of pharmacists.[73]

Analysis of participant data and integrated pharmacist activities collected through the IPAC Trial has 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. 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 the many difficulties this population faces with taking medications.

A3 PROPOSAL FOR PUBLIC FUNDING

This proposal is for baseline plus pro-rata public funding (depending on the health service client load and episodes of care) of a non-dispensing pharmacist within ACCHSs to provide the services outlined in this proposal within an integrated model of care.

While a mixed model encompassing baseline funding plus a fee-for-service (FFS) methodology may be considered for future program rollout, block funding is likely to be more appropriate to enable integrated pharmacists to most effectively meet the unique needs of Aboriginal and

[72] Hazen ACM, de Bont AA, Boelman L, et al. The degree of integration of non-dispensing pharmacists in primary care practice and the impact on health outcomes: A systematic review. Res Social Adm Pharm. 2018; 14(3):228-240. doi: 10.1016/j.sapharm.2017.04.014. Epub 2017 Apr 22.

[73] Northern Territory PHN and Northern Territory Government Top End Health Service. *IMPACT Framework - A Framework to Guide the Integration of Pharmacists into Primary Health Care Teams*. 2018 18 Dec 2018 25 February 2020]; Available from: https://www.ntphn.org.au/web_images/IMPACT%20Framework.pdf.

Torres Strait Islander peoples. A block funding approach aligns with other Commonwealth funding approaches for ACCHSs (such as Indigenous Australians' Health Programme); accommodates patient non-attendance at scheduled clinic appointments that occurred in some ACCHSs during the IPAC trial; and allows for the significant variation in preference for pharmacist services (including clinical governance, education and training, and patient-directed care) observed across ACCHSs in the IPAC trial. On this basis an MBS item descriptor is not being proposed as it would encourage a FFS funding arrangement for pharmacists' services which is inconsistent with the integration model being proposed. An MBS item descriptor may not deliver the necessary integration of pharmacists required for them to provide services consistent with the proposed core roles within ACCHSs.

Pharmacists are not currently supported through existing Australian Government of State and territory programs to deliver integrated and non-dispensing services within these primary health care service settings, except nominally through the Workforce Incentive Program (WIP). The WIP is intended for rural and remote Australia and provides financial incentives to support general practices to engage the services of nurses and other allied health staff. Many ACCHSs are currently accessing the WIP to employ practice nurses and/or Aboriginal health practitioners/workers. This means there are no remaining WIP program funds to support the proposed medical service. The quantum of funding from the WIP is insufficient to support both the integration of a non-dispensing pharmacist as well as the existing uses of the WIP funding within ACCHSs. Furthermore, non-dispensing pharmacists remain unable to claim MBS item fees for chronic disease management (CDM) services provided in a primary care setting, and therefore cannot supplement the maximum incentive payment available under the WIP.

A4 PROPOSED POPULATION AND PROPOSED SETTING

The population targeted by this proposed service are Aboriginal peoples and Torres Strait Islanders with chronic disease who are known as 'active' or 'regular' patients receiving services within ACCHSs (at least three times in the past two years). Patients to be targeted are those with 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).

These conditions represent the participant inclusion criteria for the IPAC Trial.

The proposed settings are comprehensive primary health care services that are Aboriginal Community-Controlled Health Services (ACCHSs), as indicated by the service inclusion criteria for the IPAC Trial **(Appendix 1 and 2**). As this submission aims to extend the service (integrated pharmacists) beyond the IPAC Trial to ACCHSs broadly, the proposed setting has been amended to reflect program translation beyond the research trial (Table 10)

Table 10 Proposed Health Service criteria for participation in the proposed service (integrated pharmacist)

To receive the proposed service, the health service must:

- be an *Aboriginal Community Controlled Health Service* and funded by the Department of Health for the provision of primary health care services to Aboriginal and Torres Strait Islander peoples.
- be a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
- employ at least one full-time- equivalent general practitioner per clinic who is able to prescribe medicines to patients of that organisation.
- use an electronic clinical information system.
- participate in continuing quality improvement and reporting on the national Key Performance Indicators through the use of electronic data extraction tools.
- adhere to program business rules and guidelines, data provision requirements, and patient/service consent requirements for the program.
- provide the integrated pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system.
- be an accredited practice in accordance with the *Royal Australian College of General Practitioners* Practice Standards.
- be participating or eligible to participate in the Pharmaceutical Benefits Scheme co-payment measure (practice incentive program), if in a non-remote location.
- be eligible to participate in the section 100 arrangements for the supply of pharmaceutical benefits, if in a remote location.

Aboriginal peoples and Strait Islander people are known to experience a significantly higher burden of chronic disease than non-Indigenous Australians.[74] Despite the high burden of chronic disease, under-use of medications amongst Aboriginal and Torres Strait Islander people persists.[75] The rate of potentially avoidable hospitalisations for Aboriginal and Torres Strait Islander people is almost 5 times the rate for other Australians with over half of these relate to chronic conditions.[76] Aboriginal and Torres Strait Islander people's access to primary health services remains disproportionately low particularly when considering their higher burden of chronic disease[77] and PBS medicines continue to be underutilised compared with non-Indigenous Australians.[78] Quality Use of Medicines services are accessed at lower rates and this problem is often compounded by more complex medicine regimens and more co-morbidities seen in Aboriginal and Torres Strait Islander patients.[79]

Chronic diseases are the leading cause of illness, disability and death in Australia and comorbidities are associated with poorer health outcomes, more frequent use of health services and higher healthcare costs. Aboriginal and Torres Strait Islander people have two-to-three times higher levels of illness than non-Indigenous Australians. [80] Together with changes to lifestyle factors, long term treatment with medications is usually needed to prevent or reduce disease progression and thereby mitigate outcomes of ill health. Yet, registered pharmacists currently provide only limited clinical pharmacy services to Indigenous Australians due to several barriers including in remote areas, the limited funding available through the

[74] Bainbridge R, McCalman J, Clifford A, Tsey K, : Cultural competency in the delivery of health services for Indigenous people. Issues paper no. 13. Produced for the Closing the Gap Clearinghouse. In. Edited by Welfare AIoHa, vol. 13. Canberra: Australian 2015.

[75] Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people.* Jul 2014. http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf

[76] Australian Institute of Health and Welfare 2011. Access to health services for Aboriginal and Torres Strait Islander people. Cat. No. IHW 46. Canberra: AIHW http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737418951

[77] Australian Institute of Health and Welfare: Australia's health 2014. Australia's health series no.14. In., vol. Cat.no.AUS178. Canberra: AIHW; 2014.

[78] Australian Health Ministers' Advisory Council. Aboriginal and Torres Strait Islander Health Performance Framework 2017 Report. AHMAC, Canberra, 2017.

[79] Swain L: Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people. In. Canberra, ACT, Australia: Pharmaceutical Society of Australia, 2014

[80] Australian Institute of Health and Welfare. *Expenditure on health for Aboriginal and Torres Strait Islander people, 2010–11. An analysis by remoteness and disease*. Accessed 25 August 2014. Available at: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129544363

Section 100 Support Allowance.[81] [82] [83] [84] These barriers also include prohibitive HMR business rules and processes that are not always possible or culturally acceptable.[85] [86] Many Aboriginal health services provide few HMR referrals due to issues with the cultural responsiveness of pharmacists, and lack of relationships pharmacists have with these services.[87] [88] Yet, when medication reviews are delivered in culturally appropriate settings (such as in Aboriginal health services) there is great potential to increase patients' medication knowledge, medication adherence and to improve chronic disease management.[89]

Social determinants of health, and population-based disparities also impact on adherence to prescribed medications and are factors associated with adverse health outcomes in all population groups.[90] Social circumstances, and deficiencies in health services and systems mean Aboriginal people often suffer even greater challenges in medication management than non-Indigenous Australians. Social and emotional wellbeing issues may deeply pervade the lives of many Aboriginal people and may diminish the value that individuals place upon medications and the potential for these to improve their quality of life.[91] It has been said that "Australia's mainstream medical model focuses on compliance with medical advice and often ignores the complex historical and sociocultural influences that shape patients' responses to their health and health care."[92]

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[81] Swain L. Are rural and remote HMRs viable? Australian Pharmacist. 2012; 31(3):184.
[82] Campbell Research and Consulting. Home Medicines Review Program. Qualitative Research Project. Final Report. Department of Health and Ageing, Australian Government, Canberra, 2008.
[83] NOVA Public Policy Pty Ltd. Evaluation of Indigenous Pharmacy Programs Final Report 28 June 2010. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/F520A0D5EDEA0172CA257BF0001D7B4D/$File/Indigenous%20Programs%20Report.pdf
[84] Australian Government. Australian Government response to the Senate Community Affairs References Committee Report: Inquiry into the Effectiveness of Special Arrangements for the Supply of Pharmaceutical Benefits Scheme (PBS) Medicines to Remote Area Aboriginal Health Services. March 2018. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/content/AC97597F257E6ABBCA257BF0001FE872/$File/government-response-to-senate-enquiry-into-raahs-march-2018.pdf
[85] Swain L, Barclay L. Medication reviews are useful, but the model needs to be changed: Perspectives of Aboriginal Health Service health professionals on Home Medicines Reviews. BMC Health Serv Res. 2015;15:366-.
[86] Swain L, Griffiths C, Pont L, Barclay L. Attitudes of pharmacists to provision of Home Medicines Review for Indigenous Australians. Int J Clin Pharm. 2014; 1;36(6):1260-7.
[87] Swain L, Barclay L. Medication reviews are useful, but the model needs to be changed: Perspectives of Aboriginal Health Service health professionals on Home Medicines Reviews. BMC Health Serv Res. 2015;15:366-.
[88] Swain L, Griffiths C, Pont L, Barclay L. Attitudes of pharmacists to provision of Home Medicines Review for Indigenous Australians. Int J Clin Pharm. 2014; 1;36(6):1260-7.
[89] Swain L, Barclay L. Medication reviews are useful, but the model needs to be changed: Perspectives of Aboriginal Health Service health professionals on Home Medicines Reviews. BMC Health Serv Res. 2015;15:366-.
[90] World Health Organisation. Adherence to long term therapies; evidence for action. WHO, Switzerland, 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf?ua=1 {accessed 8 October 2018].
[91] Emden C, Kowanko I, De Crespigny C, et al. *Better medication management for Indigenous Australian: findings from the field*. Aust J Prim Health 2005;11:80–90.
[92] Pharmaceutical Society of Australia. *Guide to providing pharmacy services to Aboriginal and Torres Strait Islander people.* Jul 2014. http://www.psa.org.au/download/guidelines/Guide-to-providing-pharmacy-services-to-Aboriginal-and-Torres-Strait-Islander-people.pdf

A5 COMPARATOR DETAILS

The proposed medical service supplements the usual care provided to Aboriginal and Torres Strait Islander patients with chronic disease attending existing ACCHSs. The comparator used for the evaluation of the IPAC trial was the 'usual care' provided to the enrolled participants within participating ACCHSs in the 12 months preceding their enrolment into the study. Usual care was defined as usual primary healthcare service provision to Aboriginal and Torres Strait Islander patients without the presence of an integrated pharmacist within the health service. Health service activity that was conducted prior to pharmacist integration and patient enrolment was defined as baseline activity. Baseline (usual care) comprised a period of 12 months prior to participant enrolment into the study, or the first assessment that was conducted after patient enrolment and within the first 90 days, depending on the outcome measure being evaluated.

Usual care varies across ACCHS contexts. In the absence of integrated pharmacists' services, usual care provides limited medication adherence support to Aboriginal and Torres Strait Islander patients of ACCHSs. Access is ad hoc and if it is sourced by the target population, it is usually accessed via community pharmacy. Medication management reviews (if sourced) are accessed via community pharmacies or directly from independent accredited pharmacists with delivery and content strictly guided by Program Rules.[93] Education and training is currently provided to ACCHS staff (and some patients in the target population) according to the program rules for the S100 Support Allowance, and some arrangements contracted with community pharmacy through the QUMAX Program. The following services have not been generally and routinely available as part of usual care to healthcare providers and the target population within ACCHSs:

- Opportunistic patient follow up;
- Team-based collaboration activity;
- Preventive health care delivery specifically targeting the Aboriginal and Torres Strait Islander population;
- Medicines information service on-site, including opportunistic advice;
- Stakeholder liaison services;
- Transitional care support;

[93] Pharmacy Programs Administrator. Program Rules. Home Medicines Review. Australian Government, Department of Health, Canberra, July 2019.

- Quality improvement activity (such as a drug utilisation review).

A6 CLINICAL MANAGEMENT ALGORITHM(S)

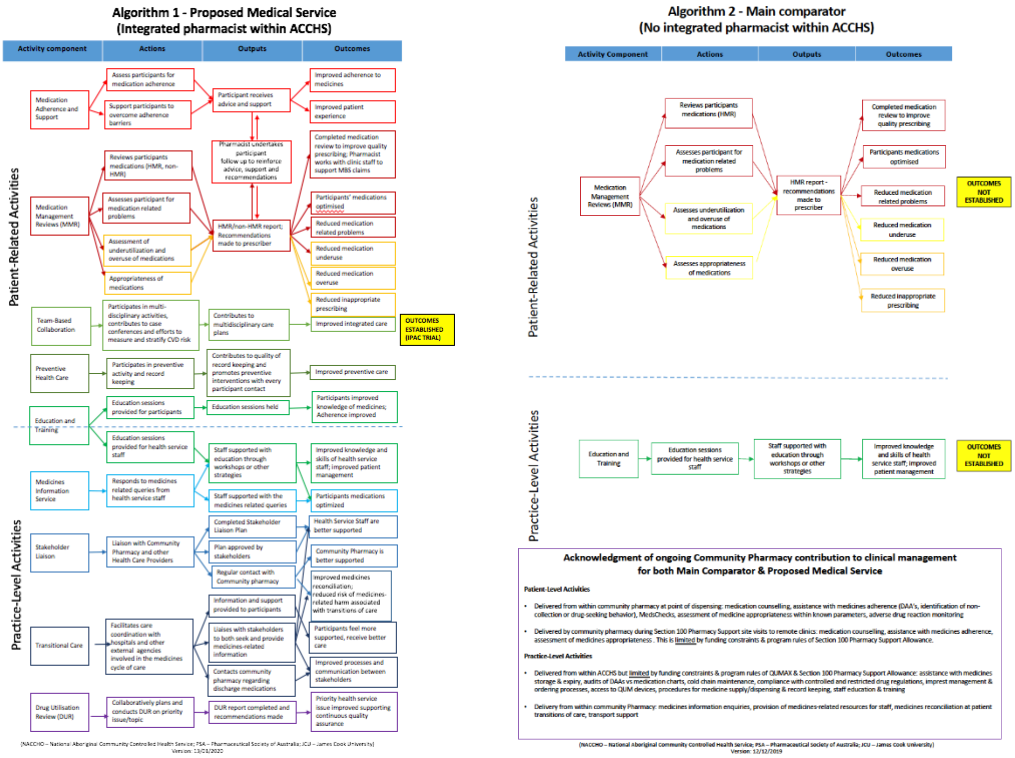
The theory of change model for the IPAC Trial outlines that if pharmacists are integrated within ACCHSs providing primary health care to Aboriginal peoples and Torres Strait Islanders, they can facilitate increased access to medication-related expertise and assessments for prescribers and other members of the primary healthcare team, compared with usual care. When that access is coupled with increased engagement with patients, as well as other stakeholders such as community pharmacy and hospitals, this will result in improved patient access to services, improved quality use of medicines such that suboptimal prescribing is reduced, increased medicines utilisation, and improvements in chronic disease outcomes for the target population. This model was tested in the IPAC Trial and the evidence now confirms these associations and outcomes as being achieved. The theory of change for the intervention is summarised as Appendix 3.

This model outlines factors influencing the impact of an integrated pharmacist and the underpinning assumptions, such as conditions outside the control of individual healthcare professionals, and also to some extent outside the control of healthcare services. These assumptions include: that prescribers are supportive and receptive to pharmacists recommendations; that many barriers to optimal medication use are socially determined and outside the control of the patient and healthcare team; and that community pharmacy is sufficiently engaged and has the capacity to support change.

A logic model developed for evaluation of the IPAC Trial is in effect, a clinical management algorithm. It depicts the context of the proposed service where a non-dispensing pharmacist integrated within the health service functions to deliver clinical care to individual Aboriginal and Torres Strait Islander patients, and to improve the overall integration of care for the patient. Pharmacists integrated within the ACCHS can themselves facilitate a 'joined-up' and more coordinated journey for the patient. This is achieved through medicines reconciliation when patients are hospitalised or discharged supporting their transition in care; through liaison with community pharmacy to support the patient and general practitioner; through consultations at time and place that suit the patient; and through improved record-keeping and team-based care. Integrated pharmacists can enhance health systems by supporting quality prescribing and quality improvement within the ACCHS context. The logic model is summarised as Appendix 4.

The proposed clinical management algorithm that depicts the context of the intended use of the proposed medical service following public funding for the service is shown as Appendix 5. It is formatted to be comparable to the usual care algorithm (without an integrated pharmacist within ACCHSs) as Appendix 6. The algorithms are placed side by side to highlight differences.

Figure 1 Clinical management algorithm/s for the proposed new service relative to current clinical practice (usual care)



A7 KEY DIFFERENCES IN THE PROPOSED MEDICAL SERVICE AND THE MAIN COMPARATOR

The differences between the proposed medical service and the main comparator have been explained in the following Table 11. The main differences pertain to a more integrated, coordinated, collaborative, and expansive set of medication- related services being introduced than is able to be provided through current and usual care within Aboriginal primary health care settings. This means that Aboriginal and Torres Strait Islander patients with chronic disease (who are particularly vulnerable to disjointed care), have a 'joined-up' experience of care with regard to medication management, within the ACCHS setting. For example, based on findings from the IPAC Trial, patients with chronic disease and substantial comorbidity, were at risk of forgoing a medication management review under usual care arrangements. Significantly more patients with chronic disease received Home Medicines

Reviews and other medication management reviews than from usual care.[94] These patients were able to be treated to optimise health outcomes, who would not otherwise have accessed this benefit through usual care mechanisms.

Table 11 Key differences in the delivery of the proposed medical service and the main comparator

Activity Component	Proposed medical service (Integrated pharmacist within ACCHS) Algorithm 1	Main comparator (No integrated pharmacist within ACCHS) Algorithm 2	Description of Difference
Medication Adherence and Support	Readily available. At each patient encounter, the pharmacist tailor's adherence assessment and support to known barriers relevant to the patient and ACCHS context.	Not readily available	Proposed medical services enable increased assessment and support for medicines adherence to help overcome related barriers to optimal medicines use and improves patient experience (Appendix 13).
Medication Management Reviews	Readily available. Option of opportunistic delivery at each patient contact. Location of service flexible to meet patient needs and preference. Unlimited follow up enables reinforcement of recommendations made and advice provided at initial medication review, and also assesses need for additional pharmacist services.	Limited availability. Restricted by CPA Medication Management Review program rules which determine frequency and location of service delivery. Follow up not readily available.	Proposed medical service offers increased uptake of Medication Management Reviews (MMR). Proposed medical service increases identification and prioritisation of patients for review, and enables flexibility with time and location as preferred by patients. This helps to overcome these known barriers to provision of the MMR service (Appendix 12).
Medication Appropriateness	Readily available. Pharmacist assesses medication appropriateness at each patient encounter.	Limited availability. Provided within Medication Management Reviews (see above).	Proposed medical service increases opportunities to assess prescribing appropriateness, overprescribing & medicines underutilization, with resultant improvements in prescribing quality (Appendices 10 and 11).
Team-Based Collaboration	Readily available. Pharmacist as integrated team member undertakes both opportunistic and scheduled collaboration with other clinicians.	Not readily available	Proposed medical service enables increased pharmacist participation in Multidisciplinary Case Conferences, & contribution to TCA/GPMPs (Appendix 16).

[94] 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 pharmacist support within Aboriginal community - controlled health services (IPAC Project). Final report to the Pharmaceutical Society of Australia for the IPAC Project, February 2020.

Activity Component	Proposed medical service (Integrated pharmacist within ACCHS) Algorithm 1	Main comparator (No integrated pharmacist within ACCHS) Algorithm 2	Description of Difference
Preventive health Care	Readily available. Pharmacist participates in health promotion activities & contributes to the recording of parameters needed to estimate CVD risk.	Not readily available	Proposed medical service increases preventive health care in relation to chronic disease management ((*Appendix 16*).
Education and Training	Readily available. Pharmacist provides education and training sessions tailored to the needs and preferences of the ACCHS, including topics, frequency, duration & intended audience. Sessions may be conducted for patient groups as well as staff.	Limited availability. Restricted by Section 100 Support Allowance and QUMAX program rules and funding.	Proposed medical service increases opportunities to improve the health literacy of patients and staff and contributes to the up skilling of health service clinicians to ultimately improve patient care (Appendices 14 and 16).
Medicines Information Service	Readily available. Pharmacist responds to medicines-related queries in a timely manner.	Not readily available	Proposed medical service improves prescribing quality (Appendices 10, 14 and 16).
Stakeholder Liaison	Readily available. Pharmacist shares relevant information with Community Pharmacy via mutually agreed methods of communication.	Not readily available	Proposed medical service increases communication between ACCHS and Community Pharmacy to optimise patient care (Appendices 14 and 16).
Transitional Care	Readily available. Pharmacist facilitates care coordination between ACCHS and other external agencies involved in the medicines cycle of care such as hospitals and renal dialysis units via mutually agreed methods of communication.	Not readily available	Proposed medical service increases communication between ACCHS and external agencies, with improvement in medicines reconciliation and reduction of risk of medicines-related harm associated with transitions of care (Appendices 14 and 16).
Drug Utilisation Review (DUR)	Readily available. Pharmacist collaborates with ACCHS staff to identify and address priority drug-related issues/topics.	Not readily available	Proposed medical service improves priority health service issues related to drug use and supports continuous quality improvement (Appendices 14 and 16).

Note: Core roles are color coded to match the logic model for the IPAC Project (Appendix 4).
The contribution of community pharmacy to usual care (algorithm 2- main comparator to the proposed service) is acknowledged as being provided within ACCHSs.

A8 CLINICAL CLAIM

Aboriginal and/or Torres Strait Islander adult patients with chronic disease receiving pharmacist services that are integrated within ACCHSs, will experience superior quality of care outcomes compared to usual care.

Services provided by pharmacists within ACCHSs is likely to lead to superior health care service utilization (towards equity) by patients with chronic disease compared to usual care.

A9 SUMMARY OF THE PICO

The summary PICO for the IPAC trial was as shown in Table 12.

Table 12 PICO criteria from the IPAC trial in Aboriginal and Torres Strait Islander adult patients with chronic disease attending Aboriginal community-controlled health services

Criteria	Description
Population	Aboriginal and/or Torres Strait Islander patients (adults ≥18 years of age and considered 'regular' clients) with chronic disease in receipt of care from eligible ACCHSs. Inclusion criteria: • 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).
Intervention	The addition of an integrated pharmacist as part of the primary health care team of ACCHSs providing evidence-based core support services and responsive needs-based services.
Comparator/s	Usual care prior to the addition of an integrated non-dispensing pharmacist.
Outcomes	To improve quality of care outcomes (primary biomedical outcome measures, secondary outcome measures, and economic cost-effectiveness analysis). Primary expected outcome was an improvement in quality of care indicators (including systolic and diastolic blood pressure, glycated haemoglobin (HbA1c), lipids, estimated absolute cardiovascular disease (CVD) risk, and albumin-creatinine ratio (ACR) in patients with chronic disease. Expected secondary outcomes included improvements in: • estimated glomerular filtration rate (eGFR); • prescribing indices (medication appropriateness, overuse, underuse, and medication-related problems); • patient use of medicines (medication adherence, self-assessed health status, and patient experience); • health service utilization indices (Medicare Benefits Schedule claims for: home medicines reviews, care plans, case conferences, team care arrangements and other items), and out-of-home medication management reviews (non-HMRs); and • stakeholder perceptions (ACCHSs staff; community pharmacies; pharmacists). An economic evaluation of the IPAC trial ascertained the incremental cost-effectiveness ratio of the pharmacy intervention in relation to usual practice (at baseline) to assess whether the IPAC trial represents value for money from a health system perspective. *Critical for decision making:* some primary outcomes and secondary outcomes pertaining to prescribing quality, health service utilisation indices such as MBS claims for Home Medicines Reviews; and stakeholder perceptions. These outcomes have been sourced from good quality data. *Important, but not critical for decision making*: other health service utilisation indices. *Low importance for decision making*: change in medication adherence, eGFR, CVD risk, ACR, self-assessed health status. These outcomes are subject to limitations in the quality of the data sourced from ACCHSs.
Primary research question	*Does the addition of an integrated pharmacist as part of the primary health care team of ACCHSs providing care to Aboriginal and/or Torres Strait Islander patients (≥18 years and considered 'regular' clients) with chronic disease, improve quality of care, and therefore health outcomes, compared with prior usual care?*

A10 CONSUMER IMPACT STATEMENT

The consumer impact is detailed in a qualitative analysis that was undertaken to investigate participant, health service staff, pharmacist and general practitioner perspectives of the intervention (see Appendix 14). Twenty-four (24) integrated pharmacists from all ACCHSs recruited in the project (n=20) [95] provided feedback on their experiences in the role and how well the project was able to be implemented within their service. Thirteen general practitioners, 12 managers and 10 community pharmacists responded to an online survey. Three ACCHSs were visited for an in-depth assessment of implementation.

The majority of participants, managers, GPs, other health services staff, and integrated pharmacists overwhelmingly supported the integration of pharmacists within ACCHSs.

Participants and health services staff benefited from having a pharmacist delivering services within the ACCHS. The majority of participants 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'. Participants felt empowered to better manage their health conditions through better understanding why they needed to take their medications and how they worked and many indicated they were more adherent to their medications. In addition to feeling better, patients 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 pharmacist and other health services staff concurred that participants' management of the health conditions (such as adherence) had improved, as had their biomedical test results, particularly their HbA1c levels for patients with diabetes.

The main benefit for health services staff was having access to an 'in-house medicines expert'. The integrated pharmacists were provided support and advice to health services staff informally such as through 'corridor conversations' as well as formally through medication reviews. 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 and with reportedly high prescriber up-take of the recommendations. Education sessions delivered for health services staff, including GPs, nurses and AHW/Ps)

[95] IPAC Project quantitative reports are based on patient data from 18 ACCHSs due to the discontinuation of two services in the implementation phase of the project.

were perceived as valuable, as was pharmacists input into their clinical team meetings and case conferences.

Many ACCHSs had strong existing relationships with their local community pharmacies, particularly through the Section 100 Remote Area Aboriginal Health Services program, and the Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) program arrangements. Relationships between ACCHSs and community pharmacies were further strengthened as a result of the IPAC trial. The qualitative evaluation found that the 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.

Activities recorded in the pharmacist logbook indicated integrated pharmacists interacted with community pharmacists on a daily basis with more occasions logged for such interactions than any other IPAC activity. The most common agency engaged by integrated pharmacists for supporting the transitional care of patients was also community pharmacy for the purpose of reconciling medication lists (Appendix 16).

Community pharmacists reported that the integrated pharmacist role was very helpful and useful to them and it facilitated communication between the community pharmacy and general practitioners. Community pharmacists also perceived that patient knowledge of their medicines and adherence to medicines had improved since the integrated pharmacists had commenced in the ACCHSs. Participating community pharmacists believed that there was a role for an IPAC-type (non-dispensing and integrated) pharmacists within ACCHSs.

SECTION B – CLINICAL EVALUATION

The clinical effectiveness of integrated pharmacists within ACCHSs is based on direct primary research evidence through the conduct of the PTP Trial known as the Integrating Pharmacists within Aboriginal Community Controlled Health Services (ACCHSs) to improve Chronic Disease Management (IPAC) Trial. The IPAC trial was funded by the Australian Government Department of Health, under the Pharmacy Trials Program (Tranche 2) funding as part of the Sixth Community Pharmacy Agreement (6CPA) that sought to improve clinical outcomes for patients utilizing the full scope of pharmacist's role in delivering primary health care services.

The IPAC Trial investigated the effectiveness of non-dispensing pharmacists integrated within ACCHSs during 2018-2019. The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study that was community-based and participatory (*Trial Registration Number and Register: ACTRN12618002002268*). The intervention was the integration of a registered pharmacist within the ACCHS primary healthcare team for up to a 15-month period. There were 22 ACCHS sites (18 ACCHSs) that participated in the project until the end, across three jurisdictions: Victoria, Queensland and the Northern Territory to ensure a sampling frame that best informed external validity of the outcomes across varied services and patient populations. Pharmacist positions were aggregated to represent a total of approximately 12.3 full time equivalents (FTE). All eligible ACCHS sites that participated received the intervention.

Two systematic reviews were sourced:

1) A systematic review of published literature was undertaken as part of the IPAC trial to explore cost-effectiveness analyses of integrated models of care involving pharmacists (Appendix 7) in the absence of existing reviews (see Section D);
2) A recently completed umbrella review of systematic reviews was sourced and included in this report, with permission granted from the authors[96] (Copyright James Cook University, in- confidence**, Appendix 8).** This umbrella review synthesised several systematic reviews that have been published exploring patient-related outcomes from integrated pharmacist interventions within primary health care

[96] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.

settings. **Please note that permission to release this report in the public domain has not been granted.**

B1 DIRECT EVIDENCE

B1.1 LITERATURE SOURCES AND SEARCH STRATEGIES

For the literature review on the 'cost-effectiveness of non-dispensing pharmacist services integrated within primary health care'[97] (Appendix 7), see Section D.

B1.2 LITERATURE SOURCES AND SEARCH STRATEGIES

This section refers to the umbrella review of systematic reviews on the 'cost-effectiveness of non-dispensing pharmacist services integrated within primary health care'[98] (Appendix 8).

This review aimed to determine the effectiveness of the integration of non-dispensing pharmacists into primary health care settings on patient outcomes such as intermediate clinical endpoints, prescribing quality, and patient-reported outcomes. Integration was defined broadly as any intervention that involved co-location of pharmacists within PHC settings, and/or pharmacists who worked as part of multidisciplinary healthcare teams using a range of integrative processes.

The umbrella review of systematic reviews did not reveal any systematic reviews nor any primary research studies that have investigated quantitative outcomes from pharmacist integration within Aboriginal health settings. The review revealed five systematic reviews- one of which was conducted in Australia exploring pharmacist integration within general practice.[99] None of the included studies identified if participants were from marginalised groups such as Indigenous peoples or peoples residing in remote geographical locations.

The medical literature was searched between August and December 2019 using Medline, PubMed, CINAHL, the Cochrane Database of Systematic Reviews, and the JBI Database of Systematic Reviews to identify all relevant systematic reviews and meta-analyses regarding the integration of non-dispensing pharmacists in primary health care. A set date range of

[97] Johnstone K, Smith D, Couzos S. Literature review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care. James Cook University, February 2020.
[98] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.
[99] Tan ECK, Stewart K, Elliot RA, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. *Res Social Adm Pharm*. 2014;10: 608-622.

1990-current was used. Searches were conducted of the databases and sources described in Appendix 8. Search terms are described in Table 13.

Table 13 Search terms used (literature search platform) for the review on the integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes.

Element of clinical question	Search terms
Population	AND (primary health care OR general practice OR family practice OR patient care team OR community health service OR community health centre OR primary care OR outpatient care OR family medicine OR multidisciplinary health care team OR team-based care)
Intervention	pharmacists OR pharmaceutical services OR non-dispensing pharmacist OR clinical pharmacist OR pharmaceutical care
Outcomes	AND (systematic review OR review).
Exclusions	Financial outcomes; analysis of interprofessional relationships; pharmacist based in community pharmacy or inpatient setting; concerned with health professionals other than pharmacists; unpublished studies or not clearly a systemic review or a meta-analysis; articles not in English.

B1.3 RESULTS OF LITERATURE SEARCH

A PRISMA flowchart (Figure 2) provides a graphic depiction of the results of the literature search and the application of the study selection criteria.

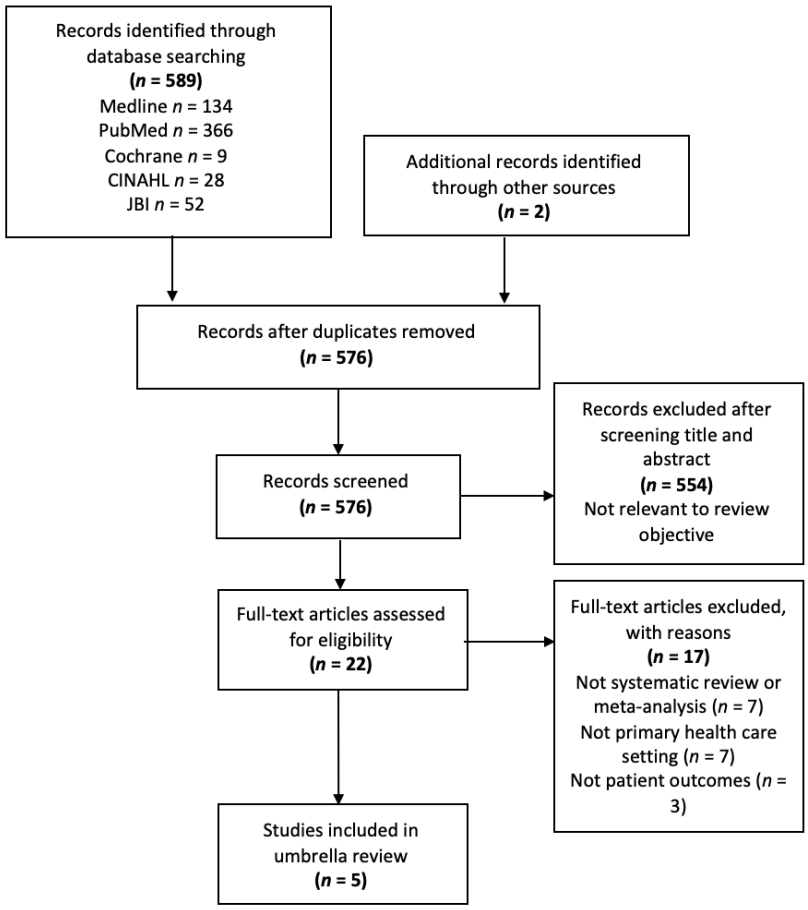
Two independent reviewers screened the titles and abstracts of all publications for eligibility (based on inclusion criteria; Table 14) and examined the full text of those considered eligible. Pre-specified criteria for excluding studies are included in Table 13. All studies that met the inclusion criteria are listed in Appendix 8.

Table 14 Population, intervention, comparison, outcome (PICO) scheme of inclusion criteria for Umbrella review.

Parameter	Description
Population	adults (over 18 years), chronic disease, any sex, any country, any ethnicity
Intervention	pharmacist integrated or co-located in PHC setting, provision of direct patient services or participation in the PHC team
Comparison	Usual care, lack of intervention

Parameter	Description
Outcome	Patient outcomes (biomedical measures, prescribing quality or appropriateness, medication adherence)

Figure 2 Summary of the process used to identify and select studies for the Umbrella review on the Integration of non-dispensing pharmacists into primary healthcare services.



A profile of each included study is given in Table 15 and in Appendix 8.

This study profile describes the authors, study ID, publication year, study design, study location, setting, study population characteristics, assessment methods, description of the comparator (and associated intervention), and the relevant outcomes assessed.

Table 15 Characteristics of included studies – Umbrella Review of integration of non-dispensing pharmacists into primary health care services (copyright: James Cook University, 2020) [100]

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
Fish et al. 2002 **The International Journal of Pharmacy Practice**	Effect and cost of practice-based pharmaceutical services	Changes in prescribing practices Prescribing quality Cholesterol BP Medication compliance QoL	Systematic review	Physicians/GPs Pharmacists/ Pharmaceutical prescribing advisors	Adults with chronic disease (hypercholesterolaemia, hypertension, polypharmacy, COPD) Patients at risk of medication-related errors	GP practice Community health centre	5	Jan 1980-March 2001	1983-2000	16 studies RCTs UK Australia Sweden Canada US	Educational outreach visits, medication reviews and patient specific prescribing advice were effective in achieving desired outcomes There is insufficient evidence to generalise about cost-effectiveness of the interventions
Tan et al. 2014 **Research in Social and Administrative Pharmacy**	Effectiveness of clinical pharmacist services delivered in primary care general practice clinics	HbA1c BP Cholesterol Framingham risk score	Systematic review and meta-analysis	GPs Pharmacists	Adults with chronic disease (CVD, diabetes, depression, metabolic syndrome, pain, COPD, menopause) or polypharmacy Patients at risk of medication-related errors	GP practice	4	1966-2013	1996-2013	38 studies RCTs US UK Canada Brazil Chile Japan Thailand Jordan	Pharmacist co-location in GP clinics delivered a range of interventions with favourable results in chronic disease management and quality use of medications

[100] Shaw C, Couzos S. Integration of non-dispensing pharmacists into primary healthcare services: an umbrella review and narrative synthesis of the effect on patient outcomes. James Cook University, January 2020.

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
					Patients at risk of adverse health problem						
Riordan et al. 2016 **SAGE Open Medicine**	Effect of pharmacist-led interventions in optimising prescribing	Change in prescribing appropriateness: Beers criteria STOPP/START MAI Clinical or patient-reported outcomes eg QoL or patient satisfaction	Systematic review	Pharmacists Physicians Nurses	Community-dwelling older adults (>65 years) with polypharmacy, drug-related problems	GP practice Family medicine clinic Veterans Affairs medical centre	11	Inception-Dec 2015	1996-2010	5 studies RCTs Quasi-RCTs Controlled before and after studies Interrupted time series US UK New Zealand	Pharmacist-led interventions involving access to medical notes and medication reviews conducted in physician practices with feedback to physicians may improve prescribing appropriateness
Fazel et al. 2017 **Annals of Pharmacotherapy**	Impact of pharmacist interventions as part of the health care team on diabetes therapeutic outcomes in ambulatory care settings	HbA1c Systolic BP LDL-C	Systematic review and meta-analysis	Pharmacists	Adults with Type 1 or Type 2 diabetes mellitus	Hospital-based outpatient clinics Community pharmacies Primary care physician offices Community clinics	9	1995-Feb 2017	1996-2016	42 studies (Systematic review = 42 studies Meta-analysis = 35 studies) RCTs Non-RCTs Pretest-posttest studies US Australia Iran Jordan	Pharmacists' interventions as part of the patient's health care team improved diabetic therapeutic outcomes by significantly reducing HbA1c, SBP, LDL-C

Author, year, journal	Objectives	Outcomes	Type of review	Participants	Patient characteristics	Setting	No. of data-bases searched	Date range of database searching	Publication date range	No. and types of studies, country of origin	Conclusions
										Thailand	
Hazen et al. 2018 **Research in Social and Administrative Pharmacy**	Impact of degree of integration of a non-dispensing pharmacist on medication related health outcomes in primary care	Real clinical health outcomes eg mortality Surrogate clinical health outcomes eg HbA1c, lipids, BP Patient reported outcomes eg QoL Proxies of health outcomes eg quality of care performance indicators	Systematic review	Pharmacists GPs	Adults with chronic disease (diabetes, hypertension, dyslipidaemia, metabolic syndrome, heart failure, depression, cardiovascular disease, osteoporosis)	Primary care practice	2	1966-June 2016	1996-2015	60 studies RCTs Two group cohort studies One group cohort study US UK Brazil Canada Hong Kong Jordan Australia Sweden	Full integration of a non-dispensing pharmacist into a primary health care setting adds value to patient-centred (heterogeneous patients such as those with multimorbidity and polypharmacy), but not disease-specific (patients with specific chronic conditions), clinical pharmacy services

BP = blood pressure, SBP = systolic blood pressure, LDL-C = low-density lipoprotein C, HbA1c = haemoglobin A1c, CVD = cardiovascular disease, COPD = chronic obstructive pulmonary disease, QoL = quality of life, GPs= general practitioners, RCT = randomised controlled trial, STOPP/START = Screening Tool for Older Persons Prescriptions/Screening Tool to Alert doctors to Right Treatment, MAI = Medication Appropriateness Index

B1.4 RISK OF BIAS ASSESSMENT

Eligible publications were assessed for methodological quality using the critical appraisal tool for systematic reviews and research syntheses developed by The Joanna Briggs Institute[101], presented in Table 16. Each element of the checklist was designated as being 'met', 'not met', 'unclear', or 'not applicable'. This tool allows for an assessment of the quality of the included publications and was not used as part of the inclusion criteria.

Table 16 Risk of bias assessment for the review on the Integration of non-dispensing pharmacists into primary healthcare services- based on Joanna Briggs Institute critical appraisal checklist for systematic reviews and research syntheses[102]

Checklist	Fish et al. 2002	Tan et al. 2014	Riordan et al. 2016	Fazel et al. 2017	Hazen et al. 2018
Review question clearly and explicitly stated	Met	Met	Met	Met	Met
Inclusion criteria appropriate for the review question	Met	Met	Met	Met	Met
Appropriate search strategy	Met	Met	Met	Met	Met
Adequate sources and resources used to search for studies	Met	Met	Met	Met	Met
Critical appraisal conducted by two or more reviewers independently	Met	Met	Met	Met	Met
Appropriate methods used to combine studies	Not applicable	Met	Not applicable	Met	Met
Likelihood of publication bias assessed	Unmet	Met	Met	Met	Unclear
Recommendations for policy and/or practice supported by reported data	Unclear	Met	Met	Met	Met
Appropriate specific directives for new research	Met	Met	Met	Unmet	Unclear

B1.5 CHARACTERISTICS OF THE EVIDENCE BASE

See Appendix 8 for details on the individual studies included in the evidence base.

A summary of literature review evidence is provided in Table 15.

B1.6 OUTCOME MEASURES AND ANALYSIS

See Appendix 8 and Table 13 for details on the outcomes measured in the included studies, along with the statistical methods used to analyse the results.

[101] Aromataris E, Fernandez R, Godfrey C et al. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthc. 2015;(13)3:132-140.
[102] Aromataris E, Fernandez R, Godfrey C et al. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthc. 2015;(13)3:132-140.

B1.7 RESULTS OF THE LITERATURE REVIEW (UMBRELLA REVIEW OF SYSTEMATIC REVIEWS)

A narrative synthesis of the findings of this Umbrella Review is presented in Appendix 8. Eligible publications were assessed for methodological quality using the critical appraisal tool for systematic reviews and research syntheses developed by The Joanna Briggs Institute.[103] A total of 161 studies were assessed across the five reviews, and included randomised controlled trials (RCTs), non-randomised controlled trials (non-RCTs), quasi RCTs, cohort studies, controlled before and after studies and pretest-posttest studies. Approximately 60% (97 of 161) of the studies were conducted in the US. The studies were heterogenous in regard to 'integration' of NDPs into primary health care teams. All studies primarily examined interprofessional collaboration between pharmacists and GPs. Across the included studies patients were either categorised according to a particular chronic disease; or were considered more broadly as patients prescribed multiple medications, those at risk of an adverse health issue or those at risk of a medication-related adverse event. All reviews except one stipulated that the comparison group was usual care or no intervention. Outcomes examined across the included studies were also heterogenous. Because of this significant heterogenicity and small number of included publications, a narrative synthesis of the evidence was completed.

Outcomes assessed in reviews were classified broadly as changes in biomedical markers (blood pressure, HbA1c, cholesterol, lipids, Framingham risk score), changes in prescribing practices or appropriateness (prescribing quality, reduction of inappropriate prescribing), and patient-reported outcomes (quality of life, patient satisfaction).

In summary, the aggregated results from the included reviews suggest that the integration of a non-dispensing pharmacist in PHC settings can improve patient outcomes and quality of care. Biomedical markers, such as HbA1c, blood pressure and cholesterol improved with pharmacist intervention across a number of trials. Pharmacist intervention also improved quality use of medications and reduced inappropriate prescribing. There was no effect on the quality of life.

On the basis of the benefits reported in the evidence-base summarised above, it is suggested that relative to usual care, the integration of pharmacists within primary health care settings has superior effectiveness with regard to biomedical and prescribing quality outcomes that benefit patients with chronic disease or who are at risk of a medication-related adverse effect. However, there are no published studies to date that inform on the impact to the Aboriginal

[103] Aromataris E, Fernandez R, Godfrey C et al. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthc. 2015;(13)3:132-140.

and Torres Strait Islander population with chronic disease, of interventions provided by pharmacists when they are integrated within ACCHS or other relevant primary healthcare settings.

B2 IPAC TRIAL (PROJECT)

This section of this submission summarises the conduct and outcomes of the IPAC Trial (Project).

The IPAC Trial was the first interventional study to investigate integrating a non-dispensing pharmacist within Aboriginal community-controlled health services (ACCHSs). All primary and secondary outcomes from the trial are summarised in Table 17 and Table 18.

The following Appendices include the reports that describe the conduct, methods, results, discussion and conclusions regarding primary and secondary outcomes from the IPAC Trial. The economic evaluation is described in Sections D and E.

Appendix 1: Published protocol for the IPAC Trial. (Integrating pharmacists into Aboriginal Community Controlled Health Services (IPAC project): Protocol for an interventional, non-randomised study to improve chronic disease outcomes)[104]

Appendix 2: Full Protocol for the IPAC Trial. V1.6 (18 November 2019)

Appendix 9: Integrated pharmacists in ACCHSs- Analysis of the assessment of clinical endpoints in Aboriginal and Torres Strait Islander patients with chronic disease (IPAC study), May 2020.

Appendix 10: Assessment of medication appropriateness using the Medication Appropriate Index (MAI) in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project), February 2020.

[104] Couzos, S, Smith D, Stephens M, Preston R, Hendrie D, Loller H, Tremlett M, Nugent A, Vaughan F, Crowther S, Boyle D, Buttner 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. [published online ahead of print, 2019 Dec 26]. Res Social Adm Pharm. 2019;S1551-7411(19)30791-0. doi:10.1016/j.sapharm.2019.12.022

Appendix 11: Assessment of medicines underutilisation in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project), February 2020.

Appendix 12: Assessment of Home Medicines Review (HMR) and non-HMR in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community-Controlled Health Services (IPAC Project), February 2020.

Appendix 13: 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), May 2020.

Appendix 14: IPAC Project: Qualitative Evaluation Report, February 2020.

Table 17 Summary of the IPAC Trial findings- primary and secondary outcomes

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
Clinical endpoints (Appendix 9), (SD, 95% CI)							
Participants with a clinical diagnosis of T2DM	HbA1c*, mmol/mol [%units]	539	284	66.8 (37.2) *[8.3% (5.5%)]*	64.0 (39.5) *[8.0% (5.8%)]*	-2.8 (19.5, -4.5 to -1.0) *[-0.3% (3.9%, - 0.4% to - 0.1%]*	0.001
All participants	SBP, mmHg	1103	266	132.7 (33.2)	132.0 (29.9)	-0.7 (16.6, -1.7 to 0.4)	0.16
	DBP, mmHg	1045	268	80.0 (35.6)	79.2 (29.1)	-0.8 (9.4, -1.4 to -0.2)	**0.008**
	TC, mmol/L	660	314	4.51 (1.80)	4.35 (2.06)	-0.15 (0.77, -0.22 to -0.09)	**<0.001**
	LDL-C, mmol/L	575	295	2.35 (1.20)	2.27 (1.20)	-0.08 (0.48, -0.13 to -0.03)	**0.001**
	HDL-C, mmol/L	622	294	1.05 (0.5)	1.06 (0.5)	0.01 (0.25, -0.02 to 0.03)	0.32
	TG, mmol/L	730	296	2.39 (2.43)	2.29 (2.21)	-0.11 (1.08, -0.20 to -0.01)	**0.006**
	ACR, mg/mmol*	475	301	57.9 (183.1)	61.7 (224.5)	3.8 (102.4, -6.32 to 13.83)	0.42
	CVD 5-year risk, %units	38	255	11.9 (7.2)	10.9 (5.4)	-1.0 (2.6, -1.8 to -0.12)	**0.027**
	eGFR* (no minimum follow-up time), ml/min/1.73m^2	895	296	49.1 (159.2)	48.4 (160.4)	1.9 (25.7, 0.1 to 3.7)**	**<0.001**
	eGFR* (6-month minimum follow-up time), ml/min/1.73m^2	720	317	49.6 (140.6)	48.1 (145.4)	-0.2 (36.0, -2.99 to 2.7)**	**0.034**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- appropriateness of medications							
MAI subset of participants	Mean MAI score per participant	357	329	6.02 (SD 23.6)	3.20 (SD 11.7)	↓46.8%	**0.003**
	Mean MAI score per medication	357	329	0.76 (SD 8.5)	0.39 (SD 4.4)	↓48.7%	**0.004**
	Number of medications with ≥1 inappropriateness rating (n, %)	357	329	647/2804 (23.1%)	357/2963 (12.1%)	-11.0%	**0.008**
	Mean number of medications per participant with ≥1 inappropriateness rating (n, %)	357	329	1.8 (SD 5.3)	1.0 (SD3.6)	↓44.4%	**0.001**
	Number of participants with at least one inappropriate medication rating (n, %)	357	329	242 (67.8%)	159 (44.5%)	-23.3%	**<0.001**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- overuse of medications (n,%)							
MAI subset of participants	Number of participants with any medications that met ≥1 overuse criterion	357	329	132 (37.0%)	87/377 (24.4%)	-12.6%	**<0.001**

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
	Number of medications that met ≥1 overuse criterion	357	329	249/2804 (8.9%)	147/2963 (5.0%)	-3.9%	**0.017**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- medications meeting MAI risk criteria (n,%)							
MAI subset of participants	Drug not indicated	357	329	156/2804 (5.6%)	97/2963 (3.3%)	-2.29%	**0.033**
	Medication is ineffective for the condition	357	329	103/2804 (3.7%)	51/2963 (1.7%)	-1.95%	**0.010**
	Dosage incorrect	357	329	194/2804 (7.0%)	92/2963 (3.1%)	-3.81%	**<0.001**
	Directions incorrect	357	329	88/2804 (3.1%)	65/2963 (2.2%)	-0.94%	0.107
	Directions Impractical	357	329	89/2804 (3.2%)	16/2963 (0.5%)	-2.63%	**0.001**
	Significant drug-drug interactions	357	329	144/2804 (5.1%)	58/2963 (2.0%)	-3.18%	0.059
	Significant drug-disease interactions	357	329	72/2804 (2.6%)	38/2963 (1.3%)	-1.29%	**0.008**
	Unnecessary duplication of drugs	357	329	83/2804 (3.0%)	46/2963 (1.6%)	-1.41%	0.066
	Unacceptable therapy duration	357	329	164/2804 (5.9%)	98/2963 (3.3%)	-2.54%	**0.029**
	Most expensive drug	357	329	41/2804 (1.5%)	33/2963 (1.1%)	-0.35%	0.447
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- medications with an inappropriateness rating by medication type (n,%)							
MAI subset of participants	Cardiovascular medications [a]	357	329	164/1014 (16.2%)	77/1056 (7.3%)	-8.9%	**0.013**
	Endocrine medications [b]	357	329	136/593 (22.9%)	64/615 (10.4%)	-12.5%	**0.002**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 10)- participants with medications with an inappropriateness rating by medication type (n,%)							
MAI subset of participants	Cardiovascular medications [a]	357	329	117/357 (32.8%)	46/357 (12.9%)	-19.9%	**<0.001**
	Endocrine medications [b]	357	329	91/357 (25.5%)	51/357 (14.3%)	-11.2%	**<0.001**
Prescribing quality according to the Medication Appropriateness Index (MAI, Appendix 11)- underuse of medications							
AoU subset of participants	Number of participants assessed with AoU, who had at least one potential prescribing omission (PPO) (n,%)	353	330	181/353 (51.3%)	76/353 (21.5%)	-29.7%	**<0.001**
	Number of PPOs/participant	353	330	0.73 (SD 1.3)	0.29 (SD 0.9)	↓60.3%	**<0.001**
Home Medicines Reviews by MBS item 900 (Appendix 12) (n/100 person years, 95%CI)							
All participants	Number of participants with ≥1 Home Medicines Reviews (HMR) based on MBS item 900 claims	1456	285	10.0 (5.2-18.0)	38.7 (29.6-49.3)	↑3.9 times (rate ratio)	**<0.001**
	Number of MBS item 900 rebate claims	1456	285	10.2 (5.5-18.0)]	41.6 (32.2-52.3)	↑4.1 times (rate ratio)	**<0.001**
Medication management reviews (Appendix 12) (n,%)							

Population	Outcome measure	Number of participants (n)	Median length of stay in the study (days)	Baseline (usual care)	End of study (follow-up)	Difference	p-value ^
All participants	Number of participants with HMR (from the logbook)	1456	285	na	609/1456 (41.8%)	↑639 reviews	na
	Number of participants with ≥1 'medication related problems' that were identified following a HMR	1456	285	na	535/609 (87.9%)	na	na
	Number of participants with a non-HMR[c]	1456	269	na	719/1456 (49.4%)	↑757 reviews	na
	Number of participants with ≥1 'medication related problems' that were identified following a non-HMR	1456	269	na	503/719 (70.0%)	na	na
	Number of assessments that were a follow-up to a HMR or non-HMR[d]	1456	285/269	na	na	↑1,548 reviews	na
Medication adherence and self-assessed health status (Appendix 13) (n,%)							
All participants	Number of participants adherent to medications (NMARS)	1103	294	808/1103 (73.3%)	950/1103 (86.1%)	12.8%	**<0.001**
	Number of participants adherent to medications (SIQ)	1103	294	781/1103 (70.8%)	895/1103 (81.1%)	10.3%	**<0.001**
	Number of participants with 'very good to excellent' self-assessed health status	975	281	175/975 (18.0%)	303/975 (31.1%)	23.9%	**<0.001**
Qualitative analysis -the patient experience and stakeholder perceptions (See **Appendix 14**							

Bold p-values imply statistically significant change at the 0.05 level. SD = cluster-adjusted standard deviation (ACCHS cluster). 'na' refers to 'not applicable'.
^p-values are cluster adjusted (ACCHS), however the adjustment may have also been conducted at the patient level – see analyses described in each individual report for the method used for each outcome measure.
↑Refers to a relative increase in the outcome measure (baseline compared with end of study).
↓Refers to a relative reduction in the outcome measure (baseline compared with end of study).
*Refers to last observation pre-enrolment and at follow-up. Unit conversion from IFCC (International Federation of Clinical Chemistry, mmol/mol) to DCCT (Diabetes Control and Complications Trial, %) units using the https://www.diabetes.co.uk/hba1c-units-converter.html units converter. eGFR reference range: Normal or Stage 1: CKD >89, Stage 2: 60-89 Stage 3A: 45-59, Stage 3B: 30-44, Stage 4: 15-29, Stage 5:<15. (Units in ml/min/1.73m^2), sourced from the National Guide (3rd Edn).[105] Albumin:creatinine ratio normal reference range: >2.5 mg/mmol for males and >3.5mg/mmol for females. Macroalbuminuria is defined as >25mg/mmol in males and >35 mg/mmol in females. Absolute CVD 5-year risk sourced from the National Guide (3rd Edn).[106]

[105] NACCHO and RACGP. National Guide to a preventive health assessment for Aboriginal and Torres Strait Islander people. 3rd Edn. RACGP, Melbourne, 2018
[106] NACCHO and RACGP. Op. Cit.

**Mean annualised difference. P-value (paired data) were derived from the cluster-adjusted (ACCHS cluster) comparison of annualised differences against -3, as this is equivalent to a paired t-test. The value of -3 is the expected mean annual eGFR (ml/min/1.73m2) linear decline in Aboriginal and Torres Strait Islander adults (*see Appendix 9*).

[a] Medications for: heart failure, angina, hypertension, arrhythmia, dyslipidaemia, pulmonary hypertension, other.

[b] Medications for: adrenal insufficiency, bone, diabetes, thyroid disorders, other.

[c] Based on logbook entries. A non-HMR was defined as a comprehensive medication management review comprising some or all the elements of a HMR, but not fulfilling all relevant MBS HMR criteria. The most common reason given by pharmacists for a non-HMR was to opportunistically provide a medication management review because the patient was at risk of forgoing a HMR. The other most common reasons for a non-HMR were because of limited patient access to an accredited pharmacist, and patient preference.

[d] A follow-up to a HMR or non-HMR was defined as a participant follow-up 3-6 months after the completion of an HMR or a non-HMR. Each activity involved reminder about the HMR and non-HMR advice and recommendations provided by the pharmacist (and the GP, if appropriate), assessment of the impact of any actions recommended from the HMR or non-HMR, and if another HMR or non-HMR or education session or preventive intervention was needed.

ACR= albumin-creatine ratio
AoU= Assessment of underutilisation
BP= blood pressure;
CVD= cardiovascular disease.
DBP= diastolic blood pressure
eGFR= estimated glomerular filtration rate
HbA1C= glycated haemoglobin
HDL-C= high density lipoprotein cholesterol
HMR= Home Medicines Review
LDL-C= low density lipoprotein cholesterol
MAI= Medication Appropriateness Index. The MAI score increases with increasing medication inappropriateness.
MBS = Medicare Benefits Schedule
NMARS = NACCHO medication adherence response scale for the reasons for non-adherence
PPO= potential prescribing omission
SBP= systolic blood pressure
SIQ = Single-item question for the extent of medication adherence
TC= total cholesterol
TG= triglycerides
T2DM= type 2 diabetes mellitus

Table 18 Summary of the IPAC Trial findings- economic analysis

Economic Analysis (Section D)							
Type of economic evaluation	**Population**	**Outcome measure**	**Number of participants (n)**	**Mean length of stay in the study (days)**	**Incremental cost**	**Incremental outcomes**	**ICER**
Cost-consequence analysis	All participants	Various biomedical indices	1,456	284	$2,173,981	Various[1]	$1,493 per participant to achieve improvements in multiple biomedical indices[1]
Cost-effectiveness analysis	Participants with a clinical diagnosis ofT2DM	Number of participants with a clinically meaningful reduction in HbA1c	539	287	**$753,774**	**200**	$3,769 per participant with a clinically meaningful reduction in HbA1c of at least 0.5%
Cost-effectiveness analysis	Participants assessed for the underutilisation of medications	Number of potentially preventable omissions (PPO)	353	326	$714,959	105	$6,809 per reduction in the number of participants with a PPO
Cost-utility analysis	Participants with a clinical diagnosis of T2DM	QALYs	539	287	$753,774	101	$7,463 per QALY

[1] 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).

Economic Analysis (Section E)						
Cost item	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total – 5 years**
Total intervention costs to extend IPAC model to all ACCHSs	$13,846,142	$13,273,542	$13,141,042	12,876,292	$12,851,292	$66.0 million
Total costs of additional health services from extending IPAC model to achieve more equitable use of PBS medicines and HMRs	5,139,777	5,139,777	5,139,777	5,139,777	5,139,777	$26.0 million
Potential reduction in costs from fewer ED presentations and hospital admissions[1]	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$633,532-$1,900,597	$3.17 million – $9.5 million

[1] Range based on assumption as to potential reduction in ED presentations and hospital admissions.

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.[107] 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.[108]

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.[109] 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.[110] 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.[111]

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

[107] Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ 2000; 321:7258: 405-412.

[108] Pousinho S, Morgado M, Falcão A, Alves G. Pharmacist Interventions in the Management of Type 2 Diabetes Mellitus: A Systematic Review of Randomized Controlled Trials. J Manag Care Spec Pharm. 2016 22:5: 493-515

[109] Hardy ST, Loehr LR, Butler KR, et al. Reducing the Blood Pressure-Related Burden of Cardiovascular Disease: Impact of Achievable Improvements in Blood Pressure Prevention and Control. *J Am Heart Assoc*. 2015;4(10):e002276. Published 2015 Oct 27. doi:10.1161/JAHA.115.002276

[110] Cook NR, Cohen J, Hebert PR, Taylor JO, Hennekens CH. Implications of small reductions in diastolic blood pressure for primary prevention. Arch Intern Med. 1995;155:701–709.

[111] Hardy ST, Loehr LR, Butler KR, et al. Op. Cit.

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).[112] [113]

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.[114] 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.[115]

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,[116] a significant reduction in underprescribing of BP-lowering medications for those with T2DM and albuminuria,[117] and significant improvements in patient self-reported medication adherence.[118] Integrated pharmacists also delivered team-based care to optimise chronic disease management (such as case conferences) and attended patient group

[112] Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170 000 participants in 26 randomised trials. Lancet 2010; 376: 1670–81.
[113] Collins R, Reith C, Emberson J, et al. Interpretation of the evidence for the efficacy and safety of statin therapy. Lancet 2016; 388: 2532–2561.
[114] Ku E, Xie D, Shlipak M, et al. Change in Measured GFR Versus eGFR and CKD Outcomes. J Am Soc Nephrol. 2016;27(7):2196–2204. doi:10.1681/ASN.2015040341
[115] Maple-Brown LJ, Hughes JT, Ritte R, Barzi F, et al. Op. cit.
[116] Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilisation in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project). Op. Cit.
[117] Couzos S, Smith D, Buttner P, Biros E. Assessment of medicines underutilisation in Aboriginal and Torres Strait Islander patients with chronic disease receiving integrated pharmacist support within Aboriginal Community -Controlled Health Services (IPAC project). Op. Cit.
[118] 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. Draft Report, May 2020.

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.

In conclusion:

On the basis of the benefits reported in the evidence base (summarised in Table 17 and 18), **relative to usual care, integrating a non-dispensing pharmacist within ACCHSs led to superior effectiveness and clinically relevant improvements in a range of primary and secondary quality of care outcomes for Aboriginal and Torres Strait Islander peoples with chronic disease attending Aboriginal community-controlled health services. Integrated pharmacists embedded into usual care in a range of geographical settings, can significantly improve the control of CVD risk factors, glycaemic control in patients with T2DM, and reduce absolute CVD risk in Aboriginal and Torres Strait islander adults with chronic disease. The intervention significantly improved glycaemic control in participants with T2DM and also brought about improvements in diastolic BP, total cholesterol, LDL-C, triglycerides, mean annual eGFR, and mean calculated absolute 5-year CVD risk in all study participants. Systolic BP significantly improved in those younger than 57 years of age. These improvements were clinically meaningful and evident in a population with a substantial chronic disease burden that occurred at a relatively younger age than other Australians.**

Improvements were evident for prescribing quality indicators reflective of significant reductions in suboptimal prescribing, reductions in the use of medications that were unnecessary, and reductions in underprescribing of high-value pharmacotherapies. There were significant and substantial increases in participant access to Home Medicines Reviews (based on item 900 MBS claims), and other medication management reviews. Services provided by pharmacists within ACCHSs relative to usual care, led to superior health care service utilization (towards equity) by Aboriginal and Torres Strait Islander participants with chronic disease compared to usual care. There were significant improvements in adherence to medications for participants who enrolled to receive pharmacist services, as well as significant improvements in their self-assessed health status. Qualitative evaluation indicated that patients, integrated pharmacists, community pharmacists, and ACCHS staff reported that the intervention had improved quality of care outcomes.

Economic analysis reported relatively low costs to be associated with increases in the utilisation of medications and primary health care services, the latter having the potential to contribute to more equitable, needs-based health care expenditure for the Aboriginal and Torres Strait Islander population. Additionally, the modelled cost-utility analysis conducted for patients with T2DM found that, based on commonly used reference ICERs for the Australian health system, the ICER of $7,463 represented good value for money.

SECTION C – TRANSLATION ISSUES

C.1. OVERVIEW

The IPAC trial investigated the integration of a non-dispensing pharmacist within ACCHS settings delivering services expected within their current scope of practice. The pragmatic study design enabled the evaluation of real-world outcomes expected in this setting for Aboriginal and Torres Strait Islander adults with chronic disease to enhance the external validity of the quality improvements expected from the intervention.[119] The study involved a large sampling frame of 18 services of varying sizes and geographic locations (across 22 sites in Queensland, Victoria, and the Northern Territory).

The IPAC trial is possibly the largest prospective and interventional study to investigate the impact of integrated pharmacists using intermediate clinical endpoints in primary health care settings, and analysed data from 1,456 enrolled Aboriginal and/or Torres Strait Islander participants. The study is also the first work globally to investigate the impact of integrated pharmacist interventions with regard to Indigenous peoples. The intervention comprised non-dispensing medicines-related services, collaborative and coordinated care, including the provision of medication management reviews by pharmacists integrated within Aboriginal community-controlled health services.

The outcomes from the intervention are generalisable to the broader Aboriginal and Torres Strait Islander patient population who are at risk of developing medication related problems and attending ACCHSs in urban, rural and remote geographical locations. The evidence for generalisability has been demonstrated for every outcome measure investigated in the project (see Appendices 9-16). The IPAC participants were representative of the proposed population, and were usual patients accessing ACCHSs, and the intervention was tested within usual clinical settings involving the ACCHS sector.

For clinical endpoint analysis, a non-probabilistic sampling method was adopted to reflect the pragmatic study design where all patients who had relevant chronic disease conditions were invited to participate without setting criteria for study compliance or other study restrictions.[120] Patients were consented into the study by pharmacists or other health service

[119] Øvretveit J, Leviton L, Parry G. Increasing the generalisability of improvement research with an improvement replication programme *BMJ Quality & Safety* 2011;20:i87-i91

[120] Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers. J Clin Epidemiol 2009; 62: 464-475

staff according to the cultural and usual protocols of the ACCHS, after which pharmacists provided supportive clinical care as part of the primary healthcare team to meet the individual needs of the participant. This pragmatic recruitment and other pragmatic features of the IPAC study meant that the findings have external validity.[121] Pragmatic trials differ from trials conducted under ideal conditions, in that similar participant recruitment methods are used to those that would be used under usual conditions within the proposed health services.[122] The delivery of the intervention was also flexible, and follow-up reflected the usual mechanisms in healthcare settings which are other hallmarks of pragmatic study design. Pragmatic trials frequently include complex interventions, including an interdependence between a range of healthcare staff to deliver the intervention,[123] as was the case with the IPAC trial. It is unique for a clinical interventional study to consent and enrol this many adult Aboriginal and Torres Strait Islander participants with chronic disease, which suggests that the community-based participatory research and pragmatic study design were success factors. This suggests that the trial enrolled and evaluated the impact of the intervention using a sample large enough to adequately represent the population for whom the broader roll-out of the intervention is proposed.

For the analysis of prescribing quality, a subset of all IPAC participants (24% of the cohort) was selected by pharmacists using methods consistent with usual care. Pharmacists selected a sample of enrolled participants according to their clinical need for a medication review to assess the appropriateness of their medications, as is undertaken with usual care. The Medication Appropriateness Index (MAI) tool was used to undertake a comprehensive prescribing quality review of participants' medications assessing for medication appropriateness. The clinical need for such a review was reflective of usual care and based on criteria such as for Home Medicines Review where the patient must have 'a chronic medical condition or a complex medication regimen, and not [have] their therapeutic goals met'.[124] The study did not formally randomize the selection of participants for MAI audit in order to reflect usual care clinical processes and services consistent with a pragmatic trial.[125] Pharmacists used the MAI assessment findings to inform medication management plans and recommendations for prescribers, as needed and as part of usual care.

[121] Thorpe KE, Zwarenstein M, Oxman AD, et al. Op. Cit.
[122] Ford I, Norrie J. Pragmatic Trials. N Engl J Med 2016; 375:454-463.
[123] Ford I, Norrie J. Pragmatic Trials. N Engl J Med 2016; 375:454-463.
[124] Australian Government Department of Health. Medicare Benefits Schedule – Item 900. MBS Online, Commonwealth of Australia. [Accessed February 2020]. http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=900&qt=ItemID
[125] Thorpe KE, Zwarenstein M, Oxman AD, et al. Op. Cit.

Due to the length of time usually required for pharmacists to undertake the MAI assessment and the large number of participants expected to be enrolled into the study, pharmacists were advised to only undertake MAI assessments on 30 participants per FTE pharmacist and to complete these within the first three months after participant recruitment into the study. The analysis subsequently showed that the characteristics of this subset (n=357) was similar to the remaining broader IPAC cohort that did not have MAI assessments (n=1099, Appendix 10). Similarities were observed in age, sex, Aboriginality, geographical location, pensioner status, number of medications, CTG script eligibility, Health Care Homes enrolment, prior HMR, self-assessed health status, clinical diagnoses, type of chronic disease, degree of comorbidity or multimorbidity, obesity, glycaemic control, or prevalence of eGFR levels. The proportion of participants who self-reported as adherent to medications was also similar between cohorts (**Appendix 13).** For this reason, it is clear that prescribing quality outcomes of the magnitude described, would be generalisable to the proposed population - patients who have a clinical need for a medication review, within a broader ACCHS context.

C.2. APPLICABILITY TRANSLATION ISSUES

Table 19 summarises translation issues related to the IPAC trial and implications of the intervention if it is rolled out to the proposed population. The proposed population for integrated pharmacist services delivered within ACCHSs are Aboriginal and Torres Strait Islander patients (irrespective of age) who have a clinical need for pharmacist support because of chronic disease and/or being at high risk of developing medication related problems.

Aboriginal and Torres Strait Islander patients who are <18 years of age who are at high risk of developing medication related problems (irrespective of chronic disease) are also recommended to be eligible for support from integrated pharmacists.

The evaluation of pharmacist services as part of the IPAC trial was restricted to adults over 18 years, mainly because of the ethics requirements for research associated with children providing informed consent. In view of the pragmatic trial design and the principles of Aboriginal self-determination, ACCHSs may have also permitted children to receive the services of integrated pharmacists. All integrated pharmacists were required to have 'working with children checks' (or state based equivalent) and were cleared to provide services to children if needed. Chronic disease emerges at younger ages in the Aboriginal and Torres Strait Islander population, such as with T2DM, than the general Australian population. This means that arbitrary age-based criteria (set for evaluation purposes) cannot logistically be applied in real-world settings for those who need medication support. There is a clear clinical

need for services to support medication use in children, which is within the scope of practice of pharmacists to provide.

Moreover, all patients who are using medications could benefit from integrated pharmacist support, not just those with chronic disease. Other schemes such as the PBS Closing the Gap co-payment measure recognise this need and have expanded criteria for accessing the initiative to all patients with chronic disease or at risk of chronic disease. Poorly treated acute conditions can lead to chronic problems. Patients requiring medication for the first time still need education. In remote areas where ACCHSs use the Section 100 scheme for remote-area Aboriginal Health Services, patients do not have the opportunity to speak to a pharmacist when being provided medications for acute conditions. Integrated pharmacists have an opportunity to improve all medication use from within ACCHS including treatment for acute conditions, Antibiotic Microbial Stewardship support and pain management services. The latter were the focus of Drug Utilisation Reviews preformed as part of the IPAC trial and activity reports from integrated pharmacists in the IPAC trial indicated that support for a range of services for non-acute disease conditions were also provided (Appendix 16).

Table 19 Summary of factors relevant to the translation of the IPAC intervention to Aboriginal community-controlled health services more broadly

Factor	Translation issues	Implications for translation
General (implementation)	The IPAC trial used data from 1,456 participants making it one of the largest interventional studies involving individually consented Aboriginal and Torres Strait Islander adults with chronic disease ever conducted in Australia. The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study that was community-based and participatory.	The large sample size, the broad geographical distribution of involved ACCHSs, and the study design supports the transferability of the study findings to other ACCHS settings and the proposed population. The IPAC study evaluated real-life outcomes within ACCHS settings arising from the intervention (integrated pharmacists within ACCHSs).
Proposed population	IPAC participant criteria were: adult (18 years and over) patients with chronic disease who had visited a participating ACCHS site at least three times in the past two years relative to the recruitment date into the study (known as 'active' or 'regular' patients). Patients had a diagnosis of: • Cardiovascular (CV) disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease),	The proposed patient population for the broader translation of the integrated pharmacist intervention includes all adult Aboriginal and Torres Strait Islander patients who have a clinical need for pharmacist support because of chronic disease and/or being at high risk of developing medication related problems. The economic evaluation

Factor	Translation issues	Implications for translation
	• Type 2 diabetes mellitus, • Chronic kidney disease, or • Other chronic conditions and at high risk of developing medication-related problems (e.g. polypharmacy).	has been outlined the financial implications for this roll-out (Section D and E). The intervention is likely to benefit a broader ACCHS population including children (who would only make up a very small portion of pharmacist patients). Broader roll-out of the intervention needs to meet the needs of all ACCHS patients using medication, and this more flexible approach aligns with the principle of ACCHS self-determination.
Consumer impact	Qualitative evaluation involved twenty-four (24) integrated pharmacists who provided feedback on their experiences in the role and how well the project was able to be implemented within their ACCHS. Thirteen general practitioners, 12 managers and 10 community pharmacists responded to an online survey. Three ACCHSs were visited for an in-depth assessment of implementation.	Consumer impact reports from the qualitative evaluation (Appendix 14) support transferability of the intervention to the broader ACCHS sector.
Participant satisfaction	Several focus groups with participants revealed the benefits and challenges of the intervention and were overwhelmingly positive. There was increased knowledge and engagement of participants in their own health care through increased engagement with the health service. (Appendix 14).	Qualitative evaluation (Appendix 14) support transferability of the intervention to the broader ACCHS sector.
ACCHS inclusion criteria	Each ACCHS underwent a health systems assessment (HSA) to explore service characteristics and identify any systems change over the trial intervention period. There was little change in health systems assessment within participating sites from baseline to the end of the study that might otherwise explain prescribing improvements (such as from non-IPAC related service activity). ACCHSs were also required to meet site inclusion criteria for the project and are reported in the published protocol (Appendix 1). For example, making sure that ACCHS have the physical space to support clinical consultations between the patient and pharmacist, to have a GP prescriber employed within the service, and pharmacist access to patient medical records (clinical information systems) and team-based care, are essential. (Appendix 14)	The intervention (integrated pharmacist) is transferable to ACCHSs that meet site inclusion criteria consistent with the core success factors of the IPAC trial. The proposed health service criteria that have been modified for transferability are shown in Table 20.

Factor	Translation issues	Implications for translation
	ACCHSs involved in the IPAC trial were representative of other ACCHSs within their jurisdiction (reported by *NACCHO Affiliates*).	The intervention (integrated pharmacist) is transferable to ACCHSs that meet site inclusion criteria shown in Table 10.
Integration model within ACCHSs	Pharmacists were integrated within ACCHSs with: identified positions and core roles; had shared access to clinical information systems; provided continuous clinical care to patients, particularly on-site within the clinic setting; 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.	Transferability will require and depend on fidelity to the integration model that was evaluated in the IPAC trial.
Pharmacist registration	Integrated pharmacists fulfilled the following eligibility criteria: registration with the Australian Health Practitioners Regulation Agency (Ahpra); more than 2 years' post-registration experience; and post-graduate clinical qualifications or demonstrated clinical experience. Accreditation to conduct an HMR was preferred, however it was not mandatory for integrated pharmacists.	Transferability will require fidelity to the eligibility criteria for registered pharmacists as was evaluated in the IPAC trial.
Pharmacists core roles	Integrated pharmacists functioned within existing and usual primary health care service delivery systems and focused on pre-determined core roles that included providing medication management reviews; assessing participant adherence and medication appropriateness; providing medicines information and education and training; collaborating with healthcare teams; delivering preventive care; liaising with stakeholders and developing stakeholder liaison plans; providing transitional care; and undertaking a drug utilisation review. Pharmacists' worked with ACCHSs to apply the roles to their individual setting to ensure the intervention was most impactful.	Transferability will require and depend on fidelity to the core pharmacist roles within the integration model that was evaluated in the IPAC trial, with allowances for each health service to prioritise pharmacist activity to meet the individual needs of the proposed population.
Pharmacist training	Pharmacists were trained by the Pharmaceutical Society of Australia (PSA) to deliver core roles (all within their existing scope of practice). Pharmacists were also provided with ongoing support through regular online communications and mentoring support.	Transferability of the intervention to broader ACCHSs will require additional resource commitments, such as the development of training materials and resources, to train registered pharmacists prior to commencing integrated pharmacist roles within ACCHSs. The PSA and PGA are well placed to provide a program of training and ongoing support for pharmacists.

Factor	Translation issues	Implications for translation
	Patient follow-up to medication management reviews as undertaken by integrated pharmacists, was substantial. There were 1,548 follow-up assessments of patients who had a review (mean time for follow-up was 30 mins), over a mean period of 284 days of participant involvement in the study. Patient follow-up is complicated as the target population is burdened by many chronic diseases and healthcare providers face many important demands. Clinical algorithms to streamline patient referral systems so that integrated pharmacists within the ACCHS model of care can follow-up patients will be valuable (Appendix 12, and Appendix 16).	Opportunistic pharmacists' assessments of the target patient population are particularly important in enhancing patient access to medication-related services. NACCHO, the Affiliates and PSA are well placed to develop generic clinical algorithms and resources to support ACCHSs to implement processes for opportunistic and patient follow-up regarding medication management.
Cultural protocols	Pharmacists integrated within ACCHSs were required to adhere to cultural and team-based principles relevant to ACCHS settings, so that study participants could benefit from the community trust this supported. Only ACCHSs were involved in the IPAC study (n=18).	Translation of the impact of the intervention is relevant only to primary healthcare settings within the ACCHS sector.
ACCHSs being service-ready	All ACCHSs received support and a site visit to be involved in the IPAC trial. Some services were well prepared for the pharmacist and understood the value of the role. Staff in other services needed time to fully understand the role and learn how to utilise the pharmacists' expertise. Support from GPs and AHW/Ps were enablers to the integration of the integrated pharmacist within the ACCHS. In particular, AHW/Ps played a vital role in assisting with patient follow-up (Appendix 14).	Support will need to be provided to clinic staff and managers (for flow-on effect to healthcare staff) to ensure ACCHSs are ready for the integrated pharmacist role. The adaption and development of policies and procedures to guide ACCHS medicine-related activity with an integrated pharmacist will be valuable. NACCHO and the Affiliates are well placed to develop these policies, support staff, and procedures, in partnership with the PSA, to support ACCHSs.
Integrated pharmacist recruitment	Integrated pharmacists were selected for the IPAC trial with skills aligned to the expected scope of practice and core roles. Placements within ACCHS were influenced by the needs, capacity, and preparedness of ACCHSs that was assessed by NACCHO. Local community pharmacies were approached first to see if they are able to provide a pharmacist to work within the ACCHS according to service requirements of the ACCHS. If community pharmacies were unable to nominate a pharmacist, or if this nomination was not accepted by the ACCHS in line with principles of self-determination, the integrated pharmacist was employed directly by the PSA for the purposes of the Trial. Analysis was not undertaken to compare outcomes	Pharmacist recruitment to integrated non-dispensing roles within ACCHSs will be influenced by the financing models for broader program roll-out. Respecting the principles of self-determination means that ACCHSs have control of pharmacist recruitment to ensure their 'fitness for the service' with respect to suitable skills and cultural safety.

Factor	Translation issues	Implications for translation
	arising from differential models of integrated pharmacist employment.	The employment of pharmacists by the PSA (which was the dominant model used in the IPAC trial) will not be applicable for broader program roll-out. Ensuring similar selection criteria and community pharmacy involvement will help with recruitment of suitable similar candidates.
Community pharmacy	Many ACCHSs already had strong existing relationships with their local community pharmacies. 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 dose administration aids for 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. Community pharmacists also perceived that patient knowledge of their medicines and adherence to medicines had improved since the integrated pharmacists had commenced in the ACCHSs. (Appendix 14). Integrated pharmacists completed 49 stakeholder liaison plans (median time taken for each plan was up to 5 hours) and 82% were completed with community pharmacies. Integrated pharmacists recorded 3,233 contacts with community pharmacy with nearly 70% being initiated by the integrated pharmacist (Appendix 16).	Pharmacists integrated within ACCHSs had substantial engagement with community pharmacy and pharmacists. Although engagement with community pharmacy is core to model of care for integrated pharmacist activity, resources to facilitate this stakeholder liaison will further encourage this activity. The PSA and the PGA are well placed to develop these resources or other supports.
Transferability of all IPAC outcomes	The trial was a pragmatic, non-randomized, prospective, pre and post quasi-experimental study that was community-based and participatory. Generalisability was explored in all evaluation reports for primary and secondary outcomes (Appendices 9-16).	Improvements to clinical endpoints, prescribing quality improvements, improvements in access to medication management reviews, and improvements to adherence and self-assessed health status are generalisable to the proposed population (Appendices 9-16).
Business rules for HMRs	Pharmacists within ACCHSs operated within existing and usual business rules for Home Medicines Review MBS item 900 rebate claim and pharmacist fee for HMR under the 6CPA.	Existing business rules for medication management reviews can be utilised by integrated pharmacists within ACCHSs.

ACCHS= Aboriginal community-controlled health service

GP= general practitioner

HCH= Health Care Homes
HMR= Home Medicines Review
IPAC= Integrated pharmacists within ACCHSs to improve chronic disease management Project
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
RAICCHO= Regional Aboriginal and Islander community-controlled health organisations

C.3. EXTRAPOLATION TRANSLATION ISSUES

See Section C.2. This section describes that the outcomes from the IPAC Trial can be extrapolated to the Aboriginal and Torres Strait Islander population attending the ACCHS more broadly. Table 19 also outlines the broader translation issues by category, so that translation can be understood according to the logistics of broader roll-out. **Section D and E** describes the transformation of trial outcomes for economic analysis, using an intermediate clinical endpoint and transforming it to a QALY equivalent.

C.4. TRANSFORMATION ISSUES

See Section C.2 and Table 19.

C.5 ANY OTHER TRANSLATION ISSUES

See Section C.2 and Table 19.

C.6 RELATIONSHIP OF EACH PRE-MODELLING STUDY TO THE ECONOMIC EVALUATION

The economic evaluation (Section D) was undertaken based on the IPAC Trial evaluation.

SECTION D – ECONOMIC EVALUATION

D.1. OVERVIEW

The economic analyses literature review (Appendix 7)[126] did not reveal studies for which cost-effectiveness was analysed for interventions involving a pharmacist integrated within primary health care services such as ACCHSs in Australia. Furthermore, there were no cost-effectiveness studies from any other country reporting interventions involving clinical pharmacist services to Indigenous peoples through Indigenous health services or any other type of primary health care service.

The review did not identify cost-effectiveness evaluations of pharmacist's interventions that were directly relevant to the integration of registered pharmacists within ACCHSs (IPAC trial). This highlights the importance of this IPAC trial to inform on the cost-effectiveness of pharmacist interventions relevant to the health of Indigenous Australians.

Of cost-effectiveness studies set in countries other than Australia involving collaborative care between a pharmacist and a general practitioner (GP), most authors concluded that the pharmacist intervention was cost-effective. However, these studies involved different health systems and therefore different ways of managing health problems within the primary health care setting than in Australia. A comparative assessment of the effectiveness and safety of integrated pharmacists based on the literature review findings was not possible due to the absence of relevant studies.

Advocating for inclusion of a pharmacist as part of the primary health care team within ACCHSs requires that such an initiative is economically feasible in addition to meeting its objective of improving quality of care outcomes. In order to address this question, an economic evaluation was conducted as part of the IPAC trial to establish its relative costs and impacts, and with the underlying objective of assessing the extent to which it represents value for money.

Consequently, a trial-based economic evaluation was undertaken (interventional pre-post quasi experimental study conducted within ACCHSs as presented in **Section B**). Three types of economic analysis were conducted:

[126] Johnstone K, Smith D, Couzos S. Literature review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care. James Cook University, February 2020.

(i) a cost-consequence analysis that included all participants with changes in biomedical indices for whom pre- and post-measures of outcomes were recorded;
(ii) a cost-effectiveness analysis for two sub-groups of participants: those with T2DM with pre- and post-measures of HbA1c and those selected for MAI assessments at baseline and at the end of the study, with potential prescribing omissions (PPOs) used as the relevant outcome measure; and
(iii) for participants with a clinical diagnosis of T2DM, a cost-utility analysis that derived lifetime quality of life changes from the decreases in HbA1c observed during the trial period based on T2DM simulation models.

The economic evaluation compared the costs and outcomes of the IPAC intervention versus usual care prior to the addition of an integrated non-dispensing pharmacist within ACCHSs (comparator) to promote the quality use of medicines. The perspective adopted was the publicly funded health system. Discounting was not applied as the mean participant enrolment period was less than one year.

The trial used a pragmatic study design to evaluate quality of care outcome measures consistent with measures usually explored for quality improvement within clinical practice, with the comparator being 'usual care'. For these reasons, quality of life measures for cost utility analysis were not collected from trial participants to reduce the burden on participants and on clinical staff. Furthermore, (i) changes in quality of life would be unlikely to have been achieved over the relatively short time frame of the IPAC Trial and (ii) problems have been demonstrated in the use of existing instruments to measure the quality of life in Aboriginal populations, especially in populations experiencing more chronic conditions.[127] For a subset of participants with a clinical diagnosis of HbA1c, the cost-utility analysis derived lifetime quality of life changes from the decreases in HbA1c observed during the trial period. The relationship between decreases in HbA1c and lifetime quality-adjusted life years (QALYs) was mapped from the results of a systematic review.[128]

Cost-consequence analysis was undertaken as this is recommended for complex interventions with multiple effects and public health interventions which have a range of

[127] Banham D, Karnon J, Lynch J. Health related quality of life (HRQoL) among Aboriginal South Australians: a perspective using survey-based health utility estimates. Health and Quality of Life Outcomes, 2018;17(1); 39.
[128] Hua X, Lung TW, Palmer A, Si L, Herman WH, Clarke P. How consistent is the relationship between improved glucose control and modelled health outcomes for people with type 2 diabetes mellitus? a systematic review. Pharmacoeconomics. 2017; 35(3):319-329.

health and non-health benefits that are difficult to measure in a common unit.[129] [130] Cost-consequence analysis differs from cost-effectiveness analysis in not reporting a single summary measure such as the incremental cost per incremental change in outcome. Rather, costs are presented alongside a range of outcomes to demonstrate the full impact of the intervention and allow policy makers to interpret the findings as appropriate to their decision-making context. Given the study had multiple biomedical endpoints, a cost-consequence analysis (CCA) was conducted, with costs presented alongside a range of relevant outcomes.

The IPAC trial economic evaluation found that the IPAC intervention generated relatively low costs associated with increases in the utilisation of medications and primary health care services, the latter having the potential to contribute to more equitable, needs-based health care expenditure for the Aboriginal and Torres Strait Islander population.

D.2. POPULATIONS AND SETTINGS

The economic evaluation included the following target groups:

(i) All participants enrolled in the IPAC Trial
(ii) All participants enrolled in the IPAC Trial with T2DM with pre-post measures of HbA1c.
(iii) A subset of participants enrolled in the IPAC Trial who were selected for Medication Appropriateness Index (MAI) assessments at baseline and at the end of the study.

Given the nature of the intervention, which was to include a non-dispensing pharmacist as part of the primary health care team to facilitate increased access to medication-related expertise and assessments, the medical services provided during the IPAC trial were available to all participants who were enrolled in the IPAC study. Similarly, the comparator, which was existing health services in the period prior to the IPAC intervention being implemented, was available to all enrolled participants. The economic evaluation compared costs and outcomes in the pre- and post-intervention periods when the proposed medical service and main comparator were and were not available respectively to enrolled participants.

The population targeted by this proposed service have been described in **Section C.**

[129] Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G. Methods for the economic evaluation of health care programmes. Oxford University Press;2005.
[130] National Institute for Health and Care Excellence. Medical technologies evaluation programme methods guide: process and methods [PMG33]. https://www.nice.org.uk/process/pmg33/resources/medical-technologies-evaluation-programme-methods-guide-pdf-72286774205893

The proposed settings are comprehensive primary health care services that are Aboriginal Community-Controlled Health Services (ACCHSs), as indicated by the service inclusion criteria for the IPAC Trial (Appendix 1). As this submission aims to extend the service (integrated pharmacists) beyond the IPAC Trial to ACCHSs broadly, the proposed setting has been slightly amended to reflect program translation beyond the research setting (Table 20)

The economic analysis evidence presented is applicable and generalisable to the proposed population and the proposed health service setting, as summarised in the study outcome reports included in **Section B, and Section C** for broader translation.

Table 20 Proposed Health Service criteria for participation in the proposed service (integrated pharmacist).

To receive the proposed service, the health service must:

- be an *Aboriginal Community Controlled Health Service* and funded by the Department of Health for the provision of primary health care services to Aboriginal and Torres Strait Islander peoples.
- be a member of NACCHO, and the relevant NACCHO State/Territory Affiliate.
- employ at least one full-time- equivalent general practitioner per clinic who is able to prescribe medicines to patients of that organisation.
- use an electronic clinical information system.
- participate in continuing quality improvement and reporting on the national Key Performance Indicators through the use of electronic data extraction tools.
- adhere to program business rules and guidelines, data provision requirements, and patient/service consent requirements for the program.
- provide the integrated pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system.
- be an accredited practice in accordance with the *Royal Australian College of General Practitioners* Practice Standards.
- be participating or eligible to participate in the Pharmaceutical Benefits Scheme co-payment measure (practice incentive program), if in a non-remote location.
- be eligible to participate in the section 100 arrangements for the supply of pharmaceutical benefits, if in a remote location.

D.3. STRUCTURE AND RATIONALE OF THE ECONOMIC EVALUATION

A summary of the key characteristics of the economic evaluation is presented in Table 21. The perspective adopted was the publicly funded health system (i.e. the cost of pharmaceuticals

not on the PBS was excluded). The comparator was usual care prior to the addition of an integrated non-dispensing pharmacist. 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).

Outcome measures included biomedical indices and, for the subset of participants for whom an assessment of underutilisation (known as an AoU) of medications, were conducted, the number of potential prescribing omissions (Appendices 9 and 11).

Table 21 Summary of the economic evaluation

Perspective	Health system (excludes private)
Comparator	Usual care pre-intervention
Type of economic evaluation[1]	Cost-effectiveness analysis (CEA) and cost-consequence analysis (CCA)
Sources of evidence	Clinical trial
Time horizon	284 days
Outcomes	Biomedical indices, HbA1c, number of potential prescribing omissions
Methods used to generate results	Trial-based
Discount rate	Not necessary due to time horizon
Software packages used	SPSS and MSExcel

1. A cost-utility analysis was included by deriving lifetime quality of life changes from a systematic review of published studies that modelled the relationship between decreases in HbA1c and lifetime gain in QALYs.

LITERATURE REVIEW

Summarised here is the literature review on the 'cost-effectiveness of non-dispensing pharmacist services integrated within primary health care'[131] (Appendix 7).

The medical literature was searched on 5th April 2019 to identify relevant randomised controlled trials published and accessible from Medline, CINAHL and Emcare databases. Searches were conducted of the databases and sources described in Appendix 7. A search of the internet was also conducted to identify reports on cost-effectiveness analyses on relevant interventions that had not been published in the academic literature. Search terms are described in Table 22.

[131] Johnstone K, Smith D, Couzos S. Literature review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care. James Cook University, February 2020.

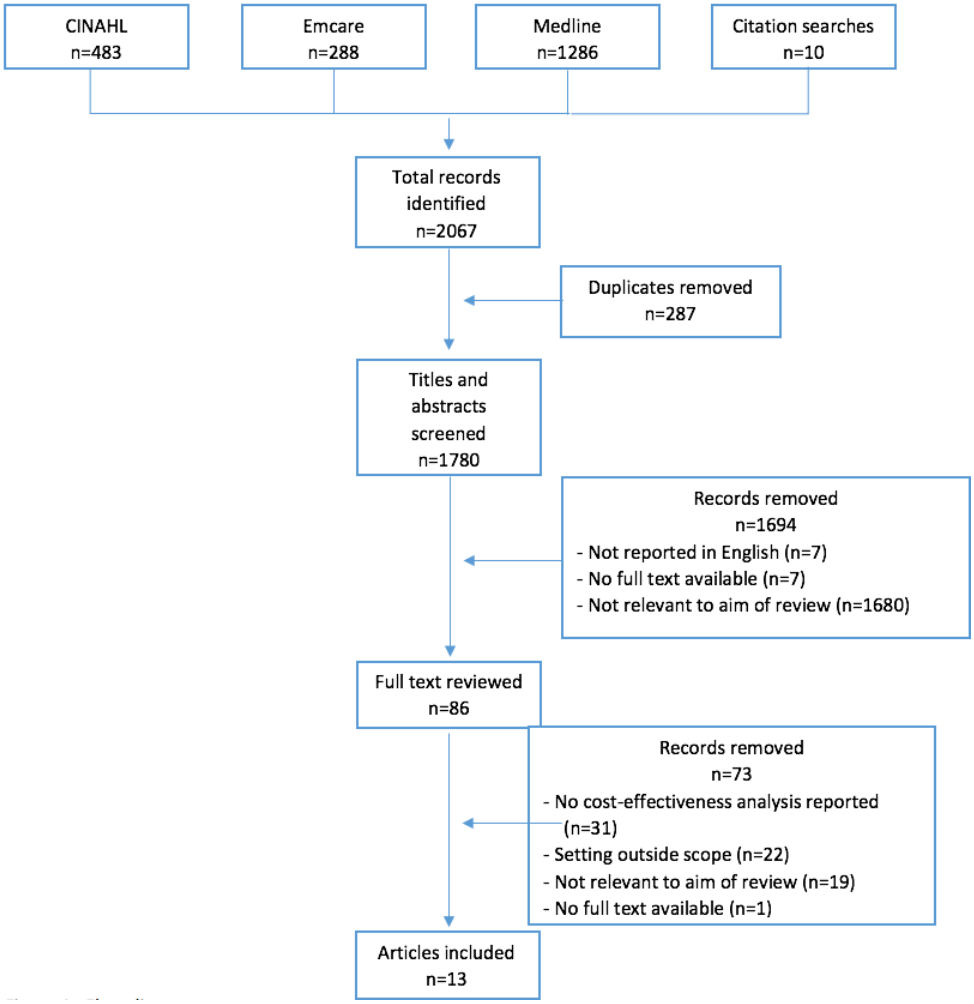
Table 22 Search terms used (literature search platform) for the review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care

Element of clinical question	Search terms
Population	"primary health care" OR "indigenous health services"
Intervention	AND "pharmacist"
Outcomes	AND "cost-effectiveness"
Exclusions	Article other than a journal article or report; study protocol; study intervention that was set within a hospital or involved specialist physicians; the intervention involved community pharmacists without specified collaboration with general practitioners (GPs); the intervention involved a team-based approach where pharmacist involvement was not explicit; the study did not include a cost-effectiveness analysis; or the full text was unavailable online or written in a language other than English.

A PRISMA flowchart (Figure 3) provides a graphic depiction of the results of the literature search and the application of the study selection criteria.

Studies were selected independently by a single reviewer. Pre-specified criteria for excluding studies are included in Table 22. All studies that met the inclusion criteria are listed in Appendix 7.

Figure 3 Summary of the process used to identify and select studies for the review on the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care



A profile of each included study is given in Table 23 and in Appendix 7.

This study profile describes the authors, study ID, publication year, study design, study location, setting, length of follow-up of patients, study population characteristics, description of the interventions and assessment methods, description of the comparator (and associated intervention), and the relevant outcomes assessed.

See Appendix 7 for details on the individual studies included in the evidence base.

Table 23 Summary of systematic literature review findings of cost-effectiveness analyses from randomised controlled trials that explored pharmacist interventions within primary health care settings

Author, year, setting, study design	Participants	Pharmacist intervention	Follow-up duration	Control	Outcome measure	Cost-effectiveness outcome
Avery et al, 2012. UK, general practice, Pragmatic Cluster randomised trial	General practices	Simple computerised feedback plus pharmacist-led interventions with practice team	12 months	Simple computerised feedback	Patients identified with potential medication error. Cost per additional medication error avoided due to the intervention at 12 months.	95% probability is cost effective if the decision-maker's ceiling willingness to pay reached £85 per error avoided (at 12 months).
Bojke et al, 2010. UK General practice. Randomised multiple interrupted timeseries.	>=75 years with polypharmacy	Pharmacist moderated drug management in collaboration with doctor, patient and carer.	12 months	Usual care	Mean incremental cost per additional QALY	78%-81% probability that pharmaceutical care is cost-effective at a threshold between £20,000 and £30,000 per QALY.
Cowper et al, 1998. USA Randomised control trial	>=65 years (males) with polypharmacy	Pharmacist medication review for prescribing appropriateness (MAI)	12 months	Nurse review of prescriptions.	Cost per 1 unit change in MAI	Cost was $7.50 per 1-unit change in MAI. Excluding drug costs, the ratio was $30/1 unit change in MAI.
Elliott et al, 2014, UK. General Practice Pragmatic cluster randomised trial	General practices	Simple computerised feedback plus pharmacist-led interventions with practice team	12 months	Simple computerised feedback	Cost per additional QALY	59% probability of being cost-effective at a threshold ceiling willingness-to-pay for a QALY of £20,000.
Kulchaitanaroaj et al, 2012, and 2017, USA Community-based clinics. Combined data from two prospective cluster-randomised controlled clinical trials	>=21 years with hypertension	Pharmacists co-located with physicians. In-person recommendations to address suboptimal drug regimens and educate physicians as needed.	6 months	Physician management only.	Cost for one additional patient to achieve blood pressure control Cost per QALY gained	Cost for one additional patient to achieve blood pressure control was $1338.05. $36.25 per additional 1mmHg reduction in systolic blood pressure and $94.32 per additional 1mmHg reduction in diastolic blood pressure. $26,807.83 per QALY gained
Obreli-Neto et al, 2015. Brazil Primary health care unit. Randomised controlled trial	>= 60 years, diagnosed with diabetes or hypertension receiving medications	Pharmacist follow-up of patients every 6 months, compliance checks; patient and family education; and physician recommendations	36 months	Usual care (3 monthly physician visits without a pharmacist)	Incremental cost-effectiveness ratio per QALY, based on patients reaching clinical outcome goals.	Incremental cost-effectiveness ratio per QALY was estimated at $53.50. The intervention did not significantly increase health care cost and significantly improved health outcomes.
Polgreen et al, 2015. USA. Primary care Offices. Cluster randomised controlled trial	>= 18 years with uncontrolled hypertension defined as SBP>140mmHg	Pharmacist collaboration with physicians with pharmacist care plans and regular patient visits.	9 months	Usual care – no pharmacist involvement	Cost to lower blood pressure by 1mmHg.	Cost to lower BP by 1mmHg was $33.27 for systolic and $69.98 for diastolic. Comparing rates in

Author, year, setting, study design	Participants	Pharmacist intervention	Follow-up duration	Control	Outcome measure	Cost-effectiveness outcome
	or DBP >90 mmHg or SBP >130 mmHg and DBP >80 mmHg in diabetes and chronic kidney disease					the intervention and control groups, the cost to increase BP control by 1 percentage point was $22.55.
Simpson et al, 2015. USA. Primary care clinic Randomised controlled trial	Patients with Type 2 diabetes	Pharmacist visits with patients with medication review and physical examination including blood pressure measurement; pharmacist recommendations to the physician; and patient follow-up by pharmacist.	12 months	Usual care – no pharmacist involvement	Cost to reduce annualised cardiovascular 10-year risk by 1%	95% probability that intervention is cost-effective at level of about $4,000 per 1% reduction in annualised cardiovascular risk.
Sorensen et al, 2004. Australia. General practice, Randomised controlled trial	Patients at risk of medication misadventure	GPs coordinated linking up of pharmacists. Patient home visit by the pharmacist for medication review, with prescriber recommendations	6 months	Usual care	Cost-saving per intervention patient	There was a net cost saving per intervention patient (marginal cost benefit) of AUS$54 per patient relative to controls. No significant difference was demonstrated in health-related quality of life, patient satisfaction, or clinical outcomes.

See Appendix 7 and Table 23 for details on the outcomes measured in the included studies, along with the statistical methods used to analyse the results.

The literature search (Appendix 7) did not reveal studies for interventions involving a pharmacist integrated within primary health care services such as ACCHSs in Australia for which cost-effectiveness was analysed. Furthermore, there were no cost-effectiveness studies from any other country reporting interventions involving clinical pharmacist services to Indigenous peoples through Indigenous health services or any other type of primary health care service. Only one study, set in the United States, commented on the participation of minority populations.

Given the lack of cost-effectiveness studies that were directly relevant to the IPAC trial, cost-effectiveness studies included in this review were selected to have a broader focus in general

practice or other primary health care settings and involving collaborative care between a pharmacist and a general practitioner (GP).

The literature review for studies assessing the cost-effectiveness of primary health care integrated pharmacist interventions, found only two studies that explicitly mentioned the co-location of the pharmacist within the primary health care facility. However, it was not clear if the pharmacists in these studies were co-located solely for the purposes of the intervention or if they were existing staff at the facility.[132] [133] The remaining studies involved community pharmacists, clinical pharmacists or research pharmacists and again it was unclear if they were co-located at the primary health care facility for the intervention period (Table 3).

In summary, this literature search did not identify any cost-effectiveness evaluations of pharmacist's interventions that were directly relevant to the IPAC trial. This highlights the importance of the IPAC trial to inform on the cost-effectiveness of pharmacist interventions relevant to the health of Indigenous Australians. The studies set in countries other than Australia have different health systems and therefore different ways of managing health problems within the primary health care setting. Studies also measured health gains in different ways. It is therefore difficult to report the cost-effectiveness of the interventions without considering and understanding the context of each setting. Most authors concluded that the pharmacist intervention was cost-effective.

STRUCTURE OF THE ECONOMIC EVALUATION

This economic evaluation compared the costs and outcomes of the IPAC intervention versus usual care prior to the addition of an integrated non-dispensing pharmacist within ACCHSs to promote the quality use of medicines. The perspective adopted was the publicly funded health system. Discounting was not applied as the trial duration was less than one year.

The analysis was trial-based, rather than model-based, with costs and outcomes compared in the post- and pre-intervention periods. As such, types of events and health states did not need to be defined. The trial used a pragmatic study design to evaluate quality of care outcome measures consistent with measures usually explored for quality improvement within clinical practice, with the comparator being 'usual care'. For these reasons, quality of

[132] Kulchaitanaroaj, P., Brooks, J. M., Ardery, G., Newman, D. & Carter, B. L. (2012). Incremental costs associated with physician and pharmacist collaboration to improve blood pressure control. Pharmacotherapy, 32(8):772-780.
[133] Kulchaitanaroaj, P., Brooks, J. M., Chaiyakunapruk, N., Goedken, A. M., Chrischilles, E. A., & Carter, B. L. (2017). Cost-utility analysis of physician-pharmacist collaborative intervention for treating hypertension compared with usual care. Journal of Hypertension, 35(1), 178-187.

life measures for cost utility analysis were not collected from trial participants to reduce the burden on participants and on clinical staff. Furthermore, (i) changes in quality of life would be unlikely to have been achieved over the relatively short time frame of the IPAC Trial and (ii) problems have been demonstrated in the use of existing instruments to measure the quality of life in Aboriginal populations, especially in populations experiencing more chronic conditions.[134] A single-item question for self-assessed health status of participants (SF1 of the SF-36 scale) was used in the IPAC evaluation but this was not suitable for use in the economic evaluation.

A cost-effectiveness analysis was undertaken for two sub-groups of participants: (i) those with T2DM with pre- and post-measures of HbA1c and (ii) those selected for MAI assessments at baseline and at the end of the study, with potential prescribing omissions (PPOs) used as the relevant outcome measure.

A cost-consequence analysis was undertaken for all participants, with changes in biomedical indices reported for participants with pre- and post-measures of each outcome. Cost-consequence analysis differs from cost-effectiveness analysis in not reporting a single summary measure such as the incremental cost per incremental change in outcome. Rather, costs are presented alongside a range of outcomes to demonstrate the full impact of the intervention and allow policy makers to interpret the findings as appropriate to their decision-making context. Cost-consequence analysis has been recommended for complex interventions with multiple effects and public health interventions which have a range of health and non-health benefits that are difficult to measure in a common unit.[135] [136]

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. The economic evaluation was conducted using SPSS and MS Excel.

A description of the proposed population, disease states and settings and justification is described in Section A.4 and repeated in Section D.2. A description of the intervention is described in the section of this report that describes the clinical algorithm (Section A.6).

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[134] Banham D, Karnon J, Lynch J. Health related quality of life (HRQoL) among Aboriginal South Australians: a perspective using survey-based health utility estimates. Health and Quality of Life Outcomes, 2018;17(1); 39.

[135] Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G. Methods for the economic evaluation of health care programmes. Oxford University Press;2005.

[136] National Institute for Health and Care Excellence. Medical technologies evaluation programme methods guide: process and methods [PMG33]. https://www.nice.org.uk/process/pmg33/resources/medical-technologies-evaluation-programme-methods-guide-pdf-72286774205893

Assumptions

The *theory of change* for the integrated pharmacist's intervention demonstrates the relationships and interactions between the various events that can influence outcomes and the economic evaluation (Appendix 3). In short, the effect of integrated pharmacists is influenced by their training and the integration model within the ACCHS (fidelity to the conditions of the IPAC intervention), as well as assumptions that are outside the control of the ACCHS and integrated pharmacist. For example, patient adherence behaviour can be mediated by social and economic factors outside the control of the patient and the healthcare team, and the effect of integrated pharmacists may also be mediated by the capacity of community pharmacy to engage and support systems that enhance patient-centredness in the quality use of medicines.

The economic evaluation estimated the net cost of medication utilisation during the IPAC trial (as a health system cost). Certain assumptions made in developing these estimates have been reported in Appendix 15 (*Net cost to the PBS*).[137] The cost of medications that were actually dispensed during the study period could not be directly ascertained as dispensing data was not collected for this study.

Consequently, assumptions were applied when estimating the cost of changes to prescription medicines and a conservative approach was taken. It is likely that each of the following assumptions had the effect of overestimating the cost of medication changes during the study period. Costs were assigned to continuous-use medicines (at a standard dosage) for: a) the whole study period; b) assumed complete participant adherence over this time; and c) assumed that prescribing changes occurred immediately following the date of the baseline medication review.

Given that there are delays in patients filling prescriptions from community pharmacy, and a usual non-adherence rate of at least 30% for Aboriginal peoples and Torres Strait Islanders,[138] the actual cost of medications dispensed for the whole follow-up period would most likely have been less than what was assumed. The same assumptions were applied to ceased medications to offset the cost of newly started medications. This may have overestimated the costs saved, as medications may not have been ceased immediately after the baseline MAI.

[137] Couzos S, Drovandi A, Smith D, Hendrie D, Biros E. Net cost to the PBS of medication changes arising from the IPAC intervention: Method used to assess health system costs for economic analysis. Supplement to the Economic Evaluation for the IPAC Project. Report to the PSA, December 2019.

[138] de Dassel JL, Ralph AP, Cass AA. systematic review of adherence in Indigenous Australians: an opportunity to improve chronic condition management. BMC Health Serv Res. 2017 Dec 27;17(1):845. doi: 10.1186/s12913-017-2794-y.

The net effect of these competing assumptions would favour an overestimation of medication costs as it is easier to cease a medication than to take it.

The costs of single-expense medications may also have been overestimated by extending the cost period to 30 days for some items according to the defined standard dosages, but this applied to only a few medications. An assumption was made that these single-expense items were not prescribed at repeated intervals during the study and this may have also underestimated the costs of these type of medications. In this case, the net effect is a more balanced set of assumptions.

The PBS patient co-payment did not factor in any of the medication cost estimates as most participants were concessional and the co-payment for Aboriginal peoples and Torres Strait Islanders in this situation is waived under the Closing the Gap PBS Co-Payment Measure. In addition, some participants were from remote locations sourcing their medications through the ACCHS under the section 100 (of the National Health Act, 1953) scheme that also waives a co-payment. The few remaining participants not in either of these situations may have paid a reduced co-payment of $6.50 (2019 prices) per medication dispensed. If the patient contribution was able to be factored into these estimates, the direction of the net effect on patient 'out of pocket' expenses arising from the medication changes is unclear given that new medications were started as well as ceased.

These assumptions provide a conservative estimate of the costs of medication changes that may be attributed to the pharmacist intervention.

D.4. INPUTS TO THE ECONOMIC EVALUATION

INTERVENTION COSTS

Resources used to deliver the intervention included the integrated pharmacists salary, training time, GP time spent with pharmacists in medicine information sessions and attending workshops conducted by integrated pharmacists, resources provided by the ACCHSs and miscellaneous items. Information on the amount of resource use was collected directly from record keeping systems implemented specifically for the IPAC trial. Unit costs were similarly obtained directly from the trial records or, in the case of GP time, from an official source (i.e.

ABS earnings data adjusted to 2019 base year based on the change in average weekly earnings).[139] [140]

The change in use of health care resources resulting from the intervention included: (i) the net change in number of MBS item number 900 consultations with GPs and corresponding Home Medicines Reviews (HMRs) in the pre- and post- periods and (ii) the net effect of new medicines started less medicines stopped (for the subset of participants who had an MAI).

Net costs do not include changes in health system resource utilisation such as hospitalisations. Hospitalisation rates were not investigated as a measure in the IPAC trial, as the trial was community-based and participatory, being restricted to data extracted from ACCHS clinical information systems in order to respect Aboriginal and Torres Strait Islander participants ownership of their own data.

Including an integrated pharmacist as part of the primary health care team also generated cost savings (i.e. cost offsets). The costs-savings related to the provision by integrated pharmacists of medication management reviews, either as a HMR (MBS item 900 rebate claim) or a comprehensive medication review that was conducted under circumstances that did not fulfil all criteria of the HMR program. Examples of such circumstances included reviews conducted outside the patient's home, or if the pharmacist conducting the review was not accredited to conduct a HMR. These comprehensive reviews were designated for the purposes of the trial as 'non-HMRs'.

In addition to (i) HMRs conducted by the integrated pharmacists for which no Sixth Community Pharmacy Agreement (6CPA) claim was made and (ii) non-HMRs conducted by integrated pharmacists that substituted for HMRs that may, in the absence of the non-HMRs, have resulted in MBS/6CPA claims, time savings for GPs due to health care activities undertaken by pharmacists, were also included as a cost offset on the basis that they relieved GPs of these duties.

[139] Australian Bureau of Statistics. Employee earnings and hours, Australia, May 2018. Published January 22 2019. https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument.

[140] Australian Bureau of Statistics. Average weekly earnings, Australia, May 2018. Published August 16 2019https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6302.0May%202019?OpenDocument

NET COST OF DIRECT HEALTH CARE RESOURCE ITEMS

Home Medicines Reviews

The number of MBS item 900 claims was obtained for each participant for the 12-month period prior to enrolment and was collected for the duration of the implementation phase of the trial. The fee for MBS item number 900 is $157.30[141] and under the 6CPA the pharmacist's fee for a HMR is $222.77 (the total of HMR fees being $380.07).[142] Given varying follow-up periods for participants, MBS item 900 claims in the 12-month period prior to enrolment were proportionately adjusted to correspond to the period for which the participant was enrolled (i.e. number of MBS item 900 claims in 12-month pre-period multiplied by days in trial divided by 365).

NET COST OF CHANGE IN MEDICINES

A method was developed to derive an estimate of the cost of additional medicines started, with cost-offsets for the number of medicines stopped for the subset of participants who had an MAI assessment (Appendix 15). Comparisons were made per patient between medicines at baseline and end of study. Whilst the study records could inform on the number and type of 'new medicine started' or 'previous medicine stopped', neither the dose of medicine prescribed nor the date when the medicine change occurred was known. Consequently, a standard, maximum or minimum medication dose was assigned by an expert panel and the dispensed price per maximum quantity (DPMQ) listed by the PBS used to assign costs for a standard time period consistent with complete adherence. A maximum drug dose for 'new drugs started' overestimates the cost of new medicines, and a minimum drug dose for 'medicines stopped' underestimates cost savings. An assumption was made that the medication change occurred from the date of the baseline MAI and continued until the date of the repeat MAI. A summary of the analysis undertaken for this assessment is included in Appendix 15. Participants for whom information on medicine use was not collected were allocated the average cost of PBS medicines per participant as calculated for participants with a medicine cost.

[141] Australian Government Department of Health. (MBS Online: Medicare Benefits Schedule. http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Downloads-201907.

[142] Australian Association of Consultant Pharmacy, The facts on remuneration for mediation reviews. Fact Sheet No. 2. https://aacp.com.au/app/uploads/No-2-Remuneration-for-MMRs-2019-2020.pdf

HMRs AND NON-HMRs CONDUCTED BY THE INTEGRATED PHARMACISTS

The number of HMRs and non-HMRs conducted during the IPAC Trial were ascertained from the integrated pharmacist logbook. The majority (96.4%) of HMRs conducted during the trial period were completed by the integrated pharmacists, with approximately half (52.8%) conducted within IPAC hours and for which no 6CPA claim was submitted. Given the fee of $222.77 per HMR, this amounts to a cost offset to the system of $113.39 per HMR (0.964 x 0.528 x $222.77). The non-HMRs were also a cost offset for which the equivalent cost of a HMR of $380.07 was assigned.[143] [144]

Omitted from the analysis was the cost of follow-ups to HMRs and non-HMRs. Approximately half of the HMRs and non-HMRs resulted in follow-up encounters within the implementation phase, which represent a cost offset. However, these follow-up encounters were excluded as a cost offset as they did not relate to an activity funded at the time of the intervention

TIME SAVED FOR GPs

Inclusion of an integrated pharmacist as part of the primary health care team resulted in time saved by GPs. A survey of GPs for the qualitative evaluation of the IPAC trial suggested a wide variation in the amount of GP time saved from the support provided to them by integrated pharmacists. This time saving ranged from 3% to 41% (Appendix 14). In view of the variation, the evaluation team adopted a minimal and conservative time saving that amounted to approximately 5% of their time. As indicated earlier, the cost of GP time was assigned based on ABS earnings data.[145]

ALLOCATING COSTS TO PARTICIPANTS

Intervention costs were divided into (i) variable costs that could be attributed directly to participants (e.g. HMRs, non-HMRs, medicines started/stopped) and (ii) fixed costs which included intervention costs plus cost offsets.

Variable costs were allocated directly to participants based on their unit costs. Fixed cost components were allocated to each ACCHS based on relative resource use. These fixed cost

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[143] Australian Government Department of Health. MBS Online: Medicare Benefits Schedule. http://www.mbsonline.gov.au/internet/m.bsonline/publishing.nsf/Content/Downloads-201907.

[144] Australian Association of Consultant Pharmacy, The facts on remuneration for mediation reviews. Fact Sheet No. 2. https://aacp.com.au/app/uploads/No-2-Remuneration-for-MMRs-2019-2020.pdf

[145] Australian Bureau of Statistics. Employee earnings and hours, Australia, May 2018. Published January 22 2019.https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument.

components were allocated to participants based on the number of months each participant was enrolled in the study as a proportion of the total number of months measured across all participants enrolled at that ACCHS. In the case of time saved by GPs, the cost was allocated to participants based on the number of months they were enrolled in the study as a proportion of the total number of months of enrolment measured across all participants. The rationale for this latter was to account for the varying number of participants at each site and thus to allocate these cost offsets in a way more likely to reflect time saved.

Total costs for each participant was calculated as the sum of their variable costs plus share of fixed costs.

Table 24 presents data relating to how direct health care resources used in delivering the IPAC intervention were calculated including unit costs, the source of unit cost data, and relevant explanatory comments. Similarly, Table 25 shows these items in regard to the utilisation of direct health care resource items by trial participants. Table 26 lists the range of outcome measures used in the primary and secondary economic evaluations.

Table 24 Direct health care resource items associated with delivering the IPAC intervention

Item	Units	Unit cost	Source	Comment
Integrated pharmacist salary	Hours	$50 per hour*	Financial records	Casual hourly rate for a pharmacist at two sites was $68.44. Salary for two discontinued sites was reallocated across other sites based on proportion of total pharmacist hours.
Integrated pharmacist on-costs	% of salary	17% ($8.50 per hour)*	Financial records	Range of $4.81 - $9.86 depending on employment arrangements.
Integrated pharmacist allowances (including relocation costs where applicable)	$	-	Financial records	Total amount across all sites allocated to pharmacists at each site based on their proportion of total hours
Out-of-pocket pharmacists' payments	$	-	Self-report	As above
Integrated pharmacist training	$	-	Financial records	As above
ACCHS support of integrated pharmacists	$	-	ACCHS records	As above
General practitioner time spent in receiving a medicines information service	Hours	$86.80 per hour	Hours from pharmacist logbook; unit cost from ABS (2019a). Updated to 2019 using ABS (2019b)[146,147]	As above

[146] Australian Bureau of Statistics. Employee earnings and hours, Australia, May 2018. Cat no 6306.0. Canberra:ABS; 2019.
[147] Australian Bureau of Statistics., Average weekly earnings, Australia, May 2019. Cat no 6302.0. Canberra:ABS; 2019.

*Cost estimates were provided by the Pharmaceutical Society of Australia. The pharmacist's salary was budgeted by the PSA for the integrated pharmacist role in the IPAC trial. For some pharmacists this rate was an increase on their salary rate prior to IPAC trial, whilst for others the rate was lower than their pay rate immediately prior to IPAC. Market rates vary depending on remoteness.

Table 25 Utilisation of direct health care resource items by trial participants

Item	Units	Unit cost	Source	Comment
Net Home Medicines Reviews (HMRs)	n	$380.07	MBS and 6CPA	Comprises $157.30 for MBS item 900 plus 6CPA fee for pharmacists of $222.77
Cost offset HMRs conducted within IPAC hours (no 6CPA claim).	n	$113.38	Financial records, MBS item 900 and 6CPA	Attributed as a cost saving
Cost offset Non-HMRs	n	$380.07	MBS and 6CPA	As above
Time saved by GPs	% of time	$86.80 per hour	% of time from GP survey; earnings from ABS (2019a); ABS (2019b)	As above
Net cost of PBS medicines	n	Various based on DPMQ listed by the PBS	See 'Net cost of change in medicines' section above	-

6CPA= 6Th Community Pharmacy Agreement; ABS= Australian bureau of Statistics; MBS= Medicare Benefits Schedule

Table 26 Outcome measures used in the primary and secondary economic evaluations

Outcomes	**Measures**	**Source**
Primary outcome measures	Biomedical indices including changes in HbA1c for participants with T2DM, and changed in SDP, DBP, TC, LDL-C, HDL-C, TG, ACR and CVD 5-year risk	Trial data
Primary outcome measure – participants with T2DM	Clinically meaningful reduction in HbA1c	Trial data
Secondary outcome measure	Potential prescribing omission	Trial data

ACR= albumin-creatine ratio
BMI= body mass index;
BP= blood pressure;
CVD= cardiovascular disease.
DBP= diastolic blood pressure
eGFR= estimated glomerular filtration rate
HbA1C= glycated haemoglobin
HDL-C= high density lipoprotein cholesterol
LDL-C= low density lipoprotein cholesterol
SBP= systolic blood pressure
TC= total cholesterol
TG= triglycerides
T2DM= type 2 diabetes mellitus

The cost-consequence analysis was undertaken using biomedical indices listed above, while the cost-effectiveness analysis was undertaken with regard to the primary outcome of a clinically meaningful reduction in HbA1c for participants with T2DM[148] and potential prescribing omissions for participants selected for MAI assessments.[149] These intermediate

[148] 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 Project). Final Report to the PSA, May 2020.
[149] Couzos S, Smith D, Buttner P, Biros E. Assessment of medication appropriateness using the Medication Appropriate 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, Feb 2020.

health outcome measures reflect 'quality of care' measures, consistent with quality measures used by the Australian Government to monitor the provision of primary health care through arrangements with Primary Health Networks and the ACCHS sector nationally.[150]

The cost of implementing the IPAC intervention was $1,946,876 (Table 27). As a result of the intervention, the net cost of health services (HMRs) increased by $132,899 ($179,012-$46,113) and the net cost of PBS medicines (i.e. medicines started less medicines stopped) increased by $553,849 ($135,800+$418,049). Cost offsets from time saved by GPs and integrated pharmacists conducting HMRs and non-HMRs during the trial period amounted to $459,643.

The net total cost of implementing the IPAC trial was $2,173,981 (calculated as [$1,946,876+($132,899+$553,849)-$459,643]). **On a per participant basis, this cost was equivalent to $1,493 per person.**

Table 27 Resource use, costs and cost offsets in delivering the IPAC intervention (n=1,456)

Item	Resource use (units)	Costs ($)	
		During-trial period	Pre-trial period ("comparator")
Integrated pharmacist salary	27,478 hours	$1,621,079	
Integrated pharmacist allowances	-	$136,658	
Pharmacist out-of-pocket payment	-	$9,741	
Integrated pharmacist training	-	$64,820	
ACCHS contribution[1]	-	$52,158	
General Practitioner time spent	719 hours	$62,420	
Total: Intervention costs	**-**	**$1,946,876**	
Home Medicines Review based on item 900 claims (HMR)	149 pre-intervention; 471 during intervention[2]	$179,012 [2]	$46,113[3]
Net cost of PBS medicines (participants for whom medicines was measured)		$135,800[4]	
- (PBS medicines started)	-	($514,467)[4]	
- (PBS medicines stopped)	-	($378,667)[4]	
Net cost of medicines (participants for whom medicines were not directly measured)	-	$418,049[5]	-
Cost of utilisation health services		**$732,861**	**$46,113[3]**
Time saved by General Practitioners	1366 hours	$118,528	

[150] Australian Institute of Health and Welfare 2018. National Key Performance Indicators for Aboriginal and Torres Strait Islander primary health care: results for 2017. National key performance indicators for Aboriginal and Torres Strait Islander primary health care series no. 5. Cat. no. IHW 200. Canberra: AIHW.

Item	Resource use (units)	Costs ($)	
		During-trial period	Pre-trial period ("comparator")
Cost offsets HMRs	-	$53,402[6]	
Non-HMRs	757	$287,713	
Cost offsets		**$459,643**	
Net total costs		**$ 2,220,094**	**$46,113[4]**

HMR= Home Medicines Review. A completed HMR represents a comprehensive medication management review that fulfils the criteria for a Medicare Benefits Scheme (MBS) claim for item 900, as sourced from the integrated pharmacist's logbook.
Non-HMR= a comprehensive medication management review that was not an HMR, as sourced from the integrated pharmacist's logbook.
PBS= Pharmaceutical Benefit Scheme.

[1] Excludes overheads and infrastructure costs (e.g. office space, computers, etc)

[2] Data from HMR report (Appendix 12).[151] A cost offset of $380.07 per HMR was applied.

[3] A cost offset of $380.07 per HMR was applied but was adjusted for each participant to reflect equivalent number of days in pre-trial period as during trial period.

[4] Derived from: *Couzos S, Drovandi A, Smith D, Hendrie D, Biros E. Net cost to the PBS of medication changes arising from the IPAC intervention: Method used to assess health system costs for economic analysis. Supplement to the Economic Evaluation for the IPAC Project. Report to the PSA, December 2019.* The costs differ slightly from this report as the costs here also include the cost of medicines for four participants who were not in the AoU group, totalling $2593.69 ($135,800 - $133,206). This cost relates to the subset of participants who had an AoU conducted.

[5]Participants for whom information on medicine use was not collected were allocated the average cost of PBS medicines per participant as calculated for participants with a medicine cost.

[6] Derived from 471 HMRs X $113.39. The majority (96.4%) of HMRs conducted during the trial period were completed by the integrated pharmacists, with approximately half (52.8%) conducted within IPAC hours and for which no 6CPA claim was submitted. Given the fee of $222.77 per HMR, this amounts to a cost offset to the system of $113.39 per HMR (0.964 x 0.528 x $222.77).

Table 28 presents costs for subgroups of participants. It was possible to report costs for subgroups as intervention costs (variable and fixed) and components of the net cost of direct health care resources were apportioned to individuals either directly or based on allocation factors. Identifying costs separately for subgroups enabled the appropriate costs to be compared with corresponding outcomes in the incremental cost-effectiveness ratios presented in the cost-effectiveness analysis. Calculating costs for subgroup of participants assumes that the costs of implementing the IPAC intervention are proportionately divisible.

Table 28 Resource use, costs and cost offsets in delivering the IPAC intervention for specific subgroups of participants.

Subgroup	No. of participants	Total intervention costs[1]	Net cost of utilisation of health services[2]	Cost offsets	Net total costs
Participants with T2DM and pre-post HbA1c measures[3]	539	$732,130	$ 198,822	$177,178	$ 753,774
Participants for whom AoU conducted[3]	353	$690,949	$161,115	$137,105	$714,959

AoU= Assessment of medication underutilisation

[151] 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 pharmacist support within Aboriginal community - controlled health services (IPAC Project). Final Report to the PSA, Feb 2020.

HbA1C= glycated haemoglobin
T2DM= type 2 diabetes mellitus
[1] Includes sum of variable and fixed costs of the IPAC intervention for participants in each subgroup.
[2] Includes net cost of utilisation of health services for participants in each subgroup.
[3] Participants with T2DM and in the AoU groups had a mean length of participation in the IPAC trial of 287 and 326 days respectively. Additionally, more participants in the AoU group were associated with ACCHSs with higher mean costs per participant.

D.5. RESULTS OF THE ECONOMIC EVALUATION

COST-CONSEQUENCE ANALYSIS

The results of the cost-consequence analysis, comparing the cost of the IPAC intervention with changes in biomedical indices for which statistically significant differences were observed, are presented below (Table 29). Changes in biomedical indices were calculated using paired pre and post-intervention measures, adjusted for health service cluster and the length of follow-up time (Table 29 above).

The total cost of implementing the IPAC intervention 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 29).

Table 29 Cost-consequence analysis comparing mean incremental cost with mean differences in biomedical indices[1]

Variable	Mean incremental cost	Mean difference in biomedical indices mean (SD, 95% CI)	p-value[1]
Net total cost (including cost offsets)	$ 1,493[2]		
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 analysis report (Appendix **9**).
BP= blood pressure;
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
[2]The estimate of $1,493 per participant, which includes the net costs of utilisation of health services and PBS medicines, is believed to be an overestimate. The net cost of medicine was estimated for a subset of participants based on assumptions that maximised the cost of new medicines started and minimised the cost of medicines that were stopped (see Appendix 15).

COST-EFFECTIVENESS ANALYSIS

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.[152]

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) are shown in Table 30. The 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%.[153]

Adopting the statistically significant but still clinically meaningful reduction in HbA1c of 0.3% as the benchmark (rather than the benchmark reduction of 0.5%), the ICER reduces to $3,235 ($753,774/233) per participant.

Table 30 Incremental cost effectiveness ratio for reduction in HbA1c in participants with Type 2 diabetes mellitus

		A		B	A/B
	Cost	**Incremental cost**	**Effectiveness: Mean HbA1c (SD) mmol/mol [% units]**	**No. of participants with a clinically meaningful reduction in HbA1c[2]**	**ICER[1]**
Intervention	$ 772,098	$ 753,774	64.0 (22.3) [8.0% (2.0%)]	200	$ 3,769
Comparator	$ 18,324[3]		66.8 (23.8) [8.3% (2.2%)]		

[1] ICER = Incremental Cost Effectiveness Ratio (defined as incremental cost divided by number of participants with a clinically meaningful reduction in HbA1c).
[2] Number with clinically meaningful reduction (mean difference) in HbA1c of at least 0.5% at the participant level, from baseline compared with end of study (n=539).[154] HbA1c conversions used the formula: %HbA1c (units)= [IFCC HbA1c (mmol/mol)* 0.0915] +2.15. See Appendix

[152] Couzos S, Smith D, Buttner P, Biros E. Assessment of medication appropriateness using the Medication Appropriate 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 Pharmaceutical Society of Australis for the IPAC Project, February 2020.
[153] Little RR, Rohlfing C. The long and winding road to optimal HbA1c measurement. Clinica Chimica Acta. 2013;418(xx):63-71.
[154] Little RR, Rohlfing C. The long and winding road to optimal HbA1c measurement. Clinica Chimica Acta. 2013;418(xx):63-71.

9. Note that a clinically meaningful reduction refers to whether the difference is likely to impact current medical practice based on change at the individual rather than population level. It differs from statistical significance, which quantifies the probability of a study's results being due to chance.[155] This analysis therefore adopted a conservative approach to estimate the ICER, as even small reductions in HbA1c can be clinically meaningful at both individual and population levels.[156]

[3] Cost reflects health system costs in the pre-intervention period; HMRs were the only cost item included.

For the sample of participants assessed for an AoU, the overall costs and outcomes, and incremental costs and outcomes, for the IPAC intervention compared with no IPAC intervention are shown below (Table 31). For this subset of participants, 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.

Table 31 Incremental cost effectiveness ratio for reduction in potential prescribing omissions in participants assessed for the underutilisation of medications (AoU)

	Cost	Incremental cost	Effectiveness PPOs (n)	Incremental effectiveness[1]	ICER
Intervention	$729,237	$714,959	181	105	$6,809
Comparator	$14,278[2]		76		

AoU = Assessment of Underutilisation
ICER = Incremental Cost Effectiveness Ratio
PPO = Potential Prescribing Omission

[1] Reduction in the number of participants with a potential prescribing omission.

[2.] Cost reflects health system costs in the pre-intervention period; HMRs were the only cost item included.

COST-UTILITY ANALYSIS

For participants with a clinical diagnosis of T2DM, and with pre and post-measures of HbA1c, changes in HbA1c during the trial period were mapped to lifetime quality of life changes based on the findings of a systematic review.[157] This review included 76 studies using T2DM simulation models to evaluate the relationship between improvements in HbA1c and modelled health outcomes in terms of quality-adjusted life years (QALYs) or life expectancy. Of the 76 studies, 57 were based on the CORE Diabetes Model.[158]

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 0.286-0.456) increase

[155] Ranganathan P, Pramesh CS, Buyse M. Common pitfalls in statistical analysis: clinical versus statistical significance. Perspectives in Clinical Research. 2015;6(3):169-170.

[156] Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ 2000; 321:7258: 405-412.

[157] Hua X, Lung TW, Palmer A Si L, Herman, WH, Clarke, P. How consistent is the relationship between improved glucose control and modelled health outcomes for people with Type 2 Diabetes Mellitus? a systematic review. Pharmacoeconomics. 2017; 35(3):319-329

[158] The IMS Core Diabetes Model. https://www.core-diabetes.com/Index.aspx?Page=About

in lifetime QALYs. However, studies did not appear to include a decrease in HbA1c exceeding 3%. 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 (CI 78-125) (Table 31a).

Table 31a 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 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.

Only one study identified in the literature review of the cost-effectiveness of non-dispensing pharmacist services integrated within primary health care presented an ICER based on lifetime cost/QALY, but its target group were patients with hypertension.[159]

While the concept of having a cost-effectiveness threshold as a guide for selecting health care interventions for inclusion in a national health insurance scheme has proved controversial,[160] these thresholds provide guidance as to which interventions provide relative value for money.[161] In Australia, analysis of public summary documents have shown that medical services with ICERs over $40,000 per QALY have been recommended for funding, whilst summary documents from the Pharmaceutical Benefits Advisory Committee have indicated an ICER threshold of between $45,000 and $75,000.[162,163] A recent study that estimated a reference ICER for the Australian health system showed a lower figure of $28,033 per QALY gained.[164] This latter threshold was based on adopting a supply-side rather than demand-side approach, which has been argued to be preferred in decisions about adding or subtracting interventions to a publicly funded health system.[165]

Based on these ICER thresholds for Australia of assessing the value of new interventions, the modelled ICER for the IPAC intervention for participants with T2DM of $7,463 (95% CI $6,030 - $9,664) per QALY indicates good value for money.

D.6. SENSITIVITY ANALYSES

The sensitivity analysis tested for uncertainty in two parameters: variability in the number of HMR claims (MBS item 900) during the trial period, which accounted for 57% of the cost of utilisation of health services; and an increase in time saved for GPs, which accounted for 29% of cost offsets. While varying the number of HMR claims adds direct health care costs, cost offsets are also generated as the majority of HMRs conducted during the trial period were conducted by integrated pharmacists with no 6CPA claims payments made. Salary and related

[159] Kulchaitanaroaj P, Brooks JM, Chaiyakunapruk N, Goedken AM, Chrischilles EA, Carter BL (2017). Cost-utility analysis of physician-pharmacist collaborative intervention for treating hypertension compared with usual care. Journal of Hypertension. 2017; 35(1):178-187.
[160] Culyer A. Cost-effectiveness thresholds in healthcare: a bookshelf guide to their meaning and use. Health Economics, Policy and Law. 2016;11(4): 415-432.
[161] Brouwer W, van Baal P, van Exel, Versteegh M. When is it too expensive? Cost-effectiveness thresholds and health care decision-making. The European Journal of Health Economics. 2019; 20(2):175-180.
[162] Edney L, Afzali HHA, Cheng TC, Karnon J. Estimating the reference incremental cost-effectiveness ratio for the Australian health system. PharmacoEconomics. 2018;36(2):239-252.
[163] George B, Harris AH, Mitchell AS. Cost effectiveness analysis and the consistency of decisions making: evidence from pharmaceutical reimbursement in Australia. Pharmacoeconomics. 2001;19(1), 1–8.
[164] Edney L, Afzali HHA, Cheng TC, Karnon J. Estimating the reference incremental cost-effectiveness ratio for the Australian health system. PharmacoEconomics. 2018;36(2):239-252.
[165] Culyer A. Cost-effectiveness thresholds in healthcare: a bookshelf guide to their meaning and use. Health Economics, Policy and Law. 2016;11(4): 415-432.

costs of including integrated pharmacists within the ACCHS setting are the key driver of the cost of the IPAC intervention but unlikely to be subjected to variability.

Variability in HMR claims may occur if, in the future roll-out of the IPAC intervention, there are more integrated pharmacists who are accredited to complete HMRs. In the IPAC study, about 75% of integrated pharmacists were accredited. If this number increases to 100%, then even more HMRs are likely to be completed (and claimed). While this will increase health system costs, it increases patient access to the HMRs (which is a health system goal). Also, the variability in HMRs (costs to the health system) may also occur if community pharmacy (external pharmacists) complete more HMRs because the integrated pharmacist refers the patient to them, which occurred during the IPAC intervention. The sensitivity analysis increased the number of HMRs during the trial period to 1.33 of the number conducted during the intervention period (n=626 rather than n=471). The number of HMRs is dependent on program rules; future changes to these rules will impact on the frequency of HMRs conducted.

Time saved for GPs may increase as the integrated pharmacists become more embedded in the practice and assume more roles related to their expertise in medication use and safety.[166] The survey of GPs for the qualitative evaluation of the IPAC trial suggested a variation in the amount of GP time saved from the support provided to them by integrated pharmacists of between 3% and 41%. In the sensitivity analysis this percentage was assumed to be 10%, an increase from 5% in the base case analysis.

Increasing the number of HMRs by one third during the trial period increased net total costs of the IPAC Trial by $76,492, while the increase in time saved for GPs by having integrated pharmacists embedded in the ACCHSs decreased costs by $118,528. The impact of varying both parameters was low (Table 32).

Table 32 Key drivers of the economic evaluation

Description	Method/Value	Impact
Increase in number of HMRs	1.33 of number completed by integrated pharmacists during trial period	Low, favours comparator
Increase in time savings for GPs	10% (instead of 5%)	Low; favours intervention

[166] Deeks, L.S., Naunton, M., Tay, G.H., Peterson, G.M., Kyle, G., Davey, R., Dawda, P., Goss, J., Cooper, G.M., Porritt, J. & Kosari, S. What can pharmacists do in general practice? A pilot study. Australian Journal of General Practice; 47(6): 545-549.

SECTION E – FINANCIAL IMPLICATIONS

E.1. JUSTIFICATION OF THE SELECTION OF SOURCES OF DATA

The financial implications have been determined based on the integrated model of care for pharmacists investigated in the IPAC Trial. Section B and Appendices outline the methods, main results, findings, limitations and generalisability of the findings. Section C outlines translation issues.

Financial implications are presented for the broader roll-out of the proposed service to Aboriginal and Torres Strait Islander patients with chronic disease (irrespective of age) attending ACCHSs .

The approach used to estimate the financial implications of the introduction of an integrated pharmacist within ACCHSs has been based on costings for recruitment, employment, training, the proposed settings and the proposed population, extrapolated to the proposed ACCHS services. Information is also drawn from the economic evaluation presented in Section D.

Financial implications include the cost of (i) delivering the proposed service and (ii) additional utilisation of health services resulting from integrated pharmacists being part of the primary health care team. Costs presented are a maximum figure that assumes all ACCHSs across Australia will participate in the extended IPAC program and be able to access suitable pharmacists.

Cost offsets from implementing the IPAC model of care will be generated as the integrated pharmacists assume tasks previously undertaken by GPs, thus freeing up time for GPs. Additionally, improvement in biomedical indices for clients is likely to lead to a reduction in the need for acute health care services over time.

Appendix 17 provides a detailed explanation of the methodology used to estimate costs associated with extending the IPAC trial to embed pharmacists in all ACCHS in Australia. In brief, the proposed funding model for salary of the pharmacists adopted the IPAC methodology for allocation of pharmacist FTE and salary, with a baseline 0.2FTE allocated to each ACCHS and a further allocation according to ACCHSs' client numbers plus a rural loading added, as is applied in the Workforce Incentive Payment program.

Client numbers were estimated from: (i) data from the Australia Institute of Health and Welfare (AIHW), with assumptions made about the relative number of ACCHSs (the AIHW

data combines the number of ACCHSs and state/territory primary health services), and (ii) the relative number of ACCHS clients likely to have their medication reviewed by an integrated pharmacist or have a HMR conducted annually, with these estimates based on findings of the IPAC trial.

Training for integrated pharmacists to enable them to work with complex patients and requiring an understanding of social determinants of health and the public health challenges related to Aboriginal and Torres Strait Islander peoples, includes the creation of online or face to face training courses (drawing on existing material) plus mentorship programs and ongoing support.

Program support for ACCHS has been based on methods for medicines-related programs within ACCHSs that have been found to be effective. The timing of program support is skewed towards the earlier stages to facilitate program uptake and early implementation including recruitment of pharmacists.

Ongoing evaluation of the extended program to embed pharmacists in ACCHSs is proposed to ensure the program is meeting its stated objectives and to identify any issues affecting implementation and address these in a timely manner.

Over the projected 5-year period, total costs of implementing the extended IPAC intervention average $13.2 million per annum (Table 33).

Table 33 Financial implications of extending the IPAC intervention to all ACCHSs

Item	Year 1 ($)	Year 2 ($)	Year 3 ($)	Year 4 ($)	Year 5 ($)
Pharmacists salary	11,735,262	11,735,262	11,735,262	11,735,262	**11,735,262**
Training and support for pharmacists	1,151,000	621,000	621,000	488,750	488,750
Program support for ACCHSs	647,500	622,500	490,000	357,500	332,500
Program monitoring and evaluation	312,380	294,780	294,780	294,780	294,780
TOTAL COSTS	13,846,142	13,273,542	13,141,042	12,876,292	12,851,292

The IPAC trial was associated with an increase in the utilisation of medications and primary health care services, an important finding with the potential to contribute to more equitable, needs-based health care expenditure. The Australian Institute of Health and Welfare has estimated that the Aboriginal and Torres Strait Islander burden of disease is 2.3 times greater

than the non-Indigenous burden,[167] yet underutilisation of mainstream services is reflected in ratios of Indigenous to non-Indigenous expenditure of 0.67 to 1.00 for the MBS and 0.80 to 1.00 for the PBS.[168]

The additional cost of utilisation of health services was based on scaling up costs presented in the economic evaluation (Section D) to the estimated number of ACCHS clients with chronic disease who would be likely to: (i) have their medication reviewed by an integrated pharmacist (approximately 2.6% of patients with chronic disease; n=11,000) or (ii) have a HMR conducted annually (see Section E2). The unit cost applied to calculate the total cost of HMRs assumes no 6CPA amount is claimed; and the additional number of HMRs is based on the increase observed during the trial period compared with the pre-trial period. Annual costs of the net cost of medicines and additional HMRs are estimated to be $5.1 million (Table 34).

Table 34 Financial implications of extending the IPAC intervention to all ACCHSs for more equitable use of PBS medicines and Home Medicines Review

Items	Year 1 ($)	Year 2 ($)	Year 3 ($)	Year 4 ($)	Year 5 ($)
Net cost of PBS medicines*	4,684,865	4,684,865	4,684,865	4,684,865	4,684,865
Cost of additional HMRs**	454,912	454,912	454,912	454,912	454,912
TOTAL	5,139,777	5,139,777	5,139,777	5,139,777	5,139,777

*Based on scaling-up of the estimated net increase in the number of medications prescribed for IPAC participants within ACCHSs. The net increase occurred in participants who had an assessment of medication appropriateness completed by integrated pharmacists. Pharmacists made recommendations for medication adjustments to prescribers (See Appendix 12).
**Based on scaling up of the observed increase in participant uptake of HMR services (based on item 900 claims) when pharmacists were integrated within ACCHSs for the IPAC trial. The additional number of HMRs will be dependent on program rules.
ACCHS= Aboriginal community-controlled health services
HMR= Home Medicines Review.
PBS= Pharmaceutical Benefits Scheme

Cost offsets from time saved for GPs across the 140 ACCHSs, assuming a conservative (and minimal) estimate of a 5% time saving, are estimated as $1,184,820 per annum. This type of cost offset may be much higher given that there was a considerable degree of variation in the estimates of GP time-saved, given by general practitioners within ACCHSs (see Section D).

[167] Australian Medical Association. 2018 AMA report card on Indigenous health. https://ama.com.au/sites/default/files/documents/AMA%20Indigenous%20Health%20Report%20Card%202018.pdf
[168] Alford KA. Indigenous health expenditure deficits obscured in Closing the Gap reports. Medical Journal of Australia. 2015; 203(10):403.

E.2. USE AND COSTS OF HEALTH SERVICES

The number of clients with chronic disease accessing ACCHS services from integrated pharmacists is based on the capacity of the pharmacists to deliver services, based on the findings of the IPAC trial (irrespective of the age of participants).

The cost of implementing the IPAC intervention and embedding pharmacists in all ACCHSs, and the additional use of health services (i.e. HMRs and appropriate use of medicines) has been estimated by scaling up the findings of the IPAC intervention to clients likely to have their medicines reviewed or have HMRs conducted across all ACCHSs (Table 35).

Table 35 Use of the proposed service and additional costs of extending the IPAC intervention to all ACCHSs

Items	Year 1	Year 2	Year 3	Year 4	Year 5
Number of clients with chronic disease likely to be reviewed by an integrated pharmacist for medicines management	11,000[1]*	11,000	11,000	11,000	11,000
Number of additional HMRs	2,892	2,892	2,892	2,892	2,892
Cost of scaled-up IPAC intervention	$13,846,142	$13,273,542	$13,141,042	$12,876,292	$12,851,292
Cost of additional use of health services[1]	$5,139,777	$5,139,777	$5,139,777	$5,139,777	$5,139,777

[1] The total number of regular clients accessing ACCHSs was 409,646 (data provided by NACCHO, from AIHW statistics related to attendance of clients at Aboriginal primary health services).[169] The estimated number of ACCHS clients with chronic disease who would be reviewed by an integrated pharmacist or have a HMR conducted was based on the findings of the IPAC trial (irrespective of age).

E.3. CHANGES IN USE AND COST OF OTHER MEDICAL SERVICES

Other MBS-funded medical services were only analysed with respect to changes in MBS claim event rates and this showed no change in claims following the IPAC trial (Appendix 16). The MBS items relevant to team-based care that were examined included: 715 (Aboriginal and Torres Strait Islander health assessment); 721 (chronic disease care plan); combined 721, 723 and 732 (chronic disease care plan, team care arrangements (TCA), and review of a care plan or TCA) respectively; combined 735, 739, 743 (organizing and coordinating a case conference); combined 747, 750, 758 (participation in a case conference; and 10987, 10997 (follow-up service to item 715 and 721 that includes a medication adherence check undertaken by a practice nurse or an Aboriginal and Torres Strait Islander health practitioner). MBS items were combined as indicated due to relatively low numbers of claims for these services based on national claims data.[170] No statistically significant change in health service utilization was observed with any of the team-based care relevant MBS item numbers when event rates were examined per 100 person-years and cluster adjusted (Appendix 16).

[169] Australian Institute of Health and Welfare. Aboriginal and Torres Strait Islander health organisations: Online Services Report — key results 2017–18. 2019 [Available from: https://www.aihw.gov.au/reports/indigenous-australians/atsi-health-organisation-osr-key-results-2017-18/contents/profile-of-organisations.

[170] Department of Health. MBS Online (Medicare Benefits Schedule). Australian Government. 2020. http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home [Accessed April 2020]

E.4. FINANCIAL IMPLICATIONS FOR THE MBS

The IPAC Trial identified that MBS item 900 claims for participants significantly increased (3.9 times in a period of 12 months, p<0.001) from the integration of pharmacists within ACCHSs.

For an integrated pharmacist program to be delivered more broadly to the proposed population, the financial implications for the MBS (with regard to item 900) are the cost of the rebate for this service multiplied by the proposed number of beneficiaries over a 12-month period.

PBS and MBS safety net implications have not been included, as co-payments may not be applicable to the majority of clients. Based on the clinical endpoints analysis (Appendix 9), over 80% of participants were pensioners or had concessional status. There is also an absence of data to make assumptions on this issue.

A cost offset from time saved for GPs as a result of the support provided by integrated pharmacists amounts to $1,184,820 per annum. This freeing up of GP capacity will allow more time for clinical activities rather than being realised in monetary terms, hence this is not included in Table 36.

Table 36 Total costs to the MBS of extending the IPAC intervention to all ACCHSs

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of services (additional HMRs)*	2,892	2,892	2,892	2,892	2,892
Costs to the MBS**	$454,912	$454,912	$454,912	$454,912	$454,912

* The calculations are based on the number of regular clients attending ACCHSs with chronic disease who would have a HMR conducted based on the capacity of the integrated pharmacists to conduct HMRs, given the additional number conducted during the IPAC trial. This was derived by multiplying as the additional capacity from the program rollout (78/12.3) by the net increase in the number of HMRs during the intervention period (annualised), (see Appendix 12), which results in an expected increase of 2,892 HMRs per annum.
**The fee for the MBS item number 900 is $157.30 multiplied by the number of potential services over 12 months.

E.5. FINANCIAL IMPLICATIONS FOR GOVERNMENT HEALTH BUDGETS

While the IPAC trial 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 ED presentations; and 25% in unplanned admission length of stay.[171] While adopting different processes to achieve service improvement, 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%.[172]

Table 37 presents the financial implications for government budgets of extending the IPAC intervention to all ACCHSs, excluding the impact on the MBS and PBS (sections E1, E2 and E4).

Estimated reductions in the utilisation of hospital services from the improvement in biomedical indices achieved by the IPAC intervention were assumed to be 10%, 20% or 30%, based on findings of studies of the effectiveness of integrated care programs. These reductions were applied to estimates of the rate of hospital utilisation by the Aboriginal and Torres Strait Islander population for ACCHS clients, including hospital admissions for chronic disease (but excluding same day dialysis admissions for renal disease)[173] and emergency department presentations.[174] Costs per hospital admissions and emergency department presentations were obtained from relevant unit costs extracted from the National Hospital Cost Data Collection Round 21 tables,[175] updated from 2016/2017 to 2018/2019 prices.[176]

The resultant impact for government budgets is a reduction in hospital costs of between $0.6 million and $1.9 million per annum, varying according to the decrease in utilisation achieved, with the majority of savings arising from fewer emergency department presentations.

[171] Cheung NW, Crampton M, Nesire V, Hng TM, Chow CK. Model for integrated care for chronic disease in the Australian context: Western Sydney Integrated Care Program. 2019;43(5):565-571.
[172] Damery S, Flanagan S, Combes G. Does integrated care reduce hospital activity for patients with chronic diseases? An umbrella review of systematic reviews. BMJ Open. 2016; 6e011952.
[173] PHIDU. Aboriginal and Torres Strait Islander social health atlas of Australia. ttp://phidu.torrens.edu.au/social-health-atlases/data.
[174] Australian Institute of Health and Welfare. Emergency department care 2017–18: Australian hospital statistics. Health services series no. 89. Cat. no. HSE 216. 2018; Canberra: AIHW.
[175] Independent Hospital Pricing Authority. National hospital cost data collection, AR-DRG cost weight tables v8.0x, round 21 (Financial year2016-17).
[176] Australian Institute of Health and Welfare. Health expenditure Australia 2017-18. Health and welfare expenditure series no. 65. 2019; Canberra: AIHW.

Table 37 Financial implications for government budgets from a potential reduction in hospital costs

Items	Current utilisation of hospital services		Estimated reduction in utilisation of hospital services	
	(n)	($)	(n)	($)
Expected number of ACCHS clients to receive services from integrated pharmacists	11,000	-	-	-
ASSUMING A 10% REDUCTION				
Hospital admissions for chronic conditions	212[1]	1,189,101	21	118,910
ED presentations	7,394 [2]	5,146,224	739	514,622
Total	**-**	**6,335,325**	**-**	**633,532**
ASSUMING A 20% REDUCTION				
Hospital admissions for chronic conditions	212[1]	1,189,101	42	237,820
ED presentations	7,394 [2]	5,146,224	1,479	1,029,245
Total	**-**	**6,335,325**	**-**	**1,267,065**
ASSUMING A 30% REDUCTION				
Hospital admissions for chronic conditions	212[1]	1,189,101	64	356,730
ED presentations	7,394[2]	5,146,224	2,218	1,543,867
Total	**-**	**6,335,325**	**-**	**1,900,597**

[1] Estimates of the rate of hospital utilisation by the Indigenous Aboriginal and Torres Strait Islander Australian population applied to ACCHS clients reviewed by an integrated pharmacist, including hospital admissions for chronic disease (but excluding same day dialysis admissions for renal disease). [177]

[2] Estimates of the rate of emergency department presentations by the Indigenous Aboriginal and Torres Strait Islander Australian population applied to ACCHS clients reviewed by an integrated pharmacist.[178]

[177] Independent Hospital Pricing Authority. National hospital cost data collection, AR-DRG cost weight tables v8.0x, round 21 (Financial year2016-17).

[178] Australian Institute of Health and Welfare. Health expenditure Australia 2017-18. Health and welfare expenditure series no. 65. 2019; Canberra: AIHW.

SECTION F – OTHER RELEVANT CONSIDERATIONS

F.1 SUPPORT FOR THE PROPOSED SERVICE

We draw the attention of the MSAC to the acceptability of the proposed service to the target population. The integration of pharmacists within ACCHSs (the proposed service) received overwhelming support from the Aboriginal and Torres Strait Islander patients, health service staff, community pharmacists, and the IPAC integrated pharmacists, who participated in the qualitative evaluation of the trial (Appendix 14). The evaluation facilitated feedback from stakeholders who identified a number of benefits and positive outcomes as a result of the role. These benefits expanded to patients, health services staff (including CEOs, managers and GPs), integrated pharmacists and community pharmacists. These stakeholders supported the acceptability and continuation of integrated pharmacist services within ACCHSs.

Patients reported numerous benefits with having a pharmacist delivering services within ACCHSs. They appreciated their medications being assessed and receiving alternative or different combinations of medications or treatment regimes, and these services resulted in them *'feeling better'*. Integrated pharmacists took a holistic approach to patient care, listened to patients and better understood the social context of their lives. Some patients reported being more involved in decisions about their care as a result of support from pharmacists who sometimes sat in on consultations with them and their GP. With education received from the pharmacists, patients felt empowered to better manage their health, better understood their conditions and why they needed to take their medications and how they worked. Many patients indicated they were more adherent to their medications. 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 for patients with diabetes. These qualitative reports were substantiated in the quantitative analysis for medication adherence and for biomedical outcome measures (Appendices 9, 13 and 14).

For health services staff, the main benefit with having a pharmacist integrated in their team was 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 medication management reviews. Integrated pharmacists and GPs reported that recommendations were commonly made by the integrated pharmacists following medication reviews. Recommendations were perceived to be of high quality and prescriber

up-take of the recommendations was reported to be high. Provision of education sessions for health services staff, including GPs, nurses and AHW/Ps) were perceived as valuable. Health services staff also benefited from the pharmacists having input into their clinical team meetings and case conferences. The pharmacists contributed to medicines safety and quality assurance activities by conducting drug utilisation reviews and assisting in reviewing ACCHS medication-related policies.

GPs reported that 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. The pharmacists could also better explain to the patient how their medications worked. Time was also saved for some GPs as they could make referrals for medication management reviews directly to the integrated pharmacist who could then facilitate transfer of the patient referrals to an accredited external community pharmacist or conduct the reviews themselves if accredited.

The majority of integrated pharmacists were able to develop meaningful relationships with patients and empower them by developing their health literacy and knowledge about their medicines. A benefit from the pharmacists' perspective was "*to sit down with the patient"* and *"spend a bit more time with patients".* The pharmacists' roles were designed to be predominantly patient-centred and the majority of pharmacists enjoyed this aspect of the role. When asked, all of the pharmacists indicated they would continue their employment if their role was continued. The integrated pharmacists enjoyed their role and experienced personal and professional satisfaction in the services they were providing.

Patients reported telling family and friends about their positive interactions and encouraged them to also see the pharmacist. This suggests that the pharmacists were accepted, practised in a way that was culturally safe and were valued by their patients. During the site visits, the majority of health services staff indicated they wanted the role to continue but that sourcing ongoing funding for this position was a barrier.

The PSA project coordinators received a number of testimonials and positive feedback submitted by various stakeholders throughout the project which supported the findings in the qualitative evaluation (Appendix 18).

INTERACTIONS WITH COMMUNITY PHARMACY

At the commencement of the project, many ACCHSs already had strong relationships with their local community pharmacy, particularly through the Section 100 arrangements for

remote area Aboriginal Health Services and Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) program. Relationships between ACCHSs and community pharmacy was further strengthened as a result of the IPAC trial.

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 facilitated provision of dose administration aids (DAAs) 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.

Community pharmacists reported benefits from the IPAC trial that included increased referrals for them to undertake HMRs and improved their participation in HMRs. They also felt that patients were more interested in their medicines. Community pharmacists also perceived that patient knowledge of their medicines and adherence to medicines had improved since the integrated pharmacists had commenced in the ACCHSs. Participating community pharmacists believed there was a role for an IPAC-type (non-dispensing) pharmacists within ACCHSs.

F.2 SUPPORTS TO BE CONSIDERED FOR BROADER PROGRAM ROLL-OUT

Specific issues were identified in the project that require MSAC's consideration in relation to continuation, or expansion of the proposed service. For the service to be delivered within ACCHSs, additional resource commitments will be necessary to train and support pharmacists, such as through the PSA, as well as supports to ACCHSs to deliver the integrated model of care (see **Sections C and E**). The qualitative evaluation of the IPAC trial (Appendix 14) also outlined some challenges that warrant consideration in the planning and support of program expansion that are summarised here.

SUPPORT FOR PHARMACIST RECRUITMENT AND TRAINING

Pharmacist recruitment to integrated non-dispensing roles within ACCHSs will be influenced by the financing models for broader program roll-out. The selection criteria and processes undertaken throughout the IPAC trial can inform future models of recruitment (Appendix 19). Pharmacists would not need to be employed by the PSA. Principles to be considered are:

- Respecting the principles of self-determination, ACCHSs have a role in pharmacist recruitment to ensure their 'fitness for the service' with respect to suitable skills and cultural safety.
- Pharmacists are selected with skills aligned to the expected scope of practice and core roles;
- Placements within ACCHS will be influenced by the needs, capacity, and preparedness of ACCHSs;
- Community pharmacies who have well developed and respectful relationships with ACCHSs are well placed to identify pharmacists to perform integrated roles

A key outcome of the qualitative evaluation relevant to pharmacist recruitment was ensuring the pharmacist had the right *'organizational fit'* and personality to suit the ACCHS, which was just as important as their skills and experience. As well as possessing relevant clinical skills, pharmacists needed to be culturally responsive, the ability to communicate, build rapport, develop relationships and collaborate with internal and external stakeholders, be flexible, non-judgmental, and resilient. Pharmacists needed to be confident and understand the need to be proactive and engage with people to make the role more effective.

Induction to the integrated pharmacist role (provided in the project by the PSA) was important and prepared the pharmacists well (Appendix 20). Pharmacists were also provided with valuable support throughout the trial by the PSA Project Coordinators who responded to queries in a timely manner and facilitated pharmacists' participation in a peer support network using technology (Appendix 21). This enabled them to develop supportive relationships with other integrated pharmacists in the same role. Indeed, pharmacists providing an integrated service within ACCHSs would benefit from a coordinated induction to the role and ongoing support to enable them to work effectively within their respective health services.

SUPPORT FOR ACCHSS

For some ACCHSs, readiness for the project was a challenge (Appendix 14). Prior to the IPAC Trial there were few pharmacists working in general practices or ACCHSs nationally, with consequently very little understanding of the role of a clinical pharmacist in the primary care setting. A few ACCHSs in the project had worked with pharmacists providing HMRs for patients of their service, and staff in these services had a slightly better understanding of the services a pharmacist could deliver within a primary care service.

Support for ACCHSs in a broader roll-out of this program should be based on the six support activities provided throughout the IPAC trial (Appendix 22). This involved support from NACCHO and its Affiliates with some collaboration and technical and pharmacy-related involvement from PSA. Affiliates of NACCHO can leverage from their public health and clinical expertise and local knowledge based on their proximity and regular involvement in daily ACCHS activity to ensure local needs are optimally met. ACCHSs received support through a site visit from a NACCHO project coordinator as part of the service induction process. Some services were well-prepared for the pharmacist and understood the value of the role, however, staff in other services needed time to further understand the role and learn how to best utilise the pharmacists' expertise.

At the time of their interview for the qualitative evaluation of the IPAC Trial (after approximately six months of practice in their service), the majority of the integrated pharmacists felt accepted and well-integrated within the PHC team. Integrated pharmacists helped ACCHS staff to understand the pharmacist role by explaining how they could contribute to the PHC team and improve health outcomes for patients. This enhanced staff understanding of their role, helped with relationship building, and assisted the pharmacist to integrate into the team. Over time, these factors contributed to increased numbers of patients referred to the pharmacist. Most pharmacists had a project 'go to' person or 'champion' who assisted with their integration.

Addressing this issue for a broader roll-out of this program, will require support to be provided to clinic managers (for flow-on to other healthcare staff) to ensure they are ready for the integrated pharmacist role. In the IPAC Trial, earlier discussion with ACCHS staff about the pharmacists' role may have assisted services to better prepare before the pharmacist commenced. In a future roll-out of the proposed program, service induction strategies such as the development of ACCHS policies and procedures to prepare and inform services of the role of the integrated pharmacist, will be valuable. For example, ACCHSs must ensure they have the physical space to support clinical consultations between the patient and pharmacist and have a GP prescriber employed within the service. Programs should ideally allow a lead-in time to enable integrated pharmacists to develop relationships with staff and patients and develop a deeper understanding of the local community and health service culture prior to requiring any outcome data related to program deliverables.

Other supports that could facilitate the integration of the pharmacist role within ACCHSs included promotional resources and encouragement with integration such as pharmacists being given the same uniform as other health staff. Promotional resources should be

developed in local languages and cater to all levels of health literacy in communities where the role is situated.

Support for ACCHSs could be provided through the Affiliates of NACCHO because of their proximity and regular involvement in ACCHS activity. Affiliate staff could take a lead role and champion the expansion of the integrated pharmacist role in services. The support they could provide includes staff education about the integrated pharmacist role, assistance developing local referral processes and assessment of resources (eg. physical space and availability of uniforms) to ensure ACCHSs are adequately prepared. Affiliates could also support ACCHSs to provide pharmacist induction into the service and the local community.

The qualitative evaluation found that support from GPs and AHW/Ps were enablers to the integration of pharmacist's into the PHC team and improved patient referral processes. AHW/Ps also played a vital role assisting with patient follow-up. Clinical algorithms to support patient referral to the pharmacists within the ACCHS model of care will be valuable. Coordinating referral processes is complicated as the target population is burdened by many chronic diseases and often patients are overwhelmed with medication appointments. This means opportunistic assessments are particularly important to close the gap in access to medication-related services. NACCHO and/or Affiliates are well placed to develop generic clinical algorithms and referral resources if there a broader roll-out of the integrated pharmacist model of care within ACCHSs. These issues have also been summarised in Section C Translation (Table 19) of this submission**.**

F.3 SUMMARY OF QUALITATIVE EVALUATION

The qualitative evaluation of the IPAC study identified many benefits from the project and demonstrated an overwhelming support for non-dispensing pharmacist services integrated within the PHC team of participating IPAC sites and in ACCHSs more broadly. Health service staff, the integrated pharmacists and patients benefited from the initiative. Relationships between ACCHSs and community pharmacy were further strengthened by the pharmacists integrated within ACCHSs. Community pharmacists also benefited from increased referrals for, and improved participation in HMRs from ACCHSs as a result of the integrated pharmacist role.

In a future roll-out of the proposed program, service induction strategies such as the development of ACCHS policies and procedures to prepare and inform services of the role of the integrated pharmacist, will be valuable. To inform future policy and implementation of integrated pharmacists within ACCHSs, the qualitative evaluation recommended:

1) Supportive policy to integrate the role of a non-dispensing pharmacist within ACCHSs;
2) Advocacy and support to ACCHSs to facilitate processes for integrating these pharmacists within their services;
3) Co-design of the pharmacist role with the ACCHS to ensure it meets their needs;
4) Training and support to prepare pharmacists for non-dispensing integrated roles within ACCHSs;
5) Continuing quality improvement through further research and evaluation.

It is recommended that MSAC consider these suggestions in the future design of the proposed program to support an integrated pharmacist within ACCHSs. Strategies to implement these suggestions were suggested by participants. Further details are documented in the qualitative evaluation report in Appendix 14.

APPENDICES