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Exploring the Experiences of the Consent Process for Aboriginal and Torres Strait Islander People Having Cardiac Surgery and Participating in Medical Research: A Study Protocol

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Abstract

Background: Gaining informed consent is a critical step before any medical procedure, and before taking part in medical research. Cultural differences in concepts of health and healing, communication, language, and racism, can play a part in forming barriers to gaining informed consent for Aboriginal and Torres Strait Islander people. For Aboriginal and Torres Strait Islander people, a lack of informed consent can worsen distrust and contribute to continuing health disparities. This protocol describes a study aimed at providing a better understanding of informed consent experiences of Aboriginal and Torres Strait Islander people undergoing heart surgery and participating in research. This will be complemented by comparing those experiences to the ones of the clinicians and researchers who obtain informed consent from Aboriginal and Torres Strait Islander people.

Methods: The study will be conducted at the Fiona Stanley Hospital in Western Australia and Townsville University Hospital in Queensland. Participants will include Aboriginal and Torres Strait Islander patients undergoing cardiac surgery, clinicians of the cardiothoracic surgery team and medical researchers at both hospitals. Yarning will be used as an Indigenous research method to collect meaningful data from Aboriginal and Torres Strait Islander people undergoing cardiac surgery whilst semi-structured interviews will be conducted to explore Clinician's and researchers' experiences. Data from Aboriginal and Torres Strait Islander participant will be analysed following a cyclical approach to ensure Aboriginal and Torres Strait Islander voices are not lost during data interpretation. Inductive thematic analysis of data will be conducted to yield practical recommendations.

Conclusions: We present the protocol of a study that will inform the development of strategies to ensure that informed consent processes are culturally appropriate and guarantee Aboriginal and Torres Strait Islander people's right to self-determination. This will contribute to the provision of culturally safe healthcare services and promote the conduct of medical research that is ethical, safe and benefits Aboriginal and Torres Strait Islander people.

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Keywords

Aboriginal, Cardiac surgery, Cultural Safety, Informed Consent, Medical research, Torres Strait Islander

Obtaining informed consent is a critical step in the interactions between practitioners and patients that has ethical and legal implications (Quick, 2010). Informed consent requires a process of communication between the patient and practitioner that results in patient's understanding of the proposed procedure, including potential risks, benefits, and alternatives (Matiasek & Wynia, 2008). Academics have advised practitioners to improve communication with patients to ensure that they receive relevant information in a way that they are able to understand and are able to ask questions. This helps in increasing patient autonomy and self-determination, and ultimately help them to make an informed choice (Coulter & Dunn, 2002).

There is scarce knowledge on the extent to which Aboriginal and Torres Strait Islander people experience informed consent processes in a culturally safe way that promotes true understanding of the procedure/ research study they are consenting to, its risks and benefits. Specifically, few studies have explored how "informed" are Aboriginal and Torres Strait Islander peoples when they consent to undergoing a medical procedure or participating in medical research.

Informed Consent to Undergo Medical Procedures Among Aboriginal and Torres Strait Islander People

International studies conducted on the quality of informed consent before a surgical procedure suggest that in many cases physicians approach the informed consent process focusing on the obtention of the patient's signature but fail to communicate relevant information ensuring patients truly understand the procedure, its benefits, risks and alternative options (de Costa et al., 2021; Lühnen et al., 2018). This has been supported by research evidencing that in many cases patients do not recall receiving explanations about risks or discussion of alternative options (Brezis et al., 2008).

Appropriate communication and obtaining true informed consent for Aboriginal and Torres Strait Islander patients can be particularly challenging for non-Indigenous health practitioners who lack knowledge and understanding of the cultural health paradigms of Aboriginal and Torres Strait Islander people, their needs, and expectations. This clash

between Western and Aboriginal and Torres Strait Islander cultures and health understandings can result in Aboriginal and Torres Strait Islander people receiving health service delivery that does not incorporate Aboriginal and Torres Strait Islander peoples' values and beliefs (Davy et al., 2016; O'Brien et al., 2021). Previous studies have shown that there are differences between Western biomedical perspectives on informed consent, and those of Aboriginal and Torres Strait Islander people (McGrath & Phillips, 2008; Russell et al., 2005). For the Western biomedical model, autonomy is a privileged core value which underpins the legal and ethical prerequisite of informed consent (Beauchamp & Walters, 1982). For Aboriginal and Torres Strait Islander people values that honour the family unit and community relationships are core parts of individual and collective decision-making processes (Beauchamp & Walters, 1982). Research has shown that informed consent is a complex process involving the translation of both concepts and languages, Aboriginal and Torres Strait Islander people and non-Indigenous people working together, and communication occurring more than once (Fitzpatrick et al., 2016; Russell et al., 2005).

A study conducted among Aboriginal and Torres Strait Islander peoples undergoing cardiac surgery demonstrated that patients who were not psychologically prepared for the processes involved in cardiac surgery, were likely to suffer a loss of cognitive control, which can lead to poor consent processes, delayed recovery, post-operative complications and increased length of hospital stay (Lawrence et al., 2009). The term 'cognitive control' refers to an individual's ability to formulate and process events in terms of their spiritual beliefs and life experience. A loss of cognitive control is described by Aboriginal peoples as "being lost spiritually", "losing memory" or "not knowing where they're going" (Lawrence et al., 2009, p.8). Miscommunication regarding a surgical procedure and failure to obtain true informed consent can exacerbate Aboriginal and Torres Strait Islander peoples' distrust towards Western healthcare systems. This can perpetuate barriers to accessing surgical treatment in a timely manner and contribute to health disparities experienced by Aboriginal and Torres Strait Islander surgical patients.

Informed Consent to Participate in Research Among Aboriginal and Torres Strait Islander People

In Australia, colonising actions against Aboriginal and Torres Strait Islander people have included the conduct of unethical and harmful research practices (Stingemore, 2010). Non-Indigenous researchers collecting, interpreting, and analysing data has failed to consider Aboriginal and Torres Strait Islander priorities, perspectives and values (Walter, 2018). These practices have perpetuated discriminatory values, reinforced negative stereotypes and lead to further mistrust of health research (Bobba, 2019; Walter, 2018; Walter & Suina, 2019). As a consequence, peak bodies such as Aboriginal Community Controlled Health Organisations, the Australian Institute of Aboriginal and Torres Strait Islander Studies, the Lowitja Institute, Guunu-Maana (Aboriginal and Torres Strait Islander health program) and the National Health and Medical Research Council have advocated for the conduct of ethical research practices and have released guidelines emphasising Aboriginal and Torres Strait Islander leadership, participation and community-driven agendas (National Health and Medical Research Council 2018; National Health and Medical Research Council, 2018).

Despite more recent advances in the way in which research is conducted with Aboriginal and Torres Strait Islander people, racism, colonisation, whiteness, different ways of knowing being and doing can hinder comprehensive understanding of the risks and benefits of participating in a medical research study (Bobba, 2019; McGrath & Phillips, 2008). This is especially relevant in a context where non-Indigenous researchers invite Aboriginal and Torres Strait Islander people to participate in a study. In such contexts, it is important to recognise and reflect on power imbalances between researchers and potential research participants where the latter may be in more disadvantaged positions. This disadvantage is due to the lack of scientific knowledge in the research field by potential participants, demeaning attitudes and beliefs towards Indigenous knowledge systems and health paradigms (Bobba, 2019; Zion et al., 2000), government policies and ongoing colonisation (Sherwood, 2013). Ensuring self-determination through true informed consent to

participate in research requires facilitating equal relationships with Aboriginal and Torres Strait Islander participants that promote dignity, respect, and autonomy (Bobba, 2019). This requires consent processes to be adapted to the different cultural and spiritual values of Aboriginal and Torres Strait Islander peoples in order to ensure research participants have a comprehensive understanding of the risks, benefits and aims of studies before their recruitment (Bobba, 2019; McGrath & Phillips, 2008).

In addition, although Aboriginal and Torres Strait Islander people are disproportionally affected by chronic conditions, they are underrepresented in clinical trial research (Umaefulam et al., 2022). This underrepresentation may be due to historical mistrust of researchers and lack of culturally safe and engaging strategies to recruit Aboriginal and Torres Strait Islander people. Data from clinical trials are critical for assessing safety and efficacy of therapies and interventions that have the potential to improve patients' health outcomes (Kennedy, 1999). Aboriginal and Torres Strait Islander representation in clinical trials is important because treatment safety and effectiveness may vary between Aboriginal and Torres Strait Islander people and non-Indigenous people (Ramamoorthy et al., 2015). Incorporating culturally safe strategies (including appropriate informed consent processes) for the recruitment of Aboriginal and Torres Strait Islander people is critical to ensure adequate representation in clinical trials whilst maintaining an ethical conduct of research that guarantees the right to self-determination and respect of Aboriginal and Torres Strait Islander ways of knowing being and doing (National Health and Medical Research Council 2018).

Globally, research has demonstrated that improving the quality of informed consent processes for medical procedures and to participate in research is needed (Fernandez, 2010; Joffe et al., 2001; Miller et al., 1994). In Australia, cultural differences and language barriers between clinicians or researchers and Aboriginal and Torres Strait Islander people could hinder even more the quality of informed consent processes. Given the scarce evidence on the quality of the informed consent processes for Aboriginal and Torres Strait Islander peoples, the aim of this study is to explore the experiences of Aboriginal and Torres

Strait Islander people when providing informed consent to undergo cardiac surgery or participate in medical research. This will be complemented by comparing those experiences to the ones of the clinicians and researchers who obtain informed consent from Aboriginal and Torres Strait Islander people.

Methods

Study Aims

a. To explore Aboriginal and Torres Strait Islander people's experiences of informed consent processes in relation to:
    i. cardiac surgery
    ii. participation in medical research.
b. To investigate clinicians' and researchers' experience of obtaining informed consent from Aboriginal and Torres Strait Islander people in relation to cardiac surgery and medical research.

Study Setting

The present study will be conducted as part of the Nasal high-flow Oxygen Therapy After Cardiac Surgery (NOTACS) study (ISRCTN14092678, 13/05/2020). NOTACS is a multicentre randomised clinical trial (RCT) aimed at comparing nasal high flow oxygen vs. standard low flow oxygen given to patients within the first 16 hours after undergoing cardiac surgery who have a high risk of developing postoperative pulmonary complications. Within Australia, The RCT will be conducted in eight Australian hospitals including the Fiona Stanley Hospital (FSH) in Western Australia, and Townsville University Hospital (TUH) in Queensland. Both hospitals care for a significant number of Aboriginal and Torres Strait Islander patients.

The NOTACS trial is funded in Australia through a grant from the Commonwealth Government Medical Research Future Fund (MRFF). In addition to the RCT component, a primary aim of the Australian MRFF funding is to develop research leadership of Aboriginal and Torres Strait Islander people. This includes the recruitment of an Aboriginal Research Coordinator at each study site to explore and improve the experiences of Aboriginal and

Torres Strait Islander patients undergoing cardiac surgery at FSH and TUH, with a focus on understanding informed consent. Eligible patients may agree to participate in the RCT alone, the Consent Study alone, or both.

Study Methodology

The processes of ongoing colonisation in Australia has meant that Aboriginal and Torres Strait Islander knowledges have not been valued, recognised nor included in health, healing and research. This then calls for the need for research to be decolonised and the voices and perspectives of Aboriginal and Torres Strait Islander people re-centred. Decolonisation in research involves researchers' acknowledgement and reflection on how colonisation has and continues to create health and research inequities and power imbalances (Doyle et al., 2017; Green & Bennett, 2018; Smith, 2021). Researchers must reflect on the way that Western Knowledge Systems are privileged and work to counteract power imbalance to enable Aboriginal and Torres Strait Islander peoples' worldviews, health paradigms and voices to be prioritised.

All aspects of the present study will use Aboriginal and Torres Strait Islander peoples' ways of knowing, being, and doing. Fundamental concepts of the interconnectedness of all living things, ecological relationships between people, place and knowledge, and an Aboriginal and Torres Strait Islander peoples' paradigm of health and healing (physical, emotional, social, cultural, and spiritual) will form the bases of this approach (Drawson et al., 2017; Nakata, 2007; Ryder et al., 2020; Sherwood & Edwards, 2006; S. S. Wilson, 2004; W. A. Wilson, 2004). The Consent Study is led by Guunu-maana, the Aboriginal and Torres Strait Islander Health Program at The George Institute for Global Health. The Senior Research Fellow and lead investigator (JC) is a proud Gumbaynggir woman with over 27 years' experience working in Aboriginal Community Health. In addition, a local Aboriginal or Torres Strait Islander person will be employed as a Research Coordinator at each hospital.

Yarning

Yarning is a process in which "talking" with each other creates different layers of understanding regarding lived experience and enables all of the nuances of "conversation" to

be synthesised into something that is meaningful and sensible (Walker et al., 2014). Yarning is used as an Indigenous research method by First Nations' peoples in a variety of ways such as social, research, therapeutic, and collaborative (Bessarab & Ng'andu, 2010; Coombes et al., 2016; Ryder et al., 2021; Sherwood & Mohamed, 2020; Walker et al., 2014). The informal and relaxed nature of the conversation facilitates in-depth discussions providing a source of rich data and thick descriptions of a particular issue (Bessarab & Ng'andu, 2010). It is very different from qualitative research inquiry in that it does not follow a linear sequential pattern. A yarning approach is flexible and centres Aboriginal and Torres Strait Islander people's voices. It involves respecting culture, walking together, sharing stories, and learning from one another. Within this study, Aboriginal and Torres Strait Islander people will be supported to tell their stories without the concern of misinterpretation (55).

Participants

Aboriginal and Torres Strait Islander Patients.

We aim to purposively recruit Aboriginal and Torres Strait Islander patients admitted to Fiona Stanley Hospital, Perth, Western Australia and Townsville University Hospital, Townsville, Queensland for cardiac surgery. Recruitment will stop at 20-30 participants or until saturation is reached. Stated recruitment targets reflect the anticipated numbers of Aboriginal and Torres Strait Islander people presenting to both Australian hospitals for cardiac surgery. Patients recruited for the study will meet the following criteria:

Inclusion criteria:

- Aboriginal and/or Torres Strait Islander people aged > 18 years.
- Who require or have undergone elective cardiac surgery.
- Who require cardiac surgery but do not consent to having the cardiac procedure
- The potential participant, their family and the Aboriginal Research Coordinator determine there is enough time to participate.

Aboriginal and Torres Strait Islander patients from the hospital who require or have undergone cardiac surgery will be screened for eligibility. Eligible patients will be identified by members of the hospital team, including the hospitals' Aboriginal Health Worker/Liaison Officer who will contact the Aboriginal Research Coordinator to let them know an eligible patient is in the hospital. Patients who decide not to consent to the cardiac procedure will also be invited to participate in the Consent Study as this will provide valuable information on how to improve the consent process.

In addition, prior to the cardiac surgery preadmission visit, the Aboriginal Research Coordinator will be notified of potential participants and will approach them at the time of the preadmission visit to invite them to participate in the study. The Research Coordinator will share the Participant Information Statement (PIS) and explain what the study is about. The participant will be given ample time to read the PIS, discuss with family and ask questions before consenting to the study. For patients who do not have a preadmission visit, the Aboriginal Research Coordinator will approach them and invite them to participate in the Consent Study at a time and place that is suitable for the potential participant. Fiona Stanley and Townsville hospitals have access to interpreting services for Aboriginal and Torres Strait Islander people which we will utilise when English is second or third language of the participant.

Medical Staff Members from The Cardiothoracic Surgery Team.

We aim to purposively include 5-10 Medical staff (specialists and junior medical staff) who have had experience obtaining informed consent for cardiac surgery from Aboriginal and Torres Strait Islander patients. Students rotating in the cardiothoracic surgery service and medical staff who have had no experience obtaining informed consent for cardiac surgery from Aboriginal and/or Torres Strait Islander patients will be excluded.

Academic Researchers.

To explore researchers' experience obtaining informed consent from Aboriginal and Torres Strait Islander people in relation to health and medical research, we will conduct semi-structured interviews with researchers from both hospitals. We aim to recruit a

purposive sample of 5-10 Researchers based at Townsville and Fiona Stanley hospitals who have obtained informed consent for participating in medical research from Aboriginal and Torres Strait Islander people.

We will include research staff who have had previous experience inviting Aboriginal and Torres Strait Islander people to participate in medical research. Research staff who have had no experience obtaining informed consent for medical research from Aboriginal and Torres Strait Islander patients will be excluded.

Data collection

Yarning sessions with Aboriginal and Torres Strait Islander patients.

A yarning session with patients will take place postoperatively once they have been discharged from the Intensive Care Unit (ICU) to the ward and before discharge from the hospital. The yarning session will be conducted in a private area within the hospital and will take no longer than 60 minutes, will be audiotaped and transcribed. During the yarning session, the researcher will ask participants about their experiences with the consent process for cardiac surgery and their experiences for medical research consent as two separated processes.

Semi-structured interviews with staff members from the cardiothoracic surgery and research teams

Semi-structured interviews with staff members from the cardiothoracic surgery and research teams will be conducted and audiotaped by the Aboriginal Research Coordinator at the hospital at a time indicated as suitable by each participant. The Aboriginal Research Coordinator will ask the clinicians and researchers about their experience obtaining informed consent to undergo cardiac surgery and participate in medical research respectively. The interviews will take 20 – 40 minutes.

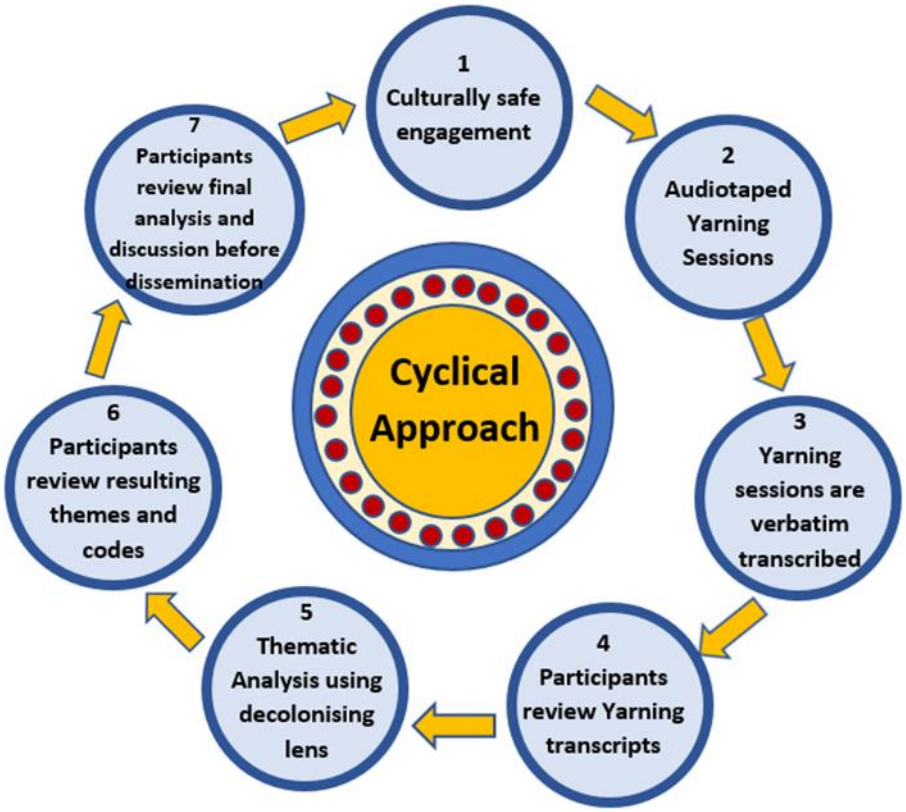
Data Analysis

To guarantee that Aboriginal and Torres Strait Islander voices and experiences are truly reflected, the data analysis of the yarning sessions with Aboriginal and Torres Strait Islander participants will follow a cyclical approach (Figure 1). The voice recording of the

yarning sessions will be transcribed verbatim. Once the yarning sessions have been transcribed, the Aboriginal Research Fellow and a Research Associate will contact the patient by phone or email and offer the patient the opportunity to read their transcript and check that it reflects what they wanted to express. The patients will be able to add or modify any information which they consider necessary. Then, a thematic analysis will be conducted prioritising Aboriginal and Torres Strait Islander voices, concepts and worldviews including health and wellbeing paradigms. After the thematic analysis has been completed, the research team will contact the participants again to share the resulting themes. We will use storytelling analysis with the participants which involves a cyclical and iterative process of reflection, analysis, and interpretation. This process involves examining the data through multiple lenses, including personal experiences, cultural traditions, and social and historical contexts. This will ensure that the interpretation of the final themes are culturally appropriate and relevant to Aboriginal and Torres Strait Islander communities. Storytelling analysis allows examination of Aboriginal and Torres Strait Islander people's experiences focusing on the content of the story, the context in which it was told and the social and cultural factors that shape the story (Michael et al., 2021).

Figure 1

Data analysis following a cyclical approach



Note. Adapted with permission from "Is Anybody Listening? Stories from Australia's First Nations Families whose Children had Sustained a Burn Injury" by J. Coombes 2021 (Coombes, 2021, p. 28).

Voice recordings from the yarning sessions with the participants from the cardiothoracic surgery and research teams will also be verbatim transcribed. They will be given the opportunity to check their transcripts and provide feedback. Data will then be analysed by an Aboriginal Research Fellow and a Research Associate through a thematic analysis.

Data Sovereignty

Indigenous Data refers to any data in any form or medium containing information on Indigenous peoples, families and their communities (Ryder et al., 2022). Indigenous Data Sovereignty is Aboriginal and Torres Strait Islander peoples' inherent rights to govern all aspect of this data, and Indigenous Data Governance are the policies and procedures which enact and support Data Sovereignty (Ryder et al., 2022). This project will apply Indigenous

Data Sovereignty principles to ensure that Aboriginal and Torres Strait Islander participants and researchers develop, maintain, control, and protect all data associated with the project.

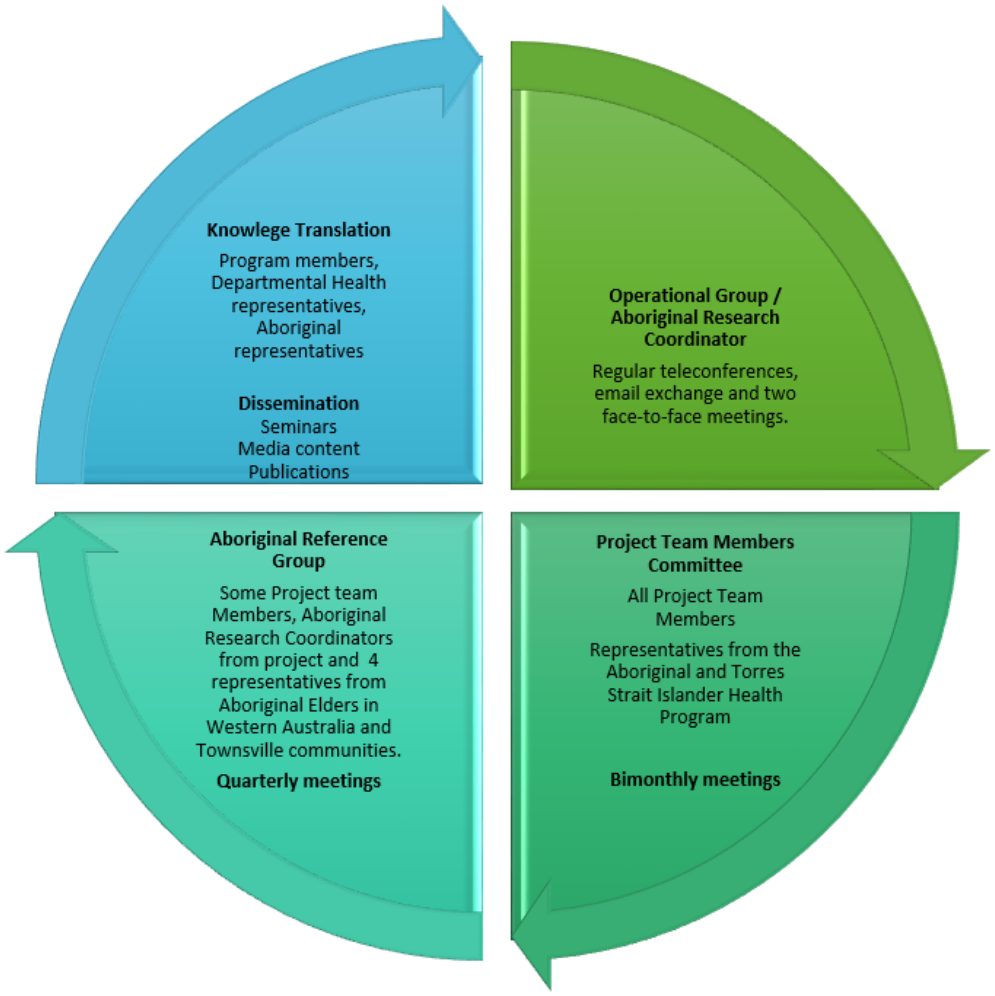
To maintain patient privacy and confidentiality, all study data, including audited participant data, will be de-identified. Confidentiality of records and participants' personal information will be always maintained on secured servers. Any document hard copies containing patient information will be locked in safe storage at each hospital.

Management and Governance

The consent study has Aboriginal and Torres Strait Islander involvement and oversight from inception. We have participation from Aboriginal organisations, community members and Elders in study governance structures. We also have Aboriginal and Torres Strait Islander researchers to oversee data collection, analysis, synthesis and dissemination (Figure 2).

Figure 2

Stakeholders



The study will ensure cultural appropriateness through several internal policies, procedures and governance established by the Guunu-maana (Heal), Aboriginal and Torres Strait Islander Health Program of The George Institute for Global Health, including a Research Committee for Aboriginal and Torres Strait Islander Health (RCATSIH) that oversees organisational and research activities and ensures alignment with national frameworks and ethical standards.

In addition, the Chief Investigator executive team will maintain regular meetings with the Aboriginal Reference Group that will provide guidance regarding the maintenance of cultural safety and sovereign rights throughout the duration of the study. The purpose of the Reference Group is to provide overall guidance and advice for the program as it pertains to

Aboriginal and Torres Strait Islander people, families, and communities in Australia. The members of the committee will be responsible for representing their respective organisations, agencies, and communities and for disseminating information where appropriate. We acknowledge that Aboriginal communities are diverse and the approaches in each site will reflect that diversity. Analysis of research will be a transparent process, ensuring sites have the opportunity to review preliminary findings and plans for reporting. The Aboriginal Reference Group and Aboriginal stakeholders will be offered co-authorship on the publications and open opportunities to present the research at conferences and symposiums.

Dissemination

Dissemination will occur across multiple platforms, via the reference group, participants, health professionals, health services and community. Additionally, in collaboration with the Reference Group, a report on key findings will be prepared and disseminated via email to participants and stakeholders including the Aboriginal Community Controlled Health Organisations and the Western Australia Aboriginal Health Planning Forums. In addition to this, the Western Australia Aboriginal Human Ethics Committee (WAAHEC) will receive a final report of the study.

The findings will be disseminated to the academic community, through the publication of manuscripts in peer-reviewed journals, and posters and oral presentations will be given at relevant scientific meetings and conferences.

Discussion

The findings from this study will inform the design and implementation of strategies and materials to help clinicians obtain culturally safe and genuine informed consent from Aboriginal and Torres Strait Islander people who require cardiac surgery. Implementing strategies to improve communication between surgeons and patients during informed consent will facilitate the provision of care that is culturally safe. This has the potential to improve health outcomes such as reduced post-operative complications and reduced length of hospital stay (Lawrence et al., 2009).

The experiences of Aboriginal and Torres Strait Islander people invited to participate in medical research conducted by non-Indigenous researchers will provide a better understanding of what processes are more culturally safe. Enhancing engagement with participants from the beginning and guaranteeing a true informed consent process may facilitate participant retention, data collection, reduce missing data and hence improve research outcomes.

List of abbreviations

FSH: Fiona Stanley Hospital

ICU: Intensive Care Unit

MRFF: Medical Research Future Fund

NOTACS: Nasal high-flow Oxygen Therapy After Cardiac Surgery

PIS: Participant Information Statement

RCATSIH: Research Committee for Aboriginal and Torres Strait Islander Health

RCT: Randomised Clinical Trial

TUH: Townsville University Hospital

WAAHEC: Western Australia Human Ethics Committee

Declarations

Ethics approval and consent to participate

Ethics applications were submitted and approved by The Western Australian Aboriginal Health Ethics Committee (WAAHEC) (HREC1146) and the South Metropolitan Health Services HREC (SMHS) (RGS5326). Written informed consent will be obtained from all participants. An informed consent form and a participant information sheet have been developed and approved by WAAHEC and SMHS.

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

All authors declare that they have no competing interests.

Funding

This project is supported by the Medical Research Future Fund International Clinical Trial Collaboration (MRFF ICTC) grant (MRF2006100). Funding is subject to conducting the research according to the funded proposal and meeting ethics, governance and reporting requirements. The funder has no role in the preparation of the study protocol, the conduct of the study, its analysis or reporting.

Authors' contributions

JC and CK conceived the idea and designed the study. JC, CK, TM and KH drafted the original protocol. EL, JA, KBB, CR, BP, BG, KY and CG reviewed and edited the protocol. All authors read and approved the final manuscript.

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