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Study protocol: primary healthcare transformation through patient-centred medical homes—improving access, relational care and outcomes in an urban Aboriginal and Torres Strait Islander population, a mixed methods prospective cohort study

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ABSTRACT

Introduction For over 40 years, Aboriginal and Torres Strait Islander Community-Controlled Health Services (ACCHS) in Australia have led strategic responses to address the specific needs of Aboriginal and Torres Strait Islander populations. Globally, there has been rapid growth in urban Indigenous populations requiring an adaptive primary healthcare response. Patient-centred medical homes (PCMH) are an evidenced-based model of primary healthcare suited to this challenge, underpinned by principles aligned with the ACCHS sector—relational care responsive to patient identified healthcare priorities. Evidence is lacking on the implementation and effectiveness of the PCMH model of care governed by, and delivered for, Aboriginal and Torres Strait Islander populations in large urban settings.

Method and analysis Our multiphased mixed-methods prospective cohort study will compare standard care provided by a network of ACCHS to an adapted PCMH model of care. Phase 1 using qualitative interviews with staff and patients and quantitative analysis of routine primary care health record data will examine the implementation, feasibility and acceptability of the PCMH. Phase 2 using linked survey, primary care and hospitalisation data will examine the impact of our adapted PCMH on access to care, relational and quality of care, health and wellbeing outcomes and economic costs. Phase 3 will synthesise evidence on mechanisms for change and discuss their implications for sustainability and transferability of PCMHs to the broader primary healthcare system

Ethics and dissemination This study has received approval from the University of Queensland Human Research Ethics Committee (2021/HE00529). This research represents an Aboriginal led and governed partnership in response to identified community priorities. The findings will contribute new knowledge on how key mechanisms underpinning the success and implementation of the model can be introduced into policy and practice. Study findings will be disseminated to service providers, researchers, policymakers and, most importantly, the communities themselves.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Prospective cohort design support data collection from intervention and standard care sites to determine the impact of the patient-centred medical homes (PCMH) on access, quality of care and health outcomes.
⇒ Triangulation of quantitative and qualitative data will enable examination of implementation, feasibility and acceptability of the PCMH from the perspective of health providers and patients.
⇒ Participatory action research which privileges Aboriginal and Torres Strait Islander worldviews, knowledge, realities and terms of reference will guide the conduct of the study.
⇒ Randomisation was not feasible in this real world, primary healthcare context, where the priority for implementation of a significant system reform was site readiness, and randomisation may also be negatively perceived by the community as restricting access to the new model of care.
⇒ Specific measures of patient's self-reported experience were developed for the study as validated culturally modified measures of self-reported patient experiences are limited.

INTRODUCTION

Health-promoting and resilience factors—such as, connection to culture, country and community and agency[1–3] are fundamental for Aboriginal and Torres Strait Islander

health and wellbeing. However, these protective factors have been undermined by ongoing colonisation and resultant intergenerational trauma.[4] Consequently, Aboriginal and Torres Strait Islander peoples experience high levels of both non-communicable and communicable diseases.[5] Added to this, improvements in healthcare over the last 50 years have resulted in an increase in the number of Aboriginal and Torres Strait Islander people reaching older age as well as a booming younger population,[6] with trends projected to increase significantly over the coming decades.[7] Furthermore, recent global trends towards urbanisation of Indigenous peoples are also reflected in the Australian context, with rapid population growth most evident in urban settings.[6] This population growth, change in the age distribution and overall health levels, has required an adaptive approach to healthcare—particularly, primary healthcare (PHC).

Aboriginal and Torres Strait Islander Community-Controlled Health Services (ACCHS) are holistic PHC services, delivered and governed by Indigenous peoples for Indigenous peoples.[8 9] Established in the 1970s, the formation of ACCHS across Australia was a political and strategic response to the health and social inequities experienced by Aboriginal and Torres Strait Islander peoples. In 2009, in response to significant growth and geographic dispersal of Aboriginal and Torres Strait Islander peoples in the South-East region of Queensland, the Institute for Urban Indigenous Health (IUIH) was established to drive innovation in delivery of health and family wellbeing services.[9] The region is one of the most populous—being home to more than 11% of Aboriginal and Torres Strait Islander peoples—and fastest population growth areas in Australia.[6] Over a 10-year period, IUIH and its member services (the 'IUIH network') have increased service coverage to the Aboriginal and Torres Strait Islander population in the region from 16% to 45%, with the number of regular patients now just under 40 000.[9] Through this and the consequent improved relational care delivered,[10] substantial gains in health outcomes have been observed.[11 12]

However, for the IUIH to continue to respond to identified community needs, and build on these health gains, further redesign of the current system of PHC was necessary. The patient-centred medical home (PCMH) is a model of healthcare delivery that has been implemented to address the challenge of growing urban populations with complex care needs, internationally and in Australia.[13–15] Defining features of PCMH models include multidisciplinary team-based care, voluntary enrolment of patients with a team of providers, patient education and self-management, the use of technology to support patient care (including data-driven improvements in care) and service planning and coordination.[16 17] Conceptually, PCMHs operationalise the core functions of PHC (universal access, comprehensive care provided within people's community, coordination, relational continuity of care and intersectoral collaboration)[18 19] with an explicit focus on—and responsiveness to—patient needs.

International evidence has established that PCMH models contribute to reductions in hospital admissions and improved clinical outcomes in diabetes, asthma and preventative care and patient satisfaction.[14 20 21] Similar findings were observed for the Southcentral Foundation's model of PCMH in Alaska, the only published example of a PCMH implemented for, and by, Indigenous peoples.[22] There are few published Australian studies examining the implementation of the PCMH model,[23 24] and none examining the effectiveness of the model for improving quality of care or health outcomes, including in urban Indigenous communities.

Leveraging from findings of a pilot study within the IUIH network, this study will undertake an evaluation of a PCMH adapted by, and for, the South-East Queensland Aboriginal and Torres Strait Islander community (IUIH PCMH System of Care – ISoC2). Conducted over 5 years, our study will extend the pilot study and expand the research programme to a second, larger health hub. This Indigenous led and governed study will generate evidence on implementing a PCMH for a large urban Aboriginal and Torres Strait Islander population in Australia. Furthermore, it will contribute new knowledge on: the effectiveness of such a model for improving access, relational care and health outcomes; the impact on economic costs; and the transferability and scalability of the model for the broader PHC sector.

Objectives

The overall aim of this study is to undertake a process and outcome evaluation of an adapted model of a PCMH (ISoC2) at two ACCHS in South-East Queensland. Specifically, this study aims to:

1. Examine the process of implementing ISoC2, including how model elements are operationalised and the extent to which the model is delivered as planned (fidelity).
2. Identify barriers and enablers to implementation and delivery (feasibility) of ISoC2 and explore its acceptability to staff and patients.
3. Evaluate the effectiveness and economic impact of ISoC2 by quantifying changes in access, quality of care (with a specific focus on relational qualities of that care) and health outcomes, following implementation compared with baseline and standard care.

METHODS AND ANALYSIS

Study setting

The IUIH network is the largest provider of PHC to the South-East Queensland Aboriginal and Torres Strait Islander population. The standard model of care offered at each of the IUIH network's 20 clinics supports universal primary care, with a blended payment model and provided at no cost to the patient. A range of comprehensive services and programmes are made available as a one-stop shop for patients.[9] The study will evaluate two IUIH ACCHS located in the greater Brisbane region of

Table 1 Comparison of care components for models of care

Care components	PCMH[16 17]	IUIH standard care	ISoC2
Leadership*	Leaders fully engaged with the process of change at all levels of the organisation	Community governance and accountability structure	Community governance and accountability structure Distinct operational working group to support model transformation
Patient enrolment†	Assigned to a clinic or 'teamlet' of PCP/PCP assistants	Administration staff or patients assign to preferred GP provider	Voluntary patient-initiated enrolment with a core multidisciplinary care team, a 'Pod'
Team-based care	Provider working with a team of other providers; may have 2–3 PCP/PCP assistants in a 'teamlet'	Providers working together with teams but work independently	Pod members working collaboratively
		Care planning scheduled intermittently	Care planning throughout patient journey
Care pathways‡	Various, in Australia mostly from GP to other services	First contact with administration staff and then to RN/AHW, followed by the GP. GP then refers to other allied or specialist services	Dynamic pathway where Pod members work collaboratively to customise a pathway to meet patient needs
Scope of practice	Various, specific and expanded roles	Traditional discipline and specific roles	Expanded, intersecting scope of practice particularly of non-GP providers.
Relationship-based care and continuity of care	Primarily between PCP/'teamlet' and patient	Primarily between GP and patient	Patient and Pod
	Supports shared decision-making	Usually supports shared decision-making	Routine use of goal setting and patient-led decision-making tools
Use of technology for data-driven care coordination and quality improvement	Shared electronic health record Variable use of data for quality improvement§	Shared electronic health record. Data-driven continuous quality improvement in care	Shared electronic health record Data-driven continuous quality improvement in care Data-driven stratification of healthcare resources according to patient needs (cultural, emotional, social and physical)
Access and availability	Use of multiple modalities with extended hours	Use of multiple modalities but mostly face to face	Use of multiple modalities: face to face, telephone and home visits with extended hours
Funding sources¶	Multiple often blended payments	Blended payments	Blended payments

*ACCHS has a specific governance structure, see section on public involvement for further details. The operational working group overseeing ISoC2 includes clinicians and managers from participating sites, personnel responsible for workforce development and service implementation, and research and evaluation partners.
†In ISoC2, a 'pod' comprises an administrative coordinator, AHW, RN and GP working together throughout the patient's care journey.
‡In most circumstances in Australia, including in Health Care Homes[15] (the PCMH implemented in some services in Australia over the last 5 years), most patients will see a GP prior to other providers.
§In the PCMH model panel registry typically used to manage and improve care.
¶PHC in Australia is funded predominantly through fee-for-service, while PCMH models often have a blended payment (capitation, pay for performance and fee-for-service), while ACCHS have blended payment as the standard funding model.
AHW, Aboriginal and Torres Strait Islander health worker; GP, general practitioner; IUIH, Institute for Urban Indigenous Health; PCMH, patient-centred medical home; PCP, primary care physician; RN, registered nurse.

Queensland, Australia. Collectively, the clinics provide services to almost 4000 Aboriginal and Torres Strait Islander patients. These services were the first sites to have their premises redesigned and workforce reconfigured to support the ISoC2 model, the first beginning 2019, and the second in early 2020. The study evaluation began in June 2020 and will conclude in June 2025 (6-year and 5-year post-implementation of ISoC2 at site one and two respectively).

Intervention

Adapted from an Alaskan Native community-controlled health service,[22 25] ISoC2 builds on the strengths of the existing IUIH model of care through adaptations intended to: strengthen access, relationship-based care, patient engagement and agency; improve health outcomes; increase efficiency by directing resources within the service to deliver greatest impact and to scale the service model to cater for growing demand.

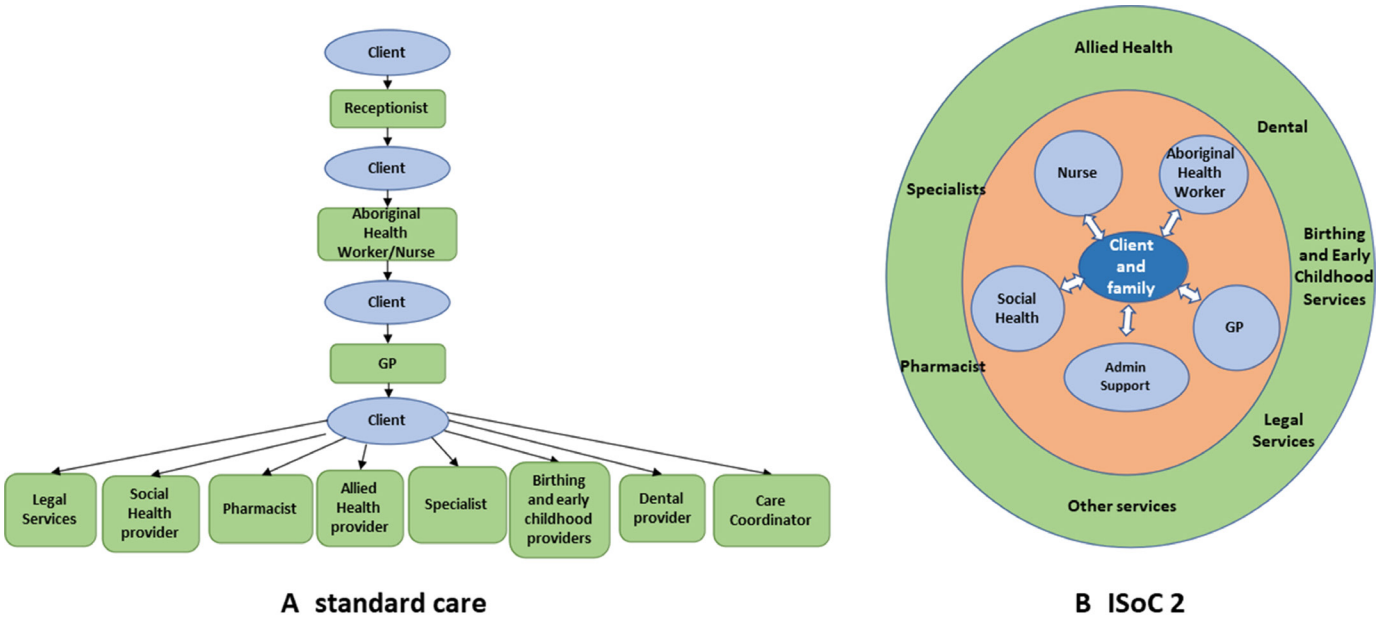

Figure 1 A) Standard care pathway compared with B) ISoC2 model of care. GP, general practitioner; ISoC2, IUIH System of Care 2.

Table 1 outlines the differences in the care components between the PCMH model, IUIH's current model of care and ISoC2. Figure 1 summarises the key changes in the care pathways that will result from implementation of ISoC2. In the ISoC2 model, team-based care comprises an Aboriginal or Torres Strait Islander health worker, administrative coordinator, registered nurse and general practitioner (GP, Australia's primary care physicians) (operationally referred to as a 'Pod') working collectively to lead and coordinate care based on the patient's identified health and wellbeing priorities. All staff in these roles were assembled into Pods, with approximately 3–4 Pods per intervention site. During implementation of ISoC2, all clients attending the service were assigned to their preferred Pod, with new clients similarly assigned throughout the evaluation study.

Study design

The study is a mixed-methods prospective cohort study, using a hybrid implementation and clinical effectiveness design (type 1)[26] where the effect of an intervention on outcomes is tested while gathering information on implementation. The study will evaluate the model of care over three sequential phases, from June 2020 to June 2025 (figure 2). Phase 1 will examine the implementation of ISoC2 (how it is operationalised, and its feasibility and acceptability from the perspective of patients and health staff). Phase 2 will examine the effectiveness of ISoC2 on access to care, quality of care, economic costs and health and wellbeing outcomes. Phase 3 will bring the findings together to synthesise evidence on the process of implementing ISoC2 and mechanisms for change, sustainability and the translation of PCMHs and their key elements into the broader PHC system. Randomisation was not feasible in this real-world context, where the priority for implementation of a significant system reform was site readiness. Further, randomisation may also be negatively perceived by the community as restricting access to the new model of care.

Participatory action research was used to codesign a programme logic to guide the research process, ensuring that the IUIH Cultural Integrity Framework[2] underpins the evaluation and Aboriginal and Torres Strait Islander worldviews, knowledge, realities and terms of reference are privileged throughout the research process.[27–29] Participatory action research will also be used to feedback research findings to health and management staff in real time to inform a continuous process of service refinement as well as the conduct and interpretation of the research itself. A steering committee, representing potential knowledge brokers and knowledge users, including Aboriginal and Torres Strait Islander and non-Indigenous researchers, clinicians, managers and community liaison officers, will oversee the project. A clinical reference group will also meet to provide advice on long-term outcomes, including those related to linked emergency department admissions and potentially preventable hospitalisations. Both the steering committee and clinical reference group will provide oversight with respect to data sovereignty ensuring that what is measured is meaningful, culturally and clinically.

Study participants

Study participants include staff and regular patients (defined as at least three visits in the preceding 24 months). Patients are eligible to participate if they are registered with the intervention clinic, identify as Aboriginal and/or Torres Strait Islander, and, for qualitative and survey data, are at least 18 years of age. Eligible patients can choose to consent to participate in qualitative

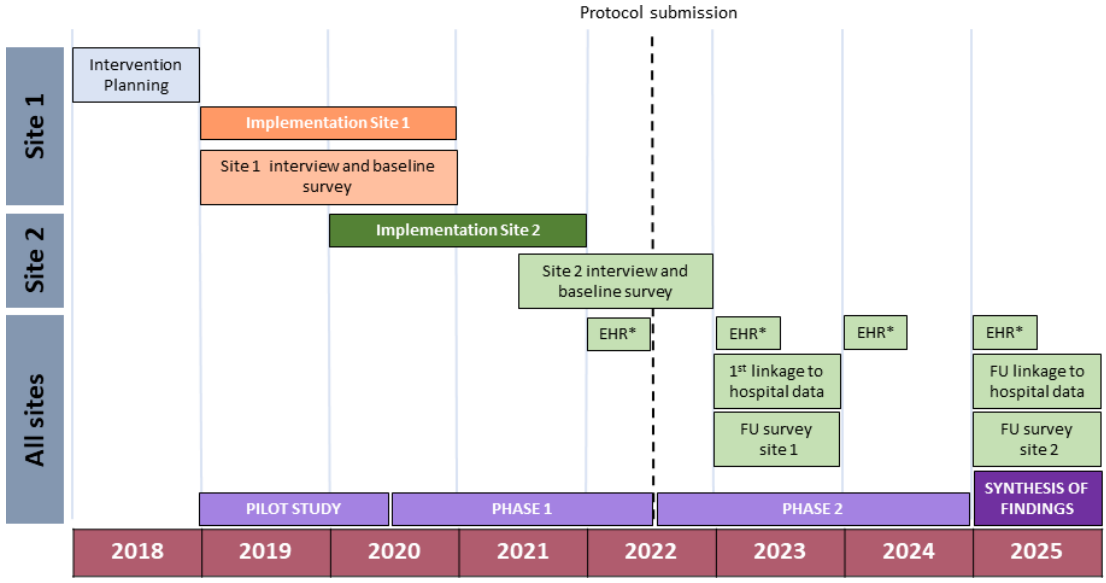

Figure 2 Timeline for research programme across intervention sites. EHR; electronic health records; FU, follow-up. Collection of interview and baseline survey data from intervention site 1 was completed by end of June 2020, as a pilot study with separate ethics approval. Collection of interview and baseline survey data from intervention site 2 and EHR data from all sites (intervention and standard care) was planned to begin June 2020. However, given the subsequent disruption to services and research activities due to the COVID-19 pandemic, actual data collection was deferred until mid-2021, with further delays due to later COVID-19 infection waves. EHR extraction in 2022 under the ISoC2 study from all sites covering period from 1 January 2016 – 31 December 2022; up to 2 years prior to implementation of site 1 accounting for disruption of services in 2018 due to a fire on the clinic premises in December 2017. Subsequent EHR update planned at approximately 12 month intervals. Survey participants will be invited to complete a follow-up survey approximately 3 years post the baseline survey. Linked hospital and emergency department data will be received in two files; first in 2023 and then a subsequent update in 2025.

interviews or complete a survey. Those completing the survey can also consent to having their data linked to deidentified electronic health records (at intervention clinics and hospital administrative data). Eligible staff are those currently employed at intervention clinics, or who were employed at the clinics during implementation of ISoC2 and consent to participate.

In addition, for quantitative analysis using routinely collected electronic clinic health record data, study participants will also include regular clients at standard care clinics located within the IUIH network and matched for clinic characteristics.

Data collection

Routinely collected health data will be extracted from electronic clinic health records for client attendance numbers, service access relative to the estimated resident population and specific health outcomes for all eligible participants. Data will be extracted retrospectively for a period of 3 years prior to implementation of ISoC2 at intervention sites, with updated extracts approximately every 12 months until the study end date. All data will be deidentified; individual participants will be given a unique identifier to enable follow-up, multilevel modelling (random effects) and for linking survey and hospital administrative data (secondary care data). Information relating to sociodemographics, long-term health conditions, medications, clinical measures (eg, blood pressure, weight and other investigation results), consultations and Medicare Benefit Schedule service item claims (for medical services funded through Medicare, Australia's universal health insurance scheme) will be collected from routinely collected health record data.

Survey data will be collected using an adapted survey questionnaire currently used in a national study of Aboriginal and Torres Strait Islander Wellbeing (the Mayi Kuwayu (MK) study), which was developed in consultation with communities across Australia.[30] Survey questions will inquire about clients' sense of connection to service and care providers, relational continuity of care, adapted from standard instruments specifically for this study,[31] and health and wellbeing outcomes from the original survey instrument (see online supplemental file for further details). Health and wellbeing outcomes are related to cultural practice and expression, health and wellbeing, health behaviours and family support and connection, which are not captured through routinely collected health record data. A random sample based on the age and sex distribution of intervention clinics will be invited to participate in the survey until final sample sizes are achieved. Two waves of survey data collection will occur—baseline survey (completed during implementation at each intervention site) and follow-up survey (completed 3 years post the baseline survey at each intervention site) (figure 2).

For controls, routinely collected clinic health data will be extracted from comparable standard care clinics based on location, clinic size and composition, history of clinic

establishment and demographics, with at least two randomly selected controls for every intervention participant. For outcomes derived from survey data, intervention participants will be matched to at least two randomly selected controls within the MK study cohort (as these survey data are unavailable from standard care sites). Subject to MK data custodian approval, matching will be performed by the data custodians and be minimally based on age, gender, remoteness/geography of residence and other relevant sociodemographic and health characteristics.

Qualitative data will be collected from patients and healthcare providers using individual interviews. Semi-structured individual interviews with staff will explore their experiences and perceptions of ISoC2 related to coherence, strengths and limitations of the model, barriers and enablers to its implementation and the nature and extent to which providers collaborate to implement the model and embed it into everyday practice for routine delivery. Interview data will be analysed thematically to identify, characterise and explain mechanisms that promote and inhibit the implementation and embedding of ISoC2 in everyday work for routine delivery. Yarning interviews, culturally respectful conversation that is relaxed, narrative-based and emphasises the value of story telling,[32] will be undertaken with patients from each intervention site to explore their experiences and perceptions of ISoC2. Interviews will be conducted using a yarning guide, developed by the lead for IUIH's Cultural Integrity Investment Framework (RB), comprising domains used in patient satisfaction surveys at IUIH: Community and Belonging, Country and Culture, Health and Wellbeing, Connection, Your Clinic and One Time. Yarns will be analysed using thematic analysis, privileging interpretations by Aboriginal and Torres Strait Islander researchers and healthcare providers. Interviews with staff and clients are expected to take between 30 min and 60 min and will be audio recorded and stored in MP3 or MP4 format.

Outcomes measures

Primary and secondary outcomes were selected on the basis that they aligned with the study objectives, were considered a priority from the services' perspective and reflected current guidelines. Measures will be calculated according to standard methods where available. Due to the lack of a validated culturally modified measure of self-reported patient experiences and outcomes for our population of interest, standard instruments have been adapted for this study (see online supplemental file for further details).

Effectiveness-access, quality of care and health outcomes

Primary outcomes

1. Proportion of clinic catchment population that will be active patients.
2. Proportion of regular patients with a continuity of care score of ≥75% by care team.[33]
3. Proportion of patients with type 2 diabetes with glycosylated haemoglobin A1C (HbA1C) <7% (or if >7%, decreased by at least 2% from baseline).[34]
4. Proportion of patients at high absolute cardiovascular disease risk.[35]
5. Rates of potentially preventable hospitalisations and emergency department presentations.[36]

Secondary outcomes

1. Regularity score[37] for clients with asthma or diabetes.
2. Self-reported relational continuity of care score (collected in patient surveys).
3. Self-reported shared decision-making and reciprocity in care planning (collected in patient surveys).
4. Proportion of regular patients who have participated in a health assessment.
5. Ratio of care plan reviews to chronic disease management plans/team care arrangements.
6. Proportion of those at high absolute risk of cardiovascular disease on guideline-recommended medications (lipid-lowering and blood pressure-lowering medication).[35]
7. Self-reported agency regarding healthcare access and engagement (collected in patient surveys).
8. Self-reported community cohesion (collected in patient surveys).[30]

Process outcomes related to the implementation of ISoC2 and its core components

1. Staff perceptions and experiences of barriers and enablers (feasibility) to delivering ISoC2 (qualitative data).
2. Staff and patient perceptions and experiences of the acceptability of ISoC2 (qualitative data).
3. Patient enrolment: % of total visits with assigned pod team.
4. Distribution of care between providers: per cent of total visits with each pod team member (quantitative data).
5. Accommodation/modalities of care (quantitative data).
   - Proportions of patient consultations delivered by modality.
   - Third next available appointment by pod team and by GP (number of days).

Power and sample size

This study has been powered to detect changes in clinical outcomes of patients accessing care at both intervention sites pre-implementation and post-implementation of ISoC2. To be able to detect a minimum difference of 5% in the proportion of people attending the clinic from baseline (38.5%) to after implementation (43.5%) with 80% power and at a 5% level of significance using an independent χ^2 test requires at least 1520 people in the catchment area (table 2). Remaining sample size calculations above are derived assuming zero correlation, thus these are conservative sample size estimates. For example, a sample size of about 250 clients with diabetes in each of the pre-time and post-time periods will have 80% power to detect a minimum difference of 0.25 SD in

Table 2 Power calculations for primary outcomes

Outcome	From	To	Sample size required (regular client or relevant subgroup)	Power
Proportion of clinic catchment population that will be active patients has an absolute increase of 5% from baseline.	38.5%	43.5%	1520	80%
Proportion of regular patients with a continuity of care score of ≥75% by care team increased by 10% from baseline	41.8%	51.8%	392	80%
Proportion of patients with type 2 diabetes with HbA1c <7% has an absolute increase of 10% from baseline	46%	56%	394	80%
Mean HbA1c difference equal to 0.5%	7.4%	6.9%	253	80%
Proportion of patients at high absolute risk of cardiovascular disease decreased by 10% and 5% from baseline*	25.3%	15.3% 20.3%	256 1107	80%
Rates of potentially preventable hospitalisations and emergency department presentations†	3.8% 8.0%	1.8% 6%	1070 2557	80%

Estimates based on data pooled from both intervention sites.
*Baseline estimates for CVD risk from ref.[42]
†Age-adjusted potentially preventable hospitalisation rates from ref.[36]
HbA1c, glycosylated haemoglobin.

continuous HbA1c (eg, from 7.4 baseline to 6.9 at post-implementation, at a 5% level of significance) using an independent samples' t test. The sample size required to detect the same difference will be smaller with a paired sample t test, for example, assuming a precoefficient and postcoefficient of correlation of 0.2, the sample size goes down to 200 clients per time point.

The sample size for qualitative interviews with patients will be determined through the course of data collection. Recruitment will cease when sufficient numbers of participants have been interviewed to reach data saturation.

Data linkage

For linkage of survey data to clinic health record data, deidentified survey data with a unique code and linkage key will be sent as a secure encrypted file to IUIH data custodians. Linkage of clinic health record data to secondary care data (hospital admission and emergency department data) and death registration data will be performed by the Statistical Services Branch, Queensland Health, subject to data custodian approval (in progress).[38] Linkage is performed by deterministic and probabilistic methods and/or the Master Linkage File, as appropriate to the in-scope cohort.

The data sets which will be linked for this study include the following:

Queensland hospital-admitted patient data collection: data for all admitted patients from public and private hospitals, and day surgery units within the state, including their date of admission and separation, primary diagnosis/other diagnoses (International Classification of Diseases [ICD] 10 codes), procedures, discharge destination, facility type as well as basic demographic and geographical information.

Emergency department minimum data collection: data for all patients presenting to emergency departments in Public Hospitals in Queensland, including their presentation/triage/discharge date and time, triage category, arrival transport mode, visit type, principle diagnosis/other diagnoses (ICD 10 codes) and other basic demographic and geographical information.

Death Registration Data (for censoring only): includes all death registrations in Queensland.

Patient and public involvement statement

This research represents an Aboriginal led and governed partnership between community, service providers and researchers, seeking to respond to identified community priorities. The project has been initiated by and is embedded in IUIH, a community-controlled health service. Community governance and ownership of IUIH have practical expression through a board of directors that combines community-elected and independent skill-based directors, underpinned by a community accountability framework, centred on the principle that decision-making should occur at the closest level possible to clients, families and communities.

Statistical analysis

Health record and survey data will be analysed at the individual patient level. Primary, secondary and quantitative process outcomes derived from electronic health record data and linked hospital data will be summarised using descriptive statistics at 3years prior to implementation (baseline), following the implementation phase, then at 12 monthly intervals for the follow-up period. Bivariate and regression analyses will be used to examine differences between cohorts for baseline characteristics and to quantify changes in primary and secondary outcome from pre-implementation to post-implementation of ISoC2, between intervention and standard care sites. Data allowing, multilevel (random-effects) or interrupted time series analysis will be used to quantify changes in outcomes over time (at minimum baseline and post-implementation) and to compare outcomes

between intervention and randomly matched control (standard care) participants. Models adjusted for covariates (minimally age and sex, additional other sociodemographic and health characteristics) will be used to determine ORs and CIs for the association of ISoC2 with outcomes. Similar analyses will be conducted for self-reported data collected through surveys, comparing differences between intervention and matched MK survey controls, and changes between baseline and follow-up responses. Qualitative interviews with staff will be analysed using The Framework Analysis, a method of qualitative data analysis that begins deductively from predefined objectives and is explicit and informed by *a priori* reasoning.[39] Interviews with patients will be analysed using Interpretative Phenomenological Analysis, a method that describes how a person experiences their world.[40]

Economic analysis

The economic component of the study will include two types of economic analysis: cost consequence analysis and cost-effectiveness analysis (CEA). Both analyses will take a perspective from the Australian Government Department of Health, and the time horizon used in this study will be 2 years to capture the changes of chronic conditions. All the direct costs related to the management of a patient's condition will be included: consultations with GPs or other health workers, diagnostic tests, pharmaceuticals, hospital inpatient admissions and emergency department admissions. The consultation costs will be estimated using the Medicare Benefits Schedule and the Pharmaceutical Benefit Scheme (for medications funded under Medicare) will be used to estimate the pharmaceutical costs. All the costs for hospital admissions will be estimated using Australian Refined Diagnosis Related Groups. Costs will be measured in 2025 Australian dollars and 3.5% discounting rate will be applied. Clinical outcomes in the CEA will be outcome measures that demonstrate a clinically significant improvement in the intervention group. The cost difference per patient and proportion of per achieved outcome will be calculated with a 95% CI between the standard care and intervention (ISoC2). The incremental cost-effectiveness ratio with a 95% CI will be estimated using non-parametric bootstrap (1000 replications) methods and the simulation results will be graphed on a cost-effectiveness plane. The cost-effectiveness acceptability curve will be drawn to summarise the impact of uncertainty on the results.

ETHICS AND DISSEMINATION

Consent

Prior, free and informed written consent will be enacted throughout the study.[41] All materials for the conduct of the study (staff interview and yarning guides, surveys, client information and consent forms) have been codesigned with the steering committee providing cultural and clinical oversight of the study. Participants for survey (clients) and interviews (clients and staff) will be provided with a plain-language information sheet about the study along with a consent form. Participants may choose to withdraw at any time during the study. Survey participants have specifically consented for linkage of survey data to routinely collected health data and for health and wellbeing research (subject to approvals by the MK Aboriginal and Torres Strait Islander governance committee). A waiver of the requirement for consent has been obtained for secondary use of routinely collected deidentified health data (electronic health record and linked hospitalisation data) for intervention and standard care sites.

Ethical approval for the study was obtained from the University of Queensland Human Research Ethics Committee (2021/HE000529).

Dissemination

Research findings will be disseminated using IUIH's existing communication strategies and those developed specifically for this study. This includes: to patients and the broader community through social media, brief yarns with existing patient groups and infographics in the form of posters and flyers; to staff through internal websites in the format of articles, short presentations and webpage for project updates; formal dissemination through conference presentations and publications in peer-reviewed journals; and seminars and roundtables with policymakers and peak bodies to share findings relevant for the broader PHC policy and practice context.

DISCUSSION AND IMPLICATIONS

This study reflects the aspirations and obligation of ACCHS in South-East Queensland to build the evidence base for high-quality PHC able to meet the needs of rapidly growing urban Aboriginal and Torres Strait Islander populations. Building from the foundations of a pilot study, this research incorporates a process, outcome and economic evaluation of a model of PCMH in an ACCHS setting in Australia derived from international best evidence and adapted to local context to optimise its acceptability, feasibility and effectiveness. The study has been powered to detect a difference in clinical outcomes shown to improve with successful implementation of a PCMH.

This study is anticipated to be of direct benefit to Aboriginal and Torres Strait Islander people living in South-East Queensland through strengthened relational care and improved access to high-quality, comprehensive and culturally responsive PHC. The knowledge, learnings and evidence from this study are likely to be of public benefit through contributing new knowledge to inform policy and service delivery in the broader Australian PHC sector. If ISoC2 can be successfully implemented and demonstrates a good return on investment, this will represent an Indigenous designed and implemented, culturally safe and cost-effective model of PCMH transferable for trialling in settings in the broader context–within Australia and globally.

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