



Government of **Western Australia**
Department of **Health**

Department of Health Western Australia Human Research Ethics Committee

Project Summaries for Approved Proposals

October to December 2022 Quarter

Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – October to December 2022 quarter.

The material contained in this document is made available to assist researchers, institutions and the general public in searching for projects that have ethics approval from the Department of Health Human Research Ethics Committee (DoH HREC). It contains lay descriptions/summaries of projects approved in the October to December 2022 quarter.

Under the WA Health mandatory Research Governance Policy, the DoH HREC, must review all research projects that require the use and disclosure of personal health information from the DoH Data Collections, including data linkage. DoH HREC approval cannot occur until approval to access a DoH data collection is approved by the data collections' Data Steward or their delegate.

The lay descriptions/summaries outlined below have been provided by the respective Principal Investigator and are shared with their consent.

Project Title	Quantifying health service utilisation, mortality and temporal trends in people with mental illness or suicidal behaviour in Western Australia
Principal Investigator	Colleen O'Leary
Institution	Office of the Chief Psychiatrist
Ethics Approval Date	Tuesday, 4 October 2022
<p>The 2019 Western Australian Auditor General's Report "Access to State-Managed Adult Mental Health Services" examined whether people with mental illness are able to access appropriate mental health services when they require them. It emphasised the problems and gaps in mental health service delivery that impacted on the patient journey, including a reduction in the availability of in-patient services and a lack of capacity to admit people requiring urgent access to care. Our study builds on those findings by examining how these issues affect standards of psychiatric care being provided and, ultimately, patient outcomes. This is an area of prime concern for the Office of the Chief Psychiatrist which has initiated this project, as the treatment and the standards of psychiatric care delivered to patients of mental health services are key statutory responsibilities of the Chief Psychiatrist (Mental Health Act (MHA) 2014 section (s.) 515).</p> <p>The primary objectives of the project are: to i) characterise people with a mental health diagnosis or suicidal behaviour/self-harm in contact with secondary (emergency department, inpatient and ambulatory) health treatment services; ii) describe their mental and physical health service utilisation; and iii) examine changes in service utilisation and outcomes before and after the WA Mental Health Act 2014.</p>	

Project Title	Assessing the risk of Long COVID in Western Australia
Principal Investigator	Paul Effler
Institution	Department of Health
Ethics Approval Date	Tuesday, 4 October 2022
<p>The SARS-CoV-2 (COVID-19) pandemic has resulted in significant morbidity and mortality worldwide. While many COVID-19 cases have no symptoms or recover within a few days after experiencing mild symptoms, some persons continue to have long-term health issues following infection, a post-COVID condition colloquially known as "Long COVID". Determining the proportion of persons with COVID-19 who go on to develop Long COVID is important for</p>	

assessing the pandemic's overall impact on health, but estimates vary widely across different study populations. Assessing the proportion of Western Australia (WA) residents who are experiencing ongoing symptoms consistent with Long COVID is critical to planning for future health care needs. This study aims to provide a population-based estimate of the incidence of Long COVID in WA and identify key characteristics associated with this condition.

Methods

Study subjects: Participants will be recruited from WA residents aged 18 years and over with COVID-19 infection reported to the Department of Health between 1 July and 31 August 2022, who agreed to be contacted for COVID-19 related research during the initial case investigation.

Data collection: We will send an SMS to potential participants 3-months after their diagnosis date. The SMS will provide a link to a Consent Statement with full study details and invite recipients to complete a brief online survey. Survey responses will be linked to selected demographic, vaccination, COVID testing, and hospitalisation information collected as part of the initial case investigation. Participants reporting Long COVID symptoms at 3-months will be asked to consent to a follow-up survey at 6-months post diagnosis.

Data analysis: The primary outcome of interest will be incidence proportion of Long COVID symptoms 3-months after COVID-19 infection and the proportion with ongoing symptoms at 6-months. Potential independent predictors for experiencing Long COVID will be examined using logistic regression and predicted probability.

Project Title	Mental health disorders among individuals with craniofacial anomalies in Western Australia – A population-based retrospective data linkage study
Principal Investigator	Linda Slack-Smith
Institution	University of Western Australia
Ethics Approval Date	Wednesday, October 12 2022

Craniofacial anomalies (CFA) including cleft lip and/or palate, craniosynostosis, craniofacial microsomia, mandibulofacial dysostosis, frontonasal dysplasia, Pierre Robin sequence and Van der Woude syndrome are a heterogeneous group of structural birth defects resulting from disturbances in craniofacial development. Most craniofacial anomalies other than cleft lip and/or palate are rare in occurrence with a birth prevalence of <1:2,000 births. Affected individuals encounter challenges relating to breathing, feeding, hearing, speech and appearance which may require ongoing multidisciplinary care. Furthermore, these challenges may be compounded by constant bullying and societal discrimination which may lead to emotional disturbances and social isolation possibly resulting in school absences, reduced participation in activities outside the home and workplace exclusion. In addition, parents of these children may face emotional, financial and social difficulties, which may lead to higher levels of stress, marital conflict and lower self-efficacy, than parents of children with no such anomalies. Prior research reports about the negative psychological outcomes including deliberate self-harm among children born with craniofacial anomalies have been published, however much of this literature is based on self-reported measures and small sample sizes which limit its generalisability. Furthermore, these studies mainly focus on children and adolescents, leaving little known about the risk of mental health disorders in adulthood.

Therefore there is a need to quantify the burden of mental health disorders among individuals born with birth defects, specifically craniofacial anomalies, across their life course to address upstream and midstream determinants for planning and developing policies to improve care pathways and identify priorities to inform new models of support services to improve outcomes of these children (families). Therefore, our proposed project aims to: (i) provide comprehensive population level information on the mental health service use among children born with birth defects, specifically craniofacial anomalies; (ii) explain this mental health burden based on the additional presence or absence of intellectual disability, autism spectrum disorder or cerebral palsy; (iii) describe the burden of deliberate self-harm among individuals born with birth defects, specifically craniofacial anomalies.

Project Title	Birthing on Country <i>Connected to Country, Birthing on Country, On Country We Grow</i>
Principal Investigator	Caron Molster
Institution	Edith Cowan University
Ethics Approval Date	Tuesday, 18 October 2022

The Birthing on Country (BoC) project is a collaboration between multiple stakeholders, including the Chief Nursing and Midwifery Office, Health Networks Unit and Aboriginal Health Policy Directorate, WA Department of Health, and Edith Cowan University. The project is guided by its Advisory and Reference Groups consisting of representatives from Aboriginal Controlled Community Health Services and the WA health system.

The project aims to provide long term direction for the delivery of culturally safe maternal and newborn health services for Aboriginal women, infants and families in WA.

This phase of the project will collect information on service availability and utilisation, via an online survey (with a telephone option if participants request this). It aims to support service improvements for organisations to provide culturally safe maternity care and transition support to child health services. It will identify exemplars in culturally safe service provision and barriers experienced.

Staff of WA Health services, Aboriginal Community Controlled Health Services, other Aboriginal maternity services and GP practices providing maternity care in WA are invited to participate. This will be achieved via a letter to the Chief Executive (CE) or CE delegate, requesting nominations of staff from their maternity service providers to participate. Subsequently an email will be sent to staff who may participate in the survey, which contains a link to the online survey. For WA Health maternity service providers, the letter will be sent to the CE/equivalent or CE delegate of the Health Service Providers (i.e., WACHS, NMHS, SMHS, EMHS).

Results from the survey, combined with the findings of a literature review, will inform a report outlining next steps and recommendations to direct action in culturally safe maternal and transition of care services to improve health outcomes for Aboriginal mothers, infants and families. It will also shape recommendations to enhance the prevention, screening and management of syphilis in Aboriginal women and non-Aboriginal women with complex social needs.

Project Title	Data Linkage of Patients Undergoing Laparoscopic Sleeve Gastrectomy in Western Australia
Principal Investigator	Jeffrey Hamdorf
Institution	West Australian Patient Blood Management Group
Ethics Approval Date	Friday, 11 November 2022

We intend to utilise a five-year retrospective linkage of patients who have undergone sleeve gastrectomy (2013-2018) under bariatric surgeons at Hollywood Private Hospital, linked with four Health Department databases (Hospital Morbidity Data, Death Registrations and the Midwives Notification Database). The linkage will be utilised to compare Western Australian data with current national and international benchmarks. It will allow for a greater understanding of the risks and benefits associated with bariatric surgery in women of childbearing age and will provide local information on maternal and neonatal outcomes following this procedure.

Rationale and justification for the project:

Current outcomes are only known for 30 days postoperatively after the major procedure of bariatric surgery. Large population databases indicate there is significant health and economic benefits to obese patients after bariatric surgery, particularly in comparison to the year prior.

Of all Australian patients undergoing bariatric surgery, 80% are female and 65% are of child-bearing age. Thus, maternal and foetal outcomes are likely to be greatly advantaged by bariatric surgery however this has not been quantified in the Australian setting.

Significance of the project

The positive impact of bariatric surgery upon the obese patient is grounded in an extensive evidence base. The unique setting of bariatric patients undergoing surgery at Hollywood Private Hospital with an excellent aftercare program provides an opportunity to quantify the improvement in comorbidities as well as economic outcomes upon Western Australia. Similarly, for women of childbearing age, there is a known linear increase in fecundity with weight loss after bariatric surgery. However, the impact upon the maternal and neonatal outcomes has not been quantified on a population-wide basis in Australia.

Our project has two major objectives:

1. Hospital Morbidity and Mortality

Utilising a cohort of patients who have undergone bariatric surgery at Hollywood Private Hospital between 2013-2018, we aim to provide a longitudinal comparison of the hospital morbidity data of the year prior and year after surgery. In particular, the morbidity associated with weight related disease (arthralgia, diabetic complications, hypertension or hypercholesterolaemia) and associated diagnoses.

The death dataset will be utilised to reduce loss to follow up in the population and to provide information relating to mortality rates following bariatric surgery. It will also provide information regarding maternal and neonatal deaths which could potentially be linked to complications of bariatric surgery. This will allow a more complete view of the population and reduce study bias.

2. Midwives Notification Database

Given the high proportion of women of childbearing age undertaking bariatric surgery we plan to cross-tabulate the identifiers of patients who have undergone bariatric surgery with those in the Midwives Notification Database. This will allow for a large cohort of post-surgery maternal and foetal outcomes which can subsequently be compared to established international benchmarks.

Research hypotheses:

1. Bariatric surgery has a strong, positive effect upon patient health outcomes particularly relating to weight related morbidity resulting in better individual metabolic parameters, quality of life years and reduced financial burden upon the WA health system
2. Maternal outcomes are greatly improved by the effect of long-term sustained weight loss without negative effects upon the neonate or in utero.

Project Title	Closing the Gap for Aboriginal Head and Neck Cancer Outcomes
Principal Investigator	Andrew Redfern
Institution	Fiona Stanley Hospital
Ethics Approval Date	Friday, 11 November 2022

Aim: This project aims to explore the patient and treatment related factors contributing to the poorer survival from head and neck cancers in Aboriginal patients.

Methods: We will retrospectively collect data, adding to an existing database, of patients treated for head and neck cancers between February 2015 to February 2021. The database currently has 1332 patients, including 85 Indigenous patients, and further cases will be identified prospectively during the data collection process. We will use electronic records to confirm histological diagnosis, anatomical primary site, and postcode to provide remoteness and socio-economic status assignment.

Stage I of our project will be to ascertain if there is significant variation in the distribution of anatomical sites for Aboriginal head and neck cancer compared to non-Aboriginal patients (e.g. tongue, tonsil, larynx).

Stage II will use the cancer registry to look at the last 20 years of data from the cancer registry to look at overall prevalence, state-wide subtyping and broad overall survival.

Stage III will be to pair Aboriginal with non-Aboriginal head and neck cancer patients who are matched to the Aboriginal cohort in terms of age, anatomical site, histological diagnosis, and remoteness, to exclude confounding by level of remoteness. Stage III of our project will look at differences in co-morbidities, BMI, ethanol and tobacco use, HPV status (oropharyngeal subsite only) and presence of other viral antigens (HIV, EBV, CMV), vitamin D deficiency, treatments offered, treatments delivered, reasons for non-treatment, reasons for treatment delay or cessation, treatment toxicities, relapse data, post-relapse treatment, survival, and second cancer incidence.

Stage IV would look at radiology-measured sarcopenia and its effect on survival outcomes and toxicity.

Stage V will be a feasibility study where we collect information on what pathology specimens are available and assess whether it would be feasible in a future study to collect cell blocks from previously resected tumours for the Stage I-IV cohort. Subject to sufficient available tissue and funding availability, we will seek WAAHEC and HREC permission to analyse tumour tissue for mutations and molecular markers, which might affect the development or behaviour of a head and neck cancer in a separate application or amendment. This will allow us to see whether head and neck cancers in ATSI patients have genetic or molecular differences that may be prognostic or predictive of response to treatments and may contribute to the mortality gap. These findings might in time have implications for future management and treatment.

Why: Head and neck cancers are the fifth most common cancer occurring in Aboriginal patients, and there is a 24% difference in mortality for Aboriginal compared to non-Aboriginal patients. To correct the disparity in cancer outcomes between Aboriginal and non-Aboriginal patients, it is imperative to first understand the contributing factors driving poorer survival to assess which factors are modifiable, in the long-term goal of improving cancer outcomes for Aboriginal cancer patients.

Project Title	Evaluation of the Early Years Initiative: Child Outcomes Sub-study
Principal Investigator	Lynne Millar
Institution	Telethon Kids Institute
Ethics Approval Date	Wednesday, 14 December 2022

The Early Years Initiative (EYI) is a long-term partnership involving the Western Australian State Government and the Minderoo Foundation operating in four 'partner' communities (one very remote, one remote, one regional and one metropolitan) to fast-track improvements to the development, health and learning of children from conception to four years of age. Day-to-day decisions and actions undertaken in each partner community are facilitated through the 'EYI Team' comprising officers from three State Government departments (Communities, Education and Health) and the Minderoo Foundation. Lessons from the EYI may apply at scale in the future to other places. An independent evaluation of the EYI will be conducted by Telethon Kids Institute to inform those lessons. This Child Outcomes Sub-study is one part of that evaluation.

The aim of the Child Outcomes Sub-study is to use linked administrative data to explore changes in health, development and learning indicators among children from conception to four years of age within EYI partner communities, and to compare changes with the same indicators in four matched comparison communities (one for each partner community). Specifically, the Child Outcomes Sub-study will address the following research questions:

- To what extent is the EYI improving child health, development and learning in partner communities, as measured by selected Children's Headline Indicators?

- To what extent is the EYI improving primary caregivers' health and wellbeing in partner communities, as measured by identified administrative supplementary indicators?
- How do the outcomes of children and their families in EYI partner communities compare to EYI comparison communities?

Data for this sub-study will comprise linked administrative data for each partner community and the corresponding comparison communities at approximately three-year intervals (2021 - 2024 - 2027) and compared over time. Administrative data from State Government agencies (Health, Education and Communities) will be extracted and linked by the WA Department of Health. These administrative data are collected on children from birth to age four (and their families) and include the Child Headline Indicators, Midwives Notification System, Preschool Collection, the Ages and Stages Questionnaire and the Australian Early Development Census.

Study participants will comprise all children aged 0-4 years and their primary caregivers living in EYI partner communities, or in a matched comparison community. EYI cohort definitions will be used as the parameters for data extraction using the datasets described above.

Findings from the project will be shared with EYI implementation partners, members of the four partner communities, local EYI staff and local EYI governance groups.

This document can be made available in alternative formats on request for a person with a disability.

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