



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

# Department of Health Western Australia Human Research Ethics Committee

**Project Summaries for Approved Proposals**

July to September 2016 Quarter

## Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – July to September 2016 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 available for the July to September 2016 quarter.

<b>Project Title</b>	<b>Improving access to primary care for Aboriginal babies in Western Australia [SHORT TITLE: Improving access to primary care for Aboriginal babies]</b>		
<b>Principal Investigator</b>	Dr Daniel McAulley		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	Wednesday, 13 July 2016	<b>Finish Date</b>	Monday, 31 December 2018
<p>Despite a decade of substantial investments in programs to improve access to primary care for Aboriginal mothers and infants, there is increasing concern that over 50% of Western Australian (WA) Aboriginal babies are still not receiving preventative care in the early months of life.</p> <p>There have been no studies of the effect of population based approaches to improve access and health outcomes for young infants especially infants who live in the most disadvantaged and mobile families. We will undertake a population based, stepped wedge cluster, randomised controlled trial of a new integrated model of early infant primary care.</p> <p>The trial will be directed from Princess Margaret Hospital for Children in Perth. The intervention is targeted support and care coordination for Aboriginal families with new babies starting as soon as possible during the antenatal period or after birth. Dedicated health professionals and research staff will: consult with families about their health care needs; provide information about health care in the first three months of life; offer assistance with birth and Medicare forms; consult with families about their choice for primary care provider; offer to notify the chosen primary care provider about their baby's health needs; and offer assistance with health care coordination at the time of discharge from hospital.</p> <p>We will evaluate this model of care using rigorous step wedge approaches and qualitative in-depth interviews to assess acceptability, feasibility and sustainability.</p> <p>Our primary outcome measure is improved hospitalisation rates in infants aged 0-3 months. Secondary outcome measures include completed Aboriginal and Torres Strait Islander child health screening assessments, immunisation coverage and satisfaction of families about early infant primary care. We will also assess the cost effectiveness of the model of care.</p> <p>This study will be conducted over a four year period in partnership with birthing hospitals and primary care providers including Western Australian Aboriginal Community Controlled Health Services and the new Primary Health Networks. The results of our trial will be used to develop improved primary care models and to improve health outcomes for all Aboriginal infants. These are vital steps towards more equitable health service delivery for Aboriginal and Torres Strait Islander children in Australia.</p>			

<b>Project Title</b>	<b>Cleft lip and palate - a comparative psychosocial perspective</b>		
<b>Principal Investigator</b>	Ms Wendy Nicholls		
<b>Institution</b>	Princess Margaret Hospital		
<b>Start Date</b>	Sunday, 1 May 2016	<b>Finish Date</b>	Wednesday, 1 May 2019
<p>Cleft lip and palate is the most common congenital craniofacial anomaly globally. It has been reported to have an average global incidence of 1 in 600 (500-750) live births with variation across racial groups. The long term care of patients with a cleft condition involves many years of multi-disciplinary therapy, treatment and surgical interventions at both fixed and varying time-points.</p> <p>The Princess Margaret Hospital Cleft Lip and Palate (CLP) Unit is the longest serving cleft unit in Australasia, which reviews and provides treatment to an average of 50 (range from 48 to 62) live-born cleft lip and palate births each year. Patients are reviewed and treated by the PMH CLP Unit until the age of 18 to 21 years, and in some cases to 28 years. This includes regular clinic follow-up, specialist consultation and treatment and review of ongoing surgical needs.</p> <p>The study aims to assess the health outcomes, mental health status and health services utilisation of people with cleft conditions and compare these to the general population. The number and type of hospital admissions, reason for admission (primary and secondary), procedures undertaken, length of stay, mental health admissions, deaths, community mental health occasions of service, ambulatory and emergency visits will be assessed.</p>			

<b>Project Title</b>	<b>Families impacted by cancer in Western Australia: a profile to support healthy child development</b>		
<b>Principal Investigator</b>	Dr Angelita Martini		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	Tuesday, 1 November 2016	<b>Finish Date</b>	Sunday, 30 December 2018
<p>In Western Australia (WA), we know very little about children, adolescents and young adults (less than 25 years of age) who are impacted by a parent or sibling with cancer. What we do know is that the diagnosis within a family causes great distress, to both the child and parent. We also know that in WA there are limited support services available to deal with this distress and what is available is often not age appropriate and is costly.</p> <p>This project aims to address this gap by describing this group. This information is essential for providing targeted services to support these children and their families, and to promote research into this much understudied area.</p>			

<b>Project Title</b>	<b>Does gastrostomy improve the lives of children with severe disability and their families [Short title: Gastrostomy in severe disability]</b>		
<b>Principal Investigator</b>	Dr Jenny Downs		
<b>Institution</b>	Telethon Kids Institute		
<b>Start Date</b>	Wednesday, 13 July 2016	<b>Finish Date</b>	Tuesday, 31 December 2019
<p>A gastrostomy is a tube that passes directly through the skin into the stomach and can provide food and fluids to the child who has feeding difficulties. We do not know how often gastrostomy is being used in children in Western Australia. Children with intellectual disability often have feeding difficulties which may cause chest infections and make it harder to take medicines for conditions such as epilepsy. Gastrostomy may help in the management of these problems.</p> <p>In this study, we will use linked data from multiple databases to ensure that we identify as many children with intellectual disability as possible. We will not know the identity of any child in any of the databases. In this study, we will find out how often children with intellectual disability receive a gastrostomy and how often complications occur. We will also find out whether having a gastrostomy reduces the number of hospital admissions for chest infections or poorly controlled epilepsy.</p> <p>Finally, we will find if children with intellectual disability from all walks of life in Western Australia have similar access to gastrostomy.</p>			

<b>Project Title</b>	<b>The association of sleep apnoea with long-term health outcomes in Western Australian adults [SHORT TITLE: Association of sleep apnoea with long-term health outcomes]</b>		
<b>Principal Investigator</b>	Dr Bhajan Singh		
<b>Institution</b>	Sir Charles Gairdner Hospital		
<b>Start Date</b>	Wednesday, 13 July 2016	<b>Finish Date</b>	Monday, 1 December 2025
<p>Obstructive sleep apnoea (OSA) is common and associated with poor health outcomes, many of which remain poorly characterised. We are in an excellent position to further investigate these outcomes because of our unique database of 21,000 patients who have undergone sleep studies over the past 26 years.</p> <p>New illnesses arising since these studies can now be examined using hospital, cancer, mortality, and mental health datasets linked by the Western Australian Data Linkage Branch (WADLB). This will tell us whether the presence and severity of OSA, and its treatment, predicts future risk of problems such as heart attacks, strokes, and cancers, independent of known risk factors.</p>			

<b>Project Title</b>	<b>New indicator “Western Australia Emergency Access Target (WEAT) Percentage of Emergency Department (ED) Attendances that are re-attendances less than or equal to 48 hours of the previous attendance” using encrypted linkage keys. [SHORT TITLE: Encrypted linkage keys to accurately calculate ED re-attendances]</b>		
<b>Principal Investigator</b>	Mr Andrew Puljic		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	Wednesday, 13 July 2016	<b>Finish Date</b>	Ongoing
<p>Key performance indicators (KPIs) are used by DOH to assess WA Health’s performance. One such KPI is the assessment of access to emergency departments and re-attendances within 48 hours. This application relates to the creation of a new KPI, “Western Australia Emergency Access Target (WEAT) Percentage of Emergency Department (ED) Attendances that are re-attendances less than or equal to 48 hours of the previous attendance” The creation and reporting of the new indicator will replace the current WEAT unplanned re-attendance within 48 hours indicator (MDG-04-102).</p> <p>The existing WEAT unplanned re-attendance within 48 hours definition relies heavily on medical staff identifying when a patient returns to the ED unplanned. Also, medical staff need to ensure the correct recording of attendances as unplanned in the Emergency Department System. Feedback from various stakeholders suggested results using this definition are undercounting unplanned re-attendances.</p> <p>The new re-attendances definition now aligns with the national definition, National Partnership Agreement on Improving Public Hospital Services:</p> <p style="text-align: center;"><i>Unplanned re-attendances to the emergency department within 48 hours of previous attendances.</i></p> <p>A vital aspect of this new KPI is for the Emergency Department Data Collection (EDDC) team to use linkage keys to establish people who re-attend EDs. The new definition provides a more accurate measure of re-attendances within an ED.</p>			

<b>Project Title</b>	<b>Hospitalisation and mortality due to cirrhosis in Western Australia [SHORT TITLE: Burden of liver cirrhosis in Western Australia]</b>		
<b>Principal Investigator</b>	Associate Professor Leon Adams		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	Wednesday, 1 June 2016	<b>Finish Date</b>	Sunday, 31 December 2017
<p>Liver cirrhosis may lead to significant ill-health by causing liver failure and liver cancer. The most common liver condition in Australia is non-alcoholic fatty liver disease (NAFLD), which is present in approximately one quarter of Australians, and may lead to cirrhosis in a small proportion of individuals.</p> <p>Currently, it is unknown whether ill-health from cirrhosis and its complications are increasing. In addition, it is unknown whether NAFLD is contributing to the health burden related to</p>			

cirrhosis.

This project will determine whether the frequency of 1) hospitalisation, 2) diagnosis of liver cancer or 3) death, due to cirrhosis have increased in Western Australia over a 20 year period.

This project will also examine the underlying causes of cirrhosis, and in particular, determine whether NAFLD is leading to an increased rate of hospitalisation, liver cancer or death related to cirrhosis.

To achieve the study aims, the project will utilise the resources of the Western Australian Data Linkage Unit, and interrogate the state-wide hospitalisation morbidity database, cancer registry and death registry.

<b>Project Title</b>	<b>Identification of markers for diagnosis and prognosis of cancer</b>		
<b>Principal Investigator</b>	Professor Mel Ziman		
<b>Institution</b>	Edith Cowan University		
<b>Start Date</b>	Friday, 16 September 2016	<b>Finish Date</b>	Tuesday, 4 June 2019
<p>As part of our ongoing research project investigating circulating tumour cells (CTCs), white blood cells, gene expression (RNA), cell free DNA and proteins in the peripheral blood of cancer patients, WA clinicians collected blood samples from melanoma patients. We anticipate that changes in cellular, genetic or protein markers in the blood of patients are indicative of tumour presence (diagnostic) or may provide information on patient outcome or tumour progression (prognostic) or response to treatment.</p> <p>WA Health Ethics approval has already been obtained through SCGH hospital ethics board and the Edith Cowan University Human Ethics Research Committee. Therefore to determine patient outcomes we are interested in requesting mortality data only from the Western Australian Cancer Registry for a cohort of melanoma patients to aid in the analysis of our markers.</p>			

<b>Project Title</b>	<b>Non Admitted Patient Activity and Wait List Data Collection Infrastructure Linkage</b>		
<b>Principal Investigator</b>	Ms Michele Russell		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	Wednesday, 10 August 2016	<b>Finish Date</b>	Ongoing
<p>This project aims to link Non Admitted Patient Activity and Wait List Data Collection (NAPAAWL DC) data. It is designed to support research and evidence-based service planning.</p>			

<b>Project Title</b>	<b>Healthdirect Australia Telehealth and E-Health Syndromic Surveillance System</b>		
<b>Principal Investigator</b>	Dr Janice Biggs		
<b>Institution</b>	Healthdirect Australia		
<b>Start Date</b>	Wednesday, 1 June 2016	<b>Finish Date</b>	Sunday, 31 December 2017
<p>Healthdirect Australia is a government funded company that provides telephone and digital advice and information throughout Australia. Each year the Healthdirect nurse triage hotline receives over 700,000 calls, in addition to over 2.2 million inquiries through the online symptom checker.</p> <p>The symptom checker is an online tool where visitors answer questions about their symptoms and receive health advice, using a similar methodology as the nurse triage hotline. Healthdirect Australia data have the ability to provide health departments with an indication of community level disease by reporting on symptoms of disease in individuals who do not access any health care providers.</p> <p>This project will significantly contribute to the monitoring of disease in Australia, and also have the ability to forewarn health departments of outbreaks. We propose using these data to inform a syndromic surveillance system. The aims are:</p> <ol style="list-style-type: none"> <li>1. To use Healthdirect Australia data to contribute to and complement public health surveillance in Australia by providing validated information about community cases of syndromes.</li> <li>2. To provide information about syndromes of high public health interest.</li> <li>3. To forewarn of any emerging public health concerns.</li> <li>4. To report to the Commonwealth, state health departments and the public in a form that is timely and relevant.</li> </ol> <p>Phase 1 of establishing the surveillance system will involve creating an advisory group with members from NSW Ministry of Health, WA Department of Health, Commonwealth Department of Health and Healthdirect Australia to advise on how best to achieve these aims.</p> <p>Phase 2 will involve data analysis to validate the data source and to complete descriptive analysis. We have identified four aspects of descriptive analysis to investigate. These are severity, incidence, temporal or geographic distribution and seasonal thresholds and signal identification.</p> <p>The methods for designing the data analysis aspect of the surveillance system are as follows. First, we will identify possible syndrome trends in the Healthdirect Australia data by extracting de-identified, aggregated records for a number of syndrome categories. We will then validate the syndrome definitions and Healthdirect data in general by comparing with a variety of verified data sources. These verified data sources are the WA and NSW emergency department surveillance, FluTracker, over-the-counter pharmacy sales and the National GP surveillance network (ASPREN.)</p>			

<b>Project Title</b>	<b>Evaluating the Undiagnosed Diseases Program, Western Australia (UDP-WA): Perspectives from parents/caregivers</b>		
<b>Principal Investigator</b>	Ms Alicia Bauskis		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	Monday, 22 August 2016	<b>Finish Date</b>	Tuesday, 22 October 2019
<p>The Undiagnosed Diseases Program, Western Australia (UDP-WA) is a new clinical program based at Genetic Services WA. The Program will try to provide a definitive diagnosis for people with complex and long-standing, yet unknown medical conditions. The program commenced in March 2016 and it has a current focus on children with undiagnosed diseases and aims to take on one new case per month.</p> <p>To monitor and evaluate the program, the Office of Population Health Genomics (OPHG), WA Department of Health, together with researchers from the School of Population Health (SPH), University of Western Australia (UWA) are undertaking an evaluative research study entitled 'Evaluating the Undiagnosed Diseases Program, Western Australia (UDP-WA) perspectives from parents/caregivers'.</p> <p>The study aims to develop new knowledge in the area of experiences from parents of children with an undiagnosed condition and to understand the outcomes of the program by:</p> <ol style="list-style-type: none"> <li>1. Building a comprehensive understanding of the diagnostic journey for parents of children with an undiagnosed condition in Western Australia.</li> <li>2. Understanding the differences made, if any, by the UDP-WA from the perspective of parents of children going through the program.</li> <li>3. From the findings of the qualitative study, identify and/or develop patient-centred outcome measures that are able to be routinely collected for the UDP-WA for future monitoring and evaluation.</li> <li>4. Conducting a health service utilisation analysis to provide further insights on how a child's health condition is managed.</li> </ol> <p>The project is the world's first known evaluation of an undiagnosed diseases program and will provide important information on the outcomes of the program from the point of view of parents/caregivers of children taking part in the program.</p> <p>A series of three semi-structured interviews will be conducted with between 10 to 12 primary caregivers of children taking part in the UDP-WA. The first interview will take place before a child is admitted to the Clinical Stage of the Program. The second interview will take place shortly following the end of the program and the third will take place 12 months following this. Data will be analysed using thematic analysis and, if appropriate, phenomenological analysis.</p> <p>The evaluative research study is expected to produce several peer reviewed journal articles and a brief questionnaire that can be administered to future parents of children going through the program as part of its ongoing monitoring and evaluation. Health utilisation data will also be collected to examine whether health service usage changes over time.</p>			



<b>Project Title</b>	<b>Long term treatment outcomes in early psychosis specialist services</b>		
<b>Principal Investigator</b>	Associate Professor Geoffrey Smith		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	Saturday, 1 October 2016	<b>Finish Date</b>	Monday, 30 September 2019
<p>There are a growing number of studies of specialist Early Intervention in Psychosis (EIP) services reporting better short-term outcomes, including symptom reduction, lower relapse rates, greater adherence to treatment, higher levels of engagement and lower cost when compared with standard care. The emerging evidence showing these benefits are sustained is at best equivocal. The important question, for this study, is whether short-term benefits can be translated into longer-term gains.</p> <p>This study is a retrospective cohort design using longitudinal, prospectively collected service data. It compares the outcomes of people with early psychosis treated in two specialist, catchment-area based EIP service with those in a matched comparison control who receive 'standard treatment'. Outcome data up to 2012 have been sourced from the WA Data Linkage System, linking data obtained from inpatient and outpatient psychiatric service, hospital morbidity, emergency department and mortality registers.</p> <p>The EIP cohort comprises of all patients admitted to two specialist EIP services between 1 January 2000 and 31 December 2008. The two services are located in the Perth metropolitan area and are part of public adult mental health services. The matched control group of individuals has been obtained from the Western Australian Mental Health Information System. The comparison group has been matched on age, gender, diagnosis, Aboriginality, socio-economic status and time of first contact with a public adult mental health service.</p> <p>The overall aim of this study is to evaluate whether patients in the two EIP services have superior short and long-term outcomes when compared to patients in standard treatment (ST) and whether diagnosis or type/model of EIP service impacts on outcomes. Major outcome measures will include use of inpatient and community mental health services, use of emergency departments and general hospital services and mortality.</p> <p>This study received ethics approval from DOH HREC in 2010 and commenced in January 2011. Over the course of the project there were a number of unforeseen, complex and time-consuming issues, which resulted in significant delays that prevented the research from being completed within the anticipated 2 year timeframe.</p> <p>Funding for the data analyst ran out in December 2012. In February 2013, the linked dataset was made available. No alternative funding source could be found for analysis of the data until recently, when the School of Population Health agreed to become partners in the project. This is a new application seeking to extend the period of ethics approval for the project.</p>			

<b>Project Title</b>	<b>Observing Recurrent Incidence of Adverse Outcomes following Hospitalisations (ORION) [Short Title: ORION]</b>		
<b>Principal Investigator</b>	Dr Isuru Ranasinghe		
<b>Institution</b>	The University of Adelaide		
<b>Start Date</b>	Wednesday, 1 February 2017	<b>Finish Date</b>	Friday, 31 December 2021
<p>As a leading cause of death and disability, and as a major cause of health expenditure, hospital-based cardiovascular care has a significant impact on the Australian health care system. However, hospital-based cardiac care varies considerably among Australian hospitals.</p> <p>Furthermore, despite concerns about suboptimal and varying care, important measures of care quality as deaths, complications and unanticipated return hospital visits following cardiovascular hospitalisations are rarely assessed. Moreover, the extent to which these adverse patient outcomes vary among hospitals, and whether patient outcomes have improved with time, is largely unknown. This is in part because we lack standardised and internationally accepted methods to assess these outcomes.</p> <p>The ORION study will evaluate adverse patient outcomes following cardiovascular hospitalisations among Australian hospitals. In doing so, we seek to adapt internationally accepted and standardised methods to assess patient outcomes for use with administrative data from Australian hospitals.</p>			

<b>Project Title</b>	<b>Characteristics and outcomes of Brightwater Care Group clients with an Acquired Brain Injury</b>		
<b>Principal Investigator</b>	Dr Angelita Martini		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	Wednesday, 1 February 2017	<b>Finish Date</b>	Monday, 30 December 2019
<p>In Western Australia (WA), people with an acquired brain injury (ABI) are a large and increasing population. They are known to have psychological, social and physical problems, and can be severely marginalised in the health system, with their needs often overlooked and misunderstood.</p> <p>This project will describe the ABI client population supported by the Brightwater Care Group (BCG) and determine their outcomes during and after their care and support with this organisation. It is designed to improve understanding of this vulnerable group and to support evidence-based service planning for BCG, so as to enable them to provide effective health and social services now and into the future.</p>			

<b>Project Title</b>	<b>Western Australian Burden of Disease Study [SHORT TITLE: WA Burden of Disease Study]</b>		
<b>Principal Investigator</b>	Dr Laura Miller		
<b>Institution</b>	Department of Health		
<b>Start Date</b>	Thursday, 1 September 2016	<b>Finish Date</b>	Wednesday, 30 June 2021
<p>Burden of disease is a modelling technique that combines information from multiple data sources to create summary measures of the fatal and non-fatal health loss from diseases and injuries in a population. The proposed WABoD Study is a collaborative study with the Australian Institute of Health and Welfare (AIHW) who have recently completed the Australian Burden of Disease Study (ABDS) 2011.</p> <p>As part of this study, the AIHW have estimated the fatal and non-fatal health loss for Australia for nearly 200 diseases and injuries, and the burden related to 30 different risk factors. The aim of the WABoD Study is to create detailed burden of disease measures for Western Australia (WA), using the knowledge and modelling system already set up by the AIHW.</p> <p>The WABoD Study will involve the provision of aggregated data on death and measures of ill-health for the WA population to the AIHW for input into their burden of disease models. The AIHW will then provide the Epidemiology Branch with burden of disease outputs which can be used by the WA Department of Health (DOH) and other health system stakeholders, for monitoring population health, informing health policy and health service planning, and measuring the health impact of interventions.</p> <p>For the majority of the estimates, the Epidemiology Branch will be using state datasets approved for their use for WA Department of Health business through a Standing Agreement with the Data Integrity Directorate (now Data Collections Directorate) and the Data Linkage Branch (DLB) of the Purchasing and System Performance Division. No identifiable data will be provided to the AIHW; only aggregated and derived datasets will be provided. These datasets will be processed at the AIHW and burden of disease measures including Years of Life Lost (YLL), Years Lost to Disability (YLD) and Disability Adjusted Life Years (DALY) figures will be provided back to the Epidemiology Branch for further analysis.</p> <p>Normally, HREC approval would not be sought as the Epidemiology Branch has approval to release aggregated and derived datasets under the Standing Agreement and the WA DOH 'Guidelines for the Release of Data', but it is planned that analysis from the WABoD study will be published in external reports and peer reviewed journal articles.</p>			

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