**Full Study Title:**  Connection and Kinship: Culturally Safe and Responsive Care for Aboriginal and Torres Strait Islander Children and Families

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**Background:**

There remains a significant gap in health outcomes for Aboriginal and Torres Strait Islander children, driven by social determinants of health including ongoing inequity in access to health care. One in five Aboriginal and Torres Strait Islander children live with disability, including sensory (12%), cognitive (9%), physical (5%) and psychosocial (4%).1 Access to early intervention and multidisciplinary supports is necessary to improve health outcomes and decrease the risk of perpetuating disadvantage and inequities across the lifespan.2, 3 Intergenerational trauma, forced assimilation, loss of culture, discrimination, exclusion and racism all impact health2 and social and cultural factors are known to impact service use, with a lack of cultural awareness and cultural safety within services deterring service use. Engaging with community to design health services, appropriate cultural training of non-Aboriginal and Torres Strait Islander staff, 2-4 and employment of more Aboriginal and Torres Strait Islander staff leads to culturally safe care, thereby increasing service utilisation and therefore health outcomes.2-5

Aboriginal and Torres Strait Islander children continue to have lower access to health services than other Australians and have increased complexity in care with coordination across multiple services. Failure to provide service to Aboriginal and Torres Strait Islander children and families is due to multiple barriers such as: experiences of institutional racism and discrimination; loss of connection to country and kinship circles; barriers relating to extra costs involved; health services that aren’t culturally safe and responsive; lack of access to transport, and distance. Despite attempts to address health inequities in Paediatrics services at TPCH by triaging all Aboriginal and Torres Strait Islander children as Category 1 priority patients, failure to provide rates (including failure to attend, cancellations and reschedules) are disproportionally high. For example, between August 2023 and February 2024, the failure to provide care rate for Aboriginal and Torres Strait Islander children in Paediatric Psychology outpatients department (OPD) (31.6% of appointments), was 25% higher than that experienced by other children. 100% of Category 1 referrals for Paediatric Psychology OPD have breached the clinically recommended waiting time, with an average wait time of 230 days (recommended timeframe is 30 days). These access equity issues persist across the lifespan, with the December 2022 TPCH OPD data demonstrating a statistically significant difference in failure to attend rates between Aboriginal and Torres Strait Islander consumers and non- Aboriginal and Torres Strait Islander consumers (11.84% vs 5.49%; p<0.001), and appointment cancellations (16.6% vs 13.9%, p<0.001).

Failure to provide service to children and families is a systemic issue that requires immediate targeted, flexible, responsive, integrated and culturally safe solutions. Implementation of cultural roles with Aboriginal and Torres Strait Islander staff have helped in other services, and we have an opportunity to translate this to a complex and multisystem cohort of children and their families at TPCH. The aim is to develop, implement, and evaluate a culturally safe, scalable and sustainable MoC which incorporates an Aboriginal and Torres Strait Islander health worker role embedded in Paediatrics OPD. This role will provide a central point of communication, engagement and coordination for all stakeholders to facilitate engagement and care for Aboriginal and Torres Strait Islander Families. We expect that the cultivation of enhanced relationships/partnerships with Aboriginal and/or Torres Strait Islander families and communities will result in improved access to appropriate services within clinically recommended timeframes, reduced metrics of failure to provide care including failure to attend and cancellation rates, and improved patient-reported experience of the service, leading to improved patient outcomes. This project addresses strategic priorities of Closing the Gap 6, 7 and Putting Queensland Kids First,8 and builds on and extends the literature into the benefits of Aboriginal and Torres Strait Islander health workers5 and Aboriginal and Torres Strait Islander clinician researchers in improving health service outcomes. 9, 10, 11

**Study Aims:**

The aims of this project are to:

1. Partner with consumers and community to identify the barriers experienced by Aboriginal and/or Torres Strait Islander families referred to TPCH Paediatrics OPD in accessing care
2. Partner with consumers and the community to design an Aboriginal and Torres Strait Islander health worker position and care pathway for Aboriginal and/or Torres Strait Islander children referred to TPCH Paediatrics OPD in order to overcome the identified barriers to accessing care
3. Implement the new health worker position and model of care into the paediatric outpatient services
4. Evaluate the new model of care pre- and post- implementation on key implementation, consumer, staff, and service-level outcomes
5. Develop a sustainability plan based on the outcomes of the project

**Hypotheses:**

When comparing to standard care (pre-implementation), the new Model of Care (post-implementation) which includes a new care pathway and Aboriginal and Torres Strait Islander health worker position will have:

1. Higher levels of satisfaction and acceptability among stakeholders, including consumers, staff, and the community.
2. Significantly lower mean wait times; and significantly fewer missed appointments, cancellations and reschedules.
3. PROMS scores on clinical outcome measures and experience measures that are equivalent to or better than standard care (non-inferior).
4. The new MOC will be more cost-effective.

**Expected Outcomes:**

It is expected that by implementing a new care pathway and Aboriginal and Torres Strait Islander health worker role in the model of care pathway for Aboriginal and/or Torres Strait Islander children referred to the TPCH Outpatient service:

1. The new MOC will be acceptable to all stakeholders including consumers, staff and community with high levels of satisfaction
2. The new MOC will provide more rapid access to treatment compared to standard care, and will result in reduced failure to provide care metrics (failure to attend, cancellations, reschedules, seen within clinically recommended time)
3. The new MOC will have equivalent or improved clinical outcomes (ie. PROMS measures related to child health and wellbeing, parenting stress and parenting efficacy)
4. The new MOC will be cost effective compared to standard care

**Study Design:**

Single site, multiphase, mixed methods pre-post evaluation of a new model of care for Aboriginal and/or Torres Strait Islander children and families accessing TPCH Outpatient Service. Pre-implementation (Standard Care) activities include; (i) retrospective analysis of patient reported experience and outcome measures and service-level data (ii) prospective patient reported experience and outcome measures and service-level data, experience questionnaires and yarning circles with consumers and Community Elders, and semi-structured interviews with staff to determine barriers to care and to design the Aboriginal and Torres Strait Islander health worker role and care pathway. Implementation phase activities include a repeat of data collection, semi-structured interviews and yarning circles to measure the impact of the service change. Implementation science methodology will be utilised throughout, with service level, stakeholder satisfaction and consumer outcomes data to be evaluated and disseminated as per the evaluation strategy.

Historically, research involving Aboriginal and/or Torres Strait Islander peoples has been conducted by non-Indigenous people and has not been a positive experience for many Aboriginal and Torres Strait Islander communities. Therefore this project focusses on six core values that should underpin all Aboriginal and Torres Strait Islander research; responsibility, reciprocity, respect, spirit and integrity, equity and cultural continuity – and the project methodology was developed with these values at the fore 12, 13 to ensure community control and that the research is community driven. 14

**Participants:**

Consumers (children and their carers) attending the Prince Charles Hospital Paediatric Outpatient service since January 2024 until the completion of the project; and consumers who identify as Aboriginal and/or Torres Strait Islander origin of who respond to our EOI for engagement in yarning circles and questionnaires are participants in this study.

Aboriginal and/or Torres Strait Islander Community Elders who have experience with services at TPCH, or family members with experience with the Paediatric service at TPCH who respond to our EOI are participants in this study.

All Paediatric Services MDT members and TPCH Executive (Executive, Medical, Nursing, Administrative, Health Practitioners, Clinical Assistants, and Indigenous Hospital Liaison Officers) employed by the Prince Charles Hospital at the time of data collection will be eligible to participate in this project.

**Inclusion and Exclusion criteria:**

There are no additional inclusion or exclusion criteria other than those described in the Participants section.

**Community Engagement and Codesign:**

This project is co-designed with community from inception and throughout. This project was first conceived out of a project being undertaken in the TPCH Paediatric Service to develop an Allied Health Led Model of Care. This model of care was co-designed with consumers and staff, including Aboriginal and Torres Strait Islander families. The data from this project showed that the failure to provide care rate for Aboriginal and Torres Strait Islander children was much higher than for other children. Our staff and consumers told us that the solution was to develop a new pathway and health worker position to support families and children to access care. Importantly, it is essential that this new care pathway and position be co-designed with community, so that we do not perpetuate the tendency in our health services to impose a “Western” solution. In developing the protocol for the project we have consulted with community both formally and informally through various means including 1:1 yarns and through presentations such as to our community elders and hospital executive as part of the Our Journey Towards Health Equity Funding round. Formal co-design activities in the developing the protocol has included our consumer researcher (DA) coming onboard early in the process to work together to develop the protocol, co-design strategy and materials for the project (eg. such as the yarning circles and questionnaires). A yarning circle with our community elders also co-designed the consumer engagement strategy alongside our project team and our Aboriginal and Torres Strait Islander Health Service team and drove many important considerations within our protocol. For example, all activities that involve engaging with community to codesign the new position and care pathway as led by our Cultural Capability team to ensure safety for our consumers and Elders. In our protocol elders do not complete formal questionnaires, instead they are asked some questions verbally before and after the yarning circle and these are inputted by a member of our Cultural Capability Team to reduce burden. Elders highlighted the importance of considering Men’s and Women’s Business in co-design yarning circles, and the important of including and empowering Uncles also in developing services that relate to children. For this reason we will provide options for our Elders who participate in the project as to whether they would like to attend a yarning with only men, only women, or mixed. Our Elders will be supported by our Cultural Capability team in completing consent forms to ensure true informed consent. In addition to our project team, which includes our Consumer researcher (DA), four community Elders are members of a monthly project meeting and will continue to follow the project through all phases. We expect this membership to grow over time. Also we have committed to provide regular updates to our community throughout the project by attending community forums and events. Our participants will be able to access aggregated findings when we present at forums, events, on request and also via the resulting publications of the research.

**Data Collection:**

The protocol was developed to take a participatory action approach with community.15 Ethics approval is sought to access standard care data already collected as part of the Paediatric Outpatient service pre- and post-implementation with a waiver of consent. TPCH data custodian approval to access patient data available through the medical record will also be sought. Informed consent will be sought via a patient information and consent form for all for consumer, community and staff member participatory research activities (questionnaires, yarning circles, semi-structured interviews). Table 1 outlines the evaluation plan with data sources. A scoping review of similar models to inform implementation as well as scoping other services with similar pathways to gather learnings and develop collaborations will be early activities of the project. Furthermore, while the research design described here was developed with our consumer researcher (DA), community elders as part of a codesign yarning circle, and the Aboriginal and Torres Strait Health Services team, further consultation with community as part of the codesign methodology will result in appropriate adaptations to the project activities to ensure community control and that the research is community driven.14 Any updates to the protocol that arise from these activities will be submitted as an amendment to the HREC for approval.

*Pre-implementation activities (July 2024-approx December 2024)*

Baseline Standard Care data will be collected from the patient record for consumers attending the Paediatric service for one year prior to the service change (ie. from January 2024) and until completion of the project (June 2026). This will include patient and family demographic information such as age, sex, gender identity, postcode, family composition and patient presenting complaint/s will be obtained from the medical record and The Viewer. Standard PREMS and PROMS are currently collected in Paediatric outpatients via RedCap as part of standard care will also be collated, as will TPCH paediatric outpatients PREMS which will be sought from TPCH Safety and Quality team. Data collected via the TPCH outpatient PREMS for children from January 2024 will be filtered for first nations status by the Safety and Quality team before being provided to the project team. A list of all questions currently collected as part of Standard Care are presented in Appendix I along with a description of each measure. The TPCH PREMs Paediatric outpatient survey is presented in Appendix II. Service level data such as failure to provide care/FTA rates and long wait data will be collected from Statewide Management Information System (SWMIS) and Power BI.

Consumer Questionnaire

A questionnaire and yarning circles with consumers (carers) will be undertaken to determine barriers to care and to design the health worker role and care pathway. The questionnaire will be sent to all consumers of the Paediatric outpatient service at TPCH with Aboriginal and/or Torres Strait Islander origin identified in the clinical record who attended the service from January 2024 to the conclusion of the project. This information will be extracted from the clinical record. The contact person/carer for each child will be emailed with information about the project and a link to a Participant Information and Consent Form (PCIF) for the project (see PCIF - consumer pre - v1). See Appendix III for email script to consumers. Consumers will be offered the option to complete the questionnaire on a paper copy also if this is their preference, in which case they will be mailed a copy with a reply paid envelope or provided a hard copy at their outpatient clinic appointment. A member of the project team will offer support to complete the questionnaire, and will provide this support if that is what the consumer indicates they want. Consenting consumers will then be directed to a RedCap questionnaire, or the paper version,exploring their barriers to care, along with background demographic information will be collected for each participant including age, sex, gender identity, postcode, family composition and reason for attending the service, and paediatric team members engaged with. This questionnaire is presented in Appendix IV. It is expected the questionnaire will take no longer than 20 minutes to complete. At the end of the questionnaire, all participants will be asked if they would like to be contacted to participate in the pre-implementation yarning circles. If the participant indicates their interest, their name and email address will be collected as part of this process. This contact information will not be linked to their questionnaire responses, nor will demographic information collected as part of the yarning circles. Consumers will have the option to complete the questionnaire only, the yarning circle only, both, or neither.

Consumer Yarning Circles

Participants responding to the questionnaire and/or indicating an interest to participate in yarning circles will be contacted by a member of the research team to participate in this project activity. In addition, an Expression of Interest (EOI) will be developed with support from the TPCH Cultural Capability team and the TPCH Safety and Quality Unit and will be disseminated via the Safety and Quality and Cultural Capability team consumer networks as well as Aboriginal and Torres Strait Islander Leadership Communications and Planning Team. Based on empirical data on the sample size required to reach saturation for thematic analysis, approximately four yarning circles with four participants each will be sought.16, 17 Verbal and written consent will be gained prior to the commencement of the yarning, (PCIF - consumer pre - v1). At the beginning of the yarning circle, non-identifying background demographic information will be collected for each participant including patient and family demographic information such as age, sex, gender identity, postcode, family composition, reason for attending the service, and paediatric team members engaged with. The yarning circle will then commence. The yarning circle guide is presented in Appendix V. The yarning circles will be conducted either in-person (preferred method), or via MS Teams. The yarning circles will be facilitated by Cultural Capability Officer and project team member Rebeckah Mooney with support from other members of the project team as needed. They will be recorded and transcribed verbatim. Yarning circle participants will be asked open questions about the barriers to care and their needs in developing strategies through a care pathway delivered via an Aboriginal and Torres Strait Islander health worker role. Yarning circles will last for approximately 90 minutes. At the conclusion of the yarning circle, consumers will complete three brief four item questionnaires asking about their perception about the acceptability of this service change, and the appropriateness of the service change, and the feasibility of the service change. The responses to the pre yarning circle questions and post yarning circle questions will be completed either electronically (RedCap) or paper format depending on the participant’s preference.

Community Elders Yarning Circles

An Expression of Interest (EOI) will be developed with support from the TPCH Cultural Capability team and the TPCH Safety and Quality Unit and will be disseminated via the Safety and Quality and Cultural Capability team consumer networks as well as Aboriginal and Torres Strait Islander Leadership Communications and Planning Team. Based on empirical data on the sample size required to reach saturation for thematic analysis, approximately four yarning circles with four participants each will be sought.16, 17 Verbal and written consent will be gained prior to the commencement of the yarning, (PCIF – elders pre - v1). At the beginning of the yarning circle, non-identifying background demographic information will be collected for each participant including patient and family demographic information such as age, sex, gender identity, postcode, engagement with the service (if any), and Paediatric Services team members engaged with. The yarning circle will then commence. The yarning circle guide is presented in Appendix VII. The yarning circles will be conducted either in-person (preferred method), or via MS Teams. The yarning circles will be facilitated by Cultural Capability Officer and project team member Rebeckah Mooney with support from other members of the project team as needed. They will be recorded and transcribed verbatim. Yarning circle participants will be asked open questions about the barriers to care and their needs in developing strategies through a care pathway delivered via an Aboriginal and Torres Strait Islander health worker role. Yarning circles will last for approximately 90 minutes. At the conclusion of the yarning circle, consumers will complete three brief four item questionnaires asking about their perception about the acceptability of this service change, and the appropriateness of the service change, and the feasibility of the service change.18 The responses to the pre yarning circle questions and post yarning circle questions will be completed either electronically (RedCap) or paper format depending on the participant’s preference.

Consumers and Elders will be reimbursed for participation in yarning circles as per the Metro North Partnering with Consumers – reimbursement and payment procedure.

Staff questionnaire

All MDT team members of the Paediatric Service along with TPCH Executive Team members relevant to the Paediatric service (eg. Executive Director; Director of Operations, EPIC; Director of Allied Health) will be emailed with information about the project and a link to a Participant Information and Consent Form (PCIF) (see PCIF – staff questionnaire pre - v1). See Appendix VIII for email script to staff. For consenting participants, a RedCap questionnaire will be provided. The staff questionnaire which will explore barriers to care and satisfaction with the service, perception of acceptability, appropriateness and feasibility of the service change, and basic non-identifiable demographic information will be collected from respondents including sex, profession, and time working in the TPCH paediatrics service. This questionnaire is presented in Appendix IX. It is expected the questionnaire will take no longer than 20 minutes to complete. At the end of the questionnaire, participants will be asked if they would like to be contacted to participate in staff semi-structured interviews. If the participant indicates their interest, their name and contact details will be collected as part of this process. Demographic information collected as part of the interviews will not be linked in any way within their questionnaire or semi-structured interview responses.

Staff semi-structured interviews

Semi-structured interviews will be undertaken with staff who have indicated that they would consent to a follow-up interview. Staff will be selected by the investigators to ensure a purposeful sample is achieved (e.g. across individual professions) to ensure a breadth of data that is representative of the broader population. Interviews will be conducted either 1:1 or as a focus group (maximum n=6 per group), based on the suitability/availability of eligible staff. It is expected that 1:1 interviews will take approximately 20 minutes, while focus groups may take upwards of 1 hour. Participants will be asked open questions about the barriers to care for Aboriginal and/or Torres Strait Islander children and families, and will seek ideas on strategies to overcome these barriers through a care pathway delivered via an Aboriginal and Torres Strait Islander health worker role. The semi-structured interview guide is presented in Appendix X. Aboriginal and/or Torres Strait Islander staff will have the option also to complete the interview/focus group in a yarning format if they prefer. Basic non-identifiable demographic information will be collected from respondents including sex, profession, and time working in the TPCH paediatrics service. Interviews will be conducted either in-person (preferred method), or via MS Teams. All interviews will be recorded and transcribed verbatim.

Refinement and endorsement of health worker role and care pathway will follow from the pre-implementation activities, led by the CI and AI team with ongoing consultation with community via the Cultural Capability team with a view to long term sustainability. The developed care pathway and role description will be endorsed by the Aboriginal and Torres Strait Islander Leadership oversight committee and presented to community for final consultation before implementation.

*Implementation activities (approx January 2025-December 2025)*

Implementation of the care pathway and health worker role will occur following recruitment to the role with an approximately 9 to 12-month trial period. The impact of the service change will be measures via ongoing collection of patient reported experience and outcomes data and service level data (Appendix I & Appendix II), a post-implementation consumer questionnaire (Appendix XI) and yarning circles (Appendix XII) to elicit feedback on the care pathway and further suggestions refinements needed, and to strengthen the sustainability plan. As per the pre-implementation phase, the consent and contact measures will follow the same processes (PCIF - consumer post - v1). Similarly, Elder groups yarning circles will be undertaken (Appendix XIII) with informed consent gained (PCIF – elders post - v1). Staff questionnaire (Appendix XIX) and semi-structured interviews with staff (Appendix XX) to elicit feedback on benefits of pathway and to strengthen sustainability plan PCIF – staff questionnaire post - v1). These staff activities will include the new Aboriginal and/or Torres Strait Islander staff member with their data included with the aggregate staff data to ensure anonymity of their responses. The aim of these implementation activities is to demonstrate the acceptability, sustainability, and appropriateness of model with aim of securing recurrent funding.

*Evaluation Activities (approx. October 2025-June 2026)*

The impact of the service change will be assessed with reference to Ngaa-bi-nya Aboriginal and Torres Strait Islander program evaluation framework across domains of landscape, resources, ways of working and learnings12, 13 as well as Implementation and Evaluation Outcomes 19-22 which will allow evaluation across implementation, service and consumer outcomes (see Table 1). A full service evaluation will be undertaken including economic analysis using a cost utility approach to determine whether the model of care is cost-effective, taking into consideration costs and QALYs. The results of the trial will be disseminated to TPCH leadership and broader Metro North stakeholders with the aim of demonstrating the sustainability of the health worker position and care pathway to secure recurring funding.

*Table 1. Evaluation Plan*

| **Evaluation Question** | **Domain** | **Indicator/Measure** | **Ngaa-bi-nya evaluation framework** | **Data Source** | **Pre-Post Implementation** | **Consent****Standard Care or Consent via PCIF** |
| --- | --- | --- | --- | --- | --- | --- |
| ***Implementation Outcomes*** |  |
| *Is the new care pathway and health worker position acceptable to all stakeholders (patients, elders, staff)?*  | **Acceptability – Stakeholders’ perceptions that implementation target is agreeable, palatable or satisfactory** | Acceptability of Intervention Measure (AIM)18 indicates that the co-designed position and care pathway is acceptable to stakeholdersConsumer, Elder and Staff interviews/yarning circles and questionnaires indicate acceptabilityConsumer PREMS indicate the new model of care is acceptable | Respecting the landscapeWays of workingLearnings | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff interviewStaff questionnaireStandard Care PREMS | Pre-implementation & Post-implementation | Consent via PCIFConsent via PCIF Consent via PCIFConsent via PCIFConsent via PCIFStandard Care (Waiver) |
| *How effective was the model of care in increasing stakeholder engagement?* | **Adoption (uptake) – Intention, initial decision or action to employ model of care by service settings** **(proportion and representativeness)** | Pathway and position are implementedStaff indicate Aboriginal and/or Torres Strait Islander children have accessed the pathwayConsumers indicate they have accessed the pathwayDemographic characteristics of consumers accessing pathway vs those who do not | Learnings | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff questionnaireMedical record | Post-implementation | Consent via PCIF Consent via PCIFConsent via PCIFConsent via PCIFStandard Care (Waiver) |
| *Is the new care pathway and health worker position appropriate to our service?* | **Appropriateness – Perceived fit, relevance or compatibility of implementation target for given context/fit for a problem**  | Intervention Appropriateness Measure (IAM)18 indicates that the co-designed position and care pathway is acceptable to stakeholdersConsumer, Elder and Staff interviews indicate acceptability | Respecting the landscapeWays of workingLearnings | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff interviewStaff questionnaire | Pre-implementation & Post-implementation | Consent via PCIF |
| *Was the model cost effective?* | **Cost – financial impact of implementation effort. V**alue for money obtained by the organisation - relates to both the costs and outcomes of the model | Economic analysis using a cost utility approach to indicates the model of care is cost-effective, taking into consideration costs and QALYs. QALY calculations as a measure of cost-effectiveness of the ‘new’ model of care compared to the ‘old’ model of standard care indicate the model is cost effective | Resources | Consumer standard care questionnairesMedical recordService level data (eg SWMIS and Power BI) | Pre-implementation & Post-implementation | Standard Care (Waiver) |
| *Is the new care pathway and health worker position feasible to implement and integrate into our service?* | **Feasibility – Extent to which an implementation target can be successfully used in a given setting** | Feasibility of Intervention Measure (FIM)18 indicates that the co-designed position and care pathway is feasible to implement Consumer, Elder and Staff interviews indicate feasibility | Resources | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff interviewStaff questionnaire | Pre-implementation | Consent via PCIF |
| *Was the model was delivered as intended?* | **Fidelity – Degree to which an intervention was implemented as intended** | % of components of model of care delivered as per co-designed model endorsed prior to implementation Differences in % of model of care elements delivered as per protocol per outpatient clinic and patient characteristics  | Ways of working Learnings | Medical recordService level data (eg SWMIS and Power BI) | Post-implementation | Standard Care (Waiver) |
|  | **Penetration – integration or saturation of an intervention into service setting and it’s subsystem** | Ratio of those to whom the intervention is delivered divided by the number of eligible or potential recipientsEvidence of scale and spread of similar models across other services internal and external to the health providerPercentage of patients referred to care pathway who were eligible for pathway | Ways of working Learnings | Medical recordService level data (eg SWMIS and Power BI) | Post-implementation | Standard Care (Waiver) |
| *How sustainable is this model of care, how well can the model of care continue to operate into the future?* | **Sustainability – Extent to which an implementation target is maintained or institutionalised within the service setting** | Percentage of components of model still operating 6 months post completion of the studyDescription of which components of the model are still operating 6 months post completion of the studyDemand for the service – number of patients engaged with new pathway and roleProgram Sustainability Assessment Tool (PSAT-SF v2) 23, 24 sustainability measure indicates organisation impression of sustainability of model of care | Ways of workingLearnings | Staff questionnaireMedical recordService level data (eg SWMIS and Power BI) | Post-implementation | Consent via PCIFStandard Care (Waiver)Standard Care (Waiver) |
| ***Service Outcomes*** |  |
| *How effective was the model of care in achieving its intended outcomes?* | **Effectiveness** | Average number of occasions of Service under ‘old’ model compared to ‘new’ model of care Reduced Failure to Provide care appointment metrics under ‘new’ model compared to ‘old’ model of carePercentage of new patient activity under ‘old’ model compared to ‘new’ model of care Reduced average wait-time to access a first appointment under ‘new’ model compared to ‘old’ model of careReduced average time to discharge from first appointment to final appointment under ‘new’ model compared to ‘old’ model of careIncreased percentage of patients discharged to community care under ‘new’ model compared to ‘old’ model of care | Respecting the landscapeWays of working | Medical recordService level data (eg SWMIS and Power BI) | Pre-implementation & Post-implementation | Standard Care (Waiver) |
| *Did patients access care as expected under the new model of care?* | **Equity** | Failure to Provide care appointment metrics are comparable for non-identified children compared to Aboriginal and/or Torres Strait Islander children under ‘new’ model when compared to ‘old’ model of care | Respecting the landscapeLearnings | Medical recordService level data (eg SWMIS and Power BI) | Pre-implementation & Post-implementation | Standard Care (Waiver) |
|  | **Patient-centeredness and Safety** | Consumer, Elder and Staff interviews and questionnaires and Standard Care consumer PREMS indicate the new care pathway meet their needs and is culturally safeConsumer, Elder and Staff interviews and questionnaires provide learnings about further improvements required to position and care pathway | Respecting the landscapeWays of workingLearnings | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff interviewStaff questionnaireMedical recordStandard Care PREMS | Pre-implementation & Post-implementation | Consent via PCIF Consent via PCIFConsent via PCIFConsent via PCIFConsent via PCIFStandard Care (Waiver)Standard Care (Waiver) |
| ***Patient Outcomes*** |  |
| *Are all stakeholders (patients, elders, staff) satisfied with the new model of care?* | **Satisfaction** | Consumer, Elder and Staff interviews/yarning circles and questionnaires indicate satisfaction with the model of careConsumer PREMS indicate satisfaction with the new model of care  | Respecting the landscapeWays of workingLearnings | Consumer yarning circles Elder yarning circlesConsumer questionnaireStaff interviewStaff questionnaireStandard Care PREMS | Pre-implementation & Post-implementation | Consent via PCIFConsent via PCIF Consent via PCIFConsent via PCIFConsent via PCIFStandard Care (Waiver) |
| *Are patient outcomes non-inferior or improved for those accessing the new model of care?* | **Function and Symptomatology** | Consumer PROMS indicate non-inferiority or improved outcomes on key measures when comparing the ‘new’ model to the ‘old’ model (EQ-5D 25-27; MaaPS 28, 29) | Ways of workingLearnings | Standard Care PROMS | Pre-implementation & Post-implementation | Standard Care (Waiver) |

**Sample size:**

The sample size estimates for consumer and elder yarning circles are based on empirical data on the sample size required to reach saturation for thematic analysis, which is approximately 16 participants each – this will equate to approximately four yarning circles with four participants each.16, 17 A similar total sample size of 16 is sought for staff interviews/focus groups with up to six participants per group, although these interviews may proceed in smaller groups or 1:1. Based on current patient flow, we expect data from approximately 80 children of Aboriginal and/or Torres Strait Islander origin to flow through the service across the timeframe of the project from which PREMS/PROMS and questionnaire data will be sought. To calculate the sample size we used a medium standard effect size of 0.5 to assess median differences between two independent samples (pre- and post- implementation) using the non-parametric Mann-Whitney U-test. A target sample size of 70 (35 per group) achieves 80% power with a significance level of 0.05 (one-tailed) to detect differences between the groups, allowing a conservative 40% attrition. Sample size calculations were performed using G-Power version 3.1.9.7. 30

**Data Analysis:**

The project will employ a mixed methods approach. Measurement of Implementation and Evaluation Outcomes 19-22 will allow evaluation across implementation, service and consumer outcomes – with key outcomes measured pre-post implementation on Access; Value of Care (patient outcomes, patient experience, clinician experience); Ease of adoption/scalability (training and education, workforce, clear description of Model of Care); Sustainability 23, 24 and Efficiency (health care cost, equity, patient-centredness and timeliness), Feasibility, Acceptability and Appropriateness.18 Baseline data of existing paediatric service PREMs and PROMs and patient flow metrics (eg. failure to provide service rates, numbers on waitlist outside of clinically recommended timeframes, occasions of service) will measure pre-implementation 'standard care'. In developing the new care pathway and health worker position model of care, outcomes from pre-implementation stakeholder engagement (questionnaires, yarning circles and staff interviews) will be analysed via descriptive analysis using Microsoft Excel and/or IBM SPSS, and reflexive thematic analysis using NVivo.31 Post-implementation stakeholder engagement activities will also be analysed via descriptive analysis and reflexive thematic analysis. Reflexive thematic analysis is a method used to analyse qualitative data by identifying, organising, and interpreting patterns (themes) within the data. This approach emphasizes the importance of reflexivity, meaning researchers actively reflect on their own perspectives, biases, and assumptions throughout the analysis. Researchers are encouraged to be transparent about how their backgrounds, experiences, and positions (e.g., cultural, social, or professional) might influence the themes they identify and interpret, thereby enhancing the reliability and depth of the findings. To ensure a robust and culturally informed analysis, at least two team members will conduct the thematic analysis, including at least one or more members of team with Aboriginal and/or Torres Strait Islander background. The process will begin with the researchers selecting and familiarising themselves with three transcripts, followed by initial discussions to explore emerging themes. These transcripts will then be independently coded using reflexive, inductive analysis. Subsequently, all remaining transcripts will be independently coded, with an equal distribution of transcripts between team members. Regular reflective team meetings will be held to review each other’s codes, maintain consensus, and make minor modifications as needed. Themes will be further categorized into sub-themes, supported by exemplar quotes, to provide a detailed and nuanced understanding of the data. Patient flow characteristics (including wait times, access within clinically recommended timeframes, occasions of service) and clinical outcomes (PREMS and PROMS), will be comparing between the ‘standard care’ pre-implementation period as a pre-measure, and the (NEW) model of care as post-measure and analysed using IBM SPSS. Quantitative data measuring pre- and post- service change outcomes on key indices of patient service satisfaction, service characteristics (e.g., occasions of service); as well as referrer and staff service satisfaction, and engagement with the new position and care pathway, will be evaluated via univariate statistical tests where indicated such as independent samples t-test, and median differences on key measures pre- and post- implementation will be tested using the non-parametric equivalent Mann-Whitney U-test as indicated. The Mann-Whitney U-test does not rely on the normal distribution of data, making it suitable for a wider range of data types, including ordinal data. Categorical comparisons will be evaluated using Pearson’s chi-square.  The distribution of outcome measures will be assessed, and appropriate transformations will be applied for use in modelling. Differences between group means will be tested using generalised linear regression modelling. Throughout the implementation phase, consumer and stakeholder feedback will be collected to assess acceptability/experience, inform decision making regarding iterative refinement of the model of care and to enhance outcomes. A brief health-related quality of life measure EuroQol-5 25,27 is already completed as part of standard care PROMS within the Paediatric Outpatient service (Appendix I) and will allow preliminary health economics evaluation by performing quality-adjusted life year calculations as a measure of cost-effectiveness of the service change compared to pre-implementation, taking into consideration costs and QALYs. The objective is to capture all service events, clinical outcomes and quality of life changes for patients referred pre- and post- service change in order to perform a full evaluation including a cost effectiveness analysis.

**Data management:**

The research team will follow the Metro North HHS research data storage and access, privacy guidelines and policies. Questionnaires (via RedCap) will be exported into a password-locked Excel spreadsheet. Spreadsheets will be securely stored on a Queensland Health network. Only members of the research team will have access to the secure files. All data extracted from questionnaires, yarning circles, semi-structured interviews, and standard care PREMS and PROMS will be deidentified (ie. removal of patient name, URN, date of birth) before being exported into a password-locked Excel spreadsheet, and securely stored on a Queensland Health network. Questionnaire respondents that provide their name and contact details for the purposes of the follow-up yarning circles/semi-structured interviews will be removed and stored in a separate password protected Master File prior to data analysis. As per the participant consent forms, participants can withdraw their consent to participate in the project. However if they withdraw after completion of the activity (eg. questionnaire/yarning circle/interview) their individual responses cannot be removed from subsequent data analyses as the information they provided is deidentified. Interviews/yarning circles (whether conducted face to face [preferred method] or online will be recorded on Microsoft Teams with the video off and auto-transcribing enabled by a member of the research team who has a Queensland Health Microsoft Teams account using a Queensland Health computer. The audio recording be immediately moved to the secure Queensland Health Network only accessible by the project team via a Queensland Health computer for subsequent transcription and analysis. The original recording on Teams will be then permanently deleted.  Any information collected on paper forms (eg. consumer and elder yarning circles) will be scanned and saved and documents password protected on a secure Queensland Health network. The original paper form will be professionally shredded. No hard copy information will be retained. In accordance with the Health Sector (Clinical Records) Retention and Disposal Schedule, data will be retained until the children who flow through the study are 18 years of age, and for a minimum of 15 years from completion of clinical research/trial or after date of publication or termination of the study. Beyond this time period, electronic data will be permanently deleted.

**Ethical Considerations:**

This study will be submitted to Metro North HREC for review and approval. The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research (2023),* the *CPMP/ICH Note for Guidance on Good Clinical Practice* and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and wellbeing of trial participants is respected.

*Waiver of Consent*

This project will seek informed consent for all active consumer and staff facing research activities including consumer and Elder questionnaires and yarning circle, and staff questionnaires and interviews. A waiver of consent is sought to collect standard of care data pre- and post-implementation in order to understand changes in PREMS and PROMS and service-level metrics such as failure to provide care rates. Whether the data is to be collected via informed consent or as a waiver of consent (standard care data) is presented in Table 1. With reference to the *National Statement on Ethical Conduct in Human Research (2023),* we believe this a waiver of consent to access standard care data is justified as:

a) involvement in the research carries no more than low risk to participants;

b) the benefits from the research outweigh potential risks/harm (negligible) of not seeking consent;

c) it is impracticable to obtain consent due to the size of the cohort, and also the likelihood of obtaining data that is not representative of the target population if this data were collected through consent via PCIF;

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;

e) there is sufficient protection of their privacy (see *data management*);

f) there is an adequate plan to protect the confidentiality of data (see *data management*);

g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via the *Dissemination* plan);

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled; and

i) the waiver is not prohibited by State, federal, or international law.

**Dissemination of results:**

The dissemination strategy is to present the results of the project to key stakeholders (e.g. clinicians, profession leads, directors) with an aim of demonstrating value and ensuring sustainability. The findings will also be published and reported via national conference presentations and at least four planned peer-reviewed manuscript publications: (1) protocol publication; (2) results of scoping review; (3) publication outlining experiences and outcomes from pre-implementation activities, (4) full implementation science evaluation paper. By sharing learnings, processes and skills through inservices, training and presentations to our other services and MDTs, we expect will lead to implementation and evaluation of similar/comparable service models in TPCH, and Queensland Health broadly.

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