Government of Western Australia
Department of Health

Human Research Ethics Committee

Project Summaries for Approved Proposals

July to September 2015 Quarter

Project summaries for proposals approved by the Department of Health Human Research Ethics Committee - July to September 2015 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 summaries available for the July to September 2015 quarter.

Project Title	**Uptake of antenatal influenza and pertussis (whooping cough) vaccination in pregnant mothers, 2015 - 2019**		
Principal Investigator	Dr Donna Mak		
Institution	Department of Health		
Start Date	15 November 2015	**Finish Date**	30 June 2020
Influenza vaccination has been recommended and funded by the Australian government for pregnant women in Australia since 2009. Uptake improved from 10% in 2009 to 36% in 2013, but is still sub-optimal. Ongoing monitoring is required to evaluate the effectiveness of strategies to improve uptake. Antenatal pertussis or whooping cough vaccination was introduced in Western Australia and most other Australian jurisdictions in April 2015. This followed the death of a four-week old baby due to pertussis. This included the lack of evidence to the effectiveness of post-natal pertussis vaccination of parents and/or caregivers in protecting babies who are too young to be immunised. This survey will provide valuable data to evaluate uptake of antenatal pertussis vaccine and its effectiveness in preventing pertussis infection in infants.			

Project Title	**Respiratory hospitalisations in children and young people with cerebral palsy: Which children and at what cost?**		
Principal Investigator	Dr Marie Blackmore		
Institution	Ability Centre		
Start Date	1 January 2016	**Finish Date**	31 December 2017
Respiratory disease is the leading cause of death and hospital admissions in children and young people with cerebral palsy (CP). CP is associated with very preterm birth. Very preterm birth is, in turn, associated with respiratory disease. This study will investigate whether people with CP who were preterm have a higher risk of serious respiratory disease during childhood and early adult life. Serious respiratory disease will be measured by respiratory hospital admissions. At the same time, the costs of respiratory hospital admissions for children and young people with CP will be described.			

Project Title	**LungScreen WA project: Targeting high risk individuals for early detection of lung cancer using low dose computed tomography**		
Principal Investigator	Dr Annette McWilliams		
Institution	Sir Charles Gairdner Hospital		
Start Date	31 August 2015	**Finish Date**	1 June 2019

The LungScreen WA project is a prospective cohort study that aims to assess the feasibility, effectiveness and cost of lung cancer screening with low dose computed tomography (LDCT) in the Australian population. This ongoing study is recruiting current and former smokers aged 55 - 74 years to receive LDCT lung cancer screening based on their individual lung cancer risk. Two groups of participants will be formed based on their eligibility for lung cancer screening as per their lung cancer risk. Individuals with increased lung cancer risk will undergo clinical interview, lung function testing and LDCT. All subsequent positive scan results will be investigated and managed by an expert team of radiologists and respiratory physicians using newly developed risk prediction tools and protocols. Low risk participants will have quality of life outcomes and smoking cessation rates measured. Cost outcomes will be modelled using data collected from the participants and population level databanks combined with the results of international trials to determine the cost effectiveness of lung cancer screening in Australia.

Project Title	**Do people with disabilities access community-based palliative care services and does this service relieve hospitals and emergency departments: A study of the needs of people with intellectual disability, multiple sclerosis and schizophrenia**		
Principal Investigator	Professor Lorna Rosenwax		
Institution	Curtin University		
Start Date	20 August 2015	**Finish Date**	31 January 2017

Very little is known about the health service needs and use of people with disabilities at the end of life. The proposed study will address this gap. The three groups chosen for investigation are adults with an intellectual disability, adults with multiple sclerosis and adults with schizophrenia. The study aims to:

1. Explore the needs of people with disabilities in their last year of life
2. Investigate potential need for community-based palliative care for these groups
3. Determine whether they access palliative care
4. For those in receipt of palliative care, inquire whether they benefit from palliative care
5. Determine if receipt of community-based palliative care by people with disabilities relieves some of the burden on hospital and emergency departments.

Project Title	**Prenatal origins and health outcomes of male reproductive congenital anomalies diagnosed at birth and testicular cancer in adulthood**		
Principal Investigator	Associate Professor Natasha Nassar		
Institution	University of Sydney		
Start Date	10 August 2015	**Finish Date**	31 December 2018

There is growing concern about the rising rates of male reproductive congenital anomalies diagnosed at birth and testicular cancer in adulthood. Evidence suggests these conditions share a common origin in fetal life through the impaired production or disrupted release of androgens during the masculinisation period in-utero. This can result in increased risk of abnormal genital development in boys and subsequent sub-fertility, reduced semen quality and testicular cancer in adulthood. Genetic factors, maternal health and lifestyle or fetal growth disorders may influence androgen levels during fetal sex development. To date, investigation of maternal and pregnancy risk factors has been limited, and their combined effects have not been assessed.

This project will use record linkage of population data on pregnancies and births, congenital anomalies, hospitalisations and cancer to investigate perinatal factors and the link between male congenital anomalies and testicular cancer.

Project Title	**Evaluating the use and effectiveness of passive immunisation in reducing RSV-associated morbidity in high risk infants**		
Principal Investigator	Dr Hannah Moore		
Institution	Telethon Kids Institute		
Start Date	1 August 2015	**Finish Date**	31 December 2016

Respiratory Syncytial Virus (RSV) causes considerable illness in young children. Pre-term infants and those with lung or heart problems admitted to Neonatal Intensive Care Units (NICUs) are at increased risk of severe illness from RSV infection. Monthly injections of palivizumab, a form of passive immunisation, is the only RSV control measure currently used in Western Australia as there is no other vaccine to prevent RSV disease.

This project is a data linkage study that will describe the use of and compliance with palivizumab treatment among pre-term infants admitted to NICUs. The study also aims to evaluate the effectiveness of palivizumab on reducing RSV.

Project Title	**Genetic analysis of complex disease**		
Principal Investigator	Professor Grant Morahan		
Institution	University of Western Australia		
Start Date	1 September 2015	**Finish Date**	31 December 2025
This study is based on previous work in which a new method of defining genetic 'signatures' in people with certain diseases was developed. This study will be a continuation in heart disease (such as heart attack and stroke) and diabetes. It will involve using genetic data from the 1994 and 1995 Busselton Health Study which will be linked with survival data from the Department of Health. The study aims to create a genetic test which would define the risk of a person developing these diseases and the possible outcomes/severity they may experience. This would allow for earlier and better treatments and possible prevention of the disease.			

Project Title	**Genetic profiling of carcinomas of unknown primary (CUP)**		
Principal Investigator	Assistant Professor Katie Meehan		
Institution	University of Western Australia		
Start Date	31 July 2015	**Finish Date**	31 December 2019
Carcinoma of unknown primary (CUP) is a histologically confirmed metastatic cancer in the absence of an identifiable primary tumour following a standard diagnostic work-up. It is a well-recognised clinical disorder, accounting for 5% of all malignant epithelial tumours. There is a long held belief that these heterogeneous cancers share common biological properties that result in an early, aggressive and atypical metastatic spread. In view of this, the hypothesis for this study is that molecular sequencing of CUP tumours may provide insights into their biology. The study will also harness the existing knowledge that certain mutations are present in certain tumours, to supplement other (diagnostic) evidence towards indicating a possible tissue of origin.			

Project Title	**Oral health care for mental health consumers**		
Principal Investigator	Associate Professor David Whyatt		
Institution	University of Western Australia		
Start Date	1 August 2015	**Finish Date**	31 December 2016
This project will examine the uptake of publically funded oral health services amongst mental health consumers. The rates of such uptake will then be compared to other eligible populations. Furthermore, the burden of oral health disease in mental health patients will be examined. Guided by this work, improvements in the delivery of oral health services to mental health consumers can be undertaken.			

Project Title	**An investigation of research outputs from data linkage projects in Western Australia**		
Principal Investigator	Mr Geoff Davis		
Institution	Department of Health		
Start Date	27 July 2015	**Finish Date**	31 December 2016

Linked data is particularly valuable in health and health-related research because it allows for people's health outcomes to be followed across many different health and social services, whose records are typically collected separately. In Western Australia administrative data collections collect information about key events such as visits to hospital, cancer registrations, births and deaths. The Data Linkage Branch (DLB) in the Department of Health links such datasets together so researchers can access linked data for research, planning and evaluation.

Since commencing in 1995, the DLB has assisted researchers to access linked data for over 800 projects. A key requirement of accessing linked data is for data recipients to inform the DLB of results of the project and provide any outputs like journal articles, news items or presentations. In 2004 the DLB 'Research Outputs Project' produced a summary of the outputs of data linkage projects from 1995 – 2003.

The DLB seeks to update this project to cover the period 1995 – 2014. DLB will use records of all projects that have received linked data in that timeframe. This will determine if any of the projects from the original report have produced any more outputs and also investigate the results and outputs from projects since 2003.

Project Title	**An investigation into the use of WA data collections in linked data projects, 1995 – 2014 and how this compares with other data linkage centres**		
Principal Investigator	Mr Geoff Davis		
Institution	Department of Health		
Start Date	27 July 2015	**Finish Date**	31 July 2016

The Data Linkage Branch (DLB) maintains the WA Data Linkage System (WADLS). Over time the WADLS has grown to include a wide variety of administrative and research datasets. The DLB therefore has a very broad data linkage system. As yet, no investigation has been made into the use of these data collections over time nor how the WADLS compares to other linkage systems around the world.

This project will investigate the frequency of requests for each data collection, the growth of requests over time and how this compares to what is available around Australia and internationally. The results of this project will help inform future planning and support for the DLB and Data Custodians in provision of data for linked data projects.

Project Title	**Risk of osteoporotic and minimal-trauma re-fracture and costs related to incident osteoporotic fractures in Western Australia: A 10 year snapshot using the WA Hospital Morbidity Data System**		
Principal Investigator	Ms Anna Huska		
Institution	Department of Health		
Start Date	13 August 2015	**Finish Date**	31 August 2016
Osteoporotic fractures impose a considerable burden to the individual and public health system. The system-related costs attributable to osteoporotic fractures are unknown in Western Australia. Therefore, the aim of this project is to quantify the direct health system costs to WA associated with hospital admissions for people who sustained one or more fractures associated with osteoporosis over a ten year period. System costs will be determined by using data from the WA Hospital Morbidity Data System. The information will be used to complement a similar preliminary analysis undertaken by the Agency for Clinical Innovation in NSW and inform the implementation plan for the WA Osteoporosis Model of Care, currently being considered by members of the WA Musculoskeletal Health Network.			

Project Title	**HER2 expression in upper GIT precancerous lesions and adenocarcinoma and its correlation with morphological subtypes, progression and prognosis**		
Principal Investigator	Clinical Professor Marian Priyanthi Kumarasinghe		
Institution	Sir Charles Gairdner Hospital		
Start Date	1 September 2015	**Finish Date**	31 January 2017
Oesophageal cancer is the eighth most common cancer worldwide with an increasing incidence rate. Barrett's Oesophagus (a change in the lining of the lower oesophagus) is a well-described precursor to oesophageal dysplasia and adenocarcinoma. A significant proportion of oesophageal cancers have been demonstrated to express human epidermal growth factor receptor 2 (HER2), which in other cancers has been shown to be a predictor of response to targeted therapies. Its role in oesophageal adenocarcinoma however remains uncertain. This study aims to correlate morphological features and immunophenotype of neoplasia arising in Barrett's Oesophagus with HER2 amplification status, stage of disease and survival in an Australian context.			

Project Title	**A measure of Australian women's private health care maternity experiences**		
Principal Investigator	Dr Tracy Reibel		
Institution	Telethon Kids Institute		
Start Date	22 September 2015	**Finish Date**	31 December 2015

This project will investigate if a previously validated survey tool collecting women's maternity care experiences in public maternity hospitals is valid for use by private hospital maternity patients. Survey data will assist maternity hospitals to report on women's experiences of maternity care as part of quality improvement and hospital accreditation.

Information for a survey user guide will be identified by disseminating the survey at the study site, St John of God Healthcare, Bunbury. The process will validate the survey for use with private maternity patients and provide a 'demonstration site' data set for analysis. This will assist with deciding what information is required for the user guide to make the survey process and outcomes meaningful to hospital management. The final project outcome will be a detailed process capable of aiding St John of God Healthcare to monitor patient perceptions of their maternity care using a standard validated tool.

Project Title	**Utility of pathological biomarkers in predicting prognosis in breast cancer patients**		
Principal Investigator	Dr Greg Sterrett		
Institution	Sir Charles Gairdner Hospital		
Start Date	15 September 2015	**Finish Date**	1 June 2018

Breast carcinoma is the second most common cancer death in Australian women. Treatment is complex and selecting the best treatment requires input from surgeons, oncologists and pathologists. Identification of patients who may benefit from chemotherapy is particularly problematic for 'intermediate risk women' (with small tumours that have not spread to other tissues) in whom only 15% may benefit from chemotherapy versus 85% who do not benefit and may actually come to harm from such therapy. Correct identification of women in this 'intermediate risk' group who may benefit from chemotherapy is extremely important and is the main aim of this project.


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