



ISLHD RESEARCH REPORT

2022

This Research Activity Report is a summary of the research that was conducted across the Illawarra Shoalhaven Local Health District (ISLHD) in 2022.

This is a synopsis of the research activities undertaken in 2022.

Please note that this report complies with Section 4.3.5 - Reporting on research activities found in Guideline [GL2011_01]: Research Governance in NSW Public Health Organisations which stipulates that:

1. Public Health Organisations are responsible for being aware of all research taking place within their premises, and reporting these activities to the public on an annual basis through their annual report or research reports.
2. To enable this, Public Health Organisations must require that all authorised research projects that are conducted at sites under their control provide progress reports at least annually and on completion.

This publication is proudly sponsored by the Staff Specialists of ISLHD and we thank them for their ongoing support.

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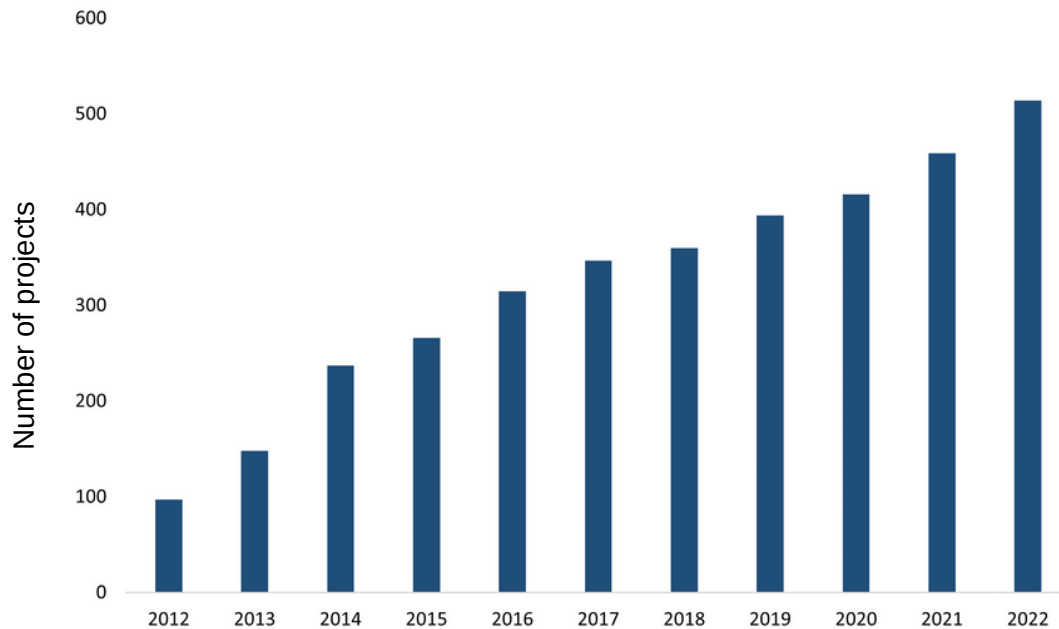
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2022 ISLHD RESEARCH AT A GLANCE

ISLHD Active Research Projects to 2022



224 Peer Reviewed Publications



338 ISLHD Staff Engaged in Research:

- 120 with first author publications
- 195 with new Projects



132 Conference Presentations



84 Site Specific Approvals:
- 16 ISLHD LNR



12 Education Sessions for 257 attendees



120 Active Clinical Trials

FOREWORD

MARGOT MAINS

CHIEF EXECUTIVE, ISLHD

I have the pleasure of bringing to you the 2022 ISLHD Annual Research Report.

Research continues to grow and there are many exciting changes planned over the next few years. In 2022 we had a record number of peer reviewed publications, a total of 224. This makes 2022 one of the most productive years on record for research output. We have approved 30 new clinical trials. We rose through the ranks within NSW to become one of the best performing Local Health Districts in the approval times for research governance applications.

I remain committed to the development of a vibrant and productive research culture and I am pleased to see the substantial progress to date



FOREWORD

ASSOCIATE PROFESSOR BRUCE ASHFORD
ISLHD EXECUTIVE DIRECTOR OF RESEARCH

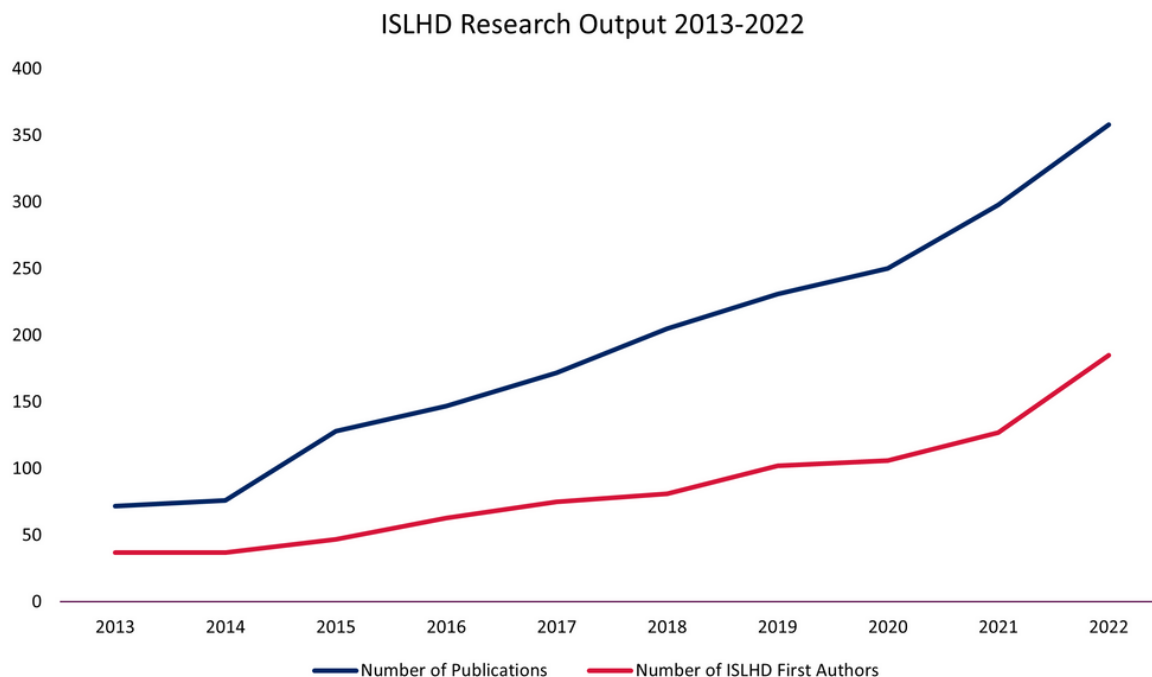
ISLHD Research elements have continued to strive to confront our most pressing clinical problems in 2022. Publications of our clinicians have never had more impact, and energy around clinical projects has increased across the entire LHD.

The central role of Research Operations has been to enable clinical research and researchers. Beyond this, we have done our best to bypass those roadblocks that serve process alone, and that have hampered so much research over so many years. By streamlining our systems we aim to encourage and nurture research by clinicians with the energy to confront our most difficult problems. And it is only clinicians who really understand the problems our patients face. By promoting research within the ranks of busy clinicians, we stand our best chance of making actual progress.



The challenge for the coming year is to engage our community to support high quality clinical research. We want to grow our collaborations and develop ISLHD as a regional leader of quality research.

Within this report are some measures of our research output. The measure of its worthiness will be the improvements in the care we deliver and the quality of life that our patients enjoy.



FOREWORD

PROFESSOR KATE CURTIS

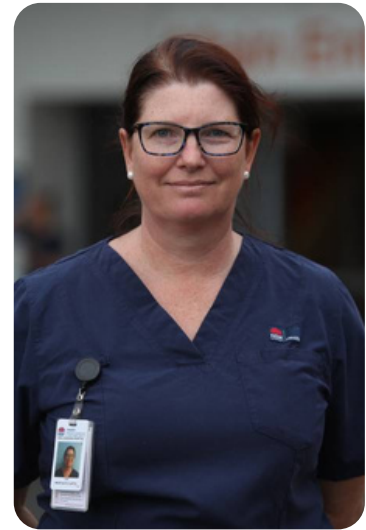
DIRECTOR CRITICAL CARE RESEARCH

In the Emergency arena we have continued our focus on clinician research capacity building to drive practice change. This grass roots focus on improving patient care delivery by enabling those at the front line to drive the research agenda has resulted in over \$6million in national research funding, 31 peer review publications, and two staff enrolling in research degrees.

Some of the areas we are generating evidence to inform clinical care are end of life care in the ED, resuscitation nurse training, patient flow, hip fractures and women with bleeding in early pregnancy.

Work on prevention and early detection of patient deterioration was awarded the 2022 Emergency Care Institute Evidence into Practice Research Paper, and we await the outcome of four other clinical trial national grants in the field of emergency department interventions for back pain and Wellbeing Health & Youth.

Work led by clinicians in ISLHD is being upscaled and/or explored by the NSW Agency for Clinical Innovation, Queensland Health and the Australian Commission for Safety and Quality in Health Care.



PROFESSOR LORRAINE CHANTRILL

MEDICAL CO-DIRECTOR AND HEAD OF DEPARTMENT MEDICAL ONCOLOGY

During 2022 we have seen an expansion in Clinical Trial activity across ISLHD across multiple disciplines and hospitals. Our shared vision for the future is to improve access to clinical trials for all patients in our area and to facilitate enrolment via innovation in highly specialised clinical trials. We are active collaborators in the Rural and Regional Clinical Trials MRFF Program to expand access to trials by partnering with some of the leading genomics teams and industry teams to provide state of the art treatments to our patients and to attract patients from other areas to participate in our clinical research.



RESEARCH OUTPUT IN 2022

NEW PROJECTS, PUBLICATIONS, CONFERENCES AND FUNDING

Clinical Stream	New Projects	Publications	Conferences	External Funding
Aboriginal Health	2			
Aged Care, Rehabilitation & Palliative Care	3	6		
Aged Care	3			
Allied Health	7	8		\$79,200
Dietetics	1			
Pharmacy	1			
Physiotherapy	1			
Podiatry	1			
Speech Pathology	3			\$79,200
Ambulatory & Primary Health Care	10	10	8	\$37,896
Health Promotion	3			\$20,000
Multicultural Health	3			\$17,896
Sexual Health	4			
Cancer and Haematology Network	24	47	25	\$2,457,459.03
Clinical Governance	1			
Critical Care	8	28	10	\$312,000
Emergency	5			
ICU	3			\$312,000
Drug & Alcohol	4	6	8	\$245,914.5
Health Management & Non-Clinical	2	4	1	
Kids & Families	1	8	6	
Maternity & Women's Health	1	6		
Medicine	20	35	23	\$748,632
Cardiology	6			\$665,807
Diabetes & Endocrinology	1			
Gastroenterology	2			
General Medicine	1			
Infectious Diseases	2			\$43,075
Medical Assessment Unit	1			
Neurology	1			
Pathology	1			
Renal Medicine	3			\$39,750
Respiratory Medicine	1			
Rheumatology	1			
Mental Health	5	15	12	
Nursing & Midwifery	3	12	24	\$9,945.85
Public Health	-	1		
Surgery	9	38	15	\$383,675
Anaesthetics	2			
General Surgery	2			
Neurosurgery	1			\$260,000
Obstetrics & Gynaecology	1			
Orthopaedic Surgery	2			
Vascular Surgery	1			
GRAND TOTAL	100	224	132	\$4,274,722.38

RESEARCH OPERATIONS

WOLLONGONG HOSPITAL, BLOCK C, LEVEL 8

Research Operations fosters the development of research skills through educational workshops, mentoring programs and resource allocation.

We provide individual project support including:

- Assistance with developing research questions or hypotheses
- Study design and planning
- Guidance with statistical analysis
- Review and feedback for manuscripts
- Assistance with dissemination through appropriate channels, and available resources

Our staff are also able to guide and support researchers through ethics and governance processes. We propagate research achievements of clinicians through appropriate channels, as well as link clinicians to researchers with specific expertise or facilitate collaborations with other entities for greater research impact.

Research Operations fosters research acculturation through establishment of relational events, and preparation of research specific, ISLHD-specific publications, in addition to advocacy, promotion and support for all levels of research for all ISLHD staff.

Our vision

Building a self-improving health system

Our Mission

Help ISLHD clinicians do research

ISLHD EXECUTIVE DIRECTOR OF RESEARCH

Associate Professor Bruce Ashford

DIRECTOR OF RESEARCH OPERATIONS

Clinical Associate Professor Marianna Milosaveljevic

ADMINISTRATIVE SUPPORT

Sharon Pearson

RESEARCH CLINICIANS

Dr. Jose Cuenca
Lina Baytieh
Dr Kimberley Davis
Olivia Fischer
Janaye Fish
Dr Geoff Melville
Dr Guiyan Ni
Anna Pryor
Dante Risi



RESEARCH GOVERNANCE

WOLLONGONG HOSPITAL, BLOCK C, LEVEL 8

The Research Governance team advises and liaises with investigators, sponsors and other stakeholders regarding the preparation and approval of site specific authorisations and ethics processes.

The team fosters effective communication with universities and research institutes, particularly in the promotion and management of collaborative research programmes and grants management.

The Research Governance team manages and assists with:

- Site-specific research governance review and authorisation in accordance with the NSW Health Policies and Guidelines, including associated contracts and support documentation
- Intellectual property arising from health and medical research that involves staff or resources from ISLHD
- Honorary Research Associate appointments for non-ISLHD research collaborators as well as IHMRI researcher affiliations
- Requests from third parties for access to patient data and transfer of human tissue

ISLHD EXECUTIVE DIRECTOR OF RESEARCH

Associate Professor Bruce Ashford

RESEARCH GOVERNANCE OFFICERS

Andrea Kennedy
Nicole Mensforth

ADMINISTRATIVE SUPPORT

Sharon Pearson



ISLHD RESEARCH COMMITTEE

BACKGROUND TO THE ISLHD RESEARCH COMMITTEE

The ISLHD Research Committee was established in October 2019, under the leadership of Associate Professor of Surgery Bruce Ashford, who champions a clear philosophy of streamlining research processes for clinicians. With the aim of facilitating research, A/Prof Ashford advocates for the district to prioritize research activities. The committee, consisting primarily of actively practicing clinicians who are also researchers, shares this vision and is committed to promoting research endeavors across the district.

ISLHD RESEARCH COMMITTEE MEMBERS

Associate Professor Bruce Ashford - Chair

A/Prof Ashford is a general surgeon with over 30 years of experience, and was commenced as the Associate Professor of Surgery in November 2018. He was appointed as the Chair of the ISLHD Research Committee in October 2019, and ISLHD Director of Research in January 2020. He is very keen to see the district establish processes that make it easier for clinicians to do research. His first two initiatives include the Early Career Grants Scheme and the establishment of a local LNR committee.



Associate Professor Daniel Brungs

A/Prof Brungs works as a medical oncologist at Wollongong Hospital, and has completed a PhD in translation research. He is keen for the district to develop stronger links between the hospital and the university, and to increase capacity for translational research within the Illawarra. He hopes that by being part of this committee he can help influence the direction and support the creation of a stronger and more vibrant research culture.



Dr Peter Jansen

Dr Jansen joined ISLHD as Executive Director of Medical Services & Clinical Governance in March 2020. He was previously Principal Clinical Advisor for the New Zealand Accident Compensation Corporation, focussing on treatment injury claims and prevention of injuries caused by medical treatment. He has also worked in pharmaceutical medicine, indigenous health research, medical education and health management. Dr Jansen hopes to maintain and strengthen the linkages between the LHD and other stakeholders in the research community.



Dr Lorraine Chantrill

Dr Chantrill is a Medical Oncologist and considers herself a clinician-researcher. She has a PhD in Pancreas Cancer Genomics, and is an ongoing and active participator in research. She believes that the creation of evidence should be embedded in our clinical practice, driving the very best outcomes for our patients and for our community as a whole. Dr Chantrill would like to see the clinical trials portfolio of ISLHD expanded into diverse clinical areas across the entire district including rural patients. The Research Committee will enable her vision through support at all levels of our service.



Dr Steven Craig

Dr Craig is a surgical oncologist and translational researcher with a specific interest in the development of prognostic biomarkers and assays that can tailor cancer treatments, and has been involved with research within ISLHD since his early days as an intern at Wollongong Hospital. He hopes that participating in this committee will help to foster a strong research culture within our junior health professionals, and make research more accessible to our busy clinicians. Being based in the Shoalhaven, Dr Craig also wants to improve access to clinical trials for Shoalhaven-based cancer patients.



Professor Kate Curtis

Professor Curtis is Director of Critical Care Research ISLHD, Clinical Director of CHRISP, RN at Wollongong ED and Professor of Emergency and Trauma Nursing at the University of Sydney. Her translational research program focuses on improving the way we deliver care to patients and their families, and has attracted more than \$8 million funding. She is the world's most published author in the field of Trauma and Emergency nursing, and has mentored more than 50 clinicians in research projects.



Dr Sue Fitzpatrick

Dr Fitzpatrick is the ISLHD Executive Director Allied Health, Disability Inclusion and NDIS lead. She has a professional background as a speech pathologist, and was awarded a Doctor of Health Science in 2016 for her examination of clinical supervision in allied health. Dr Fitzpatrick believes that Allied Health are in a unique position to increase their practice driven research – initiated from and embedded within a practice community. This takes research questions from health professionals to address issues relevant to the clinical setting.



Dr Susan Furber

Dr Furber is the Research and Evaluation Coordinator with the ISLHD Health Promotion Service. Her research interests are in population health and have included studies on lifestyle interventions to promote healthy weight and physical activity in people with cardiac disease, health impact assessments on local government urban plans in relation to physical activity, nutrition and social cohesion, falls prevention, and the role of soup kitchens in disadvantaged areas.



Carly Leighton

Carly has over 18 years clinical research experience which began in 2004 at University College London Hospital. Since Carly has held positions across health services and academic institutions including National Trial Coordinator (UK), Senior Research Nurse (UK) and Clinical Trials Manager (Aus). She has extensive knowledge and understanding of the regulatory landscape and experience in the operational conduct of Phase I to Phase IV investigator initiated, non-commercial and pharmaceutical sponsored (commercial) clinical trials.



Professor Stuart MacKay

Prof MacKay completed his medical degree at the University of NSW in 1998, graduating with honours. His Fellowship in Otolaryngology and Head and Neck Surgery was completed in 2006, and in 2007 he completed a Fellowship in Airway Reconstruction Surgery for Snoring and Obstructive Sleep Apnoea which also involved further training in Head and Neck and Laryngology (Voice). He is the Vice President of International Surgical Sleep Society, on the clinical committee of the Australasian Sleep Association, and a reviewer for journals Sleep and Breathing, and Laryngoscope.



Margot Mains

Ms Mains commenced as the Chief Executive of the Illawarra Shoalhaven Local Health District in October 2014. She has extensive health executive leadership and management experience at both hospital and Local Health Network level. Ms Mains' previous roles include Chief Executive Officer, Northern Adelaide Local Health Network, and prior to that she held senior leadership roles in the New Zealand Health system, as Chief Executive Officer, Capital and Coast District Health Board and Chief Executive Officer, Mid Central Health.



Clinical Associate Professor Marianna Milosavljevic

A/Prof Milosavljevic is the Director of Research Operations, and her job is to help clinicians do research. Marianna has 30 years experience as a clinical dietitian, and completed her PhD in 2013. Since then she has been working in research and her role on the committee is to implement the initiatives developed by this committee. She has seen many positive changes since she commenced working in research support, and believes that having a committee comprised of staff who are frontline clinicians will help make a real difference to the way research is supported throughout the district.



Dr Manash Saha

Dr Saha is a clinician scientist. Following specialisation in General and Renal Medicine, he moved from Bangladesh to Australia, where he obtained his PhD at Macquarie University and also FRACP. His PhD identified a new underlying mechanism of hypertension in Chronic Kidney Disease (CKD), and was awarded the Deputy Vice-Chancellor (Research) Commendation award. Dr Saha's main research areas of interest are cardiovascular diseases in CKD, community based modelling for prevention of chronic disease and weight disorders, as well as the use of artificial intelligence in risk assessment of different diseases.



Clinical Associate Professor Natalie Smith

A/Prof Smith trained in anaesthesia in the UK, but returned to her native Australia over 15 years ago. Along with a diverse clinical practice, she has pursued interests in education, training, and clinical research. Improving the perioperative management of patients, especially in high risk groups such as the frail elderly and people with obesity, is her main ongoing clinical and research priority.



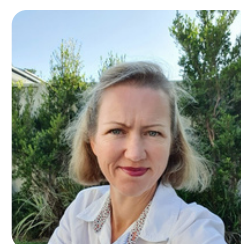
Dr Stuart Tan

Dr Tan is a specialist physician in trauma and rehabilitation medicine, with a special interest in interventional pain management. He has many years' experience in design, implementation and translational of research projects in a wide range of area with in NSW Health. As there is a scarcity of research in some clinical departments, Dr Tan would like to see increased research activities in ISLHD. Dr Tan is currently undertaking a large, longitudinal research project investigating the effects of long-COVID.



Dr Kia Wallwork

Dr Wallwork's role is in leading a team of healthcare redesign and project management specialist for ISLHD. She commenced her research career in the physical sciences, and played a leading role in building the Powder Diffraction Beamline at the Australian Synchrotron in Melbourne. She is delighted to be part of the Research Committee at ISLHD, providing strategic vision, and supporting the research of clinicians and non-clinicians alike.



CLINICAL TRIALS

DR LORRAINE CHANTRILL - CLINICAL TRIALS DIRECTOR

In 2022, our clinical trialists have continued their incredible efforts to build on our strengths in delivering a high quality clinical trials service at ISLHD. These efforts from our multi-disciplinary teams including researchers, nurses, clinical research officers, pharmacy and pathology services staff ensure that our patients have access to novel, cutting edge treatments here in the Illawarra.

There are more than 120 clinical trials underway in our LHD across Cardiology, Renal, Gastroenterology, Infectious Diseases, Diabetes, ICU, Drug & Alcohol and Cancer services that are supporting over 300 patients and contributing to evidence based care and improved health care outcomes. In cancer services we are seeing an increase in our early phase (Phase 1) clinical trial feasibilities which is a landscape shift from previous years and likely to continue.

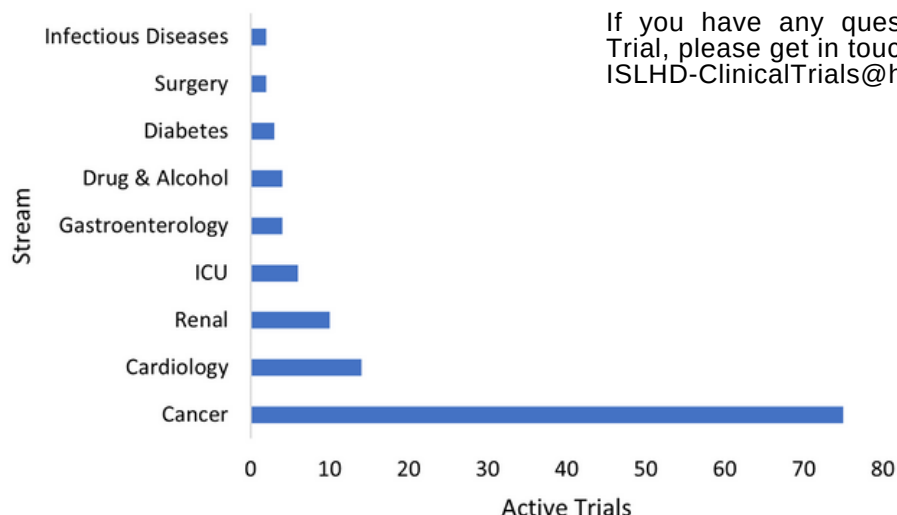


We have established a district wide clinical trial committee with representatives from our trial disciplines. The group meets bi-monthly and provides a local community of practice where knowledge is shared, strategies developed, procedures reviewed with a solution focussed goal to support our workforce capability and drive capacity opportunities in our clinical trial services.

We are continuing to embed clinical trials into our health care service delivery and this will be developed and shaped through the implementation of clinical trial accreditation standards under the National Clinical Trial Governance Framework in the year ahead.

Our research culture fosters our curiosity and drives our passion for enabling access to new and innovative treatments in a culturally sensitive and supported service. We are making consumer engagement an area of focus in the year ahead and intend to address equity of access and diversity in our trial portfolio and patient population through our collaboration on the Regional Rural and Remote Clinical Trial Enabling Program (R3-CTEP) program with our partners Southern NSW LHD, Murrumbidgee LHD with the program grant supported by ACT Health/Canberra Health Services.

2023 holds incredible opportunity for clinical trials and I am looking forward to further developing our clinical trials infrastructure and expanding the number of clinical trials offered across the district.



If you have any questions regarding a Clinical Trial, please get in touch with the team:
ISLHD-ClinicalTrials@health.nsw.gov.au

CRITICAL CARE RESEARCH

PROFESSOR KATE CURTIS - DIRECTOR OF EMERGENCY AND CRITICAL CARE RESEARCH



The enthusiasm of emergency clinicians to participate in research is inspiring given the ongoing complexity, acuity, unpredictable, confronting nature of working in the hectic ED.

In the Emergency arena in 2022 we continued our focus on clinician research capacity building to drive practice change facilitated by embedding research leadership in the ED.

This is greatly facilitated as our Professor of Emergency sits in the ED and works clinically alongside other ED clinicians. This grass roots focus on improving patient care delivery by enabling those at the front line to drive the research agenda has resulted in over \$6million in national research funding, 34 peer review publications, and two staff enrolling in research degrees. We are leading the generation of evidence to inform clinical care for those at their end of life in the ED, resuscitation nurse training, patient flow, hip fractures and women with bleeding in early pregnancy. We have participated in over 15 multi-disciplinary translational research and clinical trial projects including the Serratus anterior plane block for rib fractures and the EVIDENCE Out of hospital cardiac arrest trial with NSW Ambulance, Anaesthetics and Cardiology.

We await the outcome of five clinical trial national grants in the field of emergency department interventions for back pain and concussion management in young people. We have seven smaller grant applications in to support local research evaluating innovations such as our Critical Head Pathway, which is a team-based approach to streamline care of ED patients requiring urgent neurosurgical intervention across ISLHD, Work led by clinicians in ISLHD, such as the HIRAID™ emergency nursing model of care is being upscaled and/or explored by the NSW Agency for Clinical Innovation, Queensland Health, South Australia Health, and the US Emergency Nurses Association.

Highlights include work led by Dr Karlie Payne, one of our emergency medicine trainees investigating Factors that contribute to patient length of stay in the emergency department contributed to fulfilment of the research component of emergency physician training. Work led by Dr Belinda Munroe on prevention and early detection of patient deterioration was awarded the 2022 Emergency Care Institute Evidence into Practice Research Paper. We are building on this work in conjunction with the ICU liaison and clinical governance teams to enable LHD wide identification of trends in preventable deterioration events. Our clinician led research has also been awarded the Ed Brentnall award, Australasian College of Medicine 2022.

Over the next 12 months, we plan to increase our clinical trial activity and use of local data to inform change. We intend to maintain our reputation as one of the most research active emergency departments in Australia.



NURSING & MIDWIFERY RESEARCH UNIT**PROFESSOR VAL WILSON**

The challenges over the last few years did not stop the Nursing and Midwifery Research Unit (NMRU) from accomplishing meaningful research outcomes in 2022. The NMRU continued to engage with a wide range of nurses, midwives and allied health professionals across ISLHD to build on research capacity, capability and research productivity. Key highlights included the NMRU staff successfully submitting 11 publications within international peer reviewed journals, as well as representing ISLHD at various international and national conferences through delivering six presentations. Two HDR students, Emma Radbron and Alera Bowden submitted their PhDs.

The International Practice Development Committee hosted the 2022 Enhancing Practice Conference at the SAGE Hotel in Wollongong from 6-8 April. The focus was 20:20 Vision – Transforming Our Future Through Person-Centred Practices. Professor Val Wilson, Denise Edgar and Sharon Morgan were the ISLHD representatives on the Enhancing Practice Conference organising committee. Fourteen ISLHD staff presented at this international conference. ISLHD was the major sponsor of this conference, which saw more than 170 participants from across the globe attend this three-day event. Each day was opened by distinguished guests including Margot Mains, ISLHD Chief Executive Officer and Jacqui Cross, Chief Nursing and Midwifery Officer, NSW.

The research mentorship program (consisting of four modules) was open to nursing and allied health staff across ISLHD. The program commenced in 2021 and concluded in December 2022 and was a success with 18 staff receiving a completion certificate. Alongside this, the monthly Action Learning Sets have continued where staff members from multidisciplinary teams come together and share research learnings, ideas and actionable outcomes. Currently the group is working on a literature review to explore the concept of multidisciplinary research teams.

In collaboration with SESLHD, ISLHD hosted a series of Practice Development Masterclasses which brought together like-minded colleagues to hear inspiring talks by international and local practice development leaders including Professor Val Wilson, Professor Kim Manley (international presenter) and Professor Greta Westwood (International presenter). PD Masterclasses were popular with six sessions conducted throughout 2022, with an average attendance of 95 participants.

At the end of 2022, the NMRU has seen a 'changing of the guard' so to speak with both Professor Val Wilson and Denise Edgar resigning from their respective research positions. Denise has resigned from the Nurse Manager Research role and Val Wilson has resigned as the ISLHD/UOW Professor of Nursing. The following 2017-2022 evaluation report ties in nicely to sum up Val's and Denise's time with ISLHD/UOW and to celebrate the accomplishments and outcomes of the NMRU over the last five years:

http://islhdweb.islhd.health.nsw.gov.au/Nursing_and_Midwifery_Directorate/Research/PDFs/2023/NMRU5yearreport.pdf

Current ISLHD PHD students

- Dr Alera Bowden (CNC - Post Op Delirium Project, Nurse Manager Research) – Evaluating the influence of ageing simulation education on acute care nurses' empathy towards older people (submitted PhD December 2022)
- Miriam Coyle (Acute Dementia/Delirium CNC Bulli) - Specialising in older people (data collection and analysis phase)
- Leanne Cummins (Shared-Care Coordinator Maternity Services) - Breast feeding in Gestational Diabetes (Writing up – due to submit end of 2023) – transferred to ACU
- Vanathy David (CNC Aged Care) - Falls prevention- Action Research study (Preparing findings)
- Erinn Dawes (Physiotherapist) - Cognitive screening for amputation (data collection & analysis phase)
- Linda Deys (CMC Lactation) - Where's my baby- experience well mothers who are separated from their babies at caesarean section birth (Preparing findings) – transferred to ACU
- Denise Edgar (Clinical Supervision Coordinator) - CAREing for our new Graduates; A person-centred approach to clinical supervision during COVID-19 (Writing up due to submit end of 2023)
- Julia Kittscha (CNC Stomal Therapist) - Adjustment to a Stoma (final phase of Action Research)
- Dr Emma Radbron (previously iPAKT project manager) - Implementing and Measuring Person-centredness using an APP for Knowledge Transfer (submitted PhD September 2022)

ISLHD RESEARCH REWIND - 2022

A RETROSPECTIVE LOOK AT THE TOP STORIES OF 2022

FEBRUARY

Professor Wilfred Yeo Retires

The District said farewell to Professor Wilf Yeo, who has retired after a long and distinguished career. Prof Yeo has been a significant contributor to and supporter of research within ISLHD, not just through his own research efforts but also through his training and mentorship of junior doctors and researchers.



APRIL

ISLHD's first vascular patient in an international RCT - A new era for surgical clinical trials

The Vascular Surgery Department celebrated the successful enrolment of the first vascular patient to participate in a Multicentre International Randomised Control Trial (RCT) at Wollongong Hospital. The trial involves more than 20 centres worldwide and evaluates two different modalities for the treatment of venous insufficiency: traditional surgical stripping versus a minimally-invasive option using endovenous glue ablation.

Allied Health Research Showcase and Excellence in Allied Health Awards

The Showcase was a well-deserved continuous professional development opportunity to learn and hear about allied health research undertaken in NSW Health. There was a great line up of keynotes speakers who are recognised both nationally and internationally and the workshops have been designed for both early career and experienced allied health researchers.

MAY

23 Annual NSW Health Awards – ISLHD winner for Health Research

Congratulations to Professor Kate Curtis and the HIRAID team, who won the Health Research and Innovation category in the NSW Health Awards.

Professor Wilf Yeo – ISLHD's first Consultant Emeritus

ISLHD recently bestowed its inaugural title of Consultant Emeritus on retiring medical practitioner, Professor Wilf Yeo. Not only has he been instrumental in developing the training of doctors within the District, Prof Yeo has an extensive research track record and has been a great supporter of research development and the training of young researchers within ISLHD. We wish him all the best in his retirement.



JUNE

ISLHD recipient of the Pamela Jane Nye Working Nurse Scholarship

Congratulations to Alera Bowden, who has been awarded the Pamela Jane Nye Working Nurse Scholarship which will support her during her PhD studies at UOW. Alera's research is investigating the effect of ageing simulation suits in healthcare professionals' empathy and person-centred care.

JULY

ISLHD Health Promotion working with UOW on health eating guidelines for childcare services

Funded by the Ministry of Health Prevention Research Support Program (PRSP), ISLHD Health Promotion staff Jenny Norman, Susan Furber and Lisa Franco are working on a range of projects in collaboration with UOW's Early Start Facility.

ISLHD Governance team presentation – Lunch and Learn

ISLHD Research staff (A/Prof Marianna Milosavljevic, Dr Lyndel Hewitt, Dr Kimberley Davis & Janaye Fish) presented to almost 50 Research Office staff from around NSW and further afield on how ISLHD has streamlined its research governance process. Readers may recall an article in The Rounds from March this year reporting ISLHD's rise to become the best performing Research Governance Office in the state through streamlining of internal business processes, resulting in the invitation to present. The presentation was chaired by James Cokayne from the Research Ethics and Governance Unit at the Office of Health and Medical Research, receiving favourable comments from attendees.

AUGUST

Catch up on the livestream discussing the environmental impact of inhalational anaesthetics

ISLHD's own Dr Tanya Selak and Dr Jessica Devlin-Hegedus participated in a live discussion on Dr Hegedus' recent paper *Action guidance for addressing pollution from inhalational anaesthetics*, which appeared in the journal *Anaesthesia* and was featured in the August Gazette.

New REDCap instance now available for ISLHD Researchers

To meet the growing needs for a secure data collection tool within NSW Health, the Office for Health and Medical Research have increased their REDCap licence to include NSW local health districts, specialty networks and pillars. The new REDCap instance is hosted on eHealth managed cloud servers and has undergone the eHealth Privacy Security Assessment Framework (PSAF) process to host identifiable information. REDCap has now been activated across the LHD and can be used by staff conducting research projects which have ethics and governance approval.

Dr Toni Kelly graduates with a PhD

Congratulations to Dr Toni Kelly (ISLHD Radiation Therapist Educator) who was awarded her PhD in Medical Radiation Science earlier this year from the University of Newcastle. Several of Dr Kelly's publications have appeared in past issues of the Gazette and focus on exploring various aspects of communication in radiation therapy.



SEPTEMBER

PhD Scholarship with UOW Early Start and ISLHD Health Promotion

One of the projects to be conducted as part of the NSW Ministry of Health's Prevention Research Support Program (PRSP) is the "First Bite - Get it Right" intervention, which aims to improve children's (aged 2-5 years) healthy eating behaviours in early childhood education and care services (ECEC) and at home.

Changes to NHMRC'S Open Access Policy

The National Health and Medical Research Council (NHMRC) is the first Australian funding agency to introduce the requirement that scholarly publications arising from the research it funds be made freely available and accessible. This means that all peer-reviewed publications arising from NHMRC-funded research must be made available immediately upon publication, removing the 12-month embargo period. They must also be published with the use of an open licence, which means publications can be used and shared widely. These requirements apply to all new grants awarded under NHMRC Grant Opportunity Guidelines issued from 20 September 2022, and will be phased in for all other NHMRC grants, with full implementation by 1 January 2024.

OCTOBER

Emergency Service wins best paper and publication award

The NSW Emergency Care Institute (ECI) Evidence into Practice Best Paper was awarded for work led by Dr Belinda Munroe on the implementation evaluation of the Emergency Department (ED) rapid response system - EDCERS - which was piloted at Shoalhaven Hospital ED. The ECI annually awards this prize for a paper related to closing an important gap between the best available evidence and current clinical practice.

The use of EDCERS - rapid response calls for deteriorating admitted patients - in Shoalhaven Hospital's ED since 2019 has been shown to reduce preventable deterioration on the wards following admission through the ED. EDCERS is now being implemented across ISLHD. The Philippa Moore Publication Prize was awarded for the research publication on work led by Dr Munroe and Professor Kate Curtis on the impact that HIRAID, a structured emergency nursing framework, has on nurses' documentation accuracy. This award recognises the importance of publication to the practice and scholarship of emergency nursing and continues this legacy to advocate for emergency nursing. HIRAID was implemented and evaluated across all four ISLHD EDs and shown to improve the completeness of emergency nurses' documentation.



Pictured (L-R): Wayne Varndell, President CENA and Dr Belinda Munroe, ISLHD ED CNC

Prof Stuart Mackay participates in international research collaboration into obstructive sleep apnoea treatment in children with Down Syndrome

An amazing international funding collaboration has been founded, led by Principal Investigator Dr Derek Lam in the United States and involving Illawarra Shoalhaven's Prof Stuart MacKay in the capacity of advisor and mentor. The US \$6 million grant over five years was awarded by the National Institutes of Health (NIH), the USA's medical research agency, a branch of the US Department of Health and Human Services. The grant will fund Dr Lam's research into new advancements in obstructive sleep apnoea treatment in children with Down Syndrome.

Wollongong Hospital PACU at delirium care forefront

Wollongong Hospital Post Anaesthesia Care Unit (PACU) is excited to announce the recommencement of its involvement in the NSW Translation Research Grants Scheme Post-operative Delirium (POD) Care research project, after recent COVID-19 Delays. The POD project is funded by a \$530,000 grant and is currently being undertaken in hospitals across three local health districts, including St George, Wollongong and South East Regional Hospital (Bega). The POD project works with clinicians to improve the detection and management of delirium in older people post-surgery. July 2022 saw PACU nurses launch the next phase of the POD project with the commencement of the delirium care educational initiative.

Pictured right: Maddison Fisher, acting clinical nurse educator, PACU (left) facilitates a module of the post-operative delirium care education initiative with PACU nursing staff.



NOVEMBER

Grant Success – Dr Steven Craig receive Cancer Institute NSW Grant

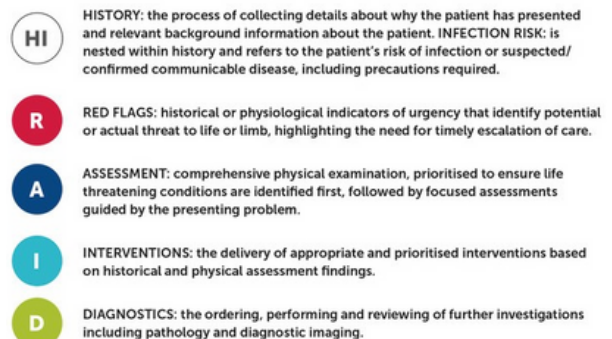
An exciting new study, led by Shoalhaven Head of Surgery Dr Steven Craig, has recently attracted \$80,000 of grant funding from Cancer Institute NSW for breast cancer research. The study will conduct oncology research using novel comprehensive machine learning and process mining methodologies to improve breast cancer outcomes in our LHD. This study collaborates with staff across ISLHD as well as the University of Wollongong – Dr Glaucia Fylyk (Radiation Oncologist and Chair, Breast MDT), Rebekah Costelloe (Illawarra Shoalhaven Cancer & Haematology Network Data Manager), Sarah Elliott (ISLHD Cancer Systems Innovation Manager) Prof Ping Yu (UOW), Dr Ting Song (UOW) and Chantal Campbell (UOW Phase 3 Medical Student).

Emeritus Professorship awarded to Wilfred Yeo

Congratulations to Professor Wilf Yeo, who was recently conferred an Emeritus Professorship by the University of Wollongong in recognition of his outstanding professional achievements in the fields of medicine and science. You can read more about his life and journey on the UOW website.

From the emergency room to aged care: the potential of HIRAID™ in healthcare

After a highly successful trial in ISLHD showed a 50 percent reduction in patient deterioration and over \$1million savings per year, HIRAID is now being evaluated for its potential to bring emergency department level assessment and infection control to aged care. Led by ISLHD's own Professor Kate Curtis, it is a proven, up-scalable emergency nursing framework aimed at ensuring emergency nurses have an evidence base to their initial assessment and management of patients who enter emergency.



DECEMBER

Congratulations A/Prof Tim Skyring – Masters of Philosophy

Congratulations to ISLHD's Division of Surgery Medical Co-Director A/Prof Tim Skyring, whose Masters of Philosophy thesis investigating 'Factors influencing treatment decision for men with prostate cancer' was recently awarded with commendation.

Retirement celebrations for Professor Val Wilson

Professor of Nursing Val Wilson was celebrated at a recent dinner, where a number of ISLHD and UOW staff gathered to show their appreciation and celebrate her time and impact at ISLHD. Prof Wilson commenced as ISLHD's Professor of Nursing and Midwifery Research in November 2016 in a joint appointment with UOW. Her work has focussed on Person-Centred Nursing and Midwifery Research aimed at improving outcomes for patients, families, staff and the organisation. She has also supervised numerous past and present ISLHD staff as HDR (Higher Degree Research) students through to completion of their PhDs.



JOINT UOW/ISLHD PHD PROGRAM

PREVIOUS PHD CANDIDATES

Name	Candidature	Project Title	Supervisors
Maryam Ghahramani	2014-2018	Developing an objective and quantifiable approach to falls risk assessment in older people.	ISLHD: Prof Jan Potter UOW: Prof Fazel Naghdly, Dr David Stirling, A/Prof Golshah Naghdly
Sina Ameli	2015-2018	Fatigue Assessment in Cancer Patients through Motion & Posture	ISLHD: Prof Morteza Aghmesheh UOW: Prof Fazel Naghdly, A/Prof Golshah Naghdly, Dr David Stirling
Kelly Lambert	2015-2018	An investigation of the impact of cognitive impairment and low health literacy on facilitating dietary change in people with renal disease& strategies to improve patient outcomes.	ISLHD: Prof Maureen Lonergan UOW: A/Prof Judy Mullan, A/Prof Kylie Mansfield
Ramya Walsan	2016-2019	An exploration of the geographic distribution of coexisting mental illness and diabetes in the context of social determinants.	ISLHD: Prof Nagesh Pai, Dr Darren Mayne UOW: Dr Andrew Bonney, Dr Xiaoqi Feng
Emily Hazzard	2016-2020	Exploring the implementation of evidence based nutritional care guidelines for patients with head and neck cancer.	ISLHD: A/Prof Marianna Milosavljevic UOW: A/Prof Karen Walton, Dr Anne McMahon, S/Prof Linda Tapsell

CURRENT PHD CANDIDATES

Name	Project Title	Supervisors
Afshan Rauf	Mindfulness, Resilience and Well-being: Its impact on organisational Outcomes	ISLHD: A/Prof Marianna Milosavljevic UOW: Dr Shamika Almeida, Dr Laura Rook
Tiffany Sandell	Follow up care in patients post cancer treatment: what works best?	ISLHD: Prof Andrew Miller UOW: Dr Heike Schutze, Dr Rowena Ivers
Helena Ibro	Using Machine Learning as a Visual Tool to assist Cancer Management	ISLHD: Dr Steven Harvey UOW: Professor Aditya Ghose, A/Prof Hoa Dam
Olivia Fischer	An Investigation into the Identification, Assessment and Treatment of Cancer-related Sarcopenia and the Development and Implementation of a New Model of Care.	ISLHD: A/Prof Marianna Milosavljevic UOW: A/Prof Karen Walton, Dr Anne McMahon

ACHIEVEMENTS OF THE JOINT UOW/ISLHD PHD PROGRAMME TO DATE IN 2022



33 Publications in Peer Reviewed Journals Arising from Doctoral Work



345 citations to 2022



9 commenced or completed candidatures

ISLHD RESEARCH PROJECTS

The projects listed on the following pages represent projects which were approved during the course of 2022, and does not include those which have previously been approved and are ongoing.

Projects have been grouped according to clinical divisions (and subdisciplines, where appropriate), and are presented in alphabetical order. Names of ISLHD Authors are in bold.

ABORIGINAL HEALTH

Brown P, Orloff C. *Exploring experiences of hospital and maternity care among Aboriginal people: An interview study.* **Locations:** TWH. **External Partners:** NSW Ministry of Health, The Sax Institute.

This project aims to build a detailed understanding of Aboriginal peoples' experiences and perceptions of hospital and maternity care in NSW. Using yarning as a qualitative method this study will interview Aboriginal general and maternity patients who have recently been admitted to a public hospital in NSW. The study will be conducted in Wollongong, Wagga Wagga and Western Sydney. Focus groups will also be held with Aboriginal staff at local Aboriginal Community Controlled Health Services. Interviews will be held with Aboriginal Health Workers and Liaison Officers at participating hospitals within these regions. From the interviews and focus groups, data will be analysed and themes will be developed that represent the experiences of participants.

Pai P, Allan J, Mackay M, Gee S, *Wellbeing when working within Community. How is the Wellbeing of Aboriginal healthcare workers affected working with chronic care patients from their Community?* **Locations:** ISLHD. **External Partners:** UOW.

This project aims to gather an understanding of the social and emotional wellbeing (SEWB) of Aboriginal healthcare workers (AHW) employed in the Illawarra Shoalhaven Local Health District (ISLHD) Aboriginal chronic care unit. The project aims to gain a better understanding of how working within community and this role intersects to impact the wellbeing of AHWs. The aim of this research is to understand ways that Aboriginal health care workers in ISLHD working within a chronic care role for Aboriginal people conceptualise wellness and challenges and barriers to maintaining SEWB.



AGED CARE, REHABILITATION & PALLIATIVE CARE

AGED CARE

Christley J, Hartwell T, French K, Hankey G, *An investigator initiated and conducted, prospective, multicentre, randomised, outcome-blinded, study of antiplatelet monotherapy in patients with a history of stroke due to intracerebral haemorrhage (ICH).* **Locations:** SDMH. **External Partners:** UWA.

The aim is to determine if antiplatelet monotherapy is of overall net benefit in reducing the incidence of serious vascular events compared to avoiding antiplatelet therapy for adults with a history of a previous stroke due to spontaneous (non-traumatic) intracerebral haemorrhage (ICH). The study design is an investigator led, multicentre, prospective, randomised, open-label, blinded outcome (PROBE), parallel-group clinical trial. The primary outcome is the composite of all serious vascular events (non-fatal stroke [including ICH], non-fatal myocardial infarction, or death from a vascular cause). The expected outcome is that survivors of spontaneous (non-traumatic) ICH will be shown to have vascular disease(s) that predispose(s) them to future vaso-occlusive, ischaemic vascular events, which can be reduced by prophylactic antiplatelet therapy without increased risk of recurrent ICH.

Potter J, Charlton K, *Food for thought: Preventing decline and improving cognition through diet and dietary advice in older people at risk.* **Locations:** TWH. **External Partners:** UOW.

Previous research associated anthocyanins with a decreased risk of age-related diseases. Previous clinical trials have already demonstrated that consumption of anthocyanin-rich fruit significantly improves both short- and long-term memory, and verbal fluency in older adults with mild to moderate Alzheimer's dementia (AD) and mixed dementia. The purpose of this study is to identify if a higher consumption of anthocyanins for 6 months through either diet/dietary advice or supplementation can sustainably delay or prevent memory loss progression in people at high risk for dementia. It will identify if the intake of anthocyanins will have any significant effect on cognitive function and mood, as well as on blood pressure, markers of inflammation in the blood, and on the gut microbiota.

Potter J, Lago L, Low LF, Phillipson L, Artiss S, Moules S, McAlister B, Kobel C, *Modelling the role of non-admitted care and its relationship to hospitalisation to guide system improvement for people living with dementia.* **Locations:** ISLHD. **External Partners:** UOW.

People with dementia experience considerable challenges trying to get their health care needs met. The healthcare system can be difficult to understand, there are often long waits for services, and the benefit of community and outpatient care are not always well understood. To live well with dementia, access timely/appropriate care to help manage their dementia symptoms and other health conditions is needed, which if not well managed result in repeat hospital visits. This will provide information to local-health services, consumers and carers on whether people with dementia, or any other group in the Illawarra Shoalhaven region are having their care needs met in and out of hospital. Consultations will be made with people with dementia, their carers, and health/aged care providers to make sure the areas of need we identify reflect patients and health providers experience; these will also assist to make a plan to improve care in the region.



ALLIED HEALTH

DIETETICS

Barone L, Casey S, Langford C, Charlton K, Rohr S, *Utilisation of Optifast VLCD diets In the sub acute rehab setting: is the inpatient setting a good opportunity to kickstart the weight loss journey of obese patients.* **Locations:** PKH. **External Partners:** UOW.

The ongoing rise in Obesity in Australia continues to place a significant strain on the health care system. In Australia, the recommendations for obesity (BMI ≥ 30 kg/m²) management include very low calorie diets (VLCDs) as an intensive weight loss strategy. We are seeing an increased number of obese patients in our inpatient settings. The inpatient rehab setting presents a unique protected environment in which to implement VLCD therapy to kickstart weight loss. The longer length of stay in the rehab setting offers an opportunity to not only implement an intensive weight loss treatment plan but also to see results. This project aims to review the implementation and monitor a group of patients following a VLCD diet during their rehab stay.

PHARMACY

Holgate C, Dashwood R, Goodacre Q, Davis K, Vine M, Bloxsome S, *Pharmacist Prescribed Nicotine Replacement Therapy for Smoking Cessation.* **Locations:** SDMH.

The purpose of this research project is to see if patients who smoke and are given Nicotine Replacement Therapy (NRT) while they are in hospital, in addition to an initial supply when they leave hospital, are better able to quit smoking long-term. A secondary aim of this project is to look at long-term health impacts for these people in terms of improved smoking-related diseases.



PHYSIOTHERAPY

Hattley H, Lever S, Lever S, Sae M, Gilchrist J, McGrath M, Power E, McCluskey A. *Evaluation of a tailored implementation strategy to improve compliance with clinical guidelines related to sexuality after stroke in metro and rural NSW.* **Locations:** SDMH. **External Partners:** University of Sydney, Ryde Hospital, Hornsby Kuringai Hospital, Beachside Rehabilitation Unit, UTS.

Australian Stroke Guidelines recommend that stroke survivors are offered the opportunity to discuss sexuality. Audits of patient records between 2008-2020 show that less than 25% of stroke survivors receive best practice care. Guided by the Theoretical Domains Framework (TDF), this project aims to develop and test an implementation protocol to support health professionals in rural and metro inpatient stroke services to address sexuality with stroke survivors and their partners. This is a multi-centre before and after implementation study using mixed methods evaluation. It will test the implementation approach for improving post-stroke sexual rehabilitation in rural and metro inpatient rehabilitation services in two Local Health Districts (ISLHD and NSLHD). Data will be collected at 2 time points: twelve months before the implementation and twelve months after the 5 month implementation period. The primary outcome is the change in the proportion of stroke survivors who have been provided with the opportunity to discuss sexuality and intimacy with a health care professional determined by the medical record audit. This secondary outcomes include a change in the proportion of stroke rehabilitation clinician knowledge, skills and comfort towards addressing sexuality following stroke and the barriers and enablers to implementing clinical guidelines in inpatient stroke rehabilitation. This innovative study has potential to be implemented across other NSW stroke services and scaled across Australia and international stroke rehabilitation services.

PODIATRY

Allen D, Lasschuit J, Andrikopoulos S, Wischer N, Twigg S, Lazzarini P, Frank G. *Australian Diabetes High Risk Foot Service Database.* **Locations:** ISLHD. **External Partners:** St Vincent's Hospital Sydney Diabetes Centre, Australian Diabetes Society, National Association of Diabetes Centres, USYD, Queensland University of Technology.

Data collection is key to determining process and patient outcomes, thereby enabling service quality review and improvement. Standardising data collection across High Risk Foot Services (HRFS) nationally will create unprecedented opportunity for audit, benchmarking and collaborative research. Several services have identified challenges in meeting Standard 8 (Quality Improvement) of the NADC Collaborative Interdisciplinary Diabetes HRFS Standards and this database is designed to help realise that Standard. This minimum dataset has been carefully and developed into a user-friendly, accessible and free e-data collection tool by use of REDCap. At sites where REDCap is not available alternative data collection will be aligned to the minimum dataset. With uptake of unified data collection across Australia we will be creating a database of international standing. Furthermore, individual services will have the means to evaluate service efficacy and resource allocation, and to direct service improvement.



SPEECH PATHOLOGY

Rowntree K, Copland D. *Implementation of Comprehensive High-dose Aphasia Treatment (CHAT) program.* **Locations:** ISLHD. **External Partners:** UQ, The Prince Charles Hospital, Princess Alexandra Hospital, Sunshine Coast University Hospital, Gympie Hospital, Cairns Hospital, Innisfail Hospital, Ipswich Hospital, Hampstead Rehabilitation Centre, Queen Elizabeth Hospital, Monash University, University of Technology Sydney, Southern Cross University.

Aphasia is a language disability that affects appropriately 30% of stroke patients. High quality evidence states individuals with aphasia benefit more when therapy is provided at a higher dose. The overall aim of this research is to evaluate the implementation of our novel, proven aphasia treatment program called Comprehensive High-dose Aphasia Treatment (CHAT) in the clinical setting. CHAT was developed to address evidence-practice gaps in aphasia treatment, using evidence-based implementation strategies. CHAT incorporates evidence-based and goal-direct treatment of impairment and function, involves carers and provides a novel hybrid face-to-face and telerehabilitation option. This translation research will provide evidence required to directly influence policy and improve aphasia management and access, thus addressing key priorities of health professionals and services. It will provide a new model of care for delivering comprehensive and effective aphasia rehabilitation and establish a practical solution to optimise outcomes for patients.

Howard S, Calleia A, Vasseleu E, de Rosnay M, Neilsen-Hewett C, *Evaluating the viability, reliability and pre-diagnostic utility of a game-like assessment of early language, literacy and communication (the Early Years Toolbox Early Language, Literacy and Communication (ELLC) Assessment).* **Locations:** ISLHD. **External Partners:** UOW.

The objective of this research is to collect data for the purpose of evaluating (e.g., cross-sectional age-related changes in performance), validating (associations with other established language/literacy measures and with other academic and behavioural outcomes) and determining the pre-diagnostic utility (sensitivity and specificity with which the assessment accurately identifies children diagnosed with a language disorder/delay) of a newly created and game-like assessment of pre-school and early primary school children's early language, literacy and communication - The Early Years Toolbox Early Language, Literacy and Communication (EYT-ELLC) Assessment. The EYT-ELLC has been developed to assess foundational aspects of language, literacy and communication development in children aged 3-7 years and provide educators with appropriate information to support their referral discussions and discussions. Data collected will also contribute in anonymous aggregate form to age benchmarks that will be published to help users interpretation of the results that they get when using the EYT-ELLC assessment.

Kendrick C, Wallace E, Thompson L, Woolveridge J, Neal E, Marks D, Dharshini M, Blyth K, Ward E. *A dysphagia telerehabilitation program for stroke survivors living in the community – evaluating the effectiveness and feasibility of a new model of care.* **Locations:** TWH. **External Partners:** USYD, War Memorial Hospital, The Sutherland Hospital, Prince of Wales Hospital, Sacred Heart Hospital.

This study will examine the effectiveness and feasibility of a new model of care for swallowing rehabilitation for stroke survivors living with dysphagia (swallowing impairment) in the community. Changes in consumer satisfaction, feasibility, quality of life and implementation cost will be evaluated.



AMBULATORY & PRIMARY HEALTH CARE HEALTH PROMOTION

Budgen P, *HNE Kids Healthy Eating and Physical Activity Program*. **Locations:** ISLHD.

Good for Kids (GFK) has been working with the NSW Ministry of Health and NSW Department of Education (DoE) to assist schools to implement the DoE's School Sports Unit policy requiring students from Kindergarten to Year 10 to participate in a minimum of 150 minutes of planned moderate to vigorous physical activity across the school week. While these implementation support strategies have been shown to be acceptable and effective at improving the scheduling of 150 minutes of physical activity across the school week; research conducted in a sample of schools from Hunter New England, Central Coast and Mid-North Coast Local Health Districts (LHDs) previously involved in the program, found that wide scale efforts to deliver these support strategies are limited due to the cost and resources required to deliver some of the support strategies (e.g. face-to-face training workshops for in-school champions). This project plans to continue to deliver the original implementation support program as well as an adapted online version to schools within the region. All schools will receive all intervention components and the impact of the intervention will be assessed by comparing changes in study outcomes from baseline to follow-up. Given recent program interest from other LHDs throughout NSW, we have sought approval to include additional sites to this study (Murrumbidgee, Illawarra Shoalhaven, and Western NSW LHDs).

Norman J, Budgen P, Wolfenden L, *HNE Kids Healthy Eating and Physical Activity Program*. **Locations:** ISLHD. **External Partners:** The University of Newcastle.

Overweight and obesity is an escalating problem. Of particular concern is the contribution of child obesity to early onset of major chronic conditions including diabetes and cardiovascular disease. The proportion of overweight children in Australia has doubled in the last 20 years, with one in four school children now overweight or obese. Preliminary data from 2004 obesity surveys estimate child obesity prevalence levels of 25-29% among Hunter school children, and 20-24% among New England 6-8 year olds. Potential determinants of obesity have been identified. Weight gain develops when energy intake exceeds expenditure. Energy dense diets and sedentary lifestyles are associated with increased obesity prevalence. Many variables within the family, school and community environments are likely to influence activity and food intake. In spite of this evidence, there is almost no knowledge of what childhood obesity prevention strategies work. The HNE Child Obesity Prevention Program represents an investment of \$7.5 million over 5 years by NSW Health and Hunter New England Health to build the knowledge of what prevention strategies work as well as preventing further expansion of the obesity epidemic. This area-wide intervention is the largest child obesity prevention program in Australia and it follows the best practice 'multi-strategy multi-setting' approach recommended in Health Weight 2008 – Australia's national plan of action. The program is being conducted as a whole-of-government initiative with the explicit support of key agencies at state and regional level (e.g. premiers department schools, child care, local government, department of sport and recreation, health services, media organisations).



Kershaw M, Furber S, Bates A, Muir KL. *BEST at Home for people with COPD who access a virtual care program.* **Locations:** ISLHD.

30% of people 65+ living in the community fall each year. People with chronic obstructive pulmonary disease (COPD) have a higher rate of falls than their healthier peers, and a greater fear of falling (FOF) associated with lower strength and balance. A home-based exercise study (BEST at Home) showed a reduction in FOF and improvement in gait speed. This study aims to test the acceptability, feasibility and effect of the BEST at Home exercise program on falls risk factors in people with COPD accessing virtual care. It will determine if the program improves strength and balance and reduces FOF. This study involves COPD patients who access ISLHD Virtually enhanced Community Care (VeCC), providing them with a home-based exercise program. Improving strength, balance and FOF would reduce falls risk. Inclusion of strength and balance exercise has been recommended in the ANZ COPD guidelines.

MULTICULTURAL HEALTH

Atkins B, Pitts L, Lema S, Rambaldini-Gooding D, Olcon K, Molloy L, Degeling C, *CoCreating local solutions to ensure cultural humility in maternity services.* **Locations:** ISLHD. **External Partners:** UOW.

Maternal health service providers are expected to perform within the cultural competence driven policy environment yet their experience is that of being inadequately supported and insufficiently resourced to deliver culturally responsive care. To alleviate providers' experiences of inadequacy and the resulting moral distress, a better translation of cultural responsiveness policies to practice is required. This project aims to mobilise health care institutions to demonstrate a commitment to culturally responsive services and an accountability in implementing a systems approach to ensure optimal care to refugee and migrant women. We will work collaboratively with maternal health service providers and managers within Illawarra Shoalhaven Local Health District (ISLHD), Multicultural Health Service (ISLHD), and refugee and migrant women to co-create local solutions to addresses some of these issues.

Coyle M, John S, Montayre J, Traynor V, Chang R, Wang SY, *Developing a Dementia Care and Support Needs Framework for Culturally and Linguistically Diverse (CALD) populations: A whole-of-community co-design approach.* **Locations:** ISLHD. **External Partners:** UOW, Western Sydney University.

There is a lack of data on how culturally and linguistically diverse (CALD) groups respond to generic services, which might have general benefit to their communities and may not require a specific, culturally-informed decision making process. While, cultural groups are diverse, dementia is different in individuals and very complex to capture the specific needs in so many cultural groups. However, it is possible to examine similarities, highlight cultural overlaps and emphasise the point of differences among cultural groups. This approach can be undertaken using a genuine co-design approach involving consumers when first mapping existing services, matching with CALD specific needs and creating a framework to guide service matching and modifying them to become culturally appropriate. Culturally-diverse Australia lacks the framework to identify CALD specific dementia care for people living with dementia and their families. Current dementia care service models are generally service and resource driven with limited, and most often without CALD, consumer involvement (Low et al. 2019). The overall research aim is to develop a dementia care and support needs framework for culturally and linguistically diverse (CALD) communities. The project consists of three specific objectives: (1) To map and explore community-based services for dementia care and support in the ISLHD region for CALD communities using a co-design approach. (2) To undertake an intergenerational, explorative and consumer focussed case study on CALD communities in the ISLHD region, specifically on dementia awareness, acceptance and support needs. (3) To develop and implement a CALD Framework of Dementia Care and Support Needs co-design with people living with dementia and their families from CALD communities.

West L, Rankin N, Yap M, Mouwad D, Rhee J, Stone E, Dodd R, Harland D, Sharman A, McCullough S, Marshall H, McWilliams A, *Acceptability and feasibility of potential lung cancer screening implementation in Australian communities*. **Locations:** ISLHD. **External Partners:** USYD, UOW, Campbelltown Hospital, Liverpool Hospital, UNSW, St Vincent's Hospital, Thoracic Oncology Group of Australia, The Prince Charles Hospital, Fiona Stanley Hospital.

Lung cancer is the number one cause of cancer death worldwide, with the majority of Australians diagnosed with late-stage incurable disease. Recent estimates suggest that by 2025, over 15,000 Australian men and women will be diagnosed with lung cancer annually. Lung cancer screening could save thousands of Australian lives by detecting lung cancer early, when outcomes are significantly improved. A national targeted lung cancer screening program would involve identifying individuals at high-risk for lung cancer from the general population. Little is known about what the community may view to be the barriers and facilitators to implementation of a potential national program in Australia.

SEXUAL HEALTH

Lade C, Rutherford A, Medland N, MacPhail C, *HIV Pre-Exposure Prophylaxis in Australian Women – Improving Access in Primary Care*. **Locations:** ISLHD. **External Partners:** UOW, UNSW.

There has been limited research regarding HIV prevention in Australian women. Prevention strategies, including HIV Pre-Exposure Prophylaxis (PrEP), are targeted towards gay and bisexual men and there is not clear guidance regarding PrEP prescribing for women. In this pilot qualitative research, we will interview PrEP prescribers in Australia regarding their experiences prescribing PrEP for women. This research will provide robust data regarding barriers to PrEP prescribing for women. This project will feed into a wider project, currently under consideration for funding by National Health and Medical Research Council, which will contribute to the development of a consensus on approach to PrEP for women in Australia.

Lam M, Rutherford A, Westley-Wise V, Hoffman N, Rowling D, *The epidemiology of infectious syphilis in the Illawarra Shoalhaven Local Health District 2009 to 2021*. **Locations:** ISLHD. **External Partners:** Queensland Syphilis Surveillance Service.

Syphilis notifications have increased over the last 10 years. There have been outbreaks in areas of the Northern Territory, Queensland, and Western Australia. Fortunately outbreaks do not appear to be occurring in NSW; however in light of the increasing infectious syphilis notifications rates, continuing outbreaks, and congenital syphilis cases, it has become a focus in recent national strategies. This is an opportune time to evaluate the current strategies of syphilis management in the Illawarra Shoalhaven Local Health District, starting by analyzing retrospective syphilis surveillance data in the district. The aim of the study is to identify the trends and patterns in infectious syphilis notifications between January 2009 and December 2021 among Illawarra and Shoalhaven residents which will inform the development of a local syphilis action plan for the local health district.

Parker G, Campbell E, Ellard R, Forster H, Caruana C, Ogilvie K, Hew E, Young S, Stone C, Jones J, Walker FC. *Interview Study: Exploring justice system experiences of complainants in sexual offence matters*. **Locations:** ISLHD. **External Partners:** RMIT University, KPMG.

The Centre for Innovative Justice (CIJ), in partnership with KPMG, has been engaged by the NSW Bureau of Crime Statistics and Research (BOCSAR) to conduct 60 in-depth interviews exploring the experiences of complainants in adult sexual offence matters. Interviews will explore complainants' experiences of reporting and the wider legal process, including where the matter did not proceed to trial. Participants for the interview study will be recruited through a range of services, including sexual assault services; domestic violence services; victim services; and wider services which participants may engage with, such as those providing support in relation to disability and mental health needs.

Rutherford A, Petoumenos K, Cohort of Australian HIV Women. Locations: ISLHD. **External Partners:** UNSW.

Women comprise approximately 10% of the population of people living with HIV in Australia but have been underrepresented in much of the research undertaken to date. The aim of this proposal is to establish the first and largest prospective cohort study of women with HIV (WHIV) in Australia focussing on gender specific issues relevant to WHIV. The cohort study will identify the gaps that exist in research on WHIV and create a strong evidence base to inform prevention and education initiatives and improve health outcomes and equity.

CANCER CARE

Aghmesheh M, Brungs D, Chantrill L, Carolan M, Splitt A, Turner R, Ranson M, Napaki S, ISLHD Biobank. Locations: SDMH, TWH. **External Partners:** UOW.

The proposed project is to establish the ISLHD Biobank, a facility which aims to collect and distribute cancer biospecimens and information for cancer research projects. It will collect, process and store tumour tissue, blood and stool samples from patients diagnosed with cancer, following informed patient consent. Only tumour tissue which is in excess to the diagnostic evaluation needs of the pathologist will be collected. The ISLHD Biobank will utilise a secure database that houses annotated biospecimen data, linked to the relevant clinical information. These aims will be achieved by using the well-established standardised operating procedures of the CONCERT Biobank, which is the former Biobank under which we previously collected, processed, and stored samples. These procedures range from data storage, specimen collection, preservation, and distribution and have been developed according to international best practice, ensuring the collected material is of the highest quality while constantly maintaining respect to the participant.

Arnold B, Arnold A, Farquar O, Williamson K, Lean C, Rushton S, Stapleton B, Vaughan-Davies K, Evans A, Evaluation of the Patient Reported Measures System in NSW cancer services: Patient wellbeing surveys. Locations: TWH. **External Partners:** Cancer Institute NSW, K2 Strategies.

This evaluation is being undertaken to assess the early impact of electronically collecting Patient Reported Measures (PRMs) at the point of care to understand their clinical usefulness to support patient care. The evaluation will explore both the implementation of the PRMs system (extent, barriers and enablers) and the experience of clinicians and patients in providing/receiving care informed by PRMs. The evaluation will involve interviewing/surveying operational and clinical staff and patients from sites where the electronic system has been implemented to understand usage, mechanisms for collection, experience and usefulness. The evaluation will also include: interviews with Cancer Institute NSW staff members; review of PRMs program documentation and reports; and analysis of user statistics from the Patient Information website. The findings will be used for quality improvement and to understand early effectiveness of the electronic PRMs system in the case study sites.



Brungs D, Chantrill L, Aghmesheh M, Clingan P, Singh S, Yeo N, Downton T, Bennett T, M20-111: A Phase 1 first in human study evaluating safety and efficacy of ABBV-637 as either monotherapy or in combination in adult subjects with relapsed and refractory solid tumors. Locations: TWH.

This is a Phase 1, first-in-human, proof of concept, open-label, dose escalation, dose expansion, and biomarker/pharmacodynamic (PD) study evaluating ABBV-637 in subjects with solid tumours. The study will include a monotherapy dose escalation of ABBV-637 in advanced solid tumors (Part 1), a dose escalation of ABBV-637 in combination with docetaxel in EGFR-expressing RR NSCLC (Part 2a), and a dose expansion of ABBV-637 in combination with docetaxel in EGFR-expressing RR NSCLC (Part 2b). The study will assess the safety and preliminary efficacy of ABBV-637 as monotherapy and in combination with docetaxel. Dose escalation will be guided by a Bayesian optimal interval (BOIN) design based on the cumulative number of subjects who experience a DLT in a given ABBV-637 dose level. Standard statistical, clinical, and laboratory procedures will be utilised in this study. All efficacy measurements are standard for assessing disease activity in subjects with solid tumours.

Brungs D, Leighton C, Chen J, Gandhidasan S, Yeo N, Cardoso E, Riddell A, Gedye C, Sim HW, Carter C, The Multi-Arm Glioblastoma Australasia (MAGMA) Trial. Locations: TWH. **External Partners:** USYD.

The MAGMA study will test changes to the standard treatment for patients with the most aggressive type of brain cancer, glioblastoma or high grade glioma. The standard treatment for this disease includes surgery followed by radiotherapy and chemotherapy tablets called temozolomide. Then, when the radiotherapy is finished, temozolomide alone is given monthly for 6 months. Patients who take part in the study could receive either the standard treatment or the standard chemotherapy with one or more changes, including: (1) To start temozolomide as soon as possible after surgery instead of at the standard time, when radiotherapy begins, and/or, (2) to continue temozolomide monthly after radiotherapy, until it is no longer controlling the growth of the tumour rather than just the standard 6 months. This study will investigate if starting temozolomide earlier than usual and/or continuing treatment with temozolomide for longer than usual will improve the outcomes of these patients.



Brungs D, Ashford B, Reddel R, Gupta R, Lee J, *Pan-Cancer retrospective proteomic review of patient samples from NSW Health Pathology and other accredited pathology sources. Locations:* TWH. **External Partners:** Royal Prince Alfred Hospital.

High throughput proteomics technologies have emerged in recent years with significant potential to uncover new insights into cancer biology, biomarkers of response and other outcomes and novel treatment targets. We have optimised proteomics analysis at ProCan at CMRI such that large-scale reproducible proteomic landscape data can now be generated. Proteomics analysis of retrospective tissue samples from patients with specific cancers with known clinical and/or molecular follow up data is the first step in developing a pan-cancer atlas and discovery of clinically applicable biomarkers with the goal of improving personalisation and selection of cancer treatments and outcomes for individual patients. A sequence of hypothesis driven research studies focusing on specific cancers will help answer these questions. In this application, we describe our plan to analyse retrospectively collected tissue from accredited pathology sources.

Chantrill L, Leighton C, Brungs D, Aghmesheh M, Maloney S, Tebbutt N, Yip E, *NEO-adjuvant chemo-IMmunotherapy in PAnCreaTic cancer. Locations:* TWH. **External Partners:** Genesis Care North Shore, Warrigal Private Hospital.

NEO-IMPACT is a Phase II single arm study evaluating the feasibility and safety of combining modified FOLFIRINOX (mFOLFIRINOX) with durvalumab in patients with resectable or borderline resectable pancreatic adenocarcinoma. The study hypothesis is that adding durvalumab [a human monoclonal antibody (mAb)] to mFOLFIRINOX prior to curative surgery will demonstrate adequate safety and tolerability (defined as receiving 80% of planned dose of all agents) in subjects with resectable or borderline resectable pancreatic adenocarcinoma. The primary objective to determine the proportion of patients receiving at least 80% of planned neoadjuvant treatment with durvalumab and mFOLFIRINOX.

Craig S, Fylyk G, Nasser E, Davis K. *Breast Cancer patients at TWH and SDMH: contributing factors to clinical management and patient outcomes. Locations:* TWH, SDMH.

The recent publication Reporting for Better Cancer Outcomes (2020) by the Cancer Institute NSW details a number of important indicators and measures for breast cancer treatment, and compares ISLHD with all other NSW LHDs as well as state averages. ISLHD cancer clinicians noted significant differences of concern in this report between treatments delivered at TWH and SDMH, as well as to the state averages, in particular around the number of mastectomies performed compared to breast conserving and/or reconstructive surgeries. Specifically, there was a significantly lower number of breast conserving surgeries at SDMH (far below the state average), and at both sites the rates of immediate breast reconstructive surgeries and neoadjuvant chemotherapy was also far lower than the state average. This project proposes to undertake a retrospective audit of clinical data of all breast cancer patients within ISLHD over the last 5 years in order to determine if there is a clinical or demographic rationale for these observed trends.

Gafoor MAA, Gandhidasan S, Chen J, Trinh H, Miller A, *Outcomes of patients with brain metastases treated with Stereotactic Radiosurgery (SRS) in ISLHD. Locations:* TWH, SDMH.

Brain metastases are the most common form of intracranial tumours in adults, accounting for over half of brain tumours with a global prevalence estimated from 8.5% to 9.6%. They occur in approximately 10% of cancer patients at some point following initial diagnosis and can cause significant symptoms such as headaches, seizures, and neurological deficits. The median overall survival following development of brain metastases is variable depending on primary tumour site and treatments but ranges from 1.3 months to 13 months.

Kasherman L, Mapagu M, Chantrill L, Singh S, Lee CK, Friedlander ML, Stockler M, Diamante K. *Phase II basket study of an Aromatase inhibitor plus PI3KCA inhibitor or CDK4/6 inhibitor in women with hormone receptor positive recurrent/metastatic Gynaecological Neoplasms (PARAGON-II).* **Locations:** TWH. **External Partners:** USYD, St George Hospital, Prince of Wales Hospital.

The PARAGON-II clinical trial seeks to improve outcomes for post-menopausal women with advanced (recurrent and/or metastatic) gynaecological cancers, that are hormone-receptor positive. The study aims to investigate if the combination treatments of letrozole plus alpelisib, and letrozole plus ribociclib, will lead to an increase in overall response rates, as compared to historical controls from the PARAGON trial, in HR+ advanced gynaecological cancers that are either PIK3CA-mutated or PIK3CA non-mutated. Participants will be allocated to one of the two treatment groups based on the PIK3CA mutation status, then followed-up to see if outcomes are improved and what side-effects occur.

Mapagu M, Naher S, Aghmesheh M, Redfern A, Zdenkowski N, Lewis C, Khan S, Karki B, Houston K, Barnett F. *A double-blind placebo controlled randomized phase III trial of Fulvestrant and Ipatasertib as treatment for advanced HER-2 Negative and Estrogen Receptor positive (ER+) breast cancer following progression on first line CDK 4/6 inhibitor and aromatase inhibitor (FINER / MA.40 / BCT2101).* **Locations:** TWH. **External Partners:** Fiona Stanley Hospital, Lake Macquarie Private Hospital, Prince of Wales Hospital, Southern Highlands Cancer Centre, Toowoomba Hospital, Sunshine Coast University Hospital, The Northern Hospital.

FINER is a multi-centre, double-blind, randomised phase III trial for women and men with oestrogen receptor positive, HER-2 negative, advanced breast cancer which has progressed on prior treatment with no cure available. The primary aim is to determine if treatment with ipatasertib and fulvestrant prolongs progression-free survival, compared with placebo and fulvestrant. Response rate, overall survival, quality of life, economic and exploratory aims will also be evaluated. Ipatasertib is an oral inhibitor of serine/threonine kinase AKT (an enzyme involved in regulating cell survival and proliferation) which is being evaluated for the treatment of cancers in which activation of the PI3K-AKT-mTOR cell signalling pathway may be relevant for tumour growth or therapeutic resistance. Participants will be randomised to either 'ipatasertib plus fulvestrant' or 'placebo plus fulvestrant' and attend clinic regularly for treatment (until disease progression or intolerance) and disease assessment. Research tumour and blood samples will be collected. Ongoing follow up will monitor disease status and survival. FINER will be conducted in Australian hospitals under the coordination of Breast Cancer Trials, a collaborative research group.

Miller A, Aly F, Smee R, Sundaresan P, Vinod S, Milross C, Holloway L. *Patterns of care and survival of older patients (≥70 years) with Head and Neck Squamous Cell Carcinoma.* **Locations:** ISLHD. **External Partners:** Ingham Institute for Applied Medical Research, Prince of Wales Hospital, Westmead Hospital, Blacktown Hospital, University of Sydney, Liverpool Hospital, Chris O'Brien Lifehouse.

Approximately 50% of new cases of Head and Neck Cancer (HNC) occur in patients over 65 years of age. Older patients with HNC can present complex challenges in terms of their clinical management. There is limited literature specifically reporting on the differences in characteristics of older versus younger patients with HNC, as well as differences in their patterns of care (i.e. what treatment they receive) and clinical outcomes (e.g. survival). Due to underrepresentation of older patients in clinical trials, such patterns of care studies are important to identify the differences between older and younger patients with HNC. Additionally, investigating the clinical outcomes of older patients and identifying factors associated with poorer outcomes are important to assist clinicians determine suitable treatment approaches. This study aims to investigate the patterns of care and survival outcomes of older (≥70y) versus younger patients with HNC in a contemporary Australian cohort.

2022 ISLHD RESEARCH ACTIVITY REPORT

Miller A, Gandhidasan S, Jan A, Radiomic prediction of local recurrence of early-stage lung cancer after stereotactic ablative radiotherapy. Locations: TWH. **External Partners:** UOW.

This study aims to extract radiomic features (values that quantify image features such as image density, intensity, course and fine texture and tumour morphology) from pretreatment CT images of patients with early-stage lung cancer to identify potential predictors of local recurrence of disease after stereotactic ablative radiotherapy treatment.

Naher S, Hanizan FM, Brown E. Outcomes, complications and recurrence of invasive cancer with intravesical treatment in non-muscle invasive bladder cancer patients in Illawarra Shoalhaven Local Health District (ISLHD). Locations: ISLHD.

Bladder cancer is the ninth-most prevalent cancer worldwide. Most patients with urothelial cell carcinoma of the bladder present with non-muscle-invasive disease and are treated with bacillus Calmette-Guerin (BCG) intravesical therapy. Other intravesical treatment options include gemcitabine and docetaxel. However, many of these patients experience disease recurrence and progression and treat the disease appropriately is important. There is limited local data describing the outcome, complication and recurrence rates of the patients described above who are treated in this region.

Parmar G. A Multi-arm Phase 1b Study of Talquetamab With Other Anticancer Therapies in Participants with Multiple Myeloma. Locations: TWH.

A Multi-arm Phase 1b Study of Talquetamab With Other Anticancer Therapies in Participants with Multiple Myeloma Talquetamab (also known as JNJ-64407564) is a humanized IgG4 PAA bispecific antibody designed to target GPRC5D and the CD3 molecule found on T-cells. By bringing myeloma cells and T-cells into close proximity, talquetamab is designed to promote the activation of T-cells with subsequent myeloma cell lysis. The primary objectives of this study are to characterize the safety and tolerability of talquetamab combination regimens by assessing the incidence and severity of AEs, laboratory values, and the frequency and type of DLTs. A key secondary study objective is to evaluate antitumor activity of each treatment combination by assessing overall response as defined by IMWG 2016 response criteria, as well as duration of response and time to response.

Parmar G, Warburton P, Cartwright K, Desai S, King K, Loi A, Bowden A, Sutton L. CA059-001: A Phase 1, open-label, dose finding study of CC-95251 alone and in combination with antineoplastic agents in subjects with acute myeloid leukaemia and myelodysplastic syndromes. Locations: TWH.

The purpose of this study is to determine the safety of CC-95251 alone and in combination with azacitidine in participants with acute myeloid leukaemia and myelodysplastic syndromes. The study will consist of 3 periods: (1) Screening period of up to 28 days; (2) Treatment period of up to 24 months; (3) Off treatment safety follow up period of up to 24 months. Participants will be enrolled to 1 of 3 parts in the study: Part A will test increasing doses of CC-95251 alone or in combination with azacitidine in patients in R/R AML or R/R MDS Part B will test CC-95251 alone and in combination with azacitidine in a larger group of patients with R/R AML or R/R MDS after corresponding dose level in Part A is completed. Part C will test CC-95251 in combination with azacitidine in a larger group of patients with TN MDS after corresponding dose level in Part A is completed.



Parmar G, Desai S, Ryan M, Rabbolini D, Chen V, Curnow J, Brighton T, Szabo F, Pasalic L, Platelet Function Testing using OPTIMUL in Patients with Undiagnosed Bleeding Disorders in regional centres in Australia. Locations: TWH. **External Partners:** Lismore Cancer Centre and Haematology Unit, Concord Hospital, Westmead Hospital, Prince of Wales Hospital, Royal Darwin Hospital, Westmead Hospital.

Platelet function disorders (PFDs) are conditions characterised by abnormal platelet function that may be inherited or acquired (secondary to autoimmune diseases, malignancies or organ dysfunction). Affected individuals have a predisposition to bleeding or bruising and often experience significant bleeding complications after surgery. Platelet function is usually assessed in laboratories by their responses to various stimuli using an instrument called a light transmission aggregometer (LTA). This is not widely available and patients outside of large metropolitan centres do not have the opportunity for appropriate diagnostic testing. This project will explore the feasibility and efficacy of 96 well platelet aggregometry (OPTIMUL), that uses the same principle as LTA, but uses basic laboratory equipment and produces results that are standardised and simple to interpret. It is envisioned introduction of the OPTIMUL assay at large regional centres will provide a diagnostic service where one does not currently exist for regionally based patients.

Parmar G, Presgrave P, Warburton P, Cartwright K, Desai S, King K, Loi A, Paterson J. A randomized, Phase 3, open label study evaluating subcutaneous versus intravenous administration of isatuximab in combination with pomalidomide and dexamethasone in adult patients with relapsed and/or refractory multiple myeloma (RRMM). Locations: TWH.

Multiple myeloma is a rare form of cancer characterised by improper function of plasma cells in the bone marrow, leading to the formation of tumours throughout the body. While there are treatments for this condition, there is a need for more effective treatments that prioritise patient comfort. This study will involve a combined treatment of oral pomalidomide and dexamethasone, with isatuximab for infusion. This study will compare the safety and efficacy of approved, IV administration of isatuximab in comparison with an investigational, wearable device that administers isatuximab subcutaneously. It is hoped that this device will lessen infusion time for patients, and allow treatment to be administered at home. This study is a randomised, open-label project. There will be two study groups, with participants either receiving IV or SC.

Parmar G, Presgrave P, Warburton P, Cartwright K, Desai S, King K, Loi A, Ginsborg L, Ai S, A Phase 3, Two-Stage, Randomized, Multicenter, Open-label Study Comparing CC-92480, Bortezomib, and Dexamethasone (480Vd) Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in Subjects with RRMM. Locations: SDMH, TWH. **External Partners:** St Vincent's Hospital Melbourne, Box Hill Hospital, Sir Charles Gairdner Hospital, Calvary Mater Newcastle, Alfred Health, Liverpool Hospital.

The purpose of this study is to see how well the drug CC-92480 in combination with bortezomib and dexamethasone works to treat multiple myeloma, when compared with pomalidomide in combination with bortezomib and dexamethasone. Participants in all treatment arms will continue to receive treatment until confirmed progressive disease (PD), unacceptable toxicity, withdrawal of consent, or death.



Parmar G, Leighton C, Presgrave P, Warburton P, Cartwright K, Desai S, King K, Ai S, Ginsborg L, Loi A, Janowski W, Joy Ho P, Bryant A, Augustson B, Sirdesai S. 64007957MMY3005 (MajesTEC-7); A Phase 3 Randomized Study Comparing Teclistamab in Combination with Daratumumab SC and Lenalidomide (Tec-DR) versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants with Newly Diagnosed Multiple Myeloma Who are Either Ineligible or not Intended for Autologous Stem Cell Transplant as Initial Therapy. **Locations:** TWH. **External Partners:** Calvary Mater Newcastle, Royal Prince Alfred Hospital, Liverpool Hospital, Sir Charles Gairdner Hospital, Barwon Health, University of Geelong.

MajesTEC-7 is randomized Phase 3 study comparing Teclistamab in Combination with Daratumumab SC and Lenalidomide (Tec-DR) versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants with Newly Diagnosed Multiple Myeloma Who are Either Ineligible or not Intended for Autologous Stem Cell Transplant as Initial Therapy. The primary objective is to compare the efficacy between Tec-DR and DRd in terms of progression free survival and sustained MRD-negative Clinical Response for 12 months and more.

Presgrave P, Parmar G, Warburton P, Cartwright K, Desai S, King K, Loi A, Sutton L, Rebeiro P. A Phase 1b/2 Study of BMS-986158 Monotherapy and in Combination with Either Ruxolitinib or Fedratinib in Participants with DIPSS-Intermediate or High Risk Myelofibrosis (CA011-023). **Locations:** TWH. **External Partners:** Blacktown Hospital.

This is a phase 1b study of BMS-986158 monotherapy and in combination with either Ruxolitinib or Fedratinib in participants with myelofibrosis. The purpose of this study is to test the safety, evaluate the side effects, and determine a dose of BMS-986158 that can be given to patients with Myelofibrosis, as monotherapy or in combination with ruxolitinib or fedratinib. There are 2 parts to this study: Part 1 (Dose Escalation) different doses of BMS-986158 in combination with ruxolitinib or fedratinib. Approximately 66 patients will be treated. Part 2 (Dose Expansion) will explore one (or more) dose levels of BMS- 986158 as monotherapy alone or in combination with ruxolitinib or fedratinib. Approximately 90 patients will be treated.

Presgrave P, Owen F, McErlean G, Halcomb E, Pradhan A, Kerridge I, Farnham G. *Transition of Chronic Care after blood and marrow transplant (BMT).* **Locations:** TWH. **External Partners:** Ingham Institute of Applied Medical Research, Royal North Shore Hospital, Liverpool Hospital.

Blood and marrow transplant (BMT) is an effective cancer treatment that results in increased survival rates and improved outcomes. However, BMT survivors are at an increased risk of a range of long-term and late effects of therapy. Accordingly, the guidelines require long-term follow-up (LTFU) to optimize the benefit and minimize the negative effects. Historically, BMT Centres have assumed responsibility for implementing and providing guideline-based LTFU care. However this is unsustainable, inefficient and can result in poor quality care. Most LTFU can and arguably should be safely and effectively managed by primary care clinicians (General Practitioners and General Practice Nurses). However, no research has been conducted into the views, capability and confidence of GPs and GPNs in managing survivors of BMT survivors. In addition, there are no programs focused on the transition of adult BMT survivors into primary care. This study contributes new knowledge which is vital to the development and adoption of processes, policies and resources for new models of care and transition to primary care settings for BMT survivors.



Tincknell G, Brungs D, Chantrill L, Aghmesheh M, Kasherman L, Mapagu M, Hanizan FM, Haggstrom L, Naher S, Goldstein D, Lipton L, Patel R. *A Phase 1b/2, Multicenter, Open-label Basket Study Evaluating the Safety and Efficacy of Bemarituzumab Monotherapy in Solid Tumors with FGFR2b Overexpression (FORTITUDE-301).* **Locations:** TWH. **External Partners:** Prince of Wales Hospital, Cabrini Health.

This is a phase 1b/2, open-label, multicenter exploratory, signal finding basket study to evaluate the efficacy and safety of bemarituzumab monotherapy in subjects across multiple solid tumors with FGFR2b overexpression and relapsed/refractory unresectable and/or metastatic disease. The study consists of 2 parts: monotherapy dose exploration (Part 1, phase 1b) across tumor types (ie, 9 to 18 subjects in total regardless of tumor type), followed by monotherapy dose expansion (Part 2, phase 2) for each of the 10 tumor cohorts at the selected dose level from Part 1. A total of between 360 to 375 subjects will be enrolled in the study, with 9 to 18 subjects in Part 1, up to 36 subjects in each of 10 planned tumor cohorts in Part 2.

Vijayakumar V, Gandhidasan S, Brungs D, Miller A. *Investigating the outcomes of WHO Grade 3 brain tumours in the ISLHD.* **Locations:** TWH, SDMH.

To determine outcomes of patients treated for WHO Grade 3 and 4 brain tumours (high grade gliomas) in the ISLHD.

CLINICAL GOVERNANCE

Cole R, Ratcliff S. *Predicting Avoidable Readmissions in the Illawarra & Shoalhaven using Machine Learning.* **Locations:** ISLHD. **External Partners:** USYD.

Avoidable readmissions have the propensity to cause significant physical harm, disproportionately consume scarce healthcare resources and materially affect organisational outcomes. Readmitting for remedial treatment has proven detrimental to patient safety, causes worse health outcomes, and increases the psychological burden of hospitalisation. Each year readmissions cost between \$26.1billion to \$41.3billion in the United States of America. This project aims to develop a more profound understanding of avoidable readmissions and their network effects. This work sets out to explain why avoidable readmissions occur, demonstrate factors that heighten risk and allow clinicians to predict likely instances before a patient leaves hospital.



CRITICAL CARE

EMERGENCY

Curtis K, Tavender E, Dent B, King A, Lawton B, Corden M, George S, Rao A, Gangathimmaiah V, Halkidis L, Lennon R. *Sustaining improvements in the management of infants with bronchiolitis – a PREDICT study.* **Locations:** TWH. **External Partners:** Melbourne Children's Campus, Ballarat Base Hospital, Toowoomba Base Hospital, Logan Hospital, Northern Hospital, Gold Coast University Hospital, Sydney Children's Hospital, Townsville University Hospital, Cairns Hospital, Royal North Shore Hospital.

The Paediatric Research in Emergency Departments International Collaborative (PREDICT) network developed an Australasian Bronchiolitis Guideline in 2016 that provided high quality evidence that widely used interventions were ineffective. The PREDICT network then undertook the 'Knowledge Translation in Australasian Paediatric Acute Care' (PREDICT KT study), a multicentred, cluster, randomised control trial of infants under the age of one with Bronchiolitis. The aim of this study is to assess sustainability of improvements in reducing inappropriate therapies in infants with Bronchiolitis, at 26 sites which participated in the PREDICT KT Study, one (2018) and two year (2019) post implementation of intervention. A retrospective medical audit will be conducted at the 26 Australian and New Zealand hospitals which participated in the PREDICT KT study. Our results will help determine the sustainability of this intervention over time, determine any improvements in control group hospitals, examine the learning and decay effects of the intervention, determine fidelity and adaptation of the intervention and explore factors which may have contributed to sustained improvements in either intervention or control group sites.

Curtis K, Jordan M, Mullan J, Bonney A, Chen T, Moules S. *Medication-related presentations to Illawarra-Shoalhaven Local Health District from 2007 to 2021.* **Locations:** ISLHD. **External Partners:** UOW, USYD.

This retrospective study aims to investigate the medicines or combination of medicines responsible for emergency presentations or admissions to an Illawarra Shoalhaven Local Health District hospital, from 2007 to 2021, using routinely collected data captured by the Centre for Health Research Illawarra Shoalhaven Population (CHRISP) in the Illawarra Health Information Platform (IHIP). The study also aims to determine the nature of reported patient harm and patient characteristics, and any trends in these outcomes that occurred over the study period. The results of the study will be disseminated to primary care clinicians responsible for aspects of medication management as well as to those clinicians within acute care settings, who not only provide care for patients presenting with medication-related harm but also initiate medicines intended for use when patients are discharged back to the community.



Curtis K, Melville G, Georgiou A, Westbrook J, Rawlinson W, Post J, Horvath A, Li J. *PathWorks: An evaluation of the impact of a digital platform on work processes and patient outcomes.* **Locations:** TWH, SDMH, SHH. **External Partners:** Macquarie University, UNSW, Prince of Wales Hospital.

The project involves the development and implementation of PathWorks, a digital health application which provides clinicians with mobile and remote access to enhance the speed and quality of pathology services using several features to support rapid communication of results and electronic decision support. In this piece of research we plan to examine the feasibility, uptake and acceptance of Pathworks. We will be investigating how the application can be incorporated into existing clinical work practices and its impact on clinical decision-making and care delivery. This will involve interviews or focus groups with multiple participants. The participants will be recruited from amongst Emergency Department inpatients, clinicians and laboratory personnel. The project will be undertaken within the Emergency Departments, Intensive Care Units and pathology laboratories of Prince of Wales, Royal Hospital for Women (Sydney), Shellharbour, Shoalhaven, St George, Sutherland and Wollongong Hospitals.

Heufel M, Curtis K, Lo A, Thomas B, Tuala E, Makoni H. *Improving End of Life Care at Wollongong Hospital Emergency Department (WH ED): A Mixed Methods Study.* **Locations:** ISLHD.

End of life care delivery in the Emergency Department (ED) is a rapidly growing area of clinical practice. Amid an ageing population with high burdens of serious health-related conditions, the number of ED presentations of people who require specialised end of life care is expected to continue to rise. This study aims to contribute to best-practice EOL care in the ED setting by developing a standardised, evidence-based audit tool and analyse current health service delivery to inform the development of an intervention to improve EOL care in the ED.

Munroe B, Hudoba M, Butina E, Makoni H, Couttie T, Middleton R, Fullick M. *Emergency Department clinicians' recognition and management of sepsis: a behavioural analysis using the Behaviour Change Wheel.* **Locations:** ISLHD.

Sepsis is the body's overwhelming and life-threatening response to infection that leads to tissue damage, organ dysfunction and death. Failure to recognise and respond to sepsis is a global issue. Representing 19.7% of all global deaths each year, sepsis is one of the leading causes of hospital mortality worldwide. Delayed recognition and treatment of sepsis has been associated with extended hospital length of stay and high rates of morbidity. In Australia, sepsis accounts for 48,005 hospitalisations per year, with an estimated cost the health service of \$39,000 per separation. Long term outcomes of sepsis can result in significant long term cognitive and physical impairment, as well increased risk of re-infection and re-admission to hospital. Timely administration of antibiotics, fluid resuscitation and respiratory support has been shown to reduce mortality in patients with sepsis by up to 30.4%. In 2022 the National Sepsis Clinical Care Standard was developed to ensure that a patient presenting to hospital with signs and symptoms of sepsis receives optimal care.



INTENSIVE CARE UNIT

Abdelhamid MSM, Abdelwahed H, Jagarlamudi V. *Prevalence of multi resistant organisms in Wollongong hospital intensive care unit during COVID time- retrospective review.* **Locations:** TWH.

This retrospective review aims to identify the prevalence of multi resistant organisms in intensive care unit in Wollongong hospital during the COVID times and compare it to pre COVID times. Background: Authors have noticed increase in number of MRO acquisition in ICU during busy COVID times as compared to pre COVID, thus willing to collect data of MRO acquisition during COVID times and compare to pre COVID times to identify any difference and its significance.

Abdelwahed H, Elgendy A, Elkady H, Gerhardy B, Elrakaiby A, Karigowda L, Orde S. *Prevalence and impact of cardiac dysfunction on outcome of COVID-19 critically ill patients – retrospective observational cohort study.* **Locations:** TWH. **External Partners:** Westmead Hospital, Nepean Hospital.

COVID-19 infection is associated with many other problems and organ failure. Heart problems can happen due to or be associated with COVID-19 infection but it is not clear how frequent it happens and what would be the outcome of this combination of medical diseases. This research is trying to identify this association and impact on the outcome of these patients.

Elgendy A, Macpartlin M, Davey-Quinn A, Sterba M, Purdon A, Davis M, Costello C, Jagarlamudi V, Orford N, Bone A, Nair P, Hodgson C, Center J, Kotowicz M, Venkatesh B, Bellomo R, Litton E, Young P, Reynolds C, Peake S, Kruger P, Delaney A, Gattas D, Udy A, Cohen J, Fletcher J, *Bone Loss Prevention with Zoledronic Acid or Denosumab in Critically ill Women – A Randomised Controlled Trial.* **Locations:** TWH. **External Partners:** Barwon Health, Austin Health, St Vincent's Health Sydney, Royal Prince Alfred Hospital, Royal North Shore Hospital, Princess Alexandra Hospital, The Queen Elizabeth Hospital, Royal Brisbane and Women's Hospital, Bendigo Health, St Vincent's Health Melbourne, John Hunter Hospital, Alice Springs Hospital, Logan Hospital, Wesley Hospital.

This research project aims to study the effects of two anti fracture medications, denosumab and zoledronic acid, compared to placebo, on the effect of bone loss associated with critical illness. The trial will enrol 450 critically ill women aged 50 years or greater who have been in ICU more than 24 hours. Participants will be randomly allocated to one of 3 groups, denosumab, zoledronic acid or placebo, with 150 in each group. Study drug will be administered at Day 0 and 6 months. Blood tests, a bone density scan (BMD) and questionnaire will be measured at baseline. The questionnaire will be repeated at 6 months. The BMD and questionnaire is repeated at 12 months. This trial will compare denosumab or zoledronic acid to placebo on change in BMD. It will assess the number of fragility fractures, hospital readmission, quality of life, bone turnover markers and mortality at 12 months after ICU.



DRUG AND ALCOHOL

Baker K, Lintzeris N, Parvaresh L, Mills L, Jansen L, Tracy M, Jamshidi N, Tremonti C, Dunlop A, *Investigating NSW Opioid Agonist Treatment clinicians' attitudes, knowledge, and perspectives regarding cannabis use by clients on Opioid Treatment Program*. **Locations:** ISLHD. **External Partners:** USYD, SESLHD, St Vincents Health Network Alcohol & Drug Service, Hunter New England Local Health District Drug and Alcohol Services.

In this study we aim to design and implement a survey on clinicians working in multi-disciplinary teams in NSW Health opioid Treatment services to understand their knowledge, attitudes, and practices regarding addressing cannabis use in opioid dependent clients in treatment. Clinicians will also be asked about the range of interventions that should be available for clients to address their cannabis use, including the role of harm reduction interventions, behavioral interventions, and medicinal cannabis medications. The results of the survey will be used to co-design interventions for opioid dependent clients in treatment for addressing cannabis use.

Reid D, Qian S, Graf C, Hampson A, Cordaro F, Lautier A, Mcalister P, Grebely J, Dore G. *The National Australian HCV Point-of-Care Testing Program: An observational cohort study to evaluate the use of finger-stick point-of-care hepatitis C testing to enhance diagnosis and treatment of HCV infection*. **Locations:** ISLHD. **External Partners:** UNSW.

This is an observational cohort study. Participants will be recruited from settings that provide services to people with a risk factor for the acquisition of HCV infection. Participants will attend a single visit to have their HCV RNA status tested and complete a self-administered survey. Participants will not receive treatment as a part of this study. Participants who are HCV RNA positive will be linked to standard of care. The purpose of this study is to look at the effect of finger-stick point-of-care hepatitis C testing, to see if it increases the number of tests, diagnoses, and treatments for people with a risk factor of having hepatitis C in Australia.

Reid D, Sinclair B, Cordaro F, Kelly P, McKetin R, Farrell M, Degenhardt L, Dore G, Shoptaw S, Turner A, Clare P, Arunogiri S, Colledge S, *The Tina trial: A phase 3 randomised placebo-controlled trial of mirtazapine as a pharmacotherapy for methamphetamine ("Ice") dependence*. **Locations:** ISLHD. **External Partners:** UOW, UNSW, Deakin University.

There are currently no approved pharmacotherapies that can be delivered as scalable and cost-effective treatment options for methamphetamine dependence. Mirtazapine has recently been identified as a promising medication based on two Phase II clinical trials. Mirtazapine is currently an approved generic antidepressant medication that can be delivered as a prescribed take-home medication, making it a potentially scalable and cost-effective treatment option. We aim to assess the effectiveness, safety, tolerability of mirtazapine for methamphetamine dependence in routine clinical care. This project will randomise 340 participants across Australia to receive either 12 weeks of mirtazapine or equivalent placebo.



Seddon S, Qian S, Riordan V, *Describing the pregnancy outcomes of SUPPS clients who identify alcohol as the primary substance of concern.* **Locations:** TWH, SDMH.

Alcohol is a neuro toxin and can cause birth defects and permanent brain injury in the fetus. Alcohol readily crosses the placenta and can cause harm at any stage of a pregnancy, including the time before pregnancy is confirmed. While, during the first 12 weeks of pregnancy there is the highest risk of harm, drinking alcohol at any time during a pregnancy can cause irreversible damage. Shelton (2018) reports that there is an increased risk of neurodevelopmental problems and preterm birth following the prenatal alcohol exposure of between 30–40g* of alcohol per occasion of drinking .Or the equivalent of approximately 2–2.5 standard drinks once or twice per week. The National Health and Medical Research Council of Australia (NHMRC) advises that the safest option for women who are pregnant or planning a pregnancy is to avoid drinking alcohol (Australian Guide to the Diagnosis of FASD, 2020). This study will investigate how many women in the ISLHD, at antenatal booking report consuming alcohol. The pregnancy outcomes for women who have consumed alcohol during the pregnancy or where there is a risk of alcohol having been consumed prior to the pregnancy being confirmed will be investigated. This study will find out how many women were referred, declined referral or engaged with the SUPPS service and describe the pregnancy and treatment outcomes.

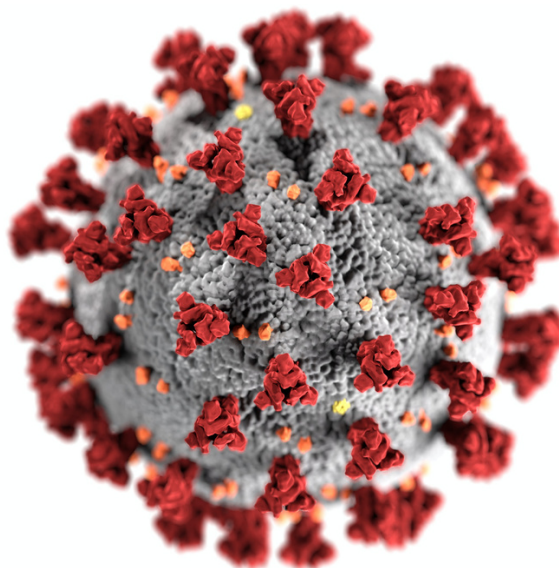
HEALTH RESEARCH

Norman J, Okely A, Wardle K, Innes-Hughes C, Kelly-Gillott B, Ryan S, Tran G, *A pilot study of an online quality improvement support tool for service providers and educators in family day care to improve nutrition and physical activity practices.* **Locations:** ISLHD. **External Partners:** UOW.

The aim of this pilot study is to test the feasibility and acceptability of an online quality improvement support tool for service providers and educators to improve nutrition and physical activity practices.

Broyd S, Muir KL, Baytieh D, Rendel P, Ghosh N. *Evaluation of the Virtually enhanced Community Care (VeCC) COVID service.* **Locations:** ISLHD.

Virtual models of care are well placed to provide safe, clinical treatment of patients with COVID-19. In Australia, recent research suggests these models of care are both safe and efficacious, however further research to validate these findings is required. Within the Illawarra Shoalhaven Local Health District, the Virtually enhanced Community Care (VeCC) service assumed the clinical management of patients with COVID-19 who were able to safely isolate at home. Through virtual clinical consultation and remote monitoring of a patients symptoms and wellbeing, VeCC supported patients for the duration of their illness and period of isolation, facilitating early intervention and hospital admission as necessary. The proposed evaluation will examine the effectiveness of this service for patients with COVID-19 from a value-based care perspective, including review of patient outcomes, efficiency and effectiveness of service, patient experience of care and staff experience delivering care.



KIDS & FAMILIES

Blakemore L, Stuhl E, Ivers R, Dickson M, Charlton K, Pulver LJ, Catling C, Dibley M, Buck M, Kelly P, Meedya S, Eckermann S, Best E, Briggs M, Taniane T, Thorne R, *Marri Gudjaga study*.
Locations: ISLHD. **External Partners:** UOW, USYD, UTS, LaTrobe University, Ministry of Health, Waminda South Coast Women's Health & Welfare Aboriginal Corporation.

This project aims to improve the nutrition of Aboriginal infants. We will evaluate the effect of scheduled breastfeeding peer support for and by Aboriginal women, on breastfeeding initiation and prevalence of exclusive breastfeeding at six weeks, four months and six months post-birth. Our intervention will utilise both face-to-face peer support for and by Aboriginal women and employ innovative aspects such as social media, video & telephone calls by Aboriginal peer workers for a period of six months postnatally.



MATERNITY AND WOMEN'S HEALTH

Reid F, Fox D, Scarf V, Levett K, *Harnessing technology in labour and birth for women with increased BMI*. **Locations:** TWH. **External Partners:** UTS.

The aim of this study is to determine how the use of an innovative monitoring technology, Non Invasive Fetal Electrocardiogram (NIFEKG) in women with increased BMI (Body Mass Index), compares with the current standard monitoring modality, cardiotocography (CTG) in: (1) Detection of fetal distress requiring intervention; (2) Fetal scalp electrode (FSE) use; (3) Maternal feelings of control and agency during labour and birth; (4) Capacity for midwives to provide woman centred care and 'Watchful Attendance'. Using the results of the above and qualitative data, the study will also explore barriers and facilitators to implementation of the NIFEKG. Hybrid RCT Type 1 methodology, following the approach of Curran et al. (2012), uses a hybrid effectiveness-implementation typology. The study design therefore enables a dual focus a priori, testing the effectiveness of a clinical intervention on specified outcomes whilst also synthesising implementation needs.

MEDICINE

CARDIOLOGY

Lee A, Mackay S, Norman S, Zaki N, Tierney M, Nelson A. *Obicetrapib and Cardiovascular Outcomes: A Placebo Controlled, Double Blind, Randomized Phase 3 Study to Evaluate the Effect of 10 mg Obicetrapib in Participants with Atherosclerotic Cardiovascular Disease (ASCVD) Who are Not Adequately Controlled Despite Maximally Tolerated Lipid Modifying Therapies.* **Locations:** TWH.

Project TA-8995-304 is a multi-site, placebo-controlled, double-blind, randomised Phase 3 study in approximately 9000 participants with established atherosclerotic cardiovascular disease (ASCVD) whose disease is not adequately controlled despite maximally tolerated lipid-modifying therapies. The median study duration for each participant is expected to be at least 32 months, including a 28-day Screening Period, a 30-month or greater Treatment Period, and a 35 to 60-day post treatment Follow-Up Period. This will be an event-driven study and will complete after approximately 959 primary endpoint events (ie, Cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or non-elective coronary revascularisation) have occurred, and after the last randomised participant has been followed for a minimum of 2.5 years

Lee A, Mackay S, Norman S, Zaki N, Tierney M. *Guideline Oriented Approach to Lipid Lowering In Asia-Pacific (GOAL-ASIA).* **Locations:** TWH.

This project aims to evaluate whether a multifaceted patient- and clinician-facing intervention can increase the proportion of patients who achieve LDL-C targets and adopt guideline-recommended therapies at 6 months post myocardial infarction. The study will be open in 8 countries in the Asia Pacific including Australia. The primary hypothesis is that implementation of a multi-faceted patient and clinician-facing intervention will result in a higher proportion of patients achieving a target LDL-C of <1.4mmol/L at 6 months compared to the standard-of-care arm.

Lee A, Mackay S, Norman S, Zaki N, Tierney M. *ZEUS - Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation.* **Locations:** TWH.

People with cardiovascular disease and chronic kidney disease often have inflammation. Inflammation is a critical process for wound healing and to fight off bacteria and viruses. Long term inflammation that goes unchecked can cause heart attack and stroke. The body makes signal molecules such as IL-6 in response to inflammation, which then gives rise to more inflammation. This is a study investigating the effects of ziltivekimab on people with cardiovascular disease, chronic kidney disease, and systemic inflammation. Ziltivekimab is an antibody designed to block the action of IL-6 to potentially help the body avoid more inflammation. This study consists of 3 periods; Screening, Treatment, and Follow-up. Eligible participants will be randomised in a 1:1 ratio to receive one of the following: (1) 15 mg ziltivekimab via subcutaneous injection once monthly; (2) Matching placebo.

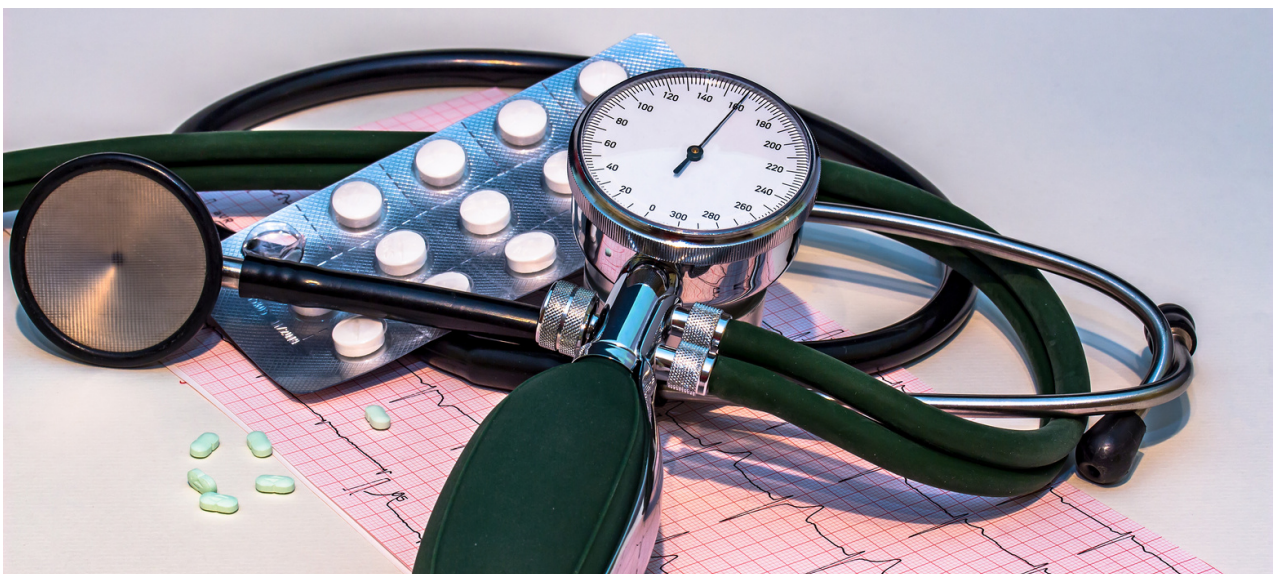


Lee A, Mackay S, Tierney M, Colquhoun D, Shinkel T, Amerena J, Kleinig T, Rahman A, Cordato D, Gan G, Poulter R, Campbell B, Choi P, Lahiri A, Cross D, Blombery P, McKenzie S, Hammett C, Garcia-Esperon C, Oqueli E, Morton J, Purnell P, Carroll P, Ghia D, Shaw J, Eccleston D, *A multicenter, international, randomized, active comparator-controlled, double-blind, double dummy, parallel-group, 2-arm, Phase 3 study to compare the efficacy and safety of the oral FXIa inhibitor asundexian (BAY 2433334) with apixaban for the prevention of stroke or systemic embolism in male and female participants aged 18 years and older with atrial fibrillation at risk for stroke.* **Locations:** TWH. **External Partners:** The Alfred Hospital, University Hospital Geelong, Royal Adelaide Hospital, Gold Coast University Hospital, Liverpool Hospital, Blacktown Hospital, Sunshine Coast University Hospital, Royal Melbourne Hospital, Box Hill Hospital, Flinders Medical Centre, GenesisCare Wesley Hospital Brisbane, The Avenue Cardiovascular Centre, The Prince Charles Hospital, Royal Brisbane and Women's Hospital, John Hunter Hospital, Ballarat Health Services, GenesisCare Leabrook, GenesisCare Joondalup, Redcliffe District Hospital, Fiona Stanley Hospital, The Canberra Hospital, Concord Repatriation General Hospital, Westmead Hospital, Nepean Hospital, University of Adelaide, Nightingale Cardiology, Queen Elizabeth Hospital, Baker Heart and Diabetes Institute, Cabrini Malvern, GenesisCare Bundoora.

Atrial fibrillation is a disease in which the heart beats abnormally, and often very quickly. It is associated with increased risk of strokes and blood clots. Asundexian works by inhibiting a molecule called coagulation factor XI (FXIa) which is thought to contribute to the formation of blood clots. By inhibiting the action of this molecule, asundexian can make your blood thinner, which may prevent blood clots forming in your body and causing serious harmful effects like strokes. In this study, participants will be randomised into 2 treatment groups. One group will receive asundexian, and the other will receive apixaban (a standard of care drug for blood clot/stroke prevention). Both groups will receive the active drug as described, and a placebo treatment for the drug they are not receiving. Participants will continue on the study drug and then participate in follow-up.

Min SS, Lee A, Amerena J, Hammett C, Roberts-Thomson P, *A Multicenter, Cross-sectional Study to Characterize the Distribution of Lipoprotein(a) Levels Among Patients With Documented History of Atherosclerotic Cardiovascular Disease (ASCVD).* **Locations:** TWH. **External Partners:** Royal Brisbane & Women's Hospital, Royal Hobart Hospital, Barwon Health.

Testing for elevated Lp(a) very rarely occurs in everyday clinical practice, despite its establishment as an important genetic cardiovascular (CV) risk factor. Subjects enrolled into this study may be invited to participate in future Amgen sponsored Lp(a) lowering clinical trials. The purpose of this study is to characterize the distribution of Lp(a) levels among subjects with a history of ASCVD as defined by their medical history and is 2 fold: (2) Evaluate the distribution of Lp(a) value in the overall subjects with documented history of myocardial infarction (MI) and/or percutaneous coronary intervention (PCI). (2) Evaluate the distribution of Lp(a) value in subjects with documented history of MI and/or PCI by demographics and regions.



Shetty P, Norman S, Mohdzaki N, Ng M, Yong A, Keech T. *Restoring microcirculatory perfusion in ST-elevation myocardial infarction: the RESTORE-MI trial.* **Locations:** TWH. **External Partners:** USYD, Concord Hospital, RPA Hospital.

Heart attacks are caused by a blood clot blocking the blood vessels of the heart, preventing blood getting to the heart muscle. Opening up the artery with a balloon (angioplasty) and a small mesh tube (stent) although life saving can cause this clot to break up and get washed downstream, which can make the heart attack worse. We can measure the amount of damage caused to the microcirculation by calculating the IMR (Index of Microcirculatory resistance). This can be measured by a wire in the coronary artery with a pressure sensor at the tip. If The IMR is elevated, it is suggestive of extensive microcirculatory damage. A clot dissolving medicine can be administered in the artery to try and reduce the IMR which can reduce damage to the heart muscle and improve outcomes. Impaired microcirculatory perfusion in patients as a result of STElevation myocardial infarction (STEMI) is associated with poor clinical outcomes. This project seeks to identify patients with impaired microcirculatory perfusion after STEMI and to assess whether acute improvement in microcirculatory perfusion in these patients by the use of intracoronary thrombolytic therapy results in improved left ventricular function. Patients presenting to the participating hospitals with a heart attack will be approached to participate in the study. After angioplasty has been performed, the IMR will be measured in the infarct related artery. If the IMR is >32 patients will be randomised to receive intracoronary clot dissolving therapy in the form of tenecteplase (TNK) or normal saline as a placebo. Patients who have an IMR <32 will be followed up in a registry. Cardiac enzymes will be measured at baseline and discharge. An echocardiogram will be performed at baseline and at follow up at 1, 6, 12, 24 months.

DIABETES & ENDOCRINOLOGY

Pape A, Nattrass N, Webb A, Fu K, Zhang J, Apostoloski Z, Luttrell M, Hickey E. *A 52-wk study (COMBINE 1).* **Locations:** ISLHD. **External Partners:** St Vincent's Hospital Melbourne.

Diabetes is a metabolic condition that affects your body's ability to regulate insulin. This causes high blood sugar, which can cause lasting damage to organs. Current treatments include insulin therapy, and monitoring of blood sugar levels. Because so many people have diabetes (about 1.8 million people in Australia alone), there is a need to develop more effective and reliable treatments. IcoSema is a medicine combining insulin icodec and semaglutide. Insulin icodec is a type of insulin like the insulin made in the body. Semaglutide is similar to a hormone made in the body called glucagon like peptide 1 (GLP 1). Insulin icodec and semaglutide both lower the level of sugar in your blood. Insulin icodec lasts significantly longer in the body than many types of insulin, and only needs to be administered once weekly. This study will involve two randomised treatment groups, one receiving IcoSema, and one receiving insulin isodec alone.



GASTROENTEROLOGY

Rogge C, Duong T, Connor S, Williams AJ, Gu B, Pipicella J, Sheng Ding N, De Gregorio M. *PROACTIVE (Prospective Randomised Controlled Trial of Adult Patients with Perianal Crohn's Disease and Optimised Therapeutic Infliximab Levels) Does infliximab dosing to target with therapeutic drug monitoring yield higher rates of remission than standard infliximab dosing in patients with perianal Crohn's disease? A prospective, randomised, controlled, multi-centre study.* **Locations:** TWH. **External Partners:** Liverpool Hospital, UNSW, Royal Prince Alfred Hospital, St Vincents Hospital Melbourne.

Crohn's disease (CD) can be complicated by fistulas which can cause perianal drainage, bleeding, abscess formation and more. Combined surgical and medical management is useful in treating perianal fistulising CD. Complex fistulas have traditionally involved the placement of non-cutting setons to ensure adequate drainage and assist tract maturation and healing through secondary intention, however, fistulas and abscesses frequently reoccur following seton removal. The introduction of biologics such as infliximab, has revolutionised the management fistulising CD. The advent of quantitative assays for therapeutic drug monitoring (TDM) of biologic levels and anti-biologic antibodies permits individualisation of dosing and has become a useful tool to guide management in response loss. This study aims to compare the proportion of patients with fistulising CD who have achieved fistula healing at week 30 with infliximab maintenance therapy where infliximab dosing is guided by TDM versus patients receiving standard induction and maintenance dosing.

Rogge C, Martin A, Kariyawasam V, Huang D, Kwan VP, Rennie M, Mitrev N, *Impact of cytomegalovirus on outcomes in acute severe ulcerative colitis.* **Locations:** TWH. **External Partners:** Blacktown Hospital, Mt Druitt Hospital, Westmead Hospital, USYD.

A retrospective cohort study; cytomegalovirus (CMV) is highly prevalent in acute severe ulcerative colitis and has been shown to lead to worse short term outcomes. This study will investigate long term outcomes of concurrent CMV infection in patients presenting to hospital with acute severe ulcerative colitis, in particular rates of surgery. This will be done by comparing outcomes after initial hospital admission in those with CMV found on biopsy vs those without CMV on biopsy.

GENERAL MEDICINE

Naher S, Yeo NKS, Maapgu MC. *Patterns of presentation and outcomes of patients with metastatic breast cancer treated in the Illawarra Shoalhaven Local Health District (ISLHD).* **Locations:** ISLHD.

Metastatic breast cancer represents a heterogeneous group of patients, and is the most commonly diagnosed cancer in females. Whilst treatment & survival have improved, it remains the 4th most common cause of cancer death in Australia. Current literature suggests that patients with de novo versus recurrent metastatic breast cancer exhibit different disease characteristics & survival durations, suggesting that these groups have distinct outcomes. There is limited data describing the real-world treatment of de novo & recurrent metastatic breast cancer, particular in regional centres.



INFECTIOUS DISEASES

Ghosh N, Leighton C, Holmes S, Miyakis S, Adams D, Shum O, Steven T, *Staphylococcus aureus* Network Adaptive Platform trial (SNAP). **Locations:** TWH. **External Partners:** Royal Melbourne Hospital, Canberra Hospital, Blacktown Hospital, John Hunter Hospital, Liverpool Hospital, Nepean Hospital, Prince of Wales Hospital, Royal Prince Alfred Hospital, St George Hospital, St Vincent's Hospital Sydney, Westmead Hospital, Royal Darwin Hospital, Cairns Hospital, Gold Coast Hospital, Logan Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital, Sunshine Coast University Hospital, Flinders Medical Centre, Adelaide Women's and Children's Hospital, Launceston General Hospital, Royal Hobart Hospital, Alfred Hospital, Austin Health, Barwon Health, Ballarat Health Services, Eastern Health, Frankston Hospital, Monash Health, Western Health, Fiona Stanley Hospital, Royal Perth Hospital, Latrobe Regional Hospital, Sydney Children's Hospital, The Children's Hospital at Westmead, Queensland Children's Hospital, Goulburn Valley Health, Bendigo Health, Melbourne Royal Children's Hospital, Perth Children's Hospital.

Staphylococcus aureus bacteraemia (SAB) is a common and severe infection with a 90-day mortality of 15-30% despite current best available therapies. There are few high-quality data to inform the management of this infection, with less than 3000 patients randomised into any therapeutic trial for SAB prior to 2020. The objective of SNAP is to identify the effect of a range of clinical interventions on all-cause 90-day mortality in patients with SAB. SNAP is an investigator initiated, Randomised Embedded Multifactorial Adaptive Platform trial, conducted across multiple hospitals in several regions of the world.

Miyakis S, Slavin M, Neoh Z, Chen S, Kong D, Worth L, Halliday C, Kidd S, Kennedy K, Daveson K, Tio SY, Crowe A, Morrissey O, Beresford R, Keighley C, Pickles R, Van Hal S, Roberts M, Tan SJ, Cooley L, Yen S, Stewart A, Menon M, Douglas A, Urbancic K, Simos P, *Invasive non-Aspergillus mould (NAM) infections: a multi-centre observational study.* **Locations: TWH. **External Partners:** Peter MacCallum Cancer Centre, National Centre for Infections in Cancer, Westmead Hospital, Ballarat Health Services, National Mycology Reference Centre, ACT Pathology, Canberra Health Services, Royal Melbourne Hospital, St Vincent's Hospital Melbourne, The Alfred, Concord Hospital, Southern IML Pathology, John Hunter Hospital, Royal Prince Alfred Hospital, Royal Adelaide Hospital, Royal Perth Hospital, Royal Darwin Hospital, Royal Brisbane and Women's Hospital, Wesley Hospital, Austin Health, Gold Coast Health Service, Peninsula Health.**

Non-Aspergillus mold (NAM) infection is one of the life-threatening fungal infections especially among patients who are immunosuppressed. This research project aims to describe the epidemiology, antifungal resistance, disease manifestations, risk factors and outcomes of invasive NAM infections. Adult patients (≥ 18 years of age) who had a diagnosis of proven or probable invasive NAM infection between January 2016 and December 2024 will be included in this study. All cases of invasive NAM infections will be reviewed and data (e.g. case demographics, details of invasive NAM infection, underlying condition, other risk factors, treatment modalities, treatment response and survival status) will be collected. The findings of this study would facilitate the understanding of these infections for effective surveillance, optimal management and improved patient outcomes.

MEDICAL ASSESSMENT UNIT

Saha M, Ivers R, Naher S, Early W, Miyakis S, Bonney A, Mullan J, Metusela C, *Formative evaluation of the Wollongong Hospital Medical Assessment Unit.* **Locations: TWH. **External Partners:** UOW.**

The effectiveness of medical assessment units has been evaluated nationally and internationally, however, the focus of these evaluations has typically centred on hospital-based measures of patient flow, costs and survey-based satisfaction measures of patients and staff. We have not been able to identify any research that explored the model of care from a patient journey perspective, incorporating qualitative data from the referring general practitioner, patients and MAU staff. This is a significant gap in the literature. Antecedents to admission to the MAU, and GP interactions with the MAU prior to admission, may strongly influence decisions for admission, timeliness of admission, or even prevent admission if MAU-GP collaboration can result in safe community-based care. This study aims to address this knowledge gap, with the objective of optimising MAU-GP interactions and improving patient care.

RENAL MEDICINE

Chowdhury S, Chen J, Kotwal S, *Glomerular Disease Registry (GRIT)*. Locations: TWH. **External Partners:** The George Institute for Global Health.

Glomerular Disease Registry is a prospective observational study. Glomerulonephritis are an important cause of significant symptoms and end stage renal disease. There is no Chronic Kidney Disease (CKD) registry in Australia and therefore no method to comprehensively and systematically collect demographic and outcome data on patients with glomerulonephritis. This is especially important in the case of rare diseases. Diabetes and hypertension are the commonest causes of chronic kidney disease with limited directed therapies to prevent nephropathy. All patients attending renal clinics at the participating hospitals with a biopsy confirmed glomerulonephritis, Diabetic Nephropathy, or Hypertensive Nephropathy, with an eGFR ≥ 20 ml/min/1.73m² will be recruited. Patients without a confirmed diagnosis of glomerulonephritis, Diabetic Nephropathy or Hypertensive Nephropathy are excluded.



Hassan HIC, Jose M, *Renal Calculi as a Cause of Kidney Failure in Australia and New Zealand*. Locations: ISLHD. **External Partners:** UTAS.

We aim to examine the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) for patients with kidney failure due to renal calculi. We will examine the registry from inception (1970) until the most recent data collection (2021). We hypothesize that people with renal calculi as their reported primary cause of ESKD will have a low incidence, but younger age at commencement of renal replacement therapy, worse graft survival and higher mortality than people without calculi as their primary renal disease. We also hypothesize that the incidence of renal calculi as a primary cause of kidney failure will change by era.

Hassan HIC, Kotwal S, Gallagher M, Polkinghorne K, Gray N, Talaulikar G, Snelling P, Badve S. *A randomised trial Comparing Catheters to fistulas in Elderly patientS Starting HaemoDialysis (ACCESS HD)*. Locations: ISLHD. **External Partners:** Prince of Wales Hospital in Sydney, South Western Sydney LHD, Monash University, ACT/Southern NSW Renal Network, Royal Prince Alfred Hospital, St George Hospital.

People over the age of 65 years are the fastest growing group of dialysis patients. The best dialysis access approach in this group is unclear due to a different risk to benefit ratio compared with younger people. The ACCESS HD study will randomly allocate patients over 65 years starting haemodialysis to an arterio-venous fistula or a dialysis catheter. The study will compare if there is a difference between the groups in additional hospital days in the first 12 months after starting dialysis.



RESPIRATORY MEDICINE

Du H, Langstaff C, Couttie T, Zanotti T, Molloy S, Campbell T, Haggie S, Mackle R, Homaira N, Asthma Care from Home: Evaluating impact, implementation and cost-effectiveness of comprehensive technology-enabled asthma care for rural children in NSW. Locations: TWH, SDMH. **External Partners:** UNSW.

Asthma Care from Home Project is evaluating the impact, implementation and cost-effectiveness of a comprehensive integrated technology enabled model of asthma care that a) supports families, communities and healthcare providers, b) is flexible and locally acceptable, and c) adopts innovations such as digital technologies so that asthma care can be provided 'from home' when necessary, thereby not only reducing the significant burden of potentially preventable asthma hospital presentations but also ensuring patients', parents/carers and families satisfaction with healthcare delivery. with families enrolled in intervention site. Analysis will assess health service use, patient reported experience measures, cost effectiveness before and after implementation. A mixed methods implementation evaluation will also determine key factors necessary for scale-up. If proven acceptable and cost effective, this model of standardised comprehensive technology enabled asthma care could be delivered to the nearly 50,000 children living with asthma across rural NSW

RHEUMATOLOGY

Lian A, Riordan J. A Retrospective Observational Study of the Treatment of Calcium Pyrophosphate Deposition Disease at a Single Centre. Locations: TWH.

Patients with calcium pyrophosphate deposition disease (CPPD) develop painful joints from crystal deposition. Conventional treatment revolves around intra-articular steroid injections, non-steroidal anti-inflammatories and glucocorticoids. More recently, anakinra has been used off-label as a treatment for refractory CPPD and has become available on hospital formulary. This study aims to identify the demographics, comorbidities of CPPD cases over a 5 year period covering as well as characterizing treatment choices, outcomes, and complications for CPPD before and after the introduction of anakinra into the formulary.

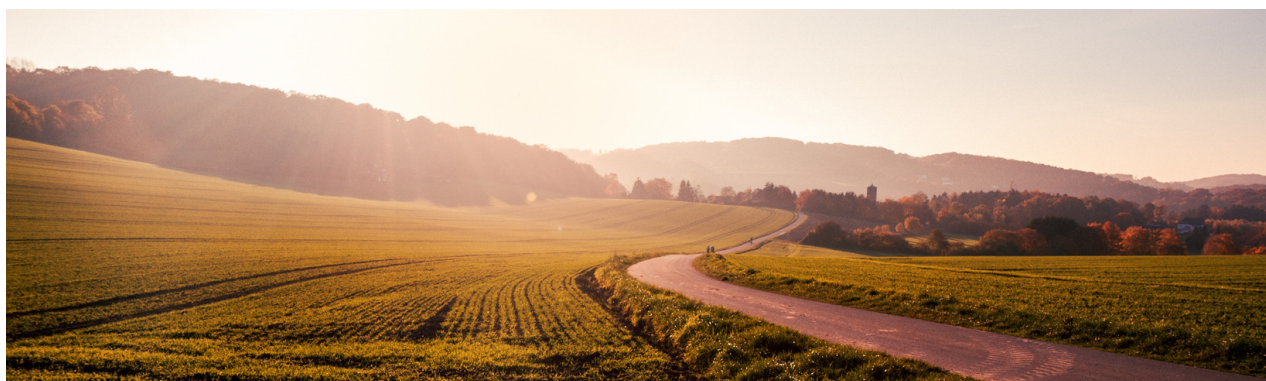
MENTAL HEALTH

Fitzpatrick S, Banfield M, Morse A, Lamb H, Giugni M, *Co-creating safe spaces: Translational research on innovative alternatives to the emergency department for people experiencing emotional distress and/or suicidal crisis*. **Locations:** ISLHD. **External Partners:** ANU.

There is increasing investment in 'safe spaces' for people experiencing emotional distress and suicidal crisis. Safe spaces are an alternative to emergency departments (ED), which can increase distress and are often not what is needed for support. This project will establish the feasibility and effectiveness of safe space models in the ACT, NSW and SA as alternatives for people who might present to the ED or choose not to access help due to past negative experiences. The project is being conducted according to the principles of community-based participatory research with lived experience embedded within all research stages. The study design promotes stakeholder engagement with the research processes and provides strong connections with stakeholder groups. Data collection will comprise multiple-methods including document analysis, surveys, semi-structured interviews, focus groups, arts-based approaches and health administrative data. The RE-AIM framework will be used to measure key outcomes related to Reach, Effectiveness, Adoption, Implementation, Maintenance.

Harman A, Gill S, Watts C, Charlton K, *Evaluation of a Multidisciplinary Physical Health Clinic within a Mental Health Rehabilitation Unit*. **Locations:** SHH. **External Partners:** UOW.

People with mental illness have an increased risk of physical disease, high rates of comorbidities and reduced access to health care resulting in 14-23 year life expectancy gap compared to the general population (NSW Ministry of Health, 2021). With mental health consumers in mind a multidisciplinary physical health clinic was implemented in March 2021 within the Illawarra Shoalhaven Local Health District's (ISLHD) Mental Health Rehabilitation Unit. The clinic was developed with the aims of promoting increased consumer access to physical health care clinicians, enhancing consumer satisfaction and experience, and potentially improving physical health outcomes of mental health consumers. This clinic is now embedded as standard care in ISLHD. This project aims to conduct a health service evaluation of the multidisciplinary physical health clinic. This evaluation will use de-identified retrospective and prospective data collected from March 2021- May 2022, with assistance from a University of Wollongong dietetics student.



Pai N, Alcorn D, Townsend M, Lago L, McAlister B, Grenyer B, Barr K, Moules S, *Early Intervention: Knowledge and resources to improve educational outcomes for students requiring multi agency support for mental health and well-being*. **Locations:** ISLHD. **External Partners:** UOW.

The aim is to understand how we can intervene more effectively in the school and other settings to support those students using an evidence-based approach. This project will establish a new regional linked dataset, combining an established mental health longitudinal dataset with child protection data, births and deaths data, Australian Early Development Census (AEDC) data on school commencement and education data including attendance, retention data, suspension and post-school destinations in addition to participation and attainment through NAPLAN. Within the study cohort we will identify students with health service use (ambulance, emergency department, public hospital admission or child and adolescent mental health service contact) for mental health, self-harm and suicidal-reasons. This group represents students experiencing moderate to severe difficulties who may be presenting in crisis and have a high need for co-ordinated support to improve their mental health or wellbeing.

Rukasha PN, Baytieh L, *Utilisation of interpreter services in the emergency department for mental health assessments in culturally and linguistically diverse patients - A clinical audit.* **Locations:** ISLHD.

In countries such as Australia where English is the main language of communication, the limitation of English proficiency in patients of the culturally and linguistically diverse population (CALD) poses concerns in the quality of care provided in the healthcare setting for these individuals. This can result in healthcare disparities in comparison to those proficient in the English language, such as poor access to medical care and lower quality of care which may lead to outcomes such as prolonged hospitalisation, medical errors and invasive management. The use of healthcare interpreter services facilitates effective communication between clinicians and patients of CALD backgrounds who have limited proficiency in English and so their routine use in healthcare is essential. The aim of the study is to evaluate the extent to which the interpreter service is being utilised on initial mental health assessments in the emergency department by emergency department clinicians and mental health clinicians for patients of CALD backgrounds with limited English proficiency. The study will explore the modalities used in the interpreter assessments including face to face assessment versus phone-based assessments and the time spent for each assessment. The study will identify any potential deficits in the utilisation of interpreters in these assessments and formulate recommendations on how to improve on these deficits if present. The study will identify the enablers, facilitators and barriers of the utilisation of interpreter services and augment them.

Tietze T, Huber J, Glozier N, Milton A, *The utility of Psychiatric Emergency Care Centers: A qualitative study.* **Locations:** TWH. **External Partners:** USYD, St Vincent's Hospital.

Psychiatric Emergency Care Centers (PECCs) and Mental Health Short-Stay Units (MHSSUs) work in disparate ways, without a standardised approach. We hypothesise that, now PECCs have been functioning for 15 years, stakeholder groups (mental health consumers, clinicians, managers and policy-makers) will have opinions on how PECCs should be used, and what outcomes and KPIs PECCs should be aiming to fulfil. This project aims to: (1) Perform an exploratory, contextual qualitative analysis, inviting clinicians from all MHSSUs and PECCs in NSW to comment on their own current clinical practice. (2) Perform a descriptive qualitative analysis, inviting stakeholders to give their own perspective on what processes or outcomes the stakeholders would value from a MHSSU or PECC, and whether clinical guidelines would be helpful. This particular stage of the project will involve clinicians, managers and policy-makers. Consumers will be engaged during the next stage of the project.

NURSING & MIDWIFERY

Jay D, Abraham V, Middleton S, McInnes E, Cadilhac D, Fasugba O, Dale S, Noetel M, Coughlan K, McElduff B, Kim J, *Evaluation of an implementation intervention to enhance national translation of nurse-initiated protocols for fever, hyperglycaemia and swallowing management following stroke: a cluster randomised controlled trial.* **Locations:** SDMH. **External Partners:** Australian Catholic University, St Vincent's Health Network Sydney, Monash University.

Our landmark trial published in The Lancet in 2011 demonstrated that facilitated implementation of nurse-initiated protocols to manage fever, hyperglycaemia (sugar) and swallowing difficulties (FeSS Protocols) resulted in significantly reduced 90-day death and dependency for stroke patients. However, ten years on, a significant gap remains in translation of the FeSS Protocols into standard stroke care across Australia, particularly notable in rural and remote settings. A program of systematic Australia-wide implementation is urgently needed to determine: (1) What intensity of external remote facilitation is required to enhance simultaneous multi-site national uptake of the FeSS Protocols to improve management of fever, hyperglycaemia and swallowing difficulties in the first 72 hours of hospital admission for stroke in metropolitan, rural and remote hospitals? (2) What is the cost effectiveness of implementing the protocols? A three-arm cluster randomised controlled trial and process evaluation will be undertaken. Hospitals will be randomised to one of two intervention (low and high intensity external remote facilitation) or control (no facilitation) groups. Australian hospitals with a pre-existing stroke unit/service will be eligible. National implementation of the proven FeSS Protocols into innovative policy and practice will result in better outcomes for survivors of stroke, particularly in rural and remote Australian settings.

Jay D, Cox M, *Trial of Advanced CT Imaging and Combined Education Support for Drip and Ship (TACTICS).* **Locations:** SDMH. **External Partners:** The University of Newcastle.

The TACTICS trial aims to improve access to stroke therapies, including intravenous thrombolysis and endovascular clot retrieval, in regional Australia. The study aims to evaluate the effectiveness of an education and training intervention including a support package of advanced acute stroke imaging, streamlined workflows, and reperfusion pathways and protocols for reperfusion therapy delivery. The trial also includes a virtual reality acute stroke workflow education package aimed at junior doctors. The trial is a stepped wedge design collecting de-identified case data over a 9 month period, including a 3 month baseline period in which no clusters are exposed to the TACTICS intervention. Following this, at regular intervals/"steps", a cluster receives the 3 month intervention whilst case data continues to be collected. The intervention phase commences with a cluster-level face-to-face/virtual hybrid workshop (1 day workshop, 8 hours in total) bringing together key staff involved in acute stroke care from the hub and spoke sites, including neurologists, stroke physicians, interventionists, ED physicians, radiographers and stroke nurses to discuss the current landscape of acute stroke care, barriers and issues to improving care and quality improvement strategies focused around action planning to enhance key performance metrics such as door to CT time, DTN, DTG and DIDO time. Sites are also invited to participate in three monthly cluster-level teleconferences (3 x 1.5 hour teleconferences) to build upon the quality improvement and performance data review process commenced at the workshop. The virtual reality training package will also be deployed during the intervention period, and include pre and post user surveys. Pre and post intervention voluntary surveys, group interviews and key informant interviews with staff will be conducted to collect information on the contextual elements. The intervention period is followed by a 3 month follow up period.



Reid F, Fox D, Woodworth R, Coddington R, Hilsabeck C, Rowlings S. *Optimising freedom of movement and choice of positioning for women in labour who are using continuous fetal monitoring technologies: Midwives' views and experiences.* **Locations:** TWH. **External Partners:** UTS, Westmead Public Hospital, Royal Prince Alfred Hospital.

There is an abundance of evidence demonstrating positive physical and psychological outcomes when women have freedom of movement and choice of positioning during labour. Despite this, women's choices and autonomy to choose their preferred position in labour are often restricted. Little is known about how continuous fetal monitoring technologies influence midwifery practice or what impact this technology has on midwives' capacity to enable mobility and women's choice of positioning during labour. This study aims to explore midwives' perspectives on the use of wired and wireless continuous fetal monitoring (CFM) technologies, including how these impact women's freedom of movement and choice of positioning during labour. Focus groups with midwives will be undertaken, in order to develop a grounded theory on how midwives optimise freedom of movement and women's choice of positioning during labour for women when using continuous fetal monitoring technologies.

Turner R, Furber S, Davis K, Couch H. *The effect of a text message program (TEXT4HealthyHeart) on reducing overweight and obesity for people referred to the Shoalhaven Cardiac Rehabilitation Program.* **Locations:** SDMH.

In Australia, coronary heart disease (CHD) is the leading chronic disease in males and females, accounting for 14% of the total chronic disease burden and costing the Australian health system \$10.4 billion annually. Cardiac rehabilitation programs (CRPs) have been shown to reduce morbidity and mortality, reduce recurrent cardiac events, to improve cardiac risk factors and enhance quality of life. The Shoalhaven CRP will collaborate with the ISLHD Health Promotion Service and ISLHD Research Central to develop and implement a text message study to reduce overweight and obesity by 3-5% in people referred to the Shoalhaven CRP. Meaningful improvements in health using behaviour change methods can be achieved through a weight loss of 3-5% of body weight.

SURGERY

ANAESTHETICS

Ashhurst C, Smith N. *Patient rating of postoperative outcome measures.* **Locations:** ISLHD.

Measuring specific post-operative complications does not necessarily provide a complete view of the patient experience in the post operative period. Patient-centred care requires clinicians to recognise patient-outcomes that are most valued and most important to the patient themselves. A systematic literature review by Moonesinghe et al. to recognise endpoints for measures of patient-centred outcomes in the peri-operative period included firm recommendations for use of the EuroQol 5 Dimension (health-related quality of life measure), WHODAS 2.0 (12-question version) (functional status measure), and days alive and out of hospital at 30 days post-surgery (life-impact measure). For this study, we plan to derive the basis for questionnaire items from the validated domains of the EuroQol 5 dimension, the WHOAS 2.0 (12-question version), and days alive and out of hospital to develop a 15-item questionnaire measuring patient importance on these outcomes. The aim of this study is to recognise the patient-centred peri-operative measures that are most important from the perspective of the patient. Identifying outcomes that are most valued to patients in the post-operative setting supports a patient-centred care model in delivering health care to surgical patients.

Smith N. *STOP: Smoking and quitting Throughout the peri-Operative Period : A Student project.* **Locations:** TWH. **External Partners:** UOW.

Smoking is the leading preventable cause of morbidity and mortality in our society. Despite the prevalence of smoking being 12.2% among adults in 2016, smoking contributes approximately 8% of the total disease burden and 20% of the total deaths per year in Australia. Current smoking is associated with higher rates of post-operative complications. These complications are responsible for longer hospital stays, inferior long-term surgical outcomes and a higher overall cost of care. In Australia, about 1/3 of smokers have tried to quit at least once, however, unaided quit attempts generally have a success rate of 4-7%. The aim of this project is to determine the number of post-operative smokers who are diagnosed with nicotine dependence as inpatients and the proportion of these patients that are prescribed nicotine replacement therapies (NRT).

GENERAL SURGERY

Hewitt L, Curtis K, Mullen J, Mullholland B, Joseph K, Rodwell A. *The Impact of COVID-19 on Appendicitis Incidence and Management.* **Locations:** TWH. **External Partners:** UOW.

The SARS-CoV-2 pandemic resulted in public health restrictions that deterred presentation to hospitals. For patients who developed acute appendicitis this would precipitate increased rates of complicated appendicitis, meaning increased rates of appendicitis associated with appendix perforation, abscess formation and gangrenous appendicitis. Despite multiple studies worldwide, it remains unknown how the COVID-19 pandemic has impacted appendicitis volume, treatment options, and outcomes in New South Wales, Australia (8, 9, 10). Using the Centre for Health Research Illawarra Shoalhaven Population database, this study aims to compare proportions of uncomplicated and complicated appendicitis, the type of treatment used and healthcare-related outcomes, including length of hospital stay, in-hospital mortality and 28-day re-admissions for patients with appendicitis during the lockdown associated with the 2020 COVID-19 outbreak in New South Wales, Australia.

2022 ISLHD RESEARCH ACTIVITY REPORT

Jones M, Tse A, Cheng E, Edwards T, *Intraoperative anastomosis air leak testing in bowel resections performed in a regional hospital setting. Locations:* SDMH. *External Partners:* UOW.

This project aims to evaluate intraoperative anastomosis leak testing and patient outcomes for those undergoing left sided bowel resections in a regional hospital. This includes the outcomes of patients who received intraoperative air leak testing and the incidence of anastomosis leaks in comparison to those whom did not undergo air leak testing.

Newton P, *Magee Equation Study. Locations:* TWH.

Not all patients with breast cancer require adjuvant chemotherapy; in particular, those with early stage oestrogen-receptor (ER) positive, Her2-negative, lymph node negative disease. For these patients multigene profiling assays can aid in estimating the risk of disease recurrence and provide a recurrence score (RS) and therefore the predicted benefit of chemotherapy. Oncotype DX® is one of the most commonly used of these assays. Others include EndoPredict, Prosigna and Mammaprint; however, none of these are covered by Medicare. If a patient is recommended to have one of these tests to determine whether they should have chemotherapy or not they need to pay between \$3000 to \$5000 out of pocket. Clearly this cost is prohibitive to most patients resulting in some who may miss out on the benefit of chemotherapy or have chemotherapy when there is no benefit. The Magee Equations™ (ME) have been developed by the University of Pittsburgh to provide an estimate of this recurrence score using standard histopathologic and immunohistochemical markers at no extra cost to the patient. The primary aim of this study is to identify patients who may have benefited from the use of the Magee Equations™ over a period of five years in order to determine the potential future benefit of implementing this in routine practice. The secondary aim of this study is to increase awareness of the Magee Equations™, not just in Wollongong, but around Australia and New Zealand.

NEUROSURGERY

Jaeger M, Pitham T, Cherukuri R, *Surgey for Spinal Stenosis – A randomised, placebo-controlled trial. Locations:* TWH. *External Partners:* USYD.

This project aims to evaluate, in a double-blind randomised controlled trial, the efficacy, safety and cost-effectiveness of decompressive surgery compared to placebo surgery for patients with chronic, symptomatic central lumbar spinal canal stenosis.

OBSTETRICS AND GYNAECOLOGY

Dikshit S, Davis W, Kelly M, Winter-Irving S. *Examination of TWH maternity services between 2010 and 2020: investigating the impacts of non-medically-indicated induction of labour on maternal and infant outcomes. Locations:* TWH. *External Partners:* UOW.

The main objective of this study is to provide an overview of the incidence of elective inductions and associated maternal and infant outcomes over a 10 year period at TWH. This study will provide evidence towards current practice for management of women with uncomplicated pregnancies >37 weeks. The primary aims of this project are to i) assess the rates of elective IOL at TWH between 2010 and 2020 and ii) determine whether elective induction has any associated increased risk of adverse maternal and infant outcomes when compared to spontaneous births. This study will allow comparison of TWH with the recent NSW-wide study by Dahlen et al. 2021 and will help inform management of low-risk women at >37 weeks gestation.



ORTHOPAEDIC SURGERY

Jansen S, Kadir A, Harris I, Smith G, Petchell J, Lieu D, Damiani M, Page R, Bokor D, *The ARC (Australian Rotator Cuff) Trial: a randomised controlled trial of surgical repair of non-acute rotator cuff tears of the shoulder.* **Locations:** SHH. **External Partners:** Liverpool Hospital, St George public Hospital, Royal Prince Alfred Hospital, Canberra Private Hospital, University Hospital Geelong, St John of God Hospital, Epworth Hospital Geelong, Macquarie University.

Shoulder pain in the presence of rotator cuff tear (injury to one or more of the tendons that support the arm at the shoulder joint) is common and become more common with age. Rotator cuff tears are commonly interpreted as the cause for shoulder disability and thus treated with arthroscopic surgical repair (a camera and small instruments inserted into the joint through a small incision). The aim of this blinded, randomised, parallel group, surgery controlled superiority trial is to: determine the effectiveness, safety and cost-effectiveness of arthroscopic rotator cuff repair compared with placebo surgery (surgery with no rotator cuff repair), in improving shoulder pain and function, and quality of life in individuals with symptoms attributed to non-acute, full-thickness rotator cuff tears. Participant's progress post surgery will be followed via completion of validated questionnaires and via other health information obtained from their treating surgeon and imaging records.

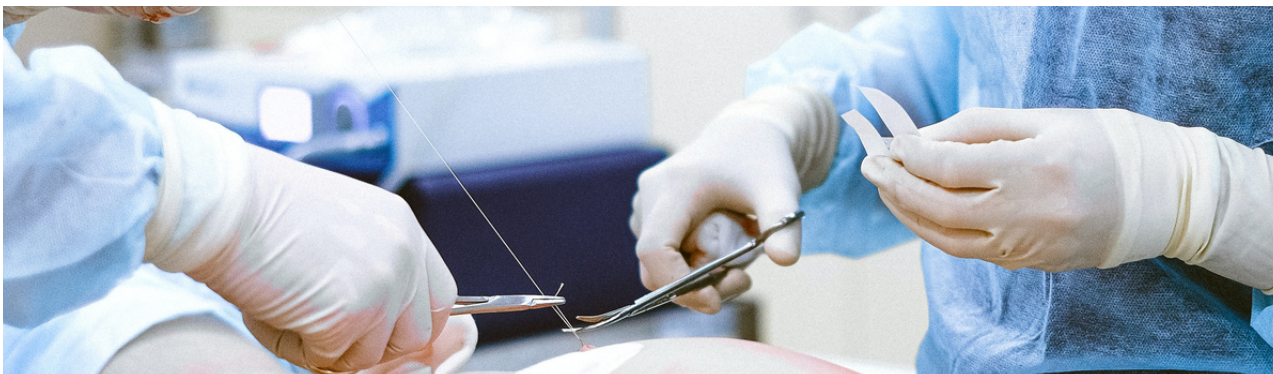
Wong D, Adie S, Harris L, Monuja M, Cradick N, *Pain Catastrophizing – Foot and Ankle Trauma.* **Locations:** TWH. **External Partners:** Sutherland Hospital, St George Hospital, UNSW.

Pain is a subjective experience affected by a plethora of biopsychosocial influences and is associated with diminished function and increased disability. Pain catastrophizing, depression and anxiety have been linked to reduced functionality after total joint arthroplasty and contribute to the pain sensation in those with Osteoarthritis. A patient's healthcare experience can be modulated by their understanding of their pre-operative disability along with their overall coping strategy. It is hypothesized that a patient's catastrophization and expectation on what they deem to be a successful surgery can affect their outcome. No previous studies have analyzed the relationship between catastrophizing and foot and ankle trauma surgery outcomes.

VASCULAR SURGERY

Villalba L, Leighton C, Nguyen T, Bullen A, Sutton L, Muir A, Tosenovsky P, Wong J. *Intravascular Ultrasound-Guided Intervention for Venous Leg Ulcers (IGuideU).* **Locations:** TWH. **External Partners:** Royal Perth Hospital.

This is a global, prospective, multi-centre, randomised controlled trial. After signing a written informed consent, patients will be randomised 1:1 to either a deferred-interrogation group which received continuation of standard compression therapy or to an interrogation group in which patients will be first evaluated with multi-planar venography (MPV) imaging during iliac-common femoral vein assessment for possible endovascular intervention and then further interrogated with intravascular ultrasound (IVUS) imaging. The treatment plan derived from venography alone will be compared to the treatment plan created with the addition of the IVUS information and any differences in treatment plan will be documented. Confirmation of whether or not the threshold of stenosis/occlusion required for endovenous stenting has been met will be determined by the IVUS imaging obtained. Any patients determined to require venous stenting will be stented according to the on-label manufacturer's instructions for the use of IVUS in guiding stent sizing and placement.



GRANTS

GRANTS PROCURED THROUGHOUT 2022

Project title	Researcher	Funding Body	AUD
Down Syndrome and Obstructive Sleep Apnoea	Stuart MacKay	-	9,256,332.00
HIRAID	Kate Curtis	MRFF	3,386,969.00
EPIC	Kate Curtis	MRFF	2,847,592.26
A randomised controlled trial to evaluate the scale-up of a technology based healthy lunchbox initiative: a solution to address poor dietary intake	Lisa Franco	TRGS Round 6	495,771.40
Solving Antimicrobial Resistance in Agribusiness, Food and Environments (CRC SAAFE)	Spiros Miyakis	CRC SAAFE	85,024.00
Breast Cancer Patients within the Illawarra Shoalhaven Local Health District: Addressing unwarranted variation in clinical management and patient outcomes	Steven Craig	Cancer Institute NSW	80,000.00
Serratus anterior plane block training implementation study	Kate Curtis	ACEM	30,000.00
Virtually Equipped Therapy Options (VETO) -Reducing CO2 and Disadvantage	Sue-Ellen Hogg	NSW Ministry of Health Sustainable Future Innovation Fund	25,144.28
Patient interview study: Exploring supports which facilitate adjustment to a stoma	Julia Kittscha	Australian Association of Stomal Therapy Nurses	3000.00
GRAND TOTAL			16,209,832.94

Note. This list is not exhaustive and relies on staff reporting any procured grants.

2022 ISLHD PUBLICATIONS AND CONFERENCES

There were a total of 358 publications or conference presentations made known to the ISLHD Research Office appearing in the year 2022, and had one or more authors listed with ISLHD affiliations. They are listed below in alphabetical order of first author surname, and names in bold font represent ISLHD clinicians.

ISLHD-Led Publication or Conference = 185

Number of ISLHD Authors having one or more first author publication = 115

PUBLICATIONS

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