Department of Health Western Australia Human Research Ethics Committee

Project Summaries for Approved Proposals

October to December 2021 Quarter

Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – October to December 2021 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 description/summaries of projects approved in the October to December 2021 quarter.

Project Title	RGS 1183: Understanding the incidence, prevalence and rates of progression of chronic kidney disease in Western Australia
Principal Investigator	Dr Aron Chakera
Institution	Sir Charles Gairdner Hospital

Start Date	21st December 2021	**Finish Date**	8th December 2024

While the general burden of Chronic Kidney Disease (CKD) has been explored nationally, there is a paucity of data on this prevalent disease at the level of jurisdiction and disease stage. This project aims to develop a Chronic Kidney Disease Patient Registry to examine the life course of patients with CKD to inform evidence-based clinical recommendations to support the continuum of care and enhance the long-term health and quality of life of CKD patients in Western Australia. An accurate picture of the incidence, prevalence and rates of progression of CKD will enable a better understanding of the individual and societal burden of CKD in Western Australia.

This study will create a state-wide dataset using pathology and hospital data from the Western Australian population. The profile of patients with CKD in Western Australia will help determine the rate and progression of CKD and availability of appropriate treatment services. This will also generate a baseline dataset for future research to inform practitioners and researchers about CKD health service utilisation, cost and patient outcomes.

Findings will specifically add value to public health services and patient care by: providing a comprehensive picture for health needs assessments; mapping the epidemiology of individuals with CKD; facilitating prediction of trends; and, informing future strategies, policies, and clinical service planning. The development and outcomes of this study will be generalisable to other areas (nationally and internationally) with similar socio-demographic profiles and health care delivery systems.

Project Title	RGS 3752: Transitioning from out-of-home care: a longitudinal population-based study
Principal Investigator	Professor Donna Chung
Institution	Curtin University

Start Date	14th December 2021	**Finish Date**	8th December 2024

Young people in and transitioning from out-of-home care experience a myriad of challenges. Care leavers, including a disproportionate number of Aboriginal young people, experience adverse outcomes across a range of domains leading to high social and economic costs for the Australian community. This longitudinal study uses a population-based method to examine the pathways of young people in and

transitioning from out-of-home care in Western Australia. The combined findings from the population-based data will identify child, family and care factors and their impact on outcomes for improving transition from care experiences to facilitate improved outcomes. Outcomes for young people investigated include heath, mental health, education, juvenile justice, child protection, and pregnancies. Outcomes and pathways for care leavers will be compared to young people who have contact with the child protection system but do not enter out-of-home care and those young people who have had no contact with the child protection system.

Project Title	RGS 3764: Privacy Preserving Record Linkage for Western Australian Birth Defects and Australian Pharmaceutical Benefits Scheme Claims Data		
Principal Investigator	Professor Gareth Baynam		
Institution	King Edward Memorial Hospital		
Start Date	14th December 2021	**Finish Date**	14th December 2024

Many health conditions such as infections, asthma, hypertension and depression may require treatment with medicines during pregnancy, but there is little guidance available to inform clinical practice. Currently the safety of medicines prescribed in pregnancy is only established after many years of clinical use; data linkage of prescribing data with pregnancy outcomes offers an important means of accelerating this process. Previous work in WA linking birth defects to pharmaceutical claims data has shown that linkage of dispensing data to pregnancy events for post-marketing surveillance is feasible and would be a major public health resource for assessing the safety of medicine use in pregnancy. However, legislative and policy barriers currently exist that prohibit the sharing of personally identifying information between States like WA and the Commonwealth.

This project proposes a data linkage method known as privacy preserving record linkage to overcome these barriers. This technique enables linkage using only encoded personal identifiers. All data are encoded prior to leaving the data custodians so that no identifying information is shared across jurisdictions. Personal data such as name, address, date of birth are encoded into Bloom filters (binary vectors). The encoded output is distorted to the extent that it is impossible to recognise an individual's information and is irreversible. Traditional probabilistic linkage methods can then be used to link these encoded data and the Centre for Data Linkage (at Curtin University) has now successfully used these methods for a number of research projects.

This project will use Privacy Preserving Record Linkage to combine information from the Midwives' Notification System, the WA Register of Developmental Anomalies and the Commonwealth Pharmaceutical Benefits Scheme (PBS). This will allow us to identify a retrospective cohort of all births (live and still born) and terminations of pregnancy for fetal anomaly in WA over an 8 year period (2012-2019) according to whether or not their mothers were dispensed prescription medications during the pregnancy. Outcome data on the prevalence of birth defects will be compared for exposed and unexposed births. We will also examine trends in the proportion of pregnancies exposed to medications over time and the number of medicines dispensed per woman.

All drugs have the potential for adverse effects and with at least 1 in 5 Australian children exposed to medicines in the first trimester of pregnancy it is critical that we understand more about the health impacts of such exposure.

Project Title	RGS 4297: Prevalence, prognosis and management of autoimmune encephalitis in Australia: a national data-linkage approach.
Principal Investigator	Associate Professor Wendyl D'Souza
Institution	St Vincent's Hospital Melbourne
Start Date	14th December 2021	Finish Date	8th December 2024

Autoimmune encephalopathies (AE) are a group of neurological disorders in which the immune system attacks the brain, sometimes in response to a cancer elsewhere in the body. This leads to inflammation of the brain, resulting in significant morbidity and mortality. Whilst we understand much of the pathophysiology of these conditions, there are many unanswered questions regarding diagnosis and management. First, we do not know the prevalence of this condition in Australia. Second, while we know these conditions often cause functional impairment, there are no large studies characterising any consequent disability. Third, there is a lack of quality data regarding underlying cancer diagnoses to inform cancer screening or surveillance guidelines. Finally, we currently do not know the optimal immunosuppression strategy.

This study will use data linkage analysis to generate a retrospective population cohort of Australian patients with AE. We will estimate the prevalence of AE in Australia, characterise the domains of disability these patients experience, determine patterns of associated cancers and timing of cancer diagnoses, and determine best therapies associated with improved outcomes.

Project Title	RGS 4315: ReCAPS Trial: Recovery focused Community support to Avoid readmissions and improve Participation after Stroke
Principal Investigator	Professor Dominique Cadilhac
Institution	Florey Institute of Neuroscience and Mental Health
Start Date	10th November 2021	Finish Date	10th November 2024

Many stroke survivors have poor functioning at time of hospital discharge, contributing to 90 day readmission rates of around 30%. This study will test a personalised discharge support program for self management comprising of: i) structured and comprehensive patient centred goal setting initiated in the hospital and reviewed with a health professional via phone within 7 to 14 days of discharge; and ii) electronic personalised and tailored support messages aligned to the goals provided for 12 weeks via SMS or email. The RCT will test the intervention in 445 participants against a control group of 445 who will not have their goals reviewed or receive the tailored messages. Hospital staff will recruit eligible patients and set 2-5 recovery goals with them prior to discharge. Patients will be randomised to either intervention arm, 7 to 14 days post discharge.

A researcher will review intervention participant's goals with them and schedule the electronic messages aligned to their recovery goals over 12 weeks. It is anticipated the discharge support program will reduce 90-day emergency presentations or readmissions, and is cost effective.

Project Title	RGS 4782: Using data analytics and economic modelling to support population health planning and clinical management of mental health patients
Principal Investigator	Dr Kim Betts
Institution	Curtin University

Start Date	30th November 2021	**Finish Date**	30th November 2024

Aims

The aim of this project is to apply sophisticated data analytical techniques to the Mental Health Linked Data Repository (MH-LDR), with the aim of supporting a better understanding of the types of patient pathways through the WA public health system and service activity interactions, and the patient outcomes and costs associated with these.

Justification

In any given year one in five (20%) Australians aged 16-85 experience a mental health disorder, with almost half experiencing mental disorder in their lifetime. Those with chronic mental disorders have poorer health outcomes and a gap in life expectancy. In this project we will utilise this data source to provide information to the WA Government concerning patient journeys through the healthcare system and how different services relate to one-another in the delivery of services to certain groups. The objective is to better understand and cost and outcomes associated with different activities and activity clusters, to identify efficiency gains.

Participant groups/project design

As part of its mental health performance audit the WA Office of Auditor General has constructed an integrated data environment using health and medical information, originating mostly from various public (including public private partnerships) hospital administrative information systems (inpatient administration, emergency department, community health and psychiatric services). Importantly, the data also includes primary care data, which is vital to understanding the challenges posed by mental health in regional WA which are underserved by inpatient facilities. This data resource, named the Mental Health Linked Data Repository (MHLDR), is now in the possession of the Department of Health, who are responsible for updating the data at regular intervals. The data covers the full data history over 15 years for all people who have engaged with the state mental health system. This is a cohort of approximately 500,000 people and currently amounts to around 20 million records and over 250 attributes. The data collection is constructed as an end-to-end automated transformation and pre-analysis (feature engineering) environment. Despite administrative data not having detailed clinical data, the MHLDR does include the PSOLIS, such that the MHLDR includes more clinical data than other administrative data resources.

Project Title	RGS 5148: Obstetric, sociodemographic, and environmental risks of adverse perinatal and early childhood outcomes in Australia
Principal Investigator	Dr Gizachew Tessema
Institution	Curtin University

Start Date	15th December 2021	**Finish Date**	08th December 2024

Perinatal morbidity (preterm birth, fetal growth restriction, and low birth weight birth) has considerable lifelong health implications for the individual and contributes to the burden of disease in Australia. It is

currently difficult to accurately predict which women are at highest risk for stillbirth or preterm birth. The best predictors – family and obstetric history – are not fully utilised. This study will investigate/predict obstetric, sociodemographic, and environmental, and familial risk factors and causes of deaths for adverse perinatal and early childhood outcomes and estimate its associated costs in WA, NSW, SA and NT. The primary perinatal outcomes that will be investigated are preterm birth, fetal growth restriction, low birth weight and early childhood outcomes which include neonatal, early childhood mortality and child development outcomes at age 5. Estimating the costs associated with adverse perinatal outcomes will be the secondary outcomes in this project.

Project Title	RGS 5159: Implementing a statewide population-based cancer staging approach into the WA Cancer Registry: A qualitative process evaluation
Principal Investigator	Professor Rachael Moorin
Institution	Curtin University
Start Date	8th December 2021	**Finish Date**	8th December 2024

Background

Stage at diagnosis is a strong predictor of cancer survival. It is important for understanding cancer outcomes, guiding cancer control activities in population-based cancer studies, health care services and comparisons with other jurisdictions. Yet, cancer registries generally do not collect detailed clinical information to aid in assessing stage of diagnosis. Therefore, it is important to evaluate the quality and completeness of stage data collected at the population level. Further, collecting stage at diagnosis is an additional data item in the setting of increasing cancer notifications and can be a challenge in resource constrained environments. Considering that it can take many months to get through a full review due to the volume of cancer notifications, the project will be developing Natural Language Processing and Machine Learning algorithms to automate and support extraction of information from relevant data sources to minimise or eliminate manual intervention. This ethics application is being sought for a process evaluation to evaluate the process undertaken when introducing Cancer Staging into Western Australian Cancer Registry (WACR).

Objective

The aim of this process evaluation is to determine whether the research processes and the integration of cancer staging into the cancer registry were implemented as planned and explore contextual factors (e.g., outer/inner setting, intervention, individuals) that may have influenced implementation.

Project Plan

This process evaluation will be undertaken over a 5-month period and guided by the recognised theoretical framework, the Consolidated Framework for Implementation Research (CFIR). CFIR provides a framework to investigate and assess the implementation including the barriers and facilitators. The process consists of Phase 1: distribution of the online open-ended proforma to registry staff, clinicians, health care staff and consumers to gather prospective perceptions, and Phase 2: distribution of the online open-ended proforma to registry staff, clinicians, health care staff and consumers to gather retrospective perceptions.

Project Title	RGS 5164: AusVaxSafety national enhanced adverse events following immunisation (AEFI) and adverse events of special interest (AESI) surveillance and follow-up
Principal Investigator	Associate Professor Nicholas Wood
Institution	National Centre for Immunisation Research and Surveillance NSW
Start Date	14th December 2021	**Finish Date**	8th December 2024

Vaccine adverse events have been detected during the rollout of COVID-19 vaccine programs around the world. In Australia this is already impacting on our national vaccine program. The collection and analysis of clinical data for serious vaccine adverse events will provide management information for treating clinicians and will assist government and advisory bodies in providing guidance around appropriate vaccine use.

This project will describe in detail the clinical profile of cases experiencing various adverse events, including their long term outcomes. This may include conducting an epidemiological study to estimate the risk of the adverse event after vaccination or identification of biological markers that contribute to the adverse event, its severity or prognosis.