Government of **Western Australia**
North Metropolitan Health Service
Sir Charles Gairdner Osborne Park Health Care Group

Sir Charles Gairdner Hospital and Osborne Park Health Care Group

Human Research Ethics Committee

Project Summaries for Approved Projects
April to June 2022 Quarter

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Project summaries for proposals approved by the SCGOPHCG Human Research Ethics Committee – April to June 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 SCGOPHCG HREC. It contains summaries of projects approved in the April to June 2022 quarter.

Project Title	Diagnostic accuracy of ROTEM Sigma to identify coagulopathy during orthotopic liver transplantation surgery
Principal Investigator	James Preuss
Institution	Sir Charles Gairdner Hospital
Approval Date	06 April 2022

Liver transplant surgery is associated with conditions where the blood does not clot effectively resulting in bleeding and significant blood loss. There are devices that assess the ability of blood to form clots, one of which is the ROTEM® SIGMA.

During liver transplant surgery it is our routine clinical practice to perform ROTEM SIGMA tests along with other laboratory tests to continually monitor the patient's ability to form blood clots in an attempt to minimise overall bleeding and blood loss during the procedure. Research in open heart surgery suggests ROTEM SIGMA has acceptable accuracy and is more rapid than routine laboratory test for the assessment of clotting however there is much less research regarding the accuracy of ROTEM in liver transplant surgery.

The aim of study is to assess the accuracy of ROTEM SIGMA to identify patients with a poor ability to form clots during liver transplant surgery.

Project Title	COVID Rapid Assessment Test Evaluation (CRATE)
Principal Investigator	Tim Inglis
Institution	PathWest QEII, PathWest Fiona Stanley Hospital
Approval Date	07 April 2022

This project will compare the accuracy and convenience of rapid COVID-19 detection methods with the current reference standard, a PCR test for the SARS coronavirus type 2. These rapid detection methods have been tested successfully overseas and are now available for local validation before they can be introduced for use in Western Australia. One method applies an advanced lateral flow format to saliva, while the other uses a fast-acting spectrophotometer to test a nasal swab. These rapid tests are candidates for rapid, convenient confirmation of results from a self-administered rapid antigen test much faster that the PCR method. One or other may be suited to a point of care setting.

The project will use specimens collected at the same time as standard PCR swabs from drive-through test centres so that the new tests can be compared with the standard PCR method. The lateral flow format test is ready for a pilot study immediately, while the spectrophotometer method requires a little more preparatory work in the laboratory with leftover specimens before it is ready for a pilot study. The two methods will therefore be tested versus PCR in series and not in parallel.

Project Title	Clinical Trial of Lycovent Portable Mechanical Ventilator
Principal Investigator	Kate Luscombe
Institution	Sir Charles Gairdner Hospital
Approval Date	7 April 2022

The Lycovent portable ventilator is a novel ventilator that is designed to be affordable, reliable, serviceable and not rely on compressed gases.
The project is to assess usability in a theatre environment.

Project Title	Nurse middle managers satisfaction with organisational communication and the impact on their job satisfaction, burnout, and intention to stay
Principal Investigator	Gemma Doleman
Institution	Sir Charles Gairdner Hospital, Osborne Park Hospital
Approval Date	14 April 2022

Whilst effective organisational communication and leadership are essential for the delivery of high-quality patient care, little is known about the impact of organisational communication satisfaction on NM and, specifically, there is a paucity of evidence in relation to NM retention, burnout and job satisfaction. Therefore, the aim of this present study is to explore NM satisfaction with organisational communication in the adult acute care sector and the impact that this has on their job satisfaction, burnout and intention to stay.

Aim: To identify how satisfied nurse managers are with organisational communication and the impact of this on nurse managers job satisfaction, burnout and intention to stay in their current job.

Design: The study will employ a cross-sectional research approach. Surveys, with both closed and open-ended questions, will be distributed to nurse managers.

Project Title	The WA Lung Cancer Clinical Quality Data Platform “LUCAP” Pilot
Principal Investigator	Fraser Brims
Institution	Sir Charles Gairdner Hospital, Royal Perth Hospital, Fiona Stanley Hospital
Approval Date	20 April 2022

WA LUCAP is a pilot, proof of concept observational project designed to demonstrate the feasibility of the Lung Cancer Clinical Quality Data Platform (LUCAP) – the vision for a national data platform which enables auditing of lung cancer treatment centres against a set of quality standards and allows comparison across centres. LUCAP will collate routinely collected clinical data from patients with lung cancer (suspected or confirmed) onto one central data platform, designed to be scalable to manage data from hundreds of treating centres. LUCAP will only capture routinely collected clinical data and outcomes; there are no interventions or novel treatments being offered to participants. The data collected from each treatment centre will be analysed through regular audit cycles against endorsed national clinical quality indicators (CQI) of care to identify unwarranted variations in care and where significant improvements can be made to deliver consistent, world-class care across Australian.

Project Title	A longitudinal qualitative exploration of the relational and socio-emotional experiences of families and young people over a sarcoma cancer trajectory.
Principal Investigator	Moira O'Connor
Institution	Sir Charles Gairdner Hospital
Approval Date	21 April 2022

Sarcoma accounts for 1% of all diagnosed cancers, and between 15% to 21% of all cancers diagnosed in the adolescent and young adult (AYA) population worldwide. Sarcoma cancers commonly occur as solid tumours in AYA patients, 60% of these are on the extremities, with around 70% in the lower limbs. Sarcoma disproportionately affects the adolescent and young adult (AYA) population. The treatment sequelae of sarcoma are complex and protracted, requiring frequent contact with a multidisciplinary team, hospitalisation, and surgical procedures that alter physical appearances and diminish physical functioning with varying side effects. The increased needs for caregiving and support on various fronts present major challenges and demands on AYA patients and family members. Currently, there is limited research that examines the impact a cancer diagnosis has on families as a unit. This longitudinal qualitative research will explore how sarcoma impacts familial relationships, subsequently how families navigate the cancer trajectory.

Project Title	Missed TB prevention opportunities: Adherence with latent TB infection (LTBI) management guidelines at WA TB Control Program
Principal Investigator	Ruad Perera
Institution	WA Tuberculosis Program
Approval Date	22 April 2022

Tuberculosis (TB) is a spectrum illness. In most cases, after first inhalation the tuberculous bacteria will settle in the patient's lungs remaining dormant and inactive and be contained by their immune system. This is called latent TB infection (LTBI). In this stage the patient does not experience any symptoms, is not infectious and has a normal chest x-ray. Over the course of the patient's lifetime there is a 10-15% risk that the latent TB infection will activate causing active TB disease. This is characterised by symptoms such as cough, fever or unexplained loss of weight, it is infectious and as such, it is a grave public health concern.
Instead of exclusively targeting treatment of patients with active TB, in recent years the global TB control strategy has expanded its focus to include treatment of LTBI. The basis of this is that successful diagnosis and treatment of LTBI can prevent future cases of active TB.
This study aims to assess whether patients diagnosed and treated for active TB at the WA TB Control Program (WATBCP) in 2019 were known to the service previously. If there were, an exploration of whether they were accurately screened and offered treatment LTBI will be ascertained. As such it can be elicited whether opportunities to prevent active TB have been missed

Project Title	Resistance exercises in patients with Intensive Care acquired weakness - an observational pilot feasibility study
Principal Investigator	Matthew Anstey
Institution	Sir Charles Gairdner Hospital
Approval Date	26 April 2022

Despite recent advances in prevention through rehabilitation and nutrition, it is estimated that one-quarter to one-half of long-stay intensive care survivors live with significant weakness (ICU acquired weakness – ICU-AW) as a consequence of their illness, resulting in impaired mobility and function, as well as a prolonged hospital stay . For working age patients, this also delays their return to work, with many patients not back at work within 6 months of discharge. In some patients with ICU-AW, their muscle weakness is so profound that is can be difficult for them to engage with physiotherapy. Early physiotherapy in the Intensive care is the only therapy currently available to patients.

There are potentially other ways of accelerating recovery of muscle weakness. Use of resistance exercises is commonly employed to build strength and endurance, and this is usually achieved by using the body weight of the patient in the ICU. An alternative, may be to use elastic band (such as the brand “theraband”) exercises. These elastic resistance bands are in widespread use in community physiotherapy, and in outpatients at SCGH, and have been trialled in other ICUs, but are not currently usual practice in SCGH ICU.

Aim: The aim of this project is to test the feasibility of using elastic band exercises in deconditioned ICU patients in the SCGH.

Project Title	Title: Investigation on out-of-field dosimetry in multiple targets Stereotactic Radiation Therapy
Principal Investigator	Godfrey Mukwada
Institution	Sir Charles Gairdner Hospital
Approval Date	05 May 2022

Investigation on out-of-field dosimetry in multiple targets Stereotactic Radiation Therapy Multiple brain metastases are now treated with stereotactic radiosurgery (SRS) technique as the preferred option due to sparing of neurocognitive functionality and quality of life. The quality of SRS treatment heavily depends on the capability of the treatment planning system (TPS) and the respective radiation delivery system. At Sir Charles Gairdner Hospital (SCGH), SRS is delivered using the CyberKnife system which comprises of a 6MV linear accelerator mounted on a robotic arm, Precision® treatment planning system (TPS) and kV imaging coupled with a motion tracking system. The Precision TPS uses Monte Carlo (MC) and Ray Tracing (RT) Algorithms for dose calculation. Accuracy of MC and RT algorithms has been thoroughly investigated in heterogeneous media and MC proved to be more accurate compared to RT. However, similar studies have been done for complex multiple brain metastases.

In this study, treatment plan and dose parameters will be extracted. This will be followed by recalculation of the same plan with MC algorithm (MUs, beam orientations and number of nodes remains unchanged). Same parameters extracted for RT calculated plans will be extracted from MC calculated treatment plans. Statistical methods will be used to find the correlation of different parameters with dose. Multiple targets treatment plans will be generated on precision TPS and delivered on CyberKnife. Measurements will be performed using microdiamond detector and cc04 ionisation chamber. Measured dose will be compared to RT and MC calculated dose. Several treatment scenarios that help simulate out-of-field (OOF) dose contribution will be intentionally created and assessed. Study outcome will be presented to appropriate radiation oncology teams and published in peer review journals. Research findings will help improve dosimetry accuracy for an increasing number of patients who need SRS for multiple metastases.

Project Title	A brief intervention to aid smoking cessation: a randomized controlled trial in Intensive Care patients
Principal Investigator	Matthew Anstey
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital
Approval Date	01 June 2022
Whilst smoking cessation interventions have been evaluated in hospital settings, the optimal intervention remains unclear and no studies looking at combination nicotine replacement therapy (NRT) and counselling have been performed specifically in Intensive care Unit (ICU) survivors. Our goal is to conduct a randomized controlled trial comparing standard care (ad hoc advice to patients and NRT) to a formal brief counselling intervention in addition to protocolized NRT. The aim is to improve smoking cessation rates in ICU survivors and thus improve their morbidity and mortality.	

Project Title	Integrating community-based primary healthcare for adults who have experienced homelessness in Australia: A realist study of what works, for whom, in what circumstances
Principal Investigator	Susan Taylor
Institution	Department of Health
Approval Date	16 June 2022
The purpose of the research project is to understand what works well about current health services for people experiencing (or at risk of) homelessness, and what could be done differently. Recommendations from this project are expected to enhance options for primary healthcare and preventive health services for people in supported housing facilities, and surrounding communities, reduce avoidable hospital use, and overall, help to provide people with an even better healthcare experience than they've had before.	

Project Title	Prediction of hypofibrinogenaemia during cardiac surgery based on the starting fibrinogen and the extent of haemodilution
Principal Investigator	James Preuss
Institution	Sir Charles Gairdner Hospital
Approval Date	20 June 2022

As fibrinogen is one of the most important clotting factors, low levels can lead to increased bleeding during surgical operations. A common cause of low fibrinogen levels (hypofibrinogenaemia) during cardiac surgery is dilution, because a large amount of fluid is added to the circulation during cardiopulmonary bypass (use of the heart lung machine). For this reason, anaesthetists regularly monitor fibrinogen levels, so they can supplement the low levels if necessary. However, we think it may be possible to predict the fall in fibrinogen levels by estimating the amount of dilution that occurs. This could be achieved by calculating the fall in haemoglobin levels (so long as no haemoglobin or fibrinogen has been administered). Haemoglobin is the main protein in red cells. It is much easier and quicker to measure haemoglobin levels, so this method could provide an early warning of the likelihood of low fibrinogen levels. The aim of this study is to investigate whether the fall in fibrinogen levels during cardiac surgery mirrors the fall in haemoglobin.

ADDENDUM TO JANUARY-MARCH 2022 QUARTERLY APPROVAL REPORT:

Project Title	West Australian Ventilation Strategies (WAVES) 2.0
Principal Investigator	Matthew Anstey
Institution	Sir Charles Gairdner Hospital, Fiona Stanley Hospital, Royal Perth Hospital, Bunbury Hospital
Approval Date	25 March 2022

A prospective observational propensity-matched cohort study comparing patients admitted to the ICU with severe ARDs and receiving mechanical ventilation, managed with APRV compared with those managed with alternative modes of ventilation, involving multiple WA ICUs.

Study questions

1. Does APRV lead to improvement in ventilation-free survival days within 90 days of admission in patients with ARDS requiring mechanical ventilation?
2. Does APRV lead to improvement in ventilation-free survival days within 90 days of admission in patients with ARDS from COVID-19 requiring mechanical ventilation?

Objectives

1. To describe mechanical ventilation strategies in patients treated in WA ICUs with severe ARDS (Berlin definition p/F ratio <100) with a focus on APRV
2. To compare APRV to “traditional modes of ventilation” for patients with ARDS, with and without COVID-19 in terms of duration of mechanical ventilation

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