Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1678 – Integrating Pharmacists within Aboriginal Community Controlled Health Services to Improve Chronic Disease Management (IPAC Project)

Applicants: **Pharmaceutical Society of Australia in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University**

Date of MSAC Consideration: **31 March – 1 April 2022**

1. Purpose of application

An application requesting public funding of Integrating Pharmacists within Aboriginal Community Controlled Health Services (IPAC) for chronic disease management was received from the Pharmaceutical Society of Australia (PSA) in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC deferred providing its advice on the IPAC Project. MSAC considered the model of care examined in the IPAC Project was an excellent example of an integrated, collaborative, patient-centred approach to primary care and has the potential to have a meaningful societal impact by improving equity of health outcomes for Aboriginal and Torres Strait Islander peoples. However, MSAC considered additional information is required to interpret the clinical significance of the biomedical outcomes, assessment of the qualitative feedback, revised economic analysis and presentation of the financial implications in the context of other relevant funding programs. MSAC considered a stakeholder meeting would be informative ahead of its further consideration.

Consumer summary
This is an application from the Pharmaceutical Society of Australia in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University requesting funding of Integrating Pharmacists within Aboriginal Community Controlled Health Services for chronic disease management. This application was seeking funding for Aboriginal Community Controlled Health Services to employ non-dispensing pharmacists. In this proposal, the pharmacist would be part of the healthcare team of an Aboriginal Community Controlled Health Service to help look after Aboriginal and Torres Strait Islander

Consumer summary

peoples who have a chronic health condition(s), such as diabetes, and who are regular patients. The pharmacist would be a non-dispensing pharmacist, which means they would not dispense medicines. The pharmacist will help patients and the health service improve medicine use.

MSAC recognised the potential value of this program, and that it has the potential to improve health outcomes for Aboriginal and Torres Strait Islander peoples.

MSAC noted that there were qualitative improvements for some patients in the program (e.g. they reported they felt better and were better at sticking to their medication schedule). There were also some improvements in health markers (such as diabetes control and cholesterol levels). However, it was not clear whether those changes were large enough to improve people's health.

MSAC's advice to the Commonwealth Minister for Health

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC deferred its decision on the funding of Integrating Pharmacists within Aboriginal Community Controlled Health Services for chronic disease management.

MSAC considered that more information was needed to decide whether the program improved clinical outcomes for patients.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this is an application from the PSA in partnership with NACCHO and James Cook University requesting public funding of IPAC for chronic disease management. MSAC noted that the proposed service is the addition of an integrated non-dispensing pharmacist as part of the primary healthcare team at Aboriginal Community Controlled Health Services (ACCHSs) to provide care to Aboriginal and/or Torres Strait Islander peoples, considered "regular clients", with chronic disease(s) to improve quality prescribing and biomedical outcomes compared to usual care. The services to be delivered by the integrated pharmacist include both patient- and practice-related activities.

MSAC recognised that there is a high unmet need for this program, and that it has the potential to have an important societal impact in a population who have poor health outcomes. MSAC commended the study for using a community-based participatory approach to tackle a complex healthcare intervention in a real-world setting.

The proposed population was Aboriginal and/or Torres Strait Islander peoples (considered 'regular' clients) with chronic disease, irrespective of age. MSAC considered that it was reasonable to extend the service to children as some children will have chronic medical conditions that are managed using medication. MSAC considered that ACCHSs are not homogenous and provide different healthcare services tailored to the needs of the people who attend the ACCHSs.

MSAC noted that over half of Aboriginal and Torres Strait Islander peoples used mainstream primary health services, therefore, the potential impact of the service would be limited to people who attend ACCHSs. MSAC queried whether the results were generalisable to primary care settings other than ACCHSs but concluded that the IPAC trial could not address this. MSAC noted

the ACCHSs also have a small proportion of clients who do not identify as Aboriginal or Torres Strait Islander.

MSAC also noted that there are now programs in place that overlap the services proposed by this application, such as the Workforce Incentive Program (WIP), the Indigenous Health Services Pharmacy Support (IHSPS) and the Home Medicines Review (HMR) Program. MSAC noted the applicant considered that the quantum of funds allocated by the IHSPS program would need to increase significantly in order to replicate the impact observed throughout the IPAC study. MSAC noted that the applicant considered that the requirement for HMRs to be performed at the patient's home is a barrier to uptake by Aboriginal and Torres Strait Islander peoples.

MSAC noted that this model of integrative care is strongly supported by the consultation feedback. This included the Royal Australian College of General Practitioners (RACGP), National Association of Aboriginal and Torres Strait Islander Health Workers and Practitioners (NAATSIHWP), and Australian Indigenous Doctors' Association (AIDA).

The IPAC study did not report any safety outcomes. MSAC considered it likely that the intervention will be at least non-inferior to usual care. MSAC considered that the intervention had the potential to improve safe use of medicines.

MSAC noted that a number of medication outcomes were statistically significantly different from baseline at study end, favouring the intervention; notably there was an increase in the number of participants with "very good to excellent" self-assessed health status.

MSAC noted that statistically significant differences were observed in glycated haemoglobin (HbA1c), diastolic blood pressure, total cholesterol, low density lipoprotein cholesterol (LDL-C), triglycerides, 5-year risk of cardiovascular disease (CVD), all favouring the intervention. However, although statistically significant, the applicant-developed assessment report (ADAR) did not address the clinical significance of these changes. MSAC considered the small incremental benefits in biomedical markers could have a cumulative effect of helping patients feel empowered and motivated to manage chronic conditions and make lifestyle modifications.

MSAC noted the positive qualitative assessments by participants, general practitioners (GP), IPAC pharmacists, health service staff and managers and community pharmacists. MSAC noted the qualitative outcomes were positive. In particular, MSAC noted that nearly all the GPs provided positive feedback. MSAC considered that a formal assessment of the qualitative data would be informative.

MSAC agreed with ESC's comments that a cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) were not appropriate approaches to the economic evaluation. MSAC considered the economic analysis could be refined to focus on clinically relevant differences in outcomes. MSAC noted the potential efficiency gains of having a dedicated pharmacist on site, as this would allow other team members to focus on their area of relative expertise and allow them to see more patients.

MSAC noted the financial implications presented in the ADAR. The cost of the program was estimated using full-time equivalent (FTE) salary costs. MSAC noted that while the salary appeared high, it reflected all employment costs such as workers' compensation insurance, superannuation and other (remote) allowances. MSAC noted the pharmacist salary costs accounted for the majority of the financial cost of the program. MSAC noted financial implications included the potential for "double dipping" where services (such as medication reviews) provided by integrated pharmacists were also being reimbursed through the HMR Program. MSAC considered that funding for services provided by non-dispensing pharmacists funded through the proposed program should not be reimbursed through other programs. MSAC considered revised financial implications were needed that reflected this. MSAC considered that it would be

reasonable to have two models of pharmacist support for ACCHSs, where ACCHSs may choose an integrated pharmacist model or support under existing programs (IHSPS, WIP and HMR).

MSAC deferred its decision because of the residual uncertainty related to the clinical outcomes, the implications of this on the economic evaluation, and the need for revised financial implications. MSAC considered further information was needed to assess the clinical significance of the magnitude of change in biomedical markers. MSAC noted that the magnitude of change in HbA1c in the IPAC study was similar to that of another pharmacist intervention in an Australian primary health setting [1]. MSAC considered a comparison of biomedical outcomes that MSAC and the Pharmaceutical Benefits Advisory Committee (PBAC) have previously considered clinically meaningful could inform this assessment. MSAC considered that changes not considered clinically significant in other contexts (such as rigorously controlled pharmaceutical trials) may be significant in this context. MSAC considered changes in HbA1c also need to be considered in the context of baseline levels in IPAC participants. MSAC considered this could be reviewed by the MSAC Executive before consideration by MSAC. MSAC noted the positive narrative assessments and considered a formal appraisal and synthesis of the of the qualitative assessments should be performed. MSAC advised that the economic evaluation needed to be revised to reflect clinically meaningful outcomes. MSAC requested updated financial implications considering programmatic funding including consideration of fixed and variable costs of the program, potential economies of scale, and needs of different geographic locations. MSAC considered the revised financial implications should present the full context of similar services, include an analysis of the extent to which the IPAC model is expected to replace services provided by other programs (such as HMRs, IHSPS, WIP) and where IPAC would provide a service to people not accessing existing programs.

MSAC requested further advice on current funding arrangements for ACCHSs and how the proposed program would interact with existing initiatives such as the Indigenous Australian Health Programme. MSAC recommended that the Department organise a stakeholder meeting so that ACCHSs could provide input, which could help inform MSAC and provide some necessary context for decision-making. MSAC considered that it was important to better understand the diversity of ACCHSs.

MSAC noted that the applicant raised concerns that MSAC and the health technology assessment (HTA) process is unresponsive to the needs and perspectives of ACCHSs and Aboriginal and Torres Strait Islander peoples. MSAC agreed that there are opportunities to enhance MSAC processes to better meet the needs of Aboriginal and Torres Strait Islander peoples.

MSAC acknowledged the importance of the pharmacist being an appropriate cultural fit for the ACCHS. MSAC noted that implementation of the proposed program would be affected by workforce distribution issues and that ACCHSs outside major cities may face difficulties recruiting pharmacists. MSAC noted that the proposed intervention could increase demand for pharmacists in rural and remote areas where there are existing skills shortages. However, MSAC also considered that the proposed intervention could provide increased opportunities for pharmacists. MSAC acknowledged the information provided that pharmacists who had left practice reported that they were motivated to take up these roles if the IPAC model was in place.

MSAC advised that the program, if implemented, should include further evidence collection and evaluation.

[1] Clifford *et al*. "Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: the Fremantle Diabetes Study." *Diabetes care* vol. 28,4 (2005): 771-6.

4. Background

The IPAC Project was funded under the Department of Health, Pharmacy Trials Program (PTP, Tranche 2) as part of the Sixth Community Pharmacy Agreement (6CPA) that sought to improve clinical outcomes for patients by utilising the full scope of pharmacist's role in delivering primary health care services. The IPAC Project was a project to investigate the potential gains in health outcomes arising from integrated models of care within Aboriginal health settings. 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 care received by Aboriginal and Torres Strait Islander peoples with chronic diseases when compared with prior (usual) care. It was anticipated that pharmacists integrated within these settings would facilitate increased access to medication-related expertise and assessments, which when coupled with increased engagements with participants, staff, and other stakeholders, would result in improved services and quality use of medicine [IPAC Project Part A, 2020[2]]. The study is hereafter referred to as the IPAC study.

$50 million was provided over the Term of the 6CPA to fund the PTP as a whole. Once finalised, consistent with the 6CPA, the outcomes of each PTP trial were to be evaluated by an independent health technology assessment body to determine the effectiveness and cost-effectiveness of the trial intervention and inform decisions about any broader rollout. A decision to fund any future programs would be a matter for Government.

MSAC review of 6CPA Medication Management Review (MMR) Programs

In 2017, MSAC appraised the evidence for Medication Management Review Programs: Home Medicines Reviews (HMRs), Residential Medication Management Review, MedsCheck and Diabetes MedsCheck programs.

MSAC advised that there was insufficient evidence to determine the clinical and cost-effectiveness of the continuing 6CPA MMR programs, and thus a weak basis upon which to recommend that funding should be supported or ceased. MSAC advised that further research would be required to make a more robust assessment of the comparative clinical and cost-effectiveness of the MMR programs.

With respect to the HMRs, MSAC advised that there is no clear evidence that HMR reduces hospitalisations and mortality or improves quality of life. MSAC also advised that there is low level of evidence to suggest that HMR increased time to next hospitalisation, although the evidence on the effect of HMR on reduction in health care resource use is conflicting. There is also insufficient evidence to assess patient satisfaction with pharmacist-led HMRs.

MSAC considered that the design and value of these pharmacy service programs could be improved by including formal collaboration with GPs and other healthcare networks, by being targeted to more appropriate patient populations, and by a reduction in the unit cost of providing each type of pharmacy service coupled with an incentive to increase this unit cost if adequate new evidence can be furnished to justify an increase. Further enhancement of these programs might better justify the provision of continued funding of these services.

[2] Integrating Pharmacists within Aboriginal Community Controlled Health Services to improve Chronic Disease Management: Executive Summary Final Report – Part A. June 2020

Current Funding Arrangements

When the IPAC study commenced, funding for integrated non-dispensing pharmacists in GP clinics, Aboriginal Health Services (AHS) and ACCHS did not exist as part of any Commonwealth Program. This has changed since February 2020, when integrated non-dispensing pharmacists were designated as eligible allied health practitioners for the purposes of the Workforce Incentive Program (WIP) – Practice Stream. Their employment is now eligible for incentive payments under the WIP, which provides a maximum incentive of $125,000. The ADAR stated that ACCHSs access this program to fund Aboriginal Health Workers and Health Practitioners.

Since 1 July 2021, the IHSPS Program is funded under the Seventh Community Pharmacy Agreement (7CPA) to support quality use of medicines (QUM) services and aims to reduce adverse events and associated hospital admissions or medical presentations. The IHSPS Program aims to improve QUM and health outcomes for Aboriginal and Torres Strait Islander peoples by providing funding for the purchase of a range of QUM Support activities. Funding is allocated amongst participating Indigenous health services on an annual basis. The QUM support activity category QUM Pharmacist support aims to facilitate pharmacist support to health service staff and clients in relation to QUM, including:

- education for staff and patients on QUM and the appropriate use of specific medicines
- medicine quality assurance, e.g., policies on the storage and supply of medicines
- continuous improvement and compliance with relevant legislative requirements
- medication management support activities where not funded through other programs.

An Indigenous Health Service is able to engage any registered pharmacist or approved pharmacy to provide this support. The range of services to be provided is by agreement with the relevant IHS. The pharmacist or pharmacy must ensure they have an understanding of the cultural needs of the community or communities they support.

5. Prerequisites to implementation of any funding advice

Pharmacists participating in the IPAC project were required to have at least 2 years post-registration experience along with a post-graduate clinical qualification or demonstration of clinical experience (e.g. hospital or Home Medicines Reviews (HMRs)).

The requirement for the integrated non-dispensing pharmacists does not mandate the pharmacist be accredited for Domiciliary Medication Management Review (DMMR, also known as HMRs) but it is desirable. Although not specifically mandated by the ADAR, pharmacists wishing to work in a general practice, AHS, or ACCHS need to undertake a training program such as that provided by the PSA, General Practice Pharmacist Foundation Training course (see General Practice Pharmacist Training). At the same time or separately a module that is tailored to working for ACCHSs needs to be provided. The pre-ESC response noted the PSA had received funding under the Indigenous Australians' Health Programme Emerging Priorities Program (IAHP to co-design with NACCHO an Aboriginal Health Service Pharmacist Foundation Training course titled "Deadly Phamacists".

Pharmacists that are employed within a ACCHSs will require experience and training. The requested requirements are consistent with those required to be a general practice pharmacist. The ADAR does not require that pharmacists have cultural awareness training to be eligible.

6. Proposal for public funding

The proposed service is the addition of an integrated non-dispensing pharmacist as part of the primary health care team of Aboriginal Community Controlled Health Services (ACCHSs) to provide care to Aboriginal and/or Torres Strait Islander patients, considered 'regular clients', with chronic disease to enhance quality prescribing and biomedical outcomes compared to usual care.

The services to be delivered by the integrated pharmacist include both patient-related and practice-related activities:

- providing medication management reviews, assessing and supporting medication adherence
- providing medicines information and education and training
- collaborating with healthcare teams
- providing medicines information and education and training
- collaborating with healthcare teams
- delivering preventive care
- liaising with stakeholders such as community pharmacy
- providing transitional care
- undertaking quality improving activity such as a drug utilisation review.

The ADAR proposes baseline plus pro-rata public funding (depending on the health service client load and episodes of care) of non-dispensing pharmacist within ACCHs to provide the services within an integrated model of care. The total funding requested is $13,316,142 in in Year 1, decreasing to 12,851,292 in Year 5.

The proposal is for the broader rollout of the IPAC clinical study program to all ACCHSs in Australia. The ADAR proposed that a new program funded by the Commonwealth be established and requested five-year block funding. The pre-ESC response requested that in the spirit of self-determination funding should be under an Indigenous health service program rather than the Community Pharmacy Agreement. The Department may explore alternative avenues of funding should a Government decision be made to fund the IPAC service. The ADAR states that block funding is in line with other Commonwealth funding approaches for ACCHSs (such as the Indigenous Australians' Health Programme). This proposed program (referred to as the IPAC Program) is requested to cover the following:

- Funding for the salary of a non-dispensing integrated pharmacist. A salary loading such as that based on the WIP-Practice Stream rural loading would also apply.
- Costs of program support for ACCHS which includes salary oncosts, plus IT, management fee, travel (project officers + meeting travel), plus annual meeting expenses.
- Training and support costs for integrated pharmacists, facilitation of mentor, clinical and other support to pharmacists working (or intending to work) in the ACCHS, creation and maintenance of a community of practice for integrated practice pharmacists in the ACCHS sector and ongoing support for the PSA/NACCHO Pharmacists Leadership Group.
- Program monitoring and evaluation costs.

In estimating the total national cost of the IPAC program, the ADAR makes the following assumptions.

- All ACCHSs would wish to participate in the IPAC program and can access a suitable pharmacist/s.

- A baseline 0.2 full-time equivalent (FTE) for all ACCHS, regardless of their size, before allowing for the estimated population.
- The proportional pharmacist FTE was based on 1 FTE pharmacist per 8,295 client population as per IPAC methodology. This is irrespective of age or chronic disease of ACCHS clients.
- Rural loading per that applied in the WIP— Practice Stream have been applied in the calculations.

The ADAR does not provide much detail on how the program will be implemented. The following table is provided estimating the number of FTE pharmacists required to undertake the intervention in all ACCHSs. The consultation feedback queried the appropriate FTE for the proposed service to be viable. The pre-MSAC response considered a minimum of 0.2 FTE pharmacist per ACCHS plus FTE proportional to client numbers, with the appropriate remote allowances, would address the majority of the workforce and implementation considerations.

Table 1: Proposed model for pharmacist salary using IPAC methodology and ACCHS remoteness

	Total clients attending Aboriginal Primary Health Services	Regular clients accessing ACCHSs, assuming constant proportion 85%	Total number of Aboriginal Primary Health Services	Approx. number of ACCHSs in each region[1]	Baseline 0.2 FTE per ACCHS	Proportional pharmacist FTE[2]	Baseline FTE plus proportional pharmacist FTE	Proposed % salary loading[3]	Pharmacist Salary[4]
Major cities	97,473	82,657	23	16	3.2	10.0	13.2	0	$1,645,586.26
Inner Regional	95,733	81,182	40	29	5.6	9.8	15.4	0	$1,923,351.18
Outer Regional	117,294	99,465	45	32	6.4	12.0	18.4	20	$2,758,649.40
Remote	82,259	69,756	26	18	3.6	8.4	12.0	30	$1,951,520.82
Very Remote	90,314	76,586	64	45	9.2	9.2	18.4	50	$3,456,154.43
Total	483,073	409,646	198	140	28	49.4	77.4		$11,735,262.09

Source: Table 2, Appendix 17
Abbreviations: ACCHS = Aboriginal Community Controlled Health Services; FTE = full-time equivalent

Based on this table, the ADAR is requesting on average $83,823 per participating ACCHS. This will vary as practice size was a determining factor in pharmacist allocation Pharmacist costs were based on a full-time pharmacist salary of $151,618. The ADAR did not provide the assumed salary costs for the pharmacist or the assumed weekly hours for FTE. The ADAR has costed for full salary for the pharmacist. The commentary considered the requested salary appeared somewhat excessive as the hourly pay rate for an experienced pharmacist is $33.59 which equates to around $66,373 a year for a 38- hour week. The pre-ESC response provided further justification for the higher salary that was accepted by ESC.

The additional funding over salary costs requested is:

- Support for integrated pharmacists $621,000 in year 1 reducing to $488,750 by Year 5.
  - This excludes the cost of an online training course as this had since been developed.
  - Facilitation of mentoring and other support to pharmacists.
  - Creation and maintenance of a community of practice.
  - Ongoing support for the PSA/NACCHO Pharmacist Leadership Group.
- Program Support for ACCHSs of $647,500 in first year reducing to $332,500 by Year 5.

- 2 Program officers FTE salary.
- On costs of 25%, IT, management fee.
- Travel costs.
- Annual meeting expenses (i.e., annual workshop).
- Project Publications & Resources.

The ADAR does not state which organisation will receive this money, but the way it is described it is not for individual ACCHSs.

- Program Monitoring and Evaluation $312,000 in Year 1 and $294,780 in Years 2-5.
  - 1.2 FTE Project Officer/Biostatistician (including on-costs).
  - Overheads (35% of salaries).
  - 1 month (160 hours) logbook adaptation, development, and setup ($110/hour ex GST*160 hours/month).
  - Logbook hosting ($60/month ex GST).
  - 1 day per month (8 hours) logbook ongoing maintenance ($110/hour ex GST*8 hours/month).

The ADAR provides descriptions of the costs additional to the salary in Appendix 17, but it does not provide the methodology underpinning how these resources are counted, how it costed the resources, any assumptions used or the need for these activities with reference to the Clinical Study. An underlying spreadsheet was not provided.

The ADAR did not consider using the existing WIP – Practice Stream scheme for funding the provision of an integrated non-dispensing pharmacists on the following grounds:

- A survey of ACCHSs suggests the majority of ACCHSs already use the maximum funds available for nurses, allied health professionals or Aboriginal Health Workers (AHWs), (a copy of this survey was not provided). Therefore, these ACCHSs cannot access WIP funds for pharmacists without displacing other clinical staff and it is thus not a viable option for funding an integrated pharmacist (Appendix 17). The upper limit of incentive payments for ACCHSs to employ eligible health professionals will be an issue if they are already employing up to their limit prior to employing a pharmacist.
- Non-dispensing pharmacists remain unable to claim MBS item fees for chronic disease management services provided in a primary care setting, and therefore cannot supplement the maximum incentive payment available under the WIP – Practice Stream. Non-dispensing pharmacists or pharmacists in general are not recognised as eligible health professionals for the purpose of MBS services. They are however eligible for reimbursement of services under the 7CPA for Home Medicines Reviews if they are accredited.

The lack of exploring and/or proposing leveraging current funding programs to implement the integration of a non-dispensing pharmacists in ACCHSs seems like a missed opportunity that would warrant further consideration.

7. Population

The intervention has core roles that include patient-related activities and staff and service-level activities. Therefore, the target population has a clinical patient component and a practice-level component.

The proposed clinical population are Aboriginal and Torres Strait Islander peoples with chronic disease who are ‘active’ or ‘regular’ patients receiving services with 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).

The ADAR does not provide any further information about the needs of the proposed clinical population (with the exception of the fourth dot point) in terms of how the proposed service will address their needs. For example, the proposed population would have been better described as:

Regular patients of a ACCHS who are at risk of developing medication-related problems due to:
- a chronic medical condition, or
- a complex medication regimen

who require review and assessment of their medication management and follow-up support.

The population described in the IPAC study is for adults ≥18 years of age who are considered regular clients of an ACCHS. This age limit has been removed in the ADAR. This will enable integrated non-dispensing pharmacist services to be administered to children who meet the nominated population criteria.

The proposed practice-level services will be provided as part of the practice team of an ACCHS. The proposed settings of the IPAC program have been extended to ACCHS broadly and the proposed criteria for an ACCHSs to be eligible to participate in the broader translation of the IPAC program are:

- Be an ACCHS 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

It cannot be assumed that all ACCHSs will be eligible for the proposed IPAC program as a small but significant proportion of ACCHSs (41 or 20.9%) are currently not accredited or registered for accreditation as a general practice against the RACGP Standards (KPMG, 2020).

8. Comparator

The ADAR nominated comparator is usual care. The ADAR defines this as usual primary healthcare service provision to Aboriginal and Torres Strait Islander peoples without the presence of an integrated pharmacist within the health service. Usual care varies across ACCHSs in the provision of medical adherence support via community pharmacy and medication management reviews via community pharmacies or directly from independent accredited pharmacists with delivery and content strictly guided by program rules. Education and training is currently provided to ACCHSs staff (and some patients in the target population) according to the program rules for the S100 Support Allowance, and some arrangement contracted with community pharmacy through the QUMAX Program. As of 1 July the Indigenous Health Services Pharmacy Support (IHSPS) Program commenced and the QUMAX and S100 Support Allowance ceased). The IHSPS Program's QUM Pharmacist support activity category aims to facilitate pharmacist support to health service staff and clients in relation to QUM. The services provided are by agreement with the health service and any registered pharmacist or approved pharmacy can provide this support. There may be some overlap between the IPAC program and services that could be provided through IHSPS. The proposed intervention will be in addition to usual care. The pre-MSAC response highlighted that the Home Medicines Review (HMR) program does not allow for HMRs to be conducted outside of the patient's home, without prior approval, a well-known and documented barrier to uptake of the HMR program for Aboriginal and Torres Strait Islander peoples.

The description of the comparator does not include the provision of an integrated non-dispensing pharmacist under the WIP scheme. The ADAR states that as the majority of ACCHSs already use the maximum funds available for nurses, allied health professionals or AHWs, they cannot access WIP – Practice Stream funds for pharmacists without displacing other clinical staff and thus it is not a viable option.

9. Summary of public consultation input

Consultation feedback was received from 13 organisations and one individual health professional (pharmacist employed by an AHS). Three organisations were Aboriginal and Torres Strait Islander specific primary health care organisations and two organisations that represent Aboriginal and Torres Strait Islander health professionals. The 12 organisations that provided input on the application were:

- Aboriginal Medical Services Alliance of Northern Territory (AMSANT),
- Australian Indigenous Doctors' Association (AIDA),
- Australian Pharmacy Council,
- Australian Pain Society,
- Katherine West Health Board (KWHB), an IPAC participant,
- Galambila Aboriginal Health Service (GABH) which funds an integrated pharmacist,
- Maari Ma Health,
- National Association of Aboriginal and Torres Strait Islander Health Workers and Practitioners (NAATSIHWP),
- National Rural Health Alliance (NRHA),

- Northern Territory Department of Health (NT Health)
- Pharmacy Guild of Australia,
- Royal Australian College of General Practitioners (RACGP),
- Rural Doctors Association of Australia (RDAA)

Consultation feedback from all eight organisations and the individual pharmacist were supportive of the proposed service: integrating practice pharmacists into Aboriginal Community Controlled Health Services. Respondents supported the clinical need for the service.

Model of care

The consultation feedback was generally supportive of the proposed model of care. The benefits included:

- Aboriginal and Torres Strait Islander leadership and self-determination. AIDA highlighted the importance of empowering Aboriginal and Torres Strait Islander workers and patients to make decisions in self-determination facilitates culturally safe, patient-centred health care.
- The ability of ACCHS to recruit a suitability qualified pharmacist who would be a good cultural fit for the ACCHS and the community they service was highlighted by many respondents.
- The proposal is for co-ordinated care leading to less fragmented delivery. Several respondents highlighted the benefits of close working relationships with GPs, AHWs and Aboriginal Health Practitioners (AHPs). This included pharmacists being able to access clinical records and AHWs and AHPs being able to provide pharmacists important cultural context. GABH considered integration into the clinical team critical to success of the role.
- Several respondents considered integrated pharmacists could provide more client-centred care such as advising on "client-friendly" prescribing practices such as prescribing of combination tablets, alternative to tablets which may be unsuitable for packaging within DAAs or alternatives to multiple daily dosing options.
- The benefits of a pharmacist to deliver opportunistic client care were highlighted by several organisations. Providing several services on a single day was considered important for clients who travel long distances and was more convenient for clients generally.
- The potential benefit of pharmacist involvement in post-discharge review, coordinated care with speciality services (renal dialysis or transplant medication needs) and neighbouring health organisations was highlighted by organisations. The GABH has a non-dispensing pharmacist who is considered an accessible contact for hospital and community pharmacists and this aided the coordination of these transfers and this helps to avoid medication errors. The GABH considered the continuity of medication management occurring post hospital discharge is often complicated and that Aboriginal and Torres Strait Islander peoples were 6.1 times more likely to discharge from hospital against medical advice. KWHB considered having an integrated pharmacist helped to bridge the gap in transitional care following discharge from an urban hospital, coordinated care with speciality services (e.g. renal services for dialysis or transplant medication needs), or transition over from a neighbouring health centre.

- Some organisations (Maari Ma and GABH) highlighted that pharmacists could perform point-of-care testing including and monitoring International Normalised Ratio (INR) for people using warfarin.
- NT Health provided a copy of its IMPACT Framework - A Framework to Guide the Integration of Pharmacists into Primary Health Care Teams. NT considered this could guide and accelerate AHSs in their integration of pharmacists into their service
- NT Health considered the integrated pharmacist service should be available to all AHSs as not to disadvantage communities which health services are delivered by the Government.

In addition to the roles outlines in the IPAC study, other benefit to ACCHSs was highlighted. This included pharmacists being able to support other health service staff as needed. KWHB considered pharmacists could be utilised throughout the service in a clinical governance context to review/establish medication frameworks, provide quality assurance checks and determine quality use of medicines structures. NRHA also noted the potential to enable quality improvement activities and support other primary care team members with medication related matters.

Potential challenges were highlighted by some organisations. RACGP and the Australian Pain Society noted the existing workload and workforce pressures may impact service delivery, especially if there are existing staff shortages. The RACGP suggested additional funding to ensure that the prescribing GP and other staff at the ACCHS are supported to provide high quality health care. Maari Ma Health considered added cost, needing to explain the pharmacist's role and potential for short-term funding as potential disadvantages. AMSANT considered the service could theoretically limit individual choice, but there are many barriers to accessing pharmacists.

Cultural appropriateness of the proposed model

- Several respondents emphasised the importance of pharmacists engaging effectively with clients and the community. Respondents highlighted the importance of building trust and rapport with clients and the community. Respondents highlighted the importance of client-centred approaches that address their health care needs.
- Several organisations emphasised the importance of having a long-term therapeutic relationship with clients and communities. KWHB considered that high turnover could create challenges in terms of trust by the client and family and trust by the other clinical staff.
- Respondents generally supported cultural awareness and cultural safety training for integrated pharmacists. However, several organisations highlighted the need for cultural competency beyond general training. GABH emphasised the importance of understanding the local community and considered immersion and learning from others a preferred approach. Maari Ma and NAATSIWP considered pharmacists working with AHPs and Indigenous managers would assist two way learning and cultural safety. AIDA considered programs that strengthen the relationships between Aboriginal and Torres Strait Islander patients and their Aboriginal Health Services and Workers are highly desirable. KWHB considered it was important that staff were knowledgeable of intricacies of remote Aboriginal healthcare such as differences in mannerisms, presentation and language used is of great benefit to the organisation and provide clients with a relaxed, relatable atmosphere in which to engage. KWHB considered local employees often had relevant background cultural understanding.

- Several organisations emphasised the importance of pharmacists understanding a holistic view of health. GABH considered time must be taken to navigate a client's view of medication taking and Western-style health care in an effort to promote adherence to a medication regimen. The Australian Pain Society considered clients' views of illness, pain, and the role of medications was important in providing a culturally appropriate service.

Existing services

- Respondents generally agreed that existing services do not meet the needs of Aboriginal and Torres Strait Islander peoples. Maari Ma and KWHB noted Indigenous Health Services Pharmacy Support (IHSPS) Program funding was limited and insufficient. KWHB and AMSANT highlighted the funding provided through the IHSPS (and the superseded Section 100 Program) does not provide sufficient funding to cover the cost of pharmacist visiting the health service. KWHB considered the IHSPS program lacks the client health literacy and medicine education aspect for which the IPAC program allowed. AMSANT considered the external pharmacy support model increases the difficulty of effectively integrating pharmacy expertise.

- KWHB and AMSANT considered the current services such as HMRs, MedsChecks and Diabetes MedsChecks were not accessible in remote areas as it is not cost effective for pharmacist to travel to remote areas despite high unmet clinical need. KWHB considered that one-off services such as HMRs lack dedicated follow up and continuation of support for client self-determination is where intervention will occur. GABH considered Aboriginal and Torres Strait Islander peoples want medication review services to be delivered by a pharmacist they trust and understands their community.

- The Pharmacy Guild considered existing services were not well utilised due to barriers such as cultural and linguistic challenges, geographical isolation, inflexible funding rules, and lack of trust in non-Indigenous health service provision.

Workforce and implementation considerations

- A number of respondents noted pharmacy workforce shortages in rural and remote areas. KWHB highlighted potential difficulties in recruiting an appropriately skilled pharmacist in a remote area and considered support from external organisations such as the NACCHO to aid in both recruitment and retention of staff.

- RDAA considered the real costs of recruiting and training pharmacists for non-dispensing roles within ACCHSs need to be considered. KWHB and AMSANT suggested a remote allowance. KWHB considered sufficient funding should be available to attract suitably qualified staff to remote areas. AMSANT noted that housing is often needed in remote areas. KWHB considered travel time for across ACCHS sites should be considered in the cost of funding.

- NT Health considered that the following factors need to be subsidised (in addition to remote loading) to support pharmacists in remote locations: infrastructure (including accommodation), peer support (to prevent isolation), lifelong learning, travel allowances and leave subsidies. RDAA considered the allocation and structure of funding including rural loadings and incentives may be needed and could impact on the success of the initiative into the longer term. NRHA considered stable employment models with flexible community driven team-based roles are likely to reap benefits in terms of a sustainable workforce.

- KWHB considered employing a pharmacist on less than 0.8 full-time equivalent (FTE) hours is unreasonable given the logistics of travel, geographical location of employment, and expectations of the services to be provided. NT Health considered 0.2 FTE did not seem viable.
- GABH funds 1 full-time full pharmacist for 3,000 annual clients and has a full workload. It had previously funded 0.6 FTE but there was more demand for the service. NAATSIHWP considered the FTE should be based on the level of chronic conditions in clients of an ACCHS.
- NT Health considered expressed concern that the size of service can influence funding comparatively to remoteness. This has been evident with the division of funding of the IHSPS program.
- NAATSIHWP considered the model of delivery needs to consider and be guided by the service within the proposed location. NHRA considered the potential for mixed employment across a ACCHS and community pharmacy could increase the attractiveness of practising rurally as a pharmacist.
- Some respondents note the potential to cross subsidise the cost of an integrated pharmacist through reimbursement for HMRs, IHSPS and other sources. AMSANT considered HMR program rules should be reviewed to allow choice of location, flexibility for opportunistic review, additional funding for rural and remote areas, removal of caps for Aboriginal people, funding for AHW/AHP support and funding for interpreters.

The pre-MSAC response considered the consultation feedback consistently reflected that existing services do not meet the needs of Aboriginal and Torres Strait Islander peoples, highlighting that existing systems, their funding and ancillary programs are inadequate to close the gap in quality healthcare outcomes.

10. Characteristics of the evidence base

The ADAR was based on the IPAC study, a non-randomised, prospective, pre and post quasi-experimental community-based, participatory, and pragmatic trial that integrated a registered pharmacist within an ACCHS primary healthcare team for up to a 15-month period.

IPAC pharmacists delivered non-dispensing clinical medication-related services within ACCHSs through a coordinated, collaborative and integrated approach to improve the quality of care of patients (the intervention). The pharmacist had 10 core roles, although each participating ACCHS had the flexibility to utilise the services of the pharmacist according to service and client priorities at the local level. It is not clear whether this reference to flexibility is constrained within the 10 core roles or includes roles beyond these.

The study included 26 integrated pharmacists across 18 ACCHSs and enrolled 1,733 participants. Of 1,733 patients who consented to participate in the study, the IPAC cohort included in the analysis after initial exclusions comprised 1,456 enrolled participants who remained in the study until the end and were followed-up for a median of 285 (IQR: 219-352) days following enrolment. Patients were also only included in the analysis cohort if they had paired outcomes (at baseline and follow-up).

The ADAR did not present a risk of bias assessment for the IPAC study. A risk of bias assessment was conducted during the evaluation using the NIH Quality Assessment Tool for Before-After (Pre-

Post) Studies With No Control Group[3]. The overall risk of bias in the IPAC study was considered to be high on the basis that the study (i) did not have a concurrent control group, (ii) included only those with pre- and post- outcomes in the analysis (attrition bias), (iii) multiple outcomes with some 'outcome cohorts' appearing underpowered, (iv) lack of blinding, and (v) potential selection bias due to the recruitment approach.

11. Comparative safety

The IPAC study did not report any safety outcomes. It is likely that the intervention will be at least non-inferior to usual care.

12. Comparative effectiveness

The results of the primary and secondary outcomes from the IPAC study are presented in Table 2.

Statistically significant differences were observed in a number of clinical endpoints (glycated haemoglobin [HbA1c], diastolic blood pressure, total cholesterol, low density lipoprotein cholesterol, triglycerides, CVD 5-year risk), all favouring the intervention. Although statistically significant, the clinical significance of any of the changes was not addressed by the ADAR.

The reported reduction in HbA1c (-0.3% [95% CI: -4.5 to -1.0) may not be a clinically meaningful difference. Recent submissions to the PBAC have suggested use of a non-inferiority margin of 0.4% (Exenatide PSD, March 2019), and guidelines suggest that a change of ≥0.5% is clinically significant or would warrant a change in treatment (General Practice management of type 2 diabetes 2016-18). In its economic evaluation, the ADAR appropriately estimates a cost per patient who achieves this clinically significant reduction in HbA1c of ≥0.5% (observed in 200 of the 539 considered in the analysis).

The MSAC Executive noted the average HbA1c was 8.3% at baseline. The MSAC Executive considered that this reflected a group of patients with relatively well-controlled Type 2 diabetes mellitus and queried whether this would be reflective of patients with poorly controlled diabetes. Generally, the HbA1c target level for Type 2 diabetes mellitus is 7.0%, however there is recognition that HbA1c targets should be individualised, where in instances of other priorities (e.g. severe comorbidities, established vascular complications) target levels may be less stringent (Management of type 2 diabetes: A handbook for general practice).

The MSAC Executive noted there was little change in blood pressure measurements [133/80 to 132/80]. Blood pressure is considered healthy if lower than about 140/90 mmHg. The commentary noted appropriate blood pressure target for a patient will depend on comorbidities and the potential for adverse events (Heart Foundation 2016)[4].

The commentary noted that the baseline HbA1c and blood pressure measurements suggested the study recruited patients who are already committed to controlling their chronic conditions. ESC did not agree with this interpretation.

[3] *https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools*

[4] National Heart Foundation of Australia. Guidelines for the diagnosis and management of hypertension in adults – 2016. Melbourne: National Health Foundation of Australia, 2016. Available from: https://www.heartfoundation.org.au/getmedia/c83511ab-835a-4fcf-96f5-88d770582ddc/PRO-167_Hypertension-guideline-2016_WEB.pdf

Similarly, a number of medication outcomes were statistically significantly different from baseline at study end, favouring the intervention; notably the increased number of participants with 'very good to excellent' self-assessed health status.

The pre-MSAC response considered the IPAC study findings demonstrated unequivocal clinical improvements in a range of quality-of-care outcome measures for patients with chronic disease (at a population level), and improvements in the utilisation of the healthcare system (as measured, in particular, by a substantial increase in Home Medicines Review uptake). The pre-MSAC response emphasised that this was demonstrated for a population experiencing a much higher predisposition to clinical deterioration, and a lesser utilisation of healthcare services than other Australians. The pre-MSAC response emphasised the importance of equitable outcomes, suggesting that the per capita primary healthcare service expenditure for Aboriginal peoples and Torres Strait Islanders has been substantially less than for other Australians (demonstrated with MBS and PBS utilisation data).

Table 2 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 ^
Biomedical endpoints (Appendix 9), mean (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 (-4.5 to -1.0) [-0.3% (-0.4% to -0.1%]	**0.001**
All participants	SBP, mmHg	1103	266	132.7 (33.2)	132.0 (29.9)	-0.7 (-1.7 to 0.4)	0.16
	DBP, mmHg	1045	268	80.0 (35.6)	79.2 (29.1)	-0.8 (-1.4 to -0.2)	**0.008**
	TC, mmol/L	660	314	4.51 (1.80)	4.35 (2.06)	-0.15 (-0.22 to -0.09)	**<0.001**
	LDL-C, mmol/L	575	295	2.35 (1.20)	2.27 (1.20)	-0.08 (-0.13 to -0.03)	**0.001**
	HDL-C, mmol/L	622	294	1.05 (0.5)	1.06 (0.5)	0.01 (-0.02 to 0.03)	0.32
	TG, mmol/L	730	296	2.39 (2.43)	2.29 (2.21)	-0.11 (-0.20 to -0.01)	**0.006**
	ACR, mg/mmol*	475	301	57.9 (183.1)	61.7 (224.5)	3.8 (-6.32 to 13.83)	0.42
	CVD 5-year risk, % units	38	255	11.9 (7.2)	10.9 (5.4)	-1.0 (-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 (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 (-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	MAI score per participant, mean (SD)	357	329	6.02 (23.6)	3.20 (11.7)	↓46.8%	**0.003**
	MAI score per medication, mean (SD)	357	329	0.76 (8.5)	0.39 (4.4)	↓48.7%	**0.004**
	Number of medications with ≥1 inappropriateness rating, n/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, mean (SD)	357	329	1.8 (5.3)	1.0 (3.6)	↓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							

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 ^
MAI subset of participants	Number of participants with any medications that met ≥1 overuse criterion, n (%)	357	329	132 (37.0)	87/377 (24.4)	-12.6%	**<0.001**
	Number of medications that met ≥1 overuse criterion, n/N (%)	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/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/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 (32.8)	46 (12.9)	-19.9%	**<0.001**
	Endocrine medications [b]	357	329	91 (25.5)	51 (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 PPO, n (%)	353	330	181 (51.3)	76 (21.5)	-29.7%	**<0.001**
	Number PPOs/participant, mean (SD)	353	330	0.73 (1.3)	0.29 (0.9)	↓60.3%	**<0.001**
Home Medicines Reviews by MBS item 900 (Appendix 12), n/100 person years (95%CI)							

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 ≥1 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 (%)							
All participants	Number of participants with HMR (from the logbook), n (%)	1456	285	na	609 (41.8)	↑639 reviews	na
	Number of participants with ≥1 MRP that were identified following a HMR, n/N (%)	1456	285	na	535/609 (87.9)	na	na
	Number of participants with a non-HMR[c], n (%)	1456	285	na	719 (49.4)	↑757 reviews	na
	Number of participants with ≥1 MRP that were identified following a non-HMR, n/N (%)	1456	285	na	503/719 (70.0)	na	na
	Number of assessments that were a follow-up to a HMR or non-HMR[d]	1456	285	na	na	↑1,548 reviews	na
Medication adherence and self-assessed health status (Appendix 13)							
All participants	Number of participants adherent to medications (NMARS), n (%)	1103	294	808 (73.3)	950 (86.1)	12.8%	**<0.001**
	Number of participants adherent to medications (SIQ), n (%)	1103	294	781 (70.8)	895 (81.1)	10.3%	**<0.001**
	Number of participants with 'very good to excellent' self-assessed health status, n/N (%)	975	281	175/975 (18.0)	303/975 (31.1)	23.9%	**<0.001**

Source: Table 17, pp84-87 of the ADAR 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/1.73m2), sourced from the National Guide (3rd Edn). 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).

** 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

Abbreviations: ACR = albumin-creatine ratio; AoU = assessment of underutilisation; BP = blood pressure; CVD = cardiovascular disease; DBP = diastolic blood pressure; eGFR = estimated glomerular filtration rate; HbA1c = glycosylated haemoglobin; HDL-C = high density lipoprotein cholesterol; HMR = Home Medicines Review; IQR = interquartile range; LDL-C = low density lipoprotein cholesterol; MAI = Medication Appropriateness Index; MBS = Medicare Benefits Schedule; MRP = medication related problems; NMARS = NACCHO Medication Adherence Response Scale; PPO = potential prescribing omission; SBP = systolic blood pressure; SD = standard deviation; SIQ = single item question; T2DM = type 2 diabetes mellitus; TC = total cholesterol; TG = triglycerides

Qualitative outcomes

The ADAR included qualitative assessment of the IPAC study. The pre-MSAC response clarified that the research methodology was selected for its appropriateness and acceptability to the Aboriginal and Torres Strait Islander community according to representative peak bodies, and to maximise the generalisability of findings across the broader ACCHS sector. For this reason, the methodology was pragmatic, interventional, community-based, and participatory. The theory of change and logic models of the wider IPAC project were the conceptual frameworks that guided the design, sampling, analysis and reporting of the qualitative evaluation

The qualitative assessment was informed by 104 participants, including 24 IPAC pharmacists, 13 general practitioners, 12 service managers, ten community pharmacists, 17 health service staff, and 17 patients. Data from 24 IPAC pharmacists was collected using multiple methods including semi-structured interviews. ACCHS staff, patients and pharmacists identified many benefits to having a pharmacist integrated within the ACCHS.

Benefits reported by patients included:

- The pharmacist had been able to suggest alternative or a different combination of medications that has resulted in them 'feeling better'.
- Pharmacists took a holistic approach to patient care and listened to patients. This meant they better understood their lives and could adapt medication regimes to suit the patients' lifestyle.
- Biomedical test results confirmed that their management of their health conditions had improved.
- Being able to discuss and negotiate with the clinical staff about what medications to try and the times that suited them to take their medications, meant that they were more likely to be adherent.
- Feeling empowered to better manage their health conditions. They better understood why they needed to take their medication and what it was doing to their bodies.
- Other benefits of changes in their medications such as losing weight, being motivated to exercise more and engaging with other support groups and the community.

Benefits reported by IPAC pharmacists included:

- Developing meaningful relationships with patients and empowering them by developing their health literacy and knowledge about their medicines. Good relationships with the pharmacist and patients resulted in some patients feeling comfortable making appointments to see the pharmacist themselves, and some patients also telephoned the pharmacists with questions.
- Having access to clinical records enabled them to undertake a more informed review of medicines.
- 'Strategic loitering' and 'hanging out' in the waiting room was a strategy that helped some pharmacists to build relationships with patients and staff.

Benefits reported by ACCHS staff included:

- Having access to an in-house medicines expert was very beneficial as it enabled them to seek advice quickly about medication queries through informal conversations and in-depth feedback through formal medication reviews.

- GPs reported that having a pharmacist as part of the health services team saved them time as the pharmacists were able to provide education to patients around their conditions and how their medications worked.
- Medication reviews and 'medication appropriateness' audits were beneficial. The recommendations made by the IPAC pharmacists were perceived to be of high quality and the take-up by prescribers of recommendations was said to be high.

Community pharmacists reported improved processes for medication supply, improved communication with GPs, greater clinical appropriateness of medicines prescribed, increases in dose-administration aids supplied and increases in HMR referrals.

A number of challenges were identified to integrating a pharmacist within the ACCHSs. This was attributed to few pharmacists working in general practices and little understanding of the role of a clinical pharmacist in the primary care setting. The majority of the IPAC pharmacists felt accepted and well-integrated within the team at the time of their interview (after approximately six months of practice in their service). Staff turnover was considered a challenge and support from GPs and Aboriginal Health Workers and a stable workforce were enablers to the integration of the IPAC pharmacist and referral process. Other challenges included providing opportunistic care for patients with irregular attendance patterns.

Participants in the qualitative evaluation suggested that the cap on the number of funded HMRs should be removed to enable ACCHSs to facilitate as many HMRs as is needed by their patients. Currently, the accredited pharmacists can undertake a total of 30 HMR services per calendar month (previously 20 per month).

Clinical claim

On the basis of the evidence presented for the IPAC study, the ADAR's clinical claim was:

- 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. The ADAR does not define "quality of care outcomes", however, the ADAR makes reference to "quality of care indicators" defined as clinical endpoints such as HbA1c and blood pressure elsewhere in the document.
- Services provided by pharmacists within ACCHSs are likely to lead to superior health care service utilisation (towards equity) by patients with chronic disease compared to usual care.

A number of statistically significant differences pre- and post-intervention for clinical endpoints, favouring the 'end of study' results, were reported in the IPAC study. Notably, 200 of 539 patients with Type 2 diabetes mellitus reported a clinically significant reduction of ≥0.5% in HbA1c; however, the clinical significance of the differences in other outcomes were uncertain. The qualitative evaluation of the IPAC study indicated that patients 'felt better' and considered themselves to be more engaged and contributing to decision making regarding their own health and better informed about how medications worked.

The commentary considered the results may be biased due to the study design (pre-, post- without a concurrent control group) and the potential for selection bias (only patients with baseline and follow-up results for any particular endpoint were considered).

ESC disagreed with the commentary's consideration that the attribution of these reported differences to the intervention alone is uncertain in the absence of a concurrent control group. The commentary queried the generalisability of the of the study results, noting biomedical

measures were relatively well-controlled. ESC considered that the results are likely applicable to the broader population proposed in the ADAR.

The ADAR does not make a claim about safety but it is likely that the intervention will be at least non-inferior to usual care but to the extent that the IPAC study demonstrates improved adherence to medications and health outcomes then it will be superior to usual care.

13. Economic evaluation

The ADAR presented an economic evaluation using the data from the pragmatic before-and-after IPAC trial. However, the cost data were not presented in a transparent manner. Some of the cost components (e.g., pharmacists' total hours delivering intervention, time saved to GPs by the pharmacists) were included with no justification. This, coupled with the absence of the underlying calculations (the spreadsheets presented only 'hard coded' values from tables in the ADAR), rendered the task of validating the reported costs virtually impossible.

The economic analysis used a trial-based approach utilising the clinical and medication management data collected in the IPAC study. The commentary considered the ADAR did not appear to adhere to the standards of an economic evaluation alongside the clinical trial, which should have been a guiding source for this study. This type of economic evaluation requires that health care resources are collected in natural units at a patient level throughout the trial and for as long as the intervention is delivered. In particular, if resource use data are not recorded for each participant (in the same way as the clinical data are) estimating costs by subgroups (T2DM, MAI) would involve a number of assumptions (e.g., rules for allocation of aggregated resources to the individual participants) potentially producing biased incremental cost effectiveness ratio (ICER) estimates. The commentary considered that was not clear how resources collected at the pharmacists' or the ACCHS' level were allocated to the participants.

The ADAR presented an economic evaluation (summarised in Table 3) which included:

(i) A cost-consequence analysis for participants with pre- and post-measures of outcomes. The commentary noted that there was no intention to treat (ITT) analysis or adjustment for missing values. The size of the samples for each outcome varied from the smallest cardiovascular disease subgroup (N=58) to the largest hypertension subgroup (N=1045). For each subgroup the ICERs calculated by the commentary show the incremental cost per unit of change in the disease-specific "biological indices".

(ii) Two cost-effectiveness analyses (CEA) for the subgroups of participants:

   a. The first with T2DM with pre- and post-measures of HbA1c, i.e., 539 participants (37% of the total analysis sample 1456); Incremental cost per additional patient achieving a clinically meaningful improvement of 0.5% reduction in HbA1c was estimated.
   b. The second with MAI assessments at baseline and at the end of the study. A single outcome – number of potential prescribing omissions (PPOs) was translated into a number of participants without a prescribing omission at baseline and at a follow up (mean length of stay 326 days, (inconsistent with the time horizon of 284 days set for the economic evaluation). All participants with <90 days of follow-up were removed from the analysis to allow for a minimum time for pharmacist's recommendations to be acted upon. It is not clear whether any adjustment for the censored nature of the data was undertaken. Incremental cost per additional patient without a PPO was estimated.

The ADAR also provided a cost-utility analysis that calculated lifetime QALY gains based on a multivariable regression by Hua (2017) that indicated a linear relationship of every 1% decrease in HbA1c resulting in a 0.371 (95% CI 0.286-0.456) increase in lifetime QALYs. This approach

produced results that were considered uninformative. For this reason, the results of the cost-utility analysis are presented in this report.

Table 3 Summary of the economic evaluation

Component	Description
Perspective	Publicly funded health system (MBS/PBS/PSA budgets)
Population	1456 clients of an ACCHS with a pre-specified chronic disease
Comparator	Pre-intervention (individual patient data collected retrospectively)
Type(s) of analysis	Trial-based cost-effectiveness analysis; cost-consequence analysis; cost-utility analysis
Outcomes	Disease-specific clinical endpoints; number of participants without potential prescribing omissions (PPO); number of T2DM patients who achieved a clinically meaningful reduction in glycated haemoglobin (HbA1c)
Time horizon	284 days (mean or median length of the follow-up of the study participants)[1]
Computational method	Pair-wise comparison of clinical endpoints in the different subgroups of the total sample; No statistical analysis of cost data was conducted
Generation of the base case	Trial based
Discount rate	Not applicable due to the short time horizon
Software	SPSS and MSExcel

Source: Table 19, p71 of the commentary

[1] Inconsistent with mean 267 days follow-up in the PPO analysis (p.37)

Abbreviations: ACCHS = Aboriginal Community Controlled Health Services; MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefits Schedule; PSA = Pharmaceutical Society of Australia; T2DM = type 2 diabetes mellitus

Cost collection, valuation and interpretation.

The commentary considered that there were multiple problems with cost data collection, valuation and interpretation. The ADAR divided intervention costs into (i) variable costs that could be attributed directly to participants (e.g. HMRs, non-HMRs, client education, adherence monitoring etc.) and (ii) fixed costs which included intervention costs plus "cost offsets" (e.g. non-HMRs that were funded by the IPAC study). The commentary highlighted that transfers across health care budgets do not constitute savings to the health care system. Expenses covered from the IPAC study budget to deliver pharmacists' services to the participants are resources that should have been estimated and included in the total cost of intervention. The error was corrected for in the commentary by adding to the total cost of the cost components inappropriately identified as savings. However, the implicit assumption of non-HMRs being a complete substitute to HMRs and attracting the same reimbursement of $380.07 ($157.30 for MBS item 900 plus 6CPA fee for pharmacists of $222.77) was retained as favouring the comparator. Nevertheless, the commentary considered that this assumption remained unjustified and appeared to overestimate the actual involvement of the providers of the medication review service. The commentary also added costs of 1,548 follow up encounters that were no included. presumably because these were also funded from the IPAC budget. The 6CPA fees (follow-ups) for medication management program were used as the unit costs, but it is uncertain whether these reflect the true extent of pharmacists' input.

The commentary considered that it is not clear where practice-related activities of the pharmacists were included but assumed to have been counted in the total 27,478 pharmacists' hours required to deliver the IPAC study. This estimate was inconsistent with the 12.3 FTEs and was amended during evaluation. The commentary considered there was little detail to ascertain the accuracy of the resource use, including identification, valuation and attribution.

The dual nature of the intervention delivered at the practice and at the participants' levels is reflected in the approach to measuring the pharmacists' input, which was measured in terms of both hours and numbers of HMRs and non-HMRs delivered. The commentary considered that double counting might have occurred and amended the total cost of intervention by excluding the estimated number of pharmacists' hours spent on HMRs (these were reimbursed and entered into the aggregated cost with MBS/6CPA fees as unit costs). The patients' expenses on over-the-counter (OTC) medications were not collected. Also excluded from the fixed costs were infrastructure support such as office facilities, computer access, transport, travel and accommodation for remote sites as well as salaries for people assisting the pharmacists. However, the total sum of pharmacist allowances across all ACCHS sites were obtained from the PSA financial records and allocated to each pharmacist based on their proportion of total hours. The same approach was used in allocating the costs of pharmacist training and "ACCHS support of integrated pharmacists" (not clarified). Finally, self-reported out-of-pocket pharmacists' payments were added to the total cost of the intervention.

The commentary considered the dual nature of the intervention poses a dilemma for attributing the pharmacists and practice-level costs to the individual participants. This was performed on an *ad-hoc* basis and the ADAR did not provide a clear justification for the method of allocation.

GPs' input was assessed as 719 GP hours spent by GPs on receiving the medicine advice from the pharmacists. The ADAR estimated time saved by GPs due to some of health care activities being undertaken by the pharmacists at 1,366 hours (equal to 5% of the total GP hours). The time saved by GPs was not included in the commentary's revised analysis as it was unsubstantiated.

The commentary's revised estimate of the total cost ($2,266,205 or $1,556 per participant) is similar to the cost reported in the ADAR ($2,220,094 or $1,525 per participant). This is because elimination of inappropriate "cost offsets" and unjustified GP time savings were compensated by the downwards correction in pharmacists' total time and correction for the likely double-counting of the pharmacists' input in HMRs, non-HMRs and the follow up encounters. The commentary noted that the sum total remained similar: the incremental cost per participant became $1,525 rather than $1,493 estimated in the ADAR.

Table 4 presents the results of the revised cost consequences analyses.

Table 4 Cost-consequence analysis comparing mean incremental cost with changes in outcomes[1]

Parameter	Cost/Consequence	p-value[1]
Net cost (including cost offsets)	$1,525 [2]	-
Biomedical outcomes (change in mean (SD, 95% CI))		
HbA1c mmol/mol [% units] (n=539 in T2DM)	-2.8 (19.5, -4.5 to -1.0)	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
Prescribing quality		
Medication appropriateness index score per participant (relative change)	↓46.8%	0.003
Mean number of medications per participant with ≥1 inappropriateness rating(relative change)	↓44.4%	0.001
Participants with any medications that met ≥1 overuse criterion	-12.6%	<0.001
Mean PPOs/participant (relative change))	↓60.3%	<0.001
Medication reviews		
Participants with HMR (%)	41.8%	-
Participants with non-HMR	49.4%	-
Adherence to medications		
Participants adherent (NMARS, absolute change)	↑12.8%	<0.001
Participants adherent (SIQ, absolute change)	↑10.3%	<0.001
Self-assessed health status		
Participants with 'very good to excellent' self-assessed health status (absolute change)	↑23.9%	<0.001

Source: Table 29, p120 of the ADAR

[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).

[2]Recalculated by the commentary, but does not correct for unaccounted methodological limitations

[2]Calculated by the commentary

Abbreviations: BP = blood pressure; CVD = cardiovascular disease; DBP = diastolic blood pressure; eGFR = estimated glomerular filtration rate; HbA1C = glycosylated haemoglobin; HMR = Home Medicines Review; LDL-C = low density lipoprotein cholesterol; NMARS = NACCHO Medication Adherence Response Scale; PPO = potential prescribing omission; SIQ = single item question; TC = total cholesterol; TG = triglycerides; T2DM = type 2 diabetes mellitus

Table 5 shows results of cost-effectiveness analyses for: (i) participants with a clinical diagnosis of T2DM with pre- and post-measures of HbA1c, which was converted into the number of participants who achieved a clinically meaningful improvement of at least 0.5%; and (ii) participants for whom the outcome measure -PPO was recorded at baseline and follow-up. This was converted into the number of participants without a PPO at the two observation points.

The commentary noted the input costs calculations were not provided in a spreadsheet. The commentary removed of the "cost offsets" but expressed little confidence in the accuracy of the revised cost estimates.

Table 5 Results of the revised cost-effectiveness analyses

Parameter	Integrated pharmacist	Current practice	Increment
CEA in T2DM subgroup (N=539) with clinically meaningful reduction in glycated haemoglobin (HbA1c)			
Costs	$930,952	$0.00	$930,952
Number of participants with clinically meaningful reduction in HbA1c of at least 0.5%	Not reported	Not reported	200
Incremental cost per participant with clinically meaningful reduction in HbA1c of at least 0.5%			**$4,655**
CEA in MAI subgroup (N=357 or 353) without potential prescribing omissions observed at the baseline and at the follow-up			
Costs	$852,064	$0.00	$852,064
Number (proportion) of participants without a PPO	76 (22%)	181 (51%)	105
Incremental cost per participant without a PPO			**$8,115**

Source: Adapted from Tables 30-31, p121-122 of the ADAR

Abbreviations: CEA = cost-effectiveness analysis, ICER = Incremental Cost Effectiveness Ratio, MAI = medication appropriateness index, PPO = Potential Prescribing Omission; T2DM = type 2 diabetes mellitus

The ICER of the integrated pharmacist intervention (IPAC) versus no IPAC intervention was estimated at $4,655 ($930,952/200) per participant with a clinically meaningful reduction in HbA1c of at least 0.5%. The ICER of the integrated pharmacist intervention (IPAC) versus no IPAC intervention was estimated at $8,115 ($852,064/105) per participant without a PPO. The ADAR offered no interpretation of the estimated incremental cost per participant who achieved clinically meaningful reduction in HbA1c or incremental cost per participant without a PPO.

The ADAR presented results of a sensitivity analysis, which "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 (in the original cost estimate); and an increase in time saved for GPs, which accounted for 29% of cost offsets." (p.124).

14. Financial/budgetary impacts

An epidemiological approach was used to estimate the financial implications of the introduction of integrated non-dispensing pharmacist to ACCHSs.

The financial implications to the MBS/7CPA resulting from the proposed integration of non-dispensing pharmacist to the ACCHSs are summarised in Table 6.

A separate table that provides the requested funding for a program to fund the placing of an integrated non-dispensing pharmacists in ACCHSs is summarised in Table 7.

Table 6 Net financial implications of integrated non-dispensing pharmacist to the MBS/PBS and 7CPA

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated use and cost of the proposed health service					
Number of people eligible for integrated non-dispensing pharmacist*	11,000	11,000	11,000	11,000	11,000
Number of people who receive DMMR**	2,594	2,892	2,892	2,892	2,892
Number of services of (DMMR)	2,594	2,892	2,892	2,892	2,892
Number of DMMRs (adjusted)	*1,687*	*1,687*	*1,687*	*1,687*	*1,687*
Cost to the 7CPA (does not attract co-payment)	$408,036	$454,912	$454,912	$454,912	$454,912
Cost to the [7CPA] (does not attract co-payment), full reimbursement fee included	***$577,865***	***$644,251***	***$644,251***	***$644,251***	***$644,251***
Change in use and cost of MBS					
Change in use of *comparator	-	-	-	-	-
Change in use of MBS item 900	$416,571	$464,426	$464,426	$464,426	$464,426
Net change in costs to the MBS 900 and 7CPA DMMR (do not attract co-payment)	$994,436	$1,108,677	$1,108,677	$1,108,677	$1,108,677
Net financial impact to the MBS	$416,571	$464,426	$464,426	$464,426	$464,426
Change in use of *comparator	11000	11000	11000	11000	11000
Average net cost in change in PBS medications	$380.39	$380.39	$380.39	$380.39	$380.39
Net change in costs to the PBS [co-payments not provided]***	$4,684,865	$4,684,865	$4,684,865	$4,684,865	$4,684,865
Net financial impact to the MBS	*$416,571*	*$464,426*	*$464,426*	*$464,426*	*$464,426*

Source: Compiled for the commentary from Tables 34 - 36, pp128-130 of the ADAR; IPAC Section 5 Worksheet; Financial estimates attachment; and calculated for the commentary

Abbreviations: 7CPA= Seventh Community Pharmacy Agreement; DMMR= Domiciliary Medication Management Review; MBS=Medicare Benefits Schedule; PBS=Pharmaceutical Benefits Schedule

* insufficient detail is provided about the ACCHSs included in clinical study to determine the accuracy of this estimate

* the number of people who receive a HMR is disputed.

*** based on IPAC study data

This table includes some revisions for the commentary in italics.

- The ADAR assumes the full number of HMRs in a 12-month period as the additional HMRs. It did not adjust for the baseline number which represents usual care. This has been changed.
- The ADAR does not include the full cost of a HMR but has adjusted it based on claimed savings from doing another type of MMR. This is incorrect, and so the cost of the HMRs has increased based on using the full reimbursed amount.
- The ADAR assumes no change in MBS items, but an increase in HMRs, as reported in the ADAR, also needs to recognise that the MBS referral item will increase by the same amount. These MBS items have been included and costed.

The commentary considered that the target population is likely an underestimate. The ADAR assumes that 2.3% of patients of ACCHSs would meet the target population of having a chronic illness and being seen at least three times in the last two years at the ACCHS. The commentary did not agree as it is reported 46% of Aboriginal and Torres Strait Islander peoples have at least one chronic condition, and of these 93% have visited their GP in the last 12 months (Aboriginal and Torres Strait Islander Health Survey, 2018-19). The pre-ESC response stated that the figure of 2.3% takes into account the fact that when placing an integrated pharmacist within an ACCHS,

only a subset of patients with chronic disease would be referred for review, as the pharmacist would also conduct a range of additional core roles tailored to the needs and priorities the service. As such, despite there being a potential acknowledged need, the pharmacist would not have capacity to see all patients with chronic disease attending the ACCHS.

The ADAR reported benefits of improved medication reviews (increase in average PBS medications) occurring for the eligible population but only the target population are recorded (increase in HMRs) as receiving a home management review.

Table 7 Total Commonwealth Funding for New Program to roll out integrated pharmacists to ACCHSs nationally

	Year 1	Year 2	Year 3	Year 4	Year 5
Pharmacist salary	**$11,735,262**	**$11,735,262**	**$11,735,262**	**$11,735,262**	**$11,735,262**
Pharmacist support [a]					
Creation of online training course	- [a]				
Facilitation of mentor, clinical and other support to pharmacists working (or intending to work) in the ACCHS sector	$529,000	$529,000	$529,000	$396,750	$396,750
Creation and maintenance of a community of practice for integrated practice pharmacists in the ACCHS sector	$62,000	$62,000	$62,000	$62,000	$62,000
Ongoing support for the PSA/NACCHO Pharmacist Leadership Group	$30,000	$30,000	$30,000	$30,000	$30,000
Subtotal	**$621,000**	**$621,000**	**$621,000**	**$488,750**	**$488,750**
Program support to ACCHSs					
Project officers FTE	2.5	2.5	2.0	1.5	1.5
Salary-project officers	$312,500	$312,500	$250,000	$187,500	$187,500
Salary on costs (25% of salary) + IT, management fee	$100,000	$100,000	$80,000	$60,000	$60,000
Travel (project officers + meeting travel)	$75,000	$75,000	$50,000	$25,000	$25,000
Annual Meeting Expenses (i.e. annual workshop)	$60,000	$60,000	$60,000	$60,000	$60,000
Project publications & Resources	$100,000	$75,000	$50,000	$25,000	$0
Total program expenses	**$647,500**	**$622,500**	**$490,000**	**$357,500**	**$332,500**
Monitoring and evaluation of service	**$312,000**	**$294,780**	**$294,780**	**$294,780**	**$294,780**
Total costs of program funding	**$13,316,142**	**$13,273,542**	**$13,141,042**	**$12,876,292**	**$12,851,292**

Source: Compiled for the commentary from Tables 33 and 35, pp127-130 of the ADAR; IPAC Section 5 Worksheet; Financial estimates attachment

Abbreviations: ACCHS = Aboriginal Community Controlled Health Services; FTE = full-time equivalent; IT = information technology; NACCHO = National Aboriginal Community Controlled Health Organisation; PSA = Pharmaceutical Society of Australia.

[a] The cost for the creation of online training course ($530,00) was removed as the pre-ESC response noted that this training course has already been developed.

The ADAR has provided the methodology by which it has calculated the number of ACCHSs and the pharmacist numbers but client numbers per pharmacist is not consistent with the stated assumption.

The commentary considered the ADAR's estimated pharmacist's salary ($151,618 yearly) to be high given the usual rates paid for experienced pharmacists ($33.59/hour) in the trial. The pre-

ESC response clarified that base salary was calculated as $125,000, reflective of the contemporary salary for a senior public hospital pharmacist and included all employment costs.

The commentary noted the additional funding requested for Program support for ACCHSs, and evaluation and monitoring was not accompanied with any methodology about how it was costed.

The commentary considered that workforce considerations may impact the ability of the program to be rolled out widely across Australia, especially to remote and very remote ACCHSs.

15. Other relevant information

ESC highlighted the IPAC intervention may help address health inequalities for Aboriginal and Torres Strait Islanders.

The ADAR presented some other relevant considerations for MSAC:

- Integrating pharmacists (the service) within ACCHSs was supported by Aboriginal and Torres Strait Islander patients, health service staff, community pharmacists and the IPAC integrated pharmacists (refer to the qualitative evaluation).
- The need for additional resources to support integrated pharmacists, such as through the PSA.
- The need to support ACCHs to deliver the integrated model of care, suggesting it should be based on the six support activities provided throughout the IPAC study (see Appendix 22 to the ADAR).

16. Key issues from ESC to MSAC

ESC key issue	ESC advice to MSAC
Quality of evidence	ESC disagreed with some of the commentary's criticisms of the IPAC study. ESC considered the IPAC study was an excellent example of a study with a community based participatory approach which examined a complex health intervention in a real-world setting. However, ESC considered the study had a high risk of bias due to the pre and post study design, attrition (outcomes reported for patients with baseline and follow-up data) and selection bias. Despite the inherent issues with the study design, ESC considered it was likely that some outcome improvements, especially Patient Reported Experience Measures (PREMs) and other qualitative outcomes, could be attributed to the IPAC intervention. ESC considered the results of the IPAC study would be generalisable to Aboriginal Community Controlled Health Services (ACCHSs).
Study outcomes	ESC noted the study reported small reductions in biomedical markers of disease although individually, these reductions were not necessarily clinically significant. ESC noted there were improvements in prescribing quality. ESC considered patient-reported outcomes were important for the assessment of the intervention.

ESC key issue	ESC advice to MSAC
Integration of qualitative research into HTA process	The qualitative assessment undertaken by the IPAC study was poorly addressed in the commentary. ESC advised that the results from the qualitative research are important for an overall understanding of the acceptability and implementability of IPAC. ESC advised that further assessment of the qualitative findings on stakeholder perspectives and potential barriers or enablers for implementation is warranted and would be informative for MSAC deliberation.
Economic model	ESC considered the corrected cost-consequence analysis should be the basis of MSAC advice. ESC also considered that the CCA should be expanded to reflect impacts of the program on additional outcomes such as MAI, PPO, acceptability and implementability. ESC considered that neither CEA nor CUA are appropriate approaches to the economic evaluation.
Utilisation	ESC agreed with the applicant that the eligible population is 2.3% ACCHSs clients. ESC considered that use by a larger group of people should be considered a positive outcome as it would likely result in a greater positive impact.
Ethical, patient and social considerations	ESC noted the potential broader impacts of the IPAC intervention. ESC considered this is particularly important as IPAC is an intervention that aims to provide equitable health services for Aboriginal and Torres Strait Islander people. ESC considered the potential societal impact of the program is large, especially as this program has been designed by and for Aboriginal and Torres Strait Islander peoples.

ESC discussion

ESC noted that the IPAC Project was a non-randomised, prospective, pre- and post- quasi-experimental trial conducted by the Pharmaceutical Society of Australia (PSA), in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University (JCU). ESC noted that the trial was developed in response to organic demand for the service from Aboriginal Community Controlled Health Services (ACCHSs). and co-designed with acceptability and cultural appropriateness as core outcomes.

ESC noted that the purpose of the application is to seek public funding for non-dispensing pharmacists within all Aboriginal Community Controlled Health Services (ACCHSs) in Australia. Funding request includes salary as well as support for administration, monitoring (some of which to go via PSA). ESC noted that in the pre-ESC response the applicant stated that the creation of an online training course was already completed and so should be removed from the costs.

ESC noted that the applicant is claiming improved clinical outcomes, based on improved prescribing quality and improvements to medication adherence. ESC noted the high clinical need for such a service. ESC noted that from a consumer perspective, the program addressed issues relating to the quality use of medicines and increased equity of access to medicines.

ESC noted the proposed intervention is intended for adults, however, consultation input noted that it may be appropriate for children. ESC noted that travel costs were not included for providing the service and queried whether this could be a barrier for people living in remote communities who may have to travel a long distance, and incur substantial costs, to receive the service. ESC considered the pharmacist may need to travel to remote communities as people who are most unwell, and could benefit the most, may be unable to travel the long distances to access the nearest ACCHS. ESC reaffirmed the importance of consultation with Aboriginal and Torres Strait Islander communities to determine the approach that will meet their needs. ESC

also queried whether the proposed program could result in an inequitable outcome to underserved Aboriginal and Torres Strait Islander communities without access to an ACCHS.

ESC noted the proposed intervention may potentially overlap with existing funding programs including the Workforce Incentive Program (WIP), the Indigenous Health Services Pharmacy Support (IHSPS) Program and the Home Medicines Review Program. The pre-ESC response noted that the quantum of funds allocated through IHSPS (currently $20 million over 4 years) would need to increase significantly in order to replicate the impact observed throughout the IPAC study.

The ADAR stated pharmacists are not currently supported through existing Australian Government or State and territory programs to deliver integrated and non-dispensing services within these primary health care service settings (except notionally though the WIP). ESC noted that the role of state and territory governments and the funding they provide for ACCHS was not considered. ESC advised that the integration of pharmacists should be considered in the context of all funding sources (including from state and territory governments) and programs that may intersect with the provision of pharmacy services in ACCHSs. ESC considered the relationship between the requested funding for an IPAC-style program and existing funding arrangements are a matter of policy.

ESC noted that the proposed comparator was usual care with no integrated pharmacist within the ACCHS and considered that this was appropriate. ESC noted that usual care would vary across different ACCHSs and the level of pharmacy and pharmacist support available. ESC noted that clients of ACCHSs would also use mainstream primary healthcare services.

ESC considered that the IPAC intervention is valuable for Aboriginal and Torres Strait Islander people. ESC considered that the intervention would help improve equitable access to medicines and help address health inequalities. ESC also noted that non-dispensing pharmacists are being integrated into some mainstream general practices.

ESC noted the study was undertaken in three jurisdictions (Queensland, Northern Territory, Victoria) across urban, regional, rural and remote settings. ESC noted the study sites and funding proposal was for ACCHSs. ESC considered an extension to funding non-Community Controlled Health Organisations would be a policy matter for the Department.

ESC considered the IPAC study was an excellent example of a study with a community based participatory approach which examined a complex health intervention in a real-world setting. ESC noted that the IPAC study was undertaken in accordance with the additional governance and ethical arrangements required for research with Aboriginal and Torres Strait Islander peoples.

ESC noted the commentary's criticisms of the trial design. The commentary considered that there was a potential risk of bias due to the pre and post study design, attrition and selection bias. The results were based on participants with both baseline and follow-up data and baseline biomedical markers appeared relatively well-controlled, suggesting the participants have been committed to controlling their chronic conditions. ESC considered these factors could contribute to the IPAC study having a high risk of bias. However, ESC expressed the importance of studies such as IPAC examining health benefits of complex health interventions in a real-world setting.

The commentary queried whether the study results could be reliably attributed to the trial intervention due to the potential risk of bias. On balance, ESC considered the improvements in outcomes could be attributed to the IPAC intervention. ESC considered that the IPAC study would be better being re-appraised using a quality assessment tool appropriate for health program evaluations.

ESC noted that the IPAC study reported biomedical markers, prescribing quality outcomes, medication management reviews and patient reported outcomes. ESC noted the changes in

biomedical outcomes were statistically significant but may not be clinically significant. ESC highlighted that 37% (200/539) of participants had a reduction in HbA1c of 0.5% or greater which is generally considered a clinically meaningful benefit. ESC considered the prescribing quality outcomes were difficult to interpret as it is not established whether improvements with these outcomes lead to improvements in patient-relevant outcomes.

ESC noted that the commentary had significant concerns about the generalisability of the results. ESC disagreed with the commentary and considered the results of the study are the most applicable research available regarding the integration of non-dispensing pharmacists in ACCHSs. ESC noted the pre-ESC response requested a larger than usual emphasis be placed upon the overwhelmingly positive qualitative evaluation results. ESC noted that qualitative feedback was available from 20 patients and carers, 24 pharmacists, clinicians and other ACCHS staff, and community pharmacists. ESC noted that although there was a clear research question for the qualitative evaluation, there was no clear conceptual framework or research methodology. ESC considered that this made it difficult to assess the qualitative work by the usual methods such as congruency analysis. ESC considered that the qualitative feedback was positive and important for MSAC's consideration of the merits of the IPAC intervention as a more culturally appropriate service for Aboriginal and Torres Strait Islander peoples.

ESC considered that the quality of IPAC intervention in practice would depend on the pharmacist having the right organisational fit for the ACCHS and being able to effectively work with other staff members and building relationships with the ACCHS clients. ESC considered that a program where integrated pharmacists can provide continuity of care, rather than short term care, may be beneficial.

ESC noted the ADAR presented several economic evaluations: a cost-consequence analysis (CCA), a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA).

ESC considered that the pre-ESC response to the criticisms raised in the commentary was appropriate. ESC noted that CEA and CUA are useful when considering allocative efficiency and marginal cost-effectiveness between different interventions, but that a program such as the IPAC project is fundamentally about equity of access and raising the levels of care delivered to particular groups in the community. ESC noted that when jurisdictional governments assess such programs they generally determine value for money by undertaking a cost-benefit analysis. Therefore, a CCA may be more appropriate when evaluating IPAC.

ESC noted the commentary had appropriately revised the cost inputs into the CCA. ESC advised that an expanded CCA using the revised costs (using the high pharmacist salary) and the inclusion of prescribing quality outcomes would be the most appropriate analysis for MSAC consideration. ESC considered that the value of the program was not able to be fully captured using the conventional economic analysis. The pre-ESC response considered some of these broader benefits included education for staff on medicines, liaison with community pharmacy and other health care providers on patient care, and contributions made to the range of quality services provided in the health care model embraced by ACCHSs.

ESC noted that the ADAR scaled up costs on the basis of the experience within the IPAC trial. ESC noted that the applicant stated that 2.3% of patients of ACCHSs would meet the target population of having a chronic illness and being seen at least three times in the past 2 years at the ACCHS. The commentary disputed these figures and considered that the target population would be much larger than that suggested by the applicant. However, in the pre-ESC response, the applicant stated that it would not be appropriate to generalise the IPAC service to the broad population because this cohort would include people with a designated chronic disease who are either not on medicines or not on the complex regimens that were reflected in the participants of the IPAC trial. It may also include people who are not regular clients of an AHS. ESC advised that a greater uptake of the service could be a positive outcome as it could result in a greater positive impact.

ESC noted the applicant's concern that HTA in Australia is unresponsive to the needs and perspectives of ACCHSs and Aboriginal and Torres Strait Islander peoples and expressed reservations about the appropriateness of the HTA process for analysing the results of the IPAC study and appropriately determining the suitability of funding for the ACCHS sector. ESC considered that impacts beyond clinical outcomes are in scope for HTA and will be important considerations for MSAC.

ESC noted concerns that shortages of pharmacists may affect the feasibility of the program. ESC agreed with the pre-ESC response that implementation of an IPAC style program may assist retention of mid-career pharmacists in non-urban settings.

17. Applicant comments on MSAC's Public Summary Document

The applicant had no comment.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website