



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

# Department of Health Western Australia Human Research Ethics Committee

**Project Summaries for Approved Proposals**  
April to June 2019 Quarter

## Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – April to June 2019 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 April to June 2019 quarter.

<b>Project Title</b>	The mid and long term clinical outcomes in patients treated with Everolimus-Eluting Bioresorbable Vascular Scaffold in public tertiary hospitals of Western Australia		
<b>Principal Investigator</b>	Dr Imran Shiekh		
<b>Institution</b>	Royal Perth Hospital		
<b>Start Date</b>	12 June 2019	<b>Finish Date</b>	12 June 2020
<p>This is a retrospective cohort study of 376 patients who were treated with Absorb Bioresorbable Vascular Scaffold in Western Australian public hospitals between 2012 to 2016. These patients were in different states of compromise, ranging from stable angina to acute coronary syndrome. Clinical registry data from the four public hospitals will be extracted for the cohort and linked with data on hospital admissions and death from the WA Data Linkage System.</p> <p>The treating clinicians see it as a duty of care to evaluate the outcomes in patients who were treated with Absorb Bioresorbable Vascular Scaffold. The study will also help to provide better quality care in the follow-up of these patients.</p>			

<b>Project Title</b>	Evaluation of post-operative care following repair of gastroduodenal ulcer perforation, effect on patient outcomes and development of a new protocol		
<b>Principal Investigator</b>	Dr Amanda Foster		
<b>Institution</b>	Fiona Stanley Hospital		
<b>Start Date</b>	30 April 2019	<b>Finish Date</b>	31 December 2027
<p>This is a retrospective study that aims to assess the post-operative management practices after surgical repair of peptic and duodenal ulcer perforation in an emergency setting. The study will cover the period from January 2010 to December 2017 and determine the impact on immediate and long-term patient outcomes at Fiona Stanley Hospital, Fremantle Hospital, Royal Perth Hospital and Sir Charles Gairdner Hospital. The study aims to assess the impact of pre-operative, intra-operative and post-operative factors influencing immediate and long-term patient outcomes and evaluate the quality of follow up and prevention measures patients are receiving after they are discharged from hospital.</p> <p>The study will also involve carrying out a survey of General Surgeons in Australia with regard to their practices and follow-up of these patients. It is intended that a protocol be developed for managing patients undergoing surgical repair of perforated gastroduodenal ulcer, which will guide immediate and long-term patient management.</p>			

<b>Project Title</b>	How is birth by Caesarean section delivery associated with the risk of childhood type 1 diabetes?		
<b>Principal Investigator</b>	Prof Elizabeth Davis		
<b>Institution</b>	Perth Children's Hospital		
<b>Start Date</b>	4 April 2019	<b>Finish Date</b>	1 April 2024

The number of children being diagnosed with type 1 diabetes has been increasing but the cause for this remains unknown. Over the past decades, there has been an increasing number of babies being born by caesarean section, with 30% of Australian babies now born this way. Several studies around the world have shown that there is an increased risk of type 1 diabetes in babies born by caesarean section. Could the increasing number of babies born by caesarean section be contributing to the increasing incidence of childhood type 1 diabetes? This project aims to address this question by looking for differences between babies born in Western Australia who go on to be diagnosed with type 1 diabetes under the age of 15 years, compared to those that do not.

<b>Project Title</b>	Influenza vaccination in Western Australian children: an economic evaluation to inform future state and national programs		
<b>Principal Investigator</b>	Associate Prof Christopher Blyth		
<b>Institution</b>	Perth Children's Hospital		
<b>Start Date</b>	10 April 2019	<b>Finish Date</b>	30 June 2020

The Western Australian Department of Health has recommended and provided free influenza vaccines to healthy preschool children since 2008. This vaccination program has been recommended in addition to the concurrent funded national program for at-risk infants. Previous studies have shown that, compared to those unvaccinated, hospital admissions and presentations to emergency departments and general practitioners for influenza-like illness were less frequent among vaccinated children. Children vaccinated against influenza are also less likely to spread influenza in the community, thereby reducing the total community burden of disease.

This study aims to evaluate the cost effectiveness of the current Western Australian preschool influenza vaccine program. Using local health outcomes data, the project team will first build a mathematical model to assess the number of Western Australians affected by influenza each year and estimate the reduction in influenza burden each year under different childhood vaccination coverage scenarios. Applying the costs of the program (vaccine purchase and administration costs) and costs averted through the expected reduction in health-care encounters, it is expected that the study demonstrates that the preschool influenza vaccination program is cost effective, saving the Western Australian Department of Health millions of dollars every year.

<b>Project Title</b>	Comparing obstetric outcomes of syntocinon regimens before and after 2012 in Geraldton Regional Hospital.		
<b>Principal Investigator</b>	Dr Terri Pikora		
<b>Institution</b>	Rural Clinical School of Western Australia		
<b>Start Date</b>	30 April 2019	<b>Finish Date</b>	2 December 2023
<p>The syntocinon regimen for the induction and augmentation of labour was changed at King Edward Memorial Hospital in 2012. Subsequently, most other sites throughout Western Australia also changed. The outcomes for mothers and babies before and after this change have not been examined. This is a single hospital study of maternal and neonatal outcomes before and after the regimen change.</p>			

<b>Project Title</b>	Development and evaluation of the Urban Health Check: an evidence-based planning support system to assist the design of health-promoting communities		
<b>Principal Investigator</b>	Dr Paula Hooper		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	3 May 2019	<b>Finish Date</b>	30 September 2021
<p>The University of Western Australia, LandCorp, the Planning Institute of Australia and the Heart Foundation will work collaboratively on this study to develop, implement and evaluate an empirically-driven, evidenced-based health impact planning support system ('Urban Health Check'). The aim of this system is to establish a greater focus on health in designing and planning Western Australian communities. It will provide those responsible for the design (and redesign) of communities with access to quantifiable evidence-based information about how their decisions impact different community health outcomes.</p> <p>The WA Health and Wellbeing Surveillance System data will be used in the study to explore the relationship between environmental exposure and health related behaviours (e.g. physical activity, mental health, diet / eating behaviours). Statistical analyses will be carried out to develop models of health impact across the course of life.</p>			

<b>Project Title</b>	The utilisation and safety of prescription drugs of dependence in pregnancy		
<b>Principal Investigator</b>	Dr Erin Kilty		
<b>Institution</b>	The University of Western Australia		
<b>Start Date</b>	10 May 2020	<b>Finish Date</b>	8 January 2024
<p>Prescription drugs of dependence are a class of medicines with a high potential for misuse, abuse and dependence. However, they are often indicated for the treatment of conditions such as severe pain, attention deficit hyperactivity disorder, opioid dependence and severe anxiety. The use of these medications during pregnancy has potential to cause harm to the developing fetus. However, ceasing treatment can also be risky, but very little evidence exists to guide the treatment of pregnant women using drugs of dependence. This study aims to examine the extent and safety of the use of these medications during pregnancy, to help patients and doctors make informed treatment decisions.</p>			

<b>Project Title</b>	Real-World Health Economic Impact of First Seizure and Newly Diagnosed Epilepsy		
<b>Principal Investigator</b>	Prof Patrick Kwan		
<b>Institution</b>	Monash University		
<b>Start Date</b>	20 May 2019	<b>Finish Date</b>	1 December 2020
<p>Epilepsy is one of the most serious chronic neurological disorders. It is estimated that over 250,000 Australians are currently living with epilepsy, and up to 3.5% of Australians will experience epilepsy during their lifetime. Antiepileptic drug therapy constitutes first line treatment for seizure management and can render two-thirds of the patients seizure-free. A preliminary study demonstrated 18% of the patients with epilepsy had delay in initiation of treatment and another 12% did not receive treatment at all. It is unclear whether the delayed and absence of treatment can impose significant health and/or economic burden in people with epilepsy. Furthermore, misdiagnosis and misclassification of epilepsy is common, with detrimental consequences, including uncontrolled seizures and increased morbidity and mortality. It remains to be determined if there are significant differences in outcomes for people with non-epileptic events causing transient loss of consciousness, including cardiogenic and vasogenic syncope.</p> <p>This study aims to assess the long-term mortality and morbidity of syncope, epileptic seizure and epilepsy. The outcomes will be compared to the general population in Western Australia. The project will also estimate and compare the long-term health economic effects of patients suffering from epilepsy who are treated immediately, after some time, or not at all.</p>			

<b>Project Title</b>	Impact of comorbidity and time in hospital on time and cost to healing of wounds		
<b>Principal Investigator</b>	Ms Joanna Smith		
<b>Institution</b>	Silver Chain Group		
<b>Start Date</b>	28 June 2020	<b>Finish Date</b>	31 December 2020

This study aims to determine whether the application of a comorbidity index to hospital administrative data will predict the impact of chronic disease and comorbidity on healing time of wounds treated in the community. The objectives of this study include:

1. quantifying the proportion of clients who had a wound treated in the community by Silver Chain who were hospitalised during the five years prior to the wound admission to Silver Chain;
2. describing the hospital admissions in terms of number and duration;
3. calculating the CCI for each admitted client as well as the number of chronic diseases documented known to impact on wound healing; and
4. determining if the CCI score is predictive of wound healing and cost of healing and compared to a simple count of conditions.

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