



ST JOHN OF GOD
Subiaco Hospital



Leading health and medical
research for advancements
in treatment, care and
technology

ANNUAL RESEARCH REPORT 2021/22



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CEO Welcome



Tina Chinery
Chief Executive Officer
St John of God Subiaco Hospital

Having recently commenced the role of Chief Executive Officer, it has been an absolute pleasure to learn about the incredible breadth and calibre of research undertaken by St John of God Subiaco Hospital's experienced researchers and clinicians.

The quality of research conducted at our hospital is truly world-class, and is resulting in improved health care outcomes not only for our own patients, but also for members of the broader national and international community.

It is for this reason that I am delighted to share SJG Subiaco Hospital's 2021/2022 Annual Research Report, and highlight the many projects which are making a real difference to peoples' lives. In many instances, these projects are saving lives.

In the past financial year, members of our research team undertook an astounding 77 research projects. Of these projects, 50 were specific to oncology, maintaining our hospital's reputation as one of Australia's leading cancer research institutes and a premier provider of innovative cancer care and services.

Vital research was also conducted across a wide variety of other specialty areas, including gynaecology, orthopaedics, inflammatory bowel disease, intensive care, respiratory medicine and palliative care, as well as nursing services.

In addition, our responsiveness to global health and social issues continued, with the commencement of a new project investigating the impact of the conflict in Ukraine on cancer clinical trials, and further investment in research specific to the COVID-19 pandemic.

One of our emerging researchers, Intensivist A/Prof Ed Litton was awarded the Premier's Early Career Scientist of the Year Award, in part for his contribution to COVID-19 research.

A/Prof Litton has played an important role in the development and implementation of the REMAP-CAP Trial focused on improving treatment for COVID-19 while leading a study to inform Australian intensive care COVID-19 preparedness, surge capacity, and evaluating, reporting and feeding back Australian intensive care COVID-19 outcomes.

Intensivist Prof Steve Webb and Anaesthesiologist Prof Tomas Corcoran were also recognised for excellence in research, at the Australian Clinical Trials Alliance (ACTA) Awards.

Prof Webb was awarded the Trial of the Year Award for the REMAP-CAP Trial, while Prof Corcoran received the Excellence in Trial Statistics Award for the PADDI Trial focused on reviewing the effects of anaesthesia on surgical wounds.

While many of our research projects are well underway, some are starting to gain traction.

Patients are currently being recruited for the MOST (Measure of Ovarian Symptoms and Treatment concerns) Trial, which is being led by Director of Gynaecological Cancer Research A/Prof Paul Cohen and has the potential to change the way that ovarian, fallopian tube and primary peritoneal cancer patients receive follow-up care.

The clinical trial aims to improve patient outcomes, as well as the patient experience, by offering more holistic care and relieving the stress of travelling to appointments, particularly for women in rural areas.

Recruitment for the LOLIPOP (Long-term outcomes of Lidocaine Infusions for persistent Postoperative Pain) Trial has also recently commenced.

Led by Prof Corcoran, the international study will investigate whether chronic pain can be prevented by giving local anaesthetic, Lidocaine, intravenously during breast cancer surgery and up to 24 hours post-surgery. It is estimated that nearly 30 per cent of breast cancer patients experience some chronic pain after surgery, and there is currently no known preventative treatment available.

Nurses, midwives and allied health professionals from across the hospital also have an important role in our research program. In particular, I want to highlight nurse led investigations into palliative care, which aim to improve our hospital's understanding of palliative care need and service utilisation.

The results of these studies will have a tremendous impact on palliative care access and delivery, and have the potential to improve quality of life for our end-of-life patients. As we know, early access to palliative care services is associated with better symptom management, prolonged survival, improved quality of life and reduced health care costs.

Finally, there are many other individuals and organisations who have made significant contributions to our comprehensive program of research.

Notably, I would like to recognise and thank the invaluable contributions of respected philanthropist and businessman Jack Bendat AM CitWA to SJG Subiaco Hospital over the years.

Members of our hospital community were deeply saddened to learn of Mr Bendat's death last year, but are consoled by the fact that his legacy lives on through the Bendat Family Comprehensive Cancer Centre, as well as the Bendat Respiratory Research and Development Fund.

We thank the Bendat Group and members of the Bendat family for their continued support.

I also express my heartfelt thanks to all of our other valued donors. Your partnership and financial support is essential to the continuation of research excellence at our hospital and enabling ongoing advancements in medical care.

And last, but certainly not least, I would like to recognise each and every member of our research and clinical trials team, whose tireless work is leading to improved health care outcomes for those in our care.

Your commitment to research, to respecting the dignity of your patients, and to improving understanding of illness and care, is exceptional.

SJG Subiaco Hospital is incredibly fortunate to benefit from your service.

Tina Chinery
Chief Executive Officer
St John of God Subiaco Hospital

Our Hospital

St John of God Subiaco Hospital is a leading private hospital in Perth, Western Australia, offering exceptional medical and surgical care in a warm and welcoming environment.

Our vision of being a world leader in patient care is underpinned by our outstanding team of caregivers and long-term, strategic investments in technology, redevelopment and research.

Many of Australia's leading and most experienced specialists choose to work at our hospital. We offer patient care and services across an extensive range of specialties spanning medical, surgical, maternity, rehabilitation and allied health.

St John of God Subiaco Hospital was established by the Sisters of St John of God in 1898. Today, we are part of St John of God Health Care, Australia's largest Catholic hospital operator and a not-for-profit organisation.

Our dedicated caregivers proudly continue the legacy of the Sisters in providing exceptional patient care through our mission-based culture and by living our values – hospitality, excellence, respect, compassion and justice.



Our Team

Our Research Management Team and Lead Investigators are committed to continually extending our research capabilities, in line with our vision of being a world leader in patient excellence.

Research Management Committee

This committee provides overall leadership and management for research at St John of God Subiaco Hospital.



Prof Steve Webb
Director Clinical Trials, Senior Staff Specialist Intensive Care Medicine, Chair Research Management Committee



Taryn Quartermaine
Research Operations Manager



Mr Gavin Clark
Consultant Orthopaedic Surgeon



A/Prof Tim Clay
Medical Oncologist Deputy Chair of the Bendat Respiratory Research and Development Committee



A/Prof Paul Cohen
Director Gynaecological Cancer Research, Gynaecologist



Dr Andrew Dean
Head of Department Cancer Services, Medical Oncologist



Dr David McCoubrie
Director Medical Services, St John of God Subiaco Hospital



Prof Eli Gabbay
Clinical Research Fellow, Respiratory Physician, Chair of the Bendat Respiratory Research and Development Fund Committee



Bianca Pietralla
Chief Executive Officer, St John of God Foundation



Prof Christobel Saunders AO
Director Breast Cancer Research Unit, Breast Cancer Surgeon
July – Oct 2021



Dr Emma Shaughnesy
Cancer Medicine Registrar



Dr Alice Talbot
Cancer Medicine Registrar

Lead Investigators

Our Lead Investigators play a vital role in guiding and supporting research endeavours within our organisation. Each is an established leader in their research field.



Mr Gavin Clark
Consultant Orthopaedic Surgeon



A/Prof Tim Clay
Medical Oncologist Deputy Chair of the Bendat Respiratory Research and Development Committee



A/Prof Paul Cohen
Director Gynaecological Cancer Research, Gynaecologist



Mr Dermot Collopy
Consultant Orthopaedic Surgeon



Prof Tomás Corcoran
Consultant Anaesthetist, Raine Foundation Clinical Research Fellow



Dr Andrew Dean
Head of Department Cancer Services, Medical Oncologist



Prof Eli Gabbay
Clinical Research Fellow, Respiratory Physician, Chair of the Bendat Respiratory Research and Development Fund Committee



Dr Tom van Hagen
Medical Oncologist



Prof Ian Lawrance
Gastroenterologist



Prof Gabriel Lee
Neurosurgeon



A/Prof Ed Litton
Clinical Research Fellow, Staff Specialist Intensive Care Medicine



Dr Daphne Tsoi
Medical Oncologist



Prof Eric Visser
Specialist Pain Medicine Physician and Anaesthesiologist, Churack Chair of Chronic Pain Education and Research



Prof Steve Webb
Director Clinical Trials, Senior Staff Specialist Intensive Care Medicine, Chair Research Management Committee



Dr Brendan McQuillan
Cardiologist



Dr David Morgan
Head of Intensive Care Medicine



Dr Tarek Meniawy
Medical Oncologist

Research Snapshot 2021/22



Research Management Committee Chairperson Report



Prof Steve Webb
Research Management Committee Chairperson, St John of God Subiaco Hospital

Healthcare systems have three broad roles: to care for and treat patients, to educate medical professionals, and to conduct research to improve outcomes for patients. The mission to deliver better patient outcomes, through research, is delivered strongly at St John of God Subiaco Hospital and reflects the strong support that exists within the organisation.

There have been many outstanding achievements in the last 12 months.

I would like to extend my congratulations to A/Prof Ed Litton, who is a clinical colleague in the Intensive Care Unit, and a caregiver at SJG Subiaco Hospital through his role as a Research Fellow. We are all extremely proud that Ed was this year's Western Australian Early Career Researcher, announced at the Premier's Science Awards. This is an extraordinary achievement and it is remarkable that two members of SJG Subiaco Hospital's community have been recognised at these Awards in recent years - Prof Christobel Saunders was named Scientist of the Year.

Researchers from SJG Subiaco Hospital were also prominently represented at the ACTA Clinical Trial of the Year Awards, Australia's highest recognition for clinical trials. The two most prestigious awards went to researchers based at the hospital. The PADDI trial, led by Prof Tomas Corcoran, was the winner of the Statistics in Trials Award and REMAP-CAP, led by myself, was the winner of the Trial of the Year. The results of PADDI are being applied globally to improve outcomes for patients having all forms of general anaesthetics. REMAP-CAP is a multifactorial (testing multiple candidate interventions simultaneously) trial for patients with life-threatening COVID. The results from REMAP-CAP, applying to interventions like corticosteroids, immune modulation, anticoagulation and antiplatelet therapy, and convalescent plasma have been applied globally, saving the lives of many tens of thousands of patients.

I would also like to highlight the work led by Prof Eli Gabby and A/Prof Tim Clay. This work is supported, very generously, by the Bendat family and plays a particularly important role in developing and mentoring junior doctors as future researchers. It has been wonderful, over many years, to see this work grow in impact, and to see the progression of junior doctors into higher degrees and on the pathway to being independent researchers who will, in turn, contribute to new knowledge that improves outcomes for patients.

SJG Health Care is served admirably by a dedicated and responsive Human Research Ethics Committee. This Committee plays an important role in ensuring that only research that meets the highest ethical standards is

conducted at SJG Health Care. I was also particularly delighted to see members of the Committee contributing to research through its publication relating to interpretation and application of changes to the Guardianship and Administration Amendment (Medical Research) Act 2020. This Act updated processes by which patients who are not competent to consent to research can still participate in research.

I would like to thank all members of the Research Management Committee (RMC) for the enormous contribution that they have made in the last 12 months. I would also particularly like to acknowledge the high quality of leadership that Taryn Quartermaine brings to her role as the Research Operations Manager. Taryn delivers efficiency and effectiveness, with enthusiasm and a calm and organised resolve.

Sadly, we have had to bid farewell to several very strong contributors to research here at SJG Subiaco Hospital. Prof Christobel Saunders has been a stalwart of research at the hospital and has left to take up the highly prestigious role as Professor of Surgery at the University of Melbourne. Christobel is still contributing to several ongoing projects but her leadership and the impact of her work will be missed. Dr Eva Denholm, in her role as the Director of Medical Services, provided oversight and leadership to the Research Unit. Eva was a very strong supporter of research, assisting in ways that were always thoughtful, pragmatic, and constructive. Lastly, Prof Shirley Bowen, our departing CEO, has left a remarkable legacy. Shirley was deeply engaged with research activities and the success of research at the hospital leans heavily on her strategic guidance and leadership. The RMC is extremely grateful to Christobel, Eva, and Shirley.



A/PROF Ed Litton (left), receiving the Premier's Early Career Scientist of the Year Award

Note from Research Operations Manager



Taryn Quartermaine
Research Operations Manager

St John of God Subiaco Hospital Research Operations has continued to provide leadership and operational support to our team in alignment with our commitment to ethical and high quality research. We have a critical focus on sound governance and patient safety, which combined with our Human Research Ethics Committee single-stream submission process, ensures that we continue to attract new opportunities to broaden our research portfolio.

Our research team, comprising clinicians, nurses, pharmacists, laboratory scientists, allied health and data professionals, facilitate investigator-led and external research across SJG Subiaco Hospital, and supports the Bendat Respiratory Research and Development Fund Committee and Junior Doctor Research Program.

Our research areas include respiratory, anaesthesia and intensive care medicine, as well as inflammatory bowel disease, orthopaedics, neurosurgery, nursing and oncology research. Our team also continues to value our collaborations with local and interstate-based tertiary hospitals and academic institutions.

We work closely with the St John of God Foundation, and with the valuable support of donors, seek to conduct research activity that results in changes to practice and improvement in patient outcomes.

This year, due to the generous support of donors, we have been pleased to partner with the Foundation to launch the inaugural 2022 St John of God Foundation Research Grants for SJG Subiaco Hospital. We would like to thank St John of God Foundation CEO Bianca Pietralla and former SJG Subiaco Hospital CEO Prof Shirley Bowen for their vision to support research project development and early career researchers at SJG Subiaco Hospital. Congratulations to the 2022 award winners. Their successful projects are highlighted later in this report.

As demonstrated throughout this year's report, the efforts and achievements of our research team have been recognised in numerous publications. Members of the team have also received several awards as highlighted below:

WA Early Career Scientist of the Year, Premier's Science Awards.
Intensivist A/Prof Ed Litton

Australian Clinical Trials Alliance (ACTA) 2022 awards
ACTA Trial of the Year Award Winner:
REMAP-CAP – Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Chief Investigator: Intensivist and Director Clinical Trials, Prof Steve Webb

This trial employed a novel design to simultaneously evaluate potential treatments, and efficiently and rapidly generate evidence, which had a significant impact on the care of critical patients during the COVID-19 pandemic.

ACTA STInG Excellence in Trial Statistics Award Winner:

The PADDI Trial - The Perioperative Administration of Dexamethasone and Infection

Chief Investigator: Anaesthetist, Prof Tomás Corcoran

This trial presented that dexamethasone can be safely administered to patients to prevent nausea and vomiting when undergoing surgery, without concern about wound infections. This trial recruited patients at SJG Subiaco Hospital.

Congratulations to our researchers for your successes and thank you all for your commitment to innovative and evidence-based research.

There have been several departures from key roles within our Institution over the past year. Our Director of Breast Cancer Research Prof Christobel Saunders AO left in October to take on a new position at the University of Melbourne (Royal Melbourne Hospital). Prof Saunders is internationally recognised for her leadership in clinical trials of new treatments and translational research, and has significantly contributed to breast cancer research at SJG Subiaco Hospital. Prof Saunders continues to be involved with ongoing breast cancer research at our hospital, which is now lead by our highly skilled group of specialist breast surgeons and oncologists.

Former Director Medical Services Dr Eva Denholm departed earlier this year. Dr Denholm was a strong supporter of research activity, and provided significant guidance to our department over the past 12 months as we navigated the challenges associated with the COVID 19 pandemic. Prof Bowen was instrumental in supporting the research activity of our clinicians and visiting medical officers in both investigator initiated and collaborative research projects. Prof Bowen's deep appreciation and dedication to research excellence at SJG Subiaco Hospital has ensured the continued growth in research and clinical trials long into the future.

We extend our sincere thanks and best wishes to Prof Bowen, Prof Saunders and Dr Denholm in their new appointments.

I would also like to thank Director of Nursing and former Acting CEO Adjunct Prof Jenny Brenton, former Acting Director of Medical Services Prof Eli Gabby, and members of our Research Management Committee, particularly Chair Prof Steve Webb, for the support and guidance they have provided to our team.

St John of God Foundation CEO's Report



Bianca Pietralla
CEO, St John of
God Foundation

The enduring generosity and philanthropic vision of our donors in support of essential medical research and transformational health care for patients at St John of God Subiaco Hospital is truly inspirational and continues to change lives for people in our community.

As we continue to emerge from an extended period of worldwide health care and economic upheaval, fundraising in support of medical research that can directly translate into new, more effective patient treatments for people fighting some of the most challenging health conditions in our hospitals, including cancer, remains our key focus.

Despite the ongoing economic uncertainty across Australia, a group of remarkable supporters have continued to play a critical role in enabling these medical discoveries and advancements, bringing hope to thousands of patients and their families in their time of greatest need.

We are especially grateful to the researchers and clinicians at St John of God Subiaco Hospital, as they embark upon some of the most important 'bench to bedside' medical research in Australia and worldwide. I'm proud to be able to share just some of those projects and achievements, fuelled by philanthropy.

This year, we were proud to announce the launch of a new research grants program to further support and grow St John of God Subiaco Hospital's world class clinician-led research, with the ultimate goal of improving patient care, treatment and health care outcomes through translatable research.

The grant recipients, including an Early Career Researcher and Seed Funding grant, were announced during the hospital's annual Research Week event in August 2022.

The grants have only been made possible thanks to donations from grateful patients, family members and other supporters, who believe in improving health care through research innovation to benefit others in the future. We are grateful for their generosity and excited to launch this program in partnership with St John of God Subiaco Hospital.

In financial year 2021/22, over \$4.27 million was raised nationally to support better health outcomes for St John of God Health Care patients and the broader community. Donations and bequests received through the Foundation this year totalled \$564,000 for St John of God Subiaco Hospital, including \$300,000 towards the Bendat Respiratory Research and Development (BRRD) Fund to advance research and clinical excellence in respiratory medicine and cancer related pathologies and over \$215,000 towards

excellence in cancer research and innovative cancer treatment.

In May 2022 the Bendat Family Foundation made an extraordinary leadership commitment to enable leading medical research into respiratory illness, through the Bendat Respiratory Research and Development (BRRD) Fund.

This will see a further \$1.5 million invested into respiratory research over the next five years, to build on and support some of the world's brightest minds to continue their work into world-leading outcomes for Western Australians living with respiratory illnesses. Through both presentation and publication of important research findings, as well as working collaboratively with others in the field, our researchers are contributing to translational research on both a national and international scale.

We are especially grateful to the Bendat Family Foundation for their ongoing support following the sad passing of Jack Bendat AM CitWA in February this year. Jack and his late wife Eleanor were passionate about improving the lives and health outcomes of West Australians, and we are proud their legacy and relationship with St John of God Health Care will continue to live on through the Bendat Family Comprehensive Cancer Centre and ongoing advancements in medical care enabled through the BRRD Fund.

In addition to achievements facilitated through the BRRD Fund, philanthropic support has also been critical in funding researchers like Dr Paul Cohen to develop improved follow-

up care for patients with ovarian, fallopian tube and primary peritoneal cancer. The MOST (Measure of Ovarian Symptoms and Treatment concerns) clinical trial aims to improve patient experience and outcomes by offering more holistic care and relieving the stress of travelling to appointments. This is one of many research projects that, with community support, holds great promise for patients.

I would particularly like to acknowledge the benefactors who made significant contributions this year to medical research and related clinical equipment at St John of God Subiaco Hospital. My special thanks to the Bendat Family Foundation, the Massey Charitable Trust, the Ladybird Foundation, and other private donors, for helping to improve lives in such a meaningful way.

On behalf of patients, families and every caregiver across St John of God Health Care, I extend our thanks to each and every supporter that has commenced or continued to support health care advancements through research at St John of God Subiaco Hospital over the past twelve months.

It is through your compassion that we can continue to transform the future of health care and give hope to patients in their time of greatest need.

We extend our most profound thanks to all of our supporters for their compassion and vision in helping us to transform health care for patients and families in our care.



The opening and blessing of the Bendat Family Comprehensive Cancer Centre in June 2008 – Jack Bendat and the fundraising committee with Archbishop Barry Hickey.

L-R: Dan Smetana, Vic Jakovich, Professor Michael Quinlan, David Goldstone, Jack Bendat, Dr Shane Kelly, Archbishop Barry Hickey, Don Good.

Winners of the 2022 St John of God Foundation Research Grants



L-R Dr Shane Kelly (CEO SJGHC), Prof Allan Kermode, Ms Tina Chinery (CEO – Subiaco Hospital), Ms Bianca Pietralla (CEO – SJG Foundation), Dr Alannah Cooper, Prof Steve Webb (Chair – Research Management Committee)

We are pleased to congratulate the inaugural winners of the 2022 St John of God Foundation Research Grants, who were recently announced during the hospital's annual Research Week event.

In the Early Career Researcher Grant category, the successful recipient of the \$15,000 grant was Dr Alannah Cooper. Dr Cooper will be using the funding to develop an instrument to measure nurse resilience.

In the Seed Funding category, the judges' panel recommended awarding the \$50,000 grant to two recipients – Professor Allan Kermode and Dr Alannah Cooper.

Using the seed funding, Professor Kermode will be studying employing serum neurofilament light chain measures for management of multiple sclerosis, while Dr Cooper's mixed methods study will be identifying barriers to palliative care access.



Message from Ethics Committee Chairman



**Clinical Prof
Dr Simon Dimmitt**
Human Research Ethics
Committee Chairperson,
St John of God Health Care

The St John of God Health Care Human Research Ethics Committee (SJGHC HREC) and Scientific Review Sub-Committee (SRC) together facilitate and support a strong research culture within the organisation with the ultimate aim of ensuring the conduct of ethical and quality studies that are impactful and can be translated into improvements in clinical practice and health care delivery.

The SJGHC HREC and SRC review, support and monitor the progress of approved research projects throughout our hospitals and services. This research spans a wide range of clinical specialties, study design, and scope – from small, single site, quality improvement projects conducted by individual St John of God Health Care caregivers through to large, collaborative, multicentre research projects, including international randomised control trials of novel medications and treatment modalities.

Our committees are managed by Ms Gorette De Jesus, Executive Officer and Ms Karen Roberts, Research Ethics Officer.

During the past year, we have welcomed a new committee member: Ms Suzanne Lawrence in the core position of Laywoman on the SJGHC HREC. Suzanne has replaced Sister Philomena Burrell whom we farewell and sincerely thank for her contribution.

SJG Health Care's annual research activity has remained steady. The COVID-19 pandemic has presented with a distinct set of challenges in research ethics for countries with low prevalence of the infection, such as Australia. In an effort to overcome these challenges, the SJGHC HREC has worked according to best practice national guidelines and with researchers and our SJG Health Care hospitals and services to ensure minimal disruption to existing open studies in oncology and other specialties. Also, by providing an expedited review pathway for COVID-19 related studies, this has facilitated the timely start-up of these studies and encouraged more rapid

dissemination and translation of COVID-19 research results in the interest of the wider global community.

How to engage and involve incapacitated patients and their families in medical research, has been a longstanding ethical and legal challenge, particularly in Western Australia (WA). Significant advancement on these issues came in WA with the enactment of the Guardianship and Administration Amendment (Medical Research) Act 2020 (GAA) on 7 April 2020. An insightful Expert Panel Discussion comprised of researchers from the broader WA research community and members of our own committees, was a highlight of the SJG Subiaco Hospital Research Week held in September 2021. The Panel shared their experiences with the GAA and possible further improvements to facilitate research. This also led to some of the Panel members publishing a paper together, elaborating on the suggestions for further refinement of the GAA to address the nuances of particular studies and the varied contexts in which research is conducted. In the interests of promoting ethical, quality research and health equity, our committees will continue to support and welcome further improvements to the GAA in future legislative reviews.

At a national level, the Australian Commission on Safety and Quality in Health Care (ACSQHC) currently has a number of projects at various stages aimed at improving the environment for health and medical research to thrive and make optimal contribution to the Australian community. One of these projects is the National Clinical Trials Governance Framework which will be implemented by the ACSQHC commencing 1 January 2023. The Framework will assess the extent to which hospitals with their clinical trials meet National Safety and Quality Health Service (NSQHS) Standards relating in particular to governance of trials and partnering with consumers in clinical trial service provision. SJG Subiaco Hospital is leading the way as our most active hospital in clinical trials. We will look forward to continuing to work with caregivers and researchers to support and promote ethical and quality research at the hospital.

SJGHC HREC Membership

- **Clinical Prof Dr Simon Dimmitt** (Chair) BMedSc (Hons) MBBS FRACP FCSANZ
- **Fr Joe Parkinson** STL PhD
- **Mr Gannon Jones** BA(Phil) BA(Psych)
- **Dr Janie Brown** BNurs MEd PhD
- **Dr Ben Carnley** MBBS FRACP FRCPATH
- **Dr Tasnuva Kabir** PhD MSc MBBS
- **Mr Eric Heenan** BLaws (Hons) The Honorary KC (Retired Judge Supreme Court WA)
- **Mr Hamish Milne** BA (Hons) GradCertEthics MPhil MBA GAICD FAIM
- **Mr Patrick O'Connor** MPsych(clinical) MBA
- **Dr Vivian Chiu** PhD BPysch BSc BComm
- **Prof Sally Sandover** BSc MPH
- **Ms Suzanne Lawrence** BA(Psych)

Dr Gail Ross-Adjie

BN MCLinNurs PhD

Dr Evan Bayliss

MBBS FRACP

SRC Membership

Prof Sally Sandover

(Chair, SRC) BSc MPH

Dr Afaf Abed

MBBS FRACP

Dr Mary Theophilus

MBChB MRCS FRACS PhD

Prof Kevin Craft

PhD FRSC

Ms Gemma McGrath

BNurs BLaws (Hons) Master of Laws

Prof Leanne Monterosso

BNurs (Hons) RN RM NNT GCert TerTeach, PhD FACNA

Mr Myles Murphy

BPhysio GCSports Physio MCLinPhysio PhD

A/Prof Kylie Russell

Master Health Science (Education) BNurs PhD Grad Cert Human Resource Management

Dr Ru-Wen Teh

MBBS FRACP

Clinical Prof Dr Simon Dimmitt (Chair)

BMedSc (Hons) MBBS FRACP FCSANZ4

Anaesthesia and Pain Research Unit



Prof Tomás Corcoran
Consultant Anaesthetist, Raine Foundation Clinical Research Fellow

Key research areas:

The Anaesthesia and Pain Research Unit remains committed to improving outcomes for patients undergoing surgery. Key research priorities for anaesthesia are post-operative acute and chronic pain, wound infection and cancer reoccurrence.

The Unit has developed a reputation for being an active contributor to large, international, multi-centre studies. These studies are led by Prof Tomás Corcoran.

Contact

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8 Number of publications in 2021/22



294
Patients consented

3
Clinical Trials

Overview

Prevention of Chronic Post-Surgical Pain (CPSP) is seen as the 'Holy Grail' of anaesthesiology; it remains a common and debilitating complication of surgery. The ROCKeT and LOLIPOP trials are investigating treatments into CPSP that could provide the evidence to transform routine anaesthesia practice worldwide and improve patients' quality of life and the associated financial healthcare burden.

Surgical site infection (SSI) remains a serious and expensive postoperative complication. The TRIGS trial examines an innovative way to reduce SSI in gastrointestinal surgery, and will evaluate the effects on immune and inflammatory responses.

Cancer remains a major public health problem and despite surgical treatment, cancer recurs in many patients. The VAPOR-C trial is investigating the role of anaesthetic agents in cancer cell survival and immunomodulation in patients undergoing colorectal and lung cancer surgery.

Clinical trials

- 1. ROCKeT: Reduction of Chronic Post-Surgical Pain with Ketamine**
This trial aims to provide evidence of a reduction of chronic post-surgical pain with the use of ketamine infusions. Thus far, 181 patients have been consented at St John of God Subiaco Hospital of the 4,884 total participants required. It is estimated that recruitment will be completed by 2022.
- 2. TRIGS: Tranexamic Acid to Reduce Infections after Gastro Intestinal Surgery**
This trial aims to investigate whether tranexamic acid reduces surgical site infection and other health care associated infections along with a reduction in red cell transfusion. Thus far, 23 patients have consented at St John of God Subiaco Hospital of the 3,300 total participants required. It is estimated that recruitment will be completed by 2022.
- 3. VAPOR-C: Volatile Anaesthesia and Perioperative Outcomes Related to Cancer**
This large randomised controlled trial (RCT) examines inhalational volatile or intravenous propofol anaesthesia and intravenous lidocaine/placebo to improve disease free survival after surgery for colorectal cancer and lung cancer. Recruitment has commenced for the 5,736 total participants required over the next five years.
- 4. Prevalence of Asymptomatic SARS-CoV-2 Infection Elective Surgical Patients in Australia**
The aim of this multicentre observational study was to determine the prevalence of active and previous SARS-CoV-2 infection among patients admitted to

hospital for elective surgery across Australia during June-July 2020. 532 patients participated from St John of God Subiaco Hospital of the 3,037 total participants. Results will help inform planning for elective surgery during the COVID-19 pandemic.

- 5. BEE Pain Free**
This is a multicentre, double-blinded, RCT to investigate honey use to reduce pain in children post-tonsillectomy. The aim of this study is to investigate if honey administration is able to improve pain scores in children post tonsillectomy in comparison to Standard of Care. The honey groups are placebo honey (sugar syrup) and peroxide honey and non-peroxide honey. A total of 400 children will be recruited from Perth Children's Hospital, Fiona Stanley Hospital, Subiaco Private and St John of God Subiaco Hospital.
- 6. PROSOX: PROspective Observational Study of perioperative OXYgen administration**
This is a multicentre observational study that aims to assess what is the current standard practice of perioperative oxygen administration to determine the proportion of anaesthetists in Australia and New Zealand who administer oxygen in accordance with the World Health Organisation guidelines. Recruitment has been completed at St John of God Subiaco Hospital, awaiting other sites to complete recruitment prior to analysis.
- 7. PCORE: Perioperative Clinical Outcomes Registry: Pilot**
The aim of this pilot is to develop a national clinical quality registry for individuals undergoing anaesthesia and surgery. *In progress.*

Highlight

Prof Tomás Corcoran was the winner of the 2022 ACTA STInG Excellence in Trial Statistics Award for his work on the PADDI Trial: The Perioperative Administration of Dexamethasone and Infection. This trial presented that dexamethasone can be safely administered to patients to prevent nausea and vomiting when undergoing surgery, without concern about wound infections.

Accolades for Australian clinical trials at annual ACTA awards – ACTA – Australian Clinical Trials Alliance
The BEE Pain Free Study was the runner up in the 2022 Australian Clinical Trials Alliance Consumer Engagement Category.

Accolades for Australian clinical trials at annual ACTA awards – ACTA – Australian Clinical Trials Alliance

The Anaesthesia Research Unit is excited and proud to have a previous trial participant advocating for breast cancer patients and providing insight and feedback from a consumer perspective. The first patient recruited at SJGSH to the LOLIPOP PILOT study in 2019 has become the **Consumer Representative** to the large international LOLIPOP study. Involvement in the study includes active participation on the Trial Steering Committee and providing feedback on patient information sheets, lay summaries, consent forms, website content and communication material.

PROJECT 1

ROCKeT: Reduction of Chronic Post-Surgical Pain with Ketamine

Principal Investigator:

- Prof Tomás Corcoran



This trial aims to provide evidence of a reduction of chronic post-surgical pain with the use of ketamine infusions compared to placebo.

This as a large randomised, blinded, multicentre trial funded by the NHMRC and sponsored by the University of Melbourne. Prevention of Chronic Post-Surgical Pain (CPSP) is seen as the "Holy Grail" of anaesthesiology; it remains a common and debilitating complication of surgery. The ROCKeT trial is investigating treatment into CPSP that could provide the evidence to transform routine anaesthesia practice worldwide and improve patients' quality of life and the associated financial healthcare burden. The targeted 4884 participants will be recruited by the end of 2022. Thus far, 251 patients have been consented by

the Anaesthesia Research Unit. Study participants are contacted up to one year after their surgery.

ROCKeT sub-studies:

Health Economic sub-study: data on health expenditure related to surgery will be measured.

Biomarker sub-study – genetic risk factors for chronic post-surgical and response to treatment will be examined.

3D-CAM Delirium sub-study – using reliable assessment tools for identifying post-operative delirium in patients over 65 years of age.

PROJECT 2

TRIGS: Tranexamic Acid to Reduce Infections after Gastro Intestinal Surgery

Principal Investigator:

- Prof Tomás Corcoran

This trial aims to investigate whether tranexamic acid reduces surgical site infection and other healthcare associated infections along with a reduction in red cell transfusion.

Surgical site infection (SSI) remains a serious and expensive postoperative complication. The TRIGS trial examines an innovative way to reduce SSI in

gastrointestinal surgery, and will evaluate the effects on immune and inflammatory responses. TRIGS is a large randomised, blinded multicentre trial with 3,300 total participants. TRIGS is funded by the NHMRC and sponsored by Alfred Health. The Anaesthesia Research Unit has consented 43 patients and the total recruitment target should be completed by 2023.

PROJECT 3

VAPOR-C: Volatile Anaesthesia and Perioperative Outcomes Related to Cancer.

This large randomised controlled trial (RCT) examines inhalational volatile or intravenous propofol anaesthesia and intravenous lidocaine/placebo to improve disease free survival after surgery for colorectal cancer and lung cancer. Recruitment has commenced for the 5736 total participants required over the next five years.

PROJECT 4

LOLIPOP: Long-term Outcomes of Lidocaine Infusions for Post-Operative Pain.

This large international randomised controlled trial is targeting women undergoing breast cancer surgery. The trial aims to evaluate the effectiveness of lidocaine infusions commenced during surgery and extending up to 24 hours postoperatively, in reducing the incidence of moderate or severe chronic post-surgical pain one year after surgery. Recruitment for the 4300 total participants will open in mid-2022 and is expected to last five years.

PROJECT 5

PCORE: Perioperative Clinical Outcomes Registry: Pilot

The aim of this pilot is to develop a national clinical quality registry for individuals undergoing anaesthesia and surgery.

Top publications in 2021/22

1. Corcoran, T.B., Myles, P.S., Forbes, A.B., Cheng, A.C., Bach, L.A., O'Loughlin, E., Leslie, K., Chan, M.T., Story, D., Short, T.G. and Martin, C., 2021. Dexamethasone and surgical-site infection. *New England Journal of Medicine*, 384(18), pp.1731-1741. *N Engl J Med* 2021; 384:1731-1741 <https://doi:10.1056/NEJMoa2028982>
2. Corcoran, T.B., O'Loughlin, E., Chan, M.T. and Ho, K.M., 2021. Perioperative Administration of Dexamethasone And blood Glucose concentrations in patients undergoing elective non-cardiac surgery—the randomised controlled PADDAG trial. *European Journal of Anaesthesiology* *EJA*, 38(9), pp.932-942. <https://doi:10.1097/EJA.0000000000001294>
3. Myles, P.S. and Corcoran, T., 2021. Benefits and risks of dexamethasone in noncardiac surgery. *Anesthesiology*, 135(5), pp.895-903. <https://doi.org/10.1097/ALN.0000000000003898>



Recruitment for potentially life-changing breast cancer pain research has commenced

A clinical trial aimed at improving quality of life for women with breast cancer has commenced recruitment of trial participants.

Led by St John of God Subiaco Hospital Anaesthetist and Clinical Research Professor Tomás Corcoran, the LOLIPOP (Long-term Outcomes of Lidocaine Infusions for Persistent Postoperative Pain) Trial is investigating whether chronic pain can be prevented by giving a local anaesthetic, lidocaine, intravenously during breast cancer surgery and up to 24 hours post-surgery.

It is estimated that nearly 30 per cent of breast cancer patients experience some chronic pain after surgery, and there is currently no known preventative treatment available.

The large, international five year trial will also use a new approach in examining a person's genes to determine whether their genetic makeup alters their response to lidocaine.

The trial is being coordinated through the Australian and New Zealand College of The Anaesthetists (ANZCA) Clinical Trials Network, based at Monash University in Melbourne.

To ensure the project's efficacy, the research team aims to recruit 4,300 trial participants world-wide who are undergoing breast cancer surgery.

Discussing the trial, Prof Corcoran said that preventing the occurrence of chronic pain after surgery is considered the 'holy grail' because treating such pain, once established, can be very difficult.

"For many women, the findings of this research could potentially be life changing," he said.

"Women affected by breast cancer are often in the prime of their life and the impact of chronic, sustained pain can be significant. It can severely affect quality of living, personal relationships, ability to work, and mental health."

"By exploring the prevention of post-surgery pain, our hope is that we can improve the outcomes for these patients, and ensure that they can comfortably return to their usual life as soon as possible following breast cancer surgery."

"We are very grateful to all patients who have consented to be part of the trial so far. Their participation is invaluable, and

has the potential to change how women impacted by breast cancer are cared for."

Following her breast cancer diagnosis in 2019, St John of God Subiaco Hospital patient Julie Mews became the first patient to sign-up to the pilot trial.

Commenting on her support, Julie said that she had no hesitation in participating and hoped her involvement would have a positive impact on someone else's life in the future.

"I recommend that anyone in the same situation consents to participating in a clinical trial and supporting vital medical research if it is presented to them as an option," she said.

"You have nothing to lose and participation isn't onerous on the patient at all. In fact, I believe wholeheartedly that my support of the LOLIPOP Trial benefitted the care I received and my overall recovery.

"I received wonderful, continuous care from Trial Coordinator Natalie Hird throughout my recovery journey. Natalie visited me regularly in hospital and following my discharge continued to contact me for a number of months to review my progress and pain levels."

"Her constant presence was very comforting and offered familiarity during what was a very unfamiliar time."

As a result of her positive experience, Julie is now the consumer engagement representative on the LOLIPOP Trial Steering Committee.

St John of God Subiaco Hospital CEO Tina Chinery added that the hospital was pleased to support the important trial and provide breast cancer patients access to latest treatment options for post-operative pain.

"St John of God Subiaco Hospital has developed a reputation as one of Australia's premier research institutes and a leading provider of cancer care and services."

"Our support of the trial has the potential to dramatically improve the quality of care delivered to women who undergo breast cancer surgery, and help them to recover with significantly less pain, which for many women, could be life-changing."

Breast Cancer Research Unit



Prof Christobel Saunders AO
Director Breast Cancer Research Unit, Breast Cancer Surgeon
(July-October 2021)

Key research areas:

- Preventative, diagnostic, surgical, medical and radiation oncology clinical trials
- Supportive care research
- Health services research
- Translational research



Overview

The Breast Cancer Research Unit covers four major aspects to assist and guide patient care. They include:

- Clinical trials from prevention through to survivorship. They cover all aspects of breast cancer, including prevention, diagnosis, treatments, post treatment, survivorship, fertility, wellness and translation of research practice
- Supportive care research to improve care, longer-term quality of life, psychological well-being and risk reduction strategies, and enable young breast cancer survivors to start a family
- Translational research driven by our Biobank in collaboration with national and international researchers
- Health services research that can help deliver more equitable and effective cancer care to Western Australians

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PROJECT 1

BRCA-P Clinical Trial

Lead researchers:

- Dr Helen Ballal
- Mr Lee Jackson
- Dr Wen Chan Yeow

Contact:

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Launched in April 2020, this international trial aims to prevent breast cancer in women with a BRCA1 gene mutation.

Women with BRCA1 gene mutation have a significantly higher chance of developing breast cancer (and ovarian cancer) and are also more likely to develop cancer at a younger age. While a preventative mastectomy is a highly effective treatment option, our hope is to provide an alternative less invasive preventative option with this medication and improve outcomes for women with BRCA1 gene mutation. We currently have two active participants, with a few more potential patients having expressed their interest to be involved.

The BRCA-P study involves a study medication injection (Denosumab or placebo) every six months for five years. Participants have a visit with their Study Doctor every six months, and have their bone health and quality of life assessed every 12 months. These assessments are not typically part of standard medical care for women carrying a BRCA1 mutation. Participants will also continue to be checked by their study team every 12 months for a further five years (total of 10 years).

In addition, BRCA-P will investigate whether Denosumab decreases the risk

of developing ovarian cancer or other types of cancers. The study will also assess its effect on bone health, patient reported outcomes, side effects and biological markers.

This study involves a self-registration system, whereby patients can express their interest in the study by completing an online questionnaire. If a patient meets the initial study criteria, the results of this questionnaire will filter through to the study team who will reach out to the patient with further details on the study.

Denosumab is approved in Australia for the treatment of osteoporosis (60mg, Prolia®) and for the prevention of bone-related problems in adults with bone metastases from cancers (120 mg, XGEVA®). It has not been approved as a prevention medication for people with a mutation in the BRCA1 gene. Its use in this study is experimental.

Eligibility:

- Women with a confirmed BRCA 1 gene mutation
- Age 25-55, no evidence of breast cancer clinically and imaging (MRI, Mammogram)
- No history of mastectomy
- No history of ovarian cancer

PROJECT 2

Breast MRI Evaluation Study BCT 2001

Lead researchers:

- Dr Helen Ballal
- Dr Lee Jackson
- Dr Wen Chan Yeow

Previous studies have proven the usefulness of breast Magnetic Resonance Imaging (MRI) and the Australian Federal Government recently funded MRI via Medical Benefit Schedule (MBS) to be used in some women with early breast cancer. However, this is temporary funding and the government has asked for more research to find out the best way to use breast MRI, when it is most useful, and if it can improve treatment options and patient outcomes.

This study is open to women diagnosed with breast cancer where the medical treatment team suggests that a MRI of the breast will help plan treatment, aiming to determine if the MRI may change the treatment plan, and how it may affect patient outcomes.

The goal of at least 400 participants for this study throughout Australia is close to achievement. The study launched at our site in April 2020 and we currently have 16 active participants.

PROJECT 3

Continuous Improvement in Care (CIC) – Cancer Project (breast)

Lead researchers:

- Prof Christobel Saunders
- Dr Helen Ballal
- Mr Lee Jackson
- Dr Wen-Chan Yeo
- Glenys Longman

Despite cancer incidence in Australia dropping over the last decade, the number of people living with cancer has more than doubled. The Continuous Improvement in Care – Cancer (CIC Cancer) Project is an innovative program of research that places cancer patients first and provides opportunities for patients to receive the care they need at the time they need it. This project aims to directly improve the lives of those diagnosed with cancer by bringing together consumers, clinicians, health services and researchers to:

- Measure both clinical outcomes and outcomes important to patients
- Identify gaps in their care
- Trial new ways to improve treatment

This is a multi-institutional program of research that seeks to bring value-based healthcare (VBHC) to public and private healthcare settings in Western Australia. To the best of our knowledge, this is the first time that VBHC processes have been implemented simultaneously across multiple hospitals in both public and private healthcare sectors within Australia.

Currently St John of God Subiaco Hospital has 88 active participants.

To date, steps one to three of the five steps in the model have been achieved and work is underway to achieve steps four and five.

PROJECT 4

The Intra-Operative Radiotherapy for Early Breast Cancer (IORT) Outcomes Registry

Lead researchers:

- Dr Yvonne Zissiadis

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Intra-operative radiotherapy (IORT) as a single dose during breast conserving surgery is supported in previous trials as an effective replacement to external beam radiotherapy (EBRT) for select women with low risk early breast cancer. IORT reduces treatment time from three to seven weeks of daily radiation with ERBT to a single targeted treatment administered while the patient is undergoing breast conserving surgery to remove the cancer.

St John of God Subiaco Hospital is the only private hospital in Australia offering IORT for early breast cancer. To date, 80 patients have received IORT and consented to participate in the data registry.

The purpose of the registry is to track short and long-term outcomes of patients with early breast cancer who are treated with

IORT. Information on breast cancer diagnosis and general health are collected. Additionally, Patient Reported Outcome Measures (Proms) and a Patient Experience Survey are completed.

Findings from this registry may be used to support changes to standard practice in the future, and will be a valuable resource in assessing the safety and quality of IORT. It is hoped that IORT becomes more available in treating early breast cancer due to significant potential benefits to patients – reducing the number of radiotherapy sessions required and the costs involved.

This is a combined project with St John of God Subiaco and GenesisCare.

PROJECT 5

Breast Cancer Survivorship

Lead researchers:

- Prof Christobel Saunders

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Based on the growing evidence of the value of the Specialist Breast Cancer Nurse (SBCN) role in breast cancer survivorship, the Wellness After Breast Cancer Clinic (WABCC) at St John of God Subiaco Hospital was established as a SBCN-led clinic in November 2017.

The implementation of the SBCN-led WABCC provides an opportunity to evaluate the service and address gaps in the literature about the experiences of breast cancer survivors who received different modes of treatment.

The aim of this study was to establish if the WABCC addresses the needs of breast cancer survivors. Objectives of the study are to:

- Understand the issues experienced by breast cancer survivors
- Compare the needs/concerns faced by those who received chemotherapy as

part of their treatment with those who did not

- Assess satisfaction with a Specialist Nurse-led clinic

Emerging models of survivorship care support within Australia are varied and include SBCNs, GPs and forms of peer support that include public, private, and community based organisations such as Cancer Councils. A review of Australian survivorship models concluded that the SBCN can be the link between supportive models of care and the transition of care from hospital into the community. Despite the differing delivery of survivorship care, the primary goal is to educate patients on wellness, as well as to identify and manage physical and psychological symptoms.

The WABCC continues to see patients, however, the study is now closed to recruitment.

PROJECT 8

BROCADE (BREast Origin CANcer tissue donated after DEath: The NBCF repository of primary tumours and metastases from breast cancer patients)

Lead researchers:

- Prof Christobel Saunders
- Dr Robin Anderson (Peter MacCallum Cancer Centre)
- Lisa Devereux

BROCADE has been designed to support breast cancer research, and aims to understand how breast cancer spreads and why it becomes treatment resistant. The information gained through BROCADE-supported research may also aid our understanding of other cancers.

Unfortunately, despite best available treatment, breast cancer sometimes spreads to other sites in the body such as bones, lungs, liver and brain, and becomes resistant to treatment.

During life, obtaining tissue samples of breast cancer that has spread to different organs is often difficult. Biopsies may be painful for the patient, or not possible due to the location of the tumour. Through BROCADE, we seek permission to obtain and study samples of tissue from patients

who have recently died of breast cancer. We hope that this will provide important information to help design more effective therapies for cancer patients in the future. Tissue donated to BROCADE will be stored in a biobank and will only be made available to researchers after a rigorous review and approval process.

BROCADE launched at St John of God Subiaco Hospital in September 2017. Since then, seven patients consented to study and their tissue was collected after death for further research.

This study is sponsored by Peter MacCallum Cancer Centre that is a world leading cancer research, education and treatment centre. St John of God Subiaco Hospital is one of the active sites in this study.

PROJECT 6

POSITIVE study

Lead researcher:

- Dr Tim Clay
- Dr Daphne Tsoi
- Dr Helen Ballal and ETOP IBCSG Partners Foundation.

The POSITIVE study evaluates the safety of interrupting endocrine therapy for young women with hormone-sensitive breast cancer who wish to become pregnant. St John of God Subiaco Hospital is the first Australian site to be actively involved in this large international research effort coordinated by the ETOP IBCSG Partners Foundation.

We have 6 active participants in this trial with 10 positive babies! The first participant is in her eighth year of participation, and the last patient is in her third. Since the beginning of this trial, there has not been any recurrence among SJG Subiaco Hospital participants who interrupted their endocrine therapy due to pregnancy or breast feeding.

PROJECT 7

POSNOC

Lead researcher:

- Dr Yvonne Zissiadis
- Mr Lee Jackson
- Dr Wen Chan Yeow
- Dr Eugene Leong

As part of a bigger international trial, St John of God Subiaco Hospital, in collaboration with Breast Cancer Trials Group (BCT), is now the first Western Australian site looking at treatment after surgery for women whose early stage breast cancer has spread to one or two lymph nodes. The results are likely to improve the future treatment of women with early breast cancer.

In this study, our site has recruited 11 participants who are all actively followed up as per protocol.

Top publications in 2021/22

1. Ding, J., Johnson, C.E., Saunders, C., Licqurish, S., Chua, D., Mitchell, G. and Cook, A., 2022. Provision of end-of-life care in primary care: a survey of issues and outcomes in the Australian context. *BMJ open*, 12(1), p.e053535. <https://doi.org/10.1136/bmjopen-2021-053535>
2. MacConnell, S., Ballal, H., Singh, V. and Saunders, C., 2021. EP. TH. 243 Western Australian Multicentre review of management of the axilla in breast cancer patients receiving neoadjuvant chemotherapy. *British Journal of Surgery*, 108(Supplement_7), pp.znab309-030. <https://doi.org/10.1093/bjs/znab309.0300>
3. Stafford L, Sinclair M, Gerber K, et al. Isolation experienced by women with gestational cancer: could peer support and tailored information be the answer? *Support Cancer Care* 29, 7135-7138 (2021). <https://doi.org/10.1007/s00520-021-06396-2>
4. Hersch, J., Nickel, B., Dixon, A., Houssami, N., Saunders, C., Jansen, J., Rutherford, C., Barratt, A., Spillane, A., Wylie, L. and Stuart, K., 2022. 135 Treating low-risk ductal carcinoma in situ (DCIS)... or not? Qualitative study of patient perspectives. <http://dx.doi.org/10.1136/bmjebm-2022-PODabstracts.62>
5. Mazariego, C., Jefford, M., Chan, R.J., Roberts, N., Millar, L., Anazodo, A., Hayes, S., Brown, B., Saunders, C., Webber, K. and Vardy, J., 2022. Priority recommendations for the implementation of patient-reported outcomes in clinical cancer care: a Delphi study. *Journal of Cancer Survivorship*, 16(1), pp.33-43. <https://doi.org/10.1007/s11764-021-01135-2>

Colorectal Cancer Research Group

Key research areas:

- Improving survival and quality of life after colorectal surgery
- Biomarkers of prognosis and treatment response
- Harnessing the immune system to fight colorectal cancer
- Finding ways to better predict the risk of disease recurrence and metastases

Overview

More than 1,300 people are diagnosed with colorectal (bowel) cancer in Western Australia every year. Despite continual improvements in diagnosis and treatment, almost one in three people still sadly die from the disease*. Of those who survive, many experience long-term side-effects from the treatment they receive, impacting their quality of life. There is therefore an urgent need for continued research aimed at improving survival and quality of life for patients with colorectal cancer. Within the Colorectal Cancer Research Group, clinicians, scientists and laboratory staff work closely together towards this common goal.

*Data from the Australian Institute of Health and Welfare

Highlight

We have been very fortunate to receive additional funding from St John of God Foundation to expand our project investigating biomarkers of colorectal cancer metastasis, led by clinician-researcher Dr Ryan Cohen. This funding will enable us to use cutting edge technology to investigate potential indicators of metastasis risk that can be identified in a simple blood sample.

Contact

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9
Active research studies

123
Patients consented to be involved in the colorectal research program in 2021/22



6
Publications in 2021/22

PROJECT 1

Biomarkers of colorectal cancer metastasis

Lead researcher:

- Dr Ryan Cohen

Despite surgery, 10-20% of patients with localised bowel cancer will develop cancer spread (metastasis). To prevent people from dying from this disease, we need to find better ways of identifying those at risk of metastasis. This study involves linking long-term patient data with potential 'biomarkers' of bowel cancer metastasis. These biomarkers include the immune response to bowel cancer, cancer DNA in the bloodstream and extracellular vesicles, which are sac-like structures released into the bloodstream by cancer cells.

PROJECT 2

Outcomes and treatment pattern over time for resected stage II and stage III colorectal cancer based on real-life data

Lead researcher:

- Dr Yat Hang To (The Walter and Eliza Hall Institute of Medical Research)
- St John of God Subiaco Hospital Lead researcher: Dr Melanie McCoy

Post-operative chemotherapy is currently recommended for patients with colorectal cancer which has spread to the lymph nodes (Stage III), or patients with localised disease (Stage II) considered to be at high risk of relapse. However, there is some debate around the benefit for patients with Stage II

colorectal cancer and the optimal duration of chemotherapy for patients with Stage III disease as this is unclear. This project is analysing data from around 4,000 patients across Australia to better understand current treatment patterns and survival outcomes.

PROJECT 3

Do regulatory T cells inhibit the response of rectal carcinomas to neoadjuvant chemoradiotherapy?

Lead researcher:

- Dr Melanie McCoy

This project is investigating whether the immune system plays a role in how well people with rectal cancer respond to chemoradiotherapy, with a particular focus on regulatory T cells, a subset of immune

cells that suppress immune responses. The work aims to enable better prediction of treatment response, which would allow selection of the most appropriate treatment for individual patients.

PROJECT 4

Could immune checkpoint blockade improve response to chemoradiotherapy in locally advanced rectal cancer?

Lead researcher:

- *Dr Melanie McCoy*

'Immune checkpoints' are molecules found on immune cells that can dampen down immune responses. The aim of this project is to determine whether the interaction between the immune checkpoint PD-1 and a molecule called PD-L1 influences response to chemoradiotherapy in rectal cancer. If so, drugs that block this interaction might help to improve treatment response.

PROJECT 5

Developing blood-based biomarkers of colorectal cancer metastasis

Lead researcher:

- *Dr Kathy Fuller (University of Western Australia)*
- *St John of God Subiaco Hospital lead researcher: Dr Melanie McCoy*

This was a pilot study to optimise laboratory methods for using blood samples to identify patients who may be at higher risk of developing metastasis. This work is being continued in our current project investigating markers of metastasis risk in a larger patient group.

PROJECT 7

Long term outcomes of positive resection margin following rectal resection

Lead researcher:

- *Dr Patrick Walker*

This study involves performing a survival analysis of prospectively collected data on rectal resections performed at St John of God Subiaco Hospital to discern the significance of positive resection margins with relation to overall survival and recurrence free survival.

PROJECT 8

Functional bowel disorders

Lead researcher:

- *Dr Alicia Mackowski*

This project is exploring methods of diagnosing and assessing disease severity in functional bowel disorders (FBDs) commonly encountered in colorectal surgical practice. We are investigating the use of a newly developed assessment tool for diagnosing and managing these conditions in the outpatient clinic setting.

PROJECT 6

Novel insights into immune control of dormant tumours

Lead researcher:

- *Dr Alison McDonnell (Telethon Kids Institute)*
- *St John of God Subiaco Hospital lead researcher: Dr Melanie McCoy*

The immune system can fight cancer by eliminating malignant cells or by preventing the growth and spread of cells that escape eradication. This project is aiming to understand how the immune system can keep cancer cells in a dormant state to help develop new therapies to eliminate cancer. We are using cutting edge technology to investigate how immune cells communicate with each other and with cancer cells to prevent cancer growth.

PROJECT 9

Long term outcomes of patients with rectal cancer with complete pathological response after neoadjuvant chemotherapy and resection

Lead researcher:

- *Dr Zi Ng*

Standard treatment for patients with locally advanced rectal cancer involves chemoradiotherapy followed by surgery. In recent years, a 'watch-and-wait' approach for patients who experience a complete response to chemoradiotherapy (no remaining tumour apparent on scans or clinical examination) is gaining traction

worldwide. In order to evaluate the safety of this approach it is important to understand the long-term outcome for complete responders who do go on to have surgery. This project is comprehensively assessing the long-term outcome of such patients at St John of God Subiaco Hospital.



Gynaecological Cancer Research Group



A/Prof Paul Cohen
 Director Gynaecological Cancer
 Research, Gynaecologist

Key research areas:

Gynaecological Oncology

Overview

Every day in Australia 18 women are diagnosed with a gynaecological cancer. In Australia last year, an estimated 6,576* women were diagnosed with a gynaecological malignancy including ovarian, endometrial, cervical and vulval cancers. The estimated number of deaths from gynaecological cancer in 2021 was 2,139 females. Our research aims to improve outcomes and quality of life for patients and focuses on patient-reported outcomes and the supportive care of those affected by gynaecological cancers. We also conduct research in gynaecological cancer genetics, the epidemiology of gynaecological malignancies, and biomarkers to predict relapse in women

with high-grade serous ovarian cancer, the most common type of ovarian cancer. We are a recruiting site for clinical trials in gynaecological cancer and lead national and international multicentre randomised trials.

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Top publications in 2021/22

- Rye, M. S.; Garrett, K. L.; Holt, R. A.; Platell, C. F.; McCoy, M. J., Fusobacterium nucleatum and Bacteroides fragilis detection in colorectal tumours: Optimal target site and correlation with total bacterial load. PLoS One 2022, 17 (1), e0262416. <https://doi:10.1371/journal.pone.0262416>
- Miller, T. J.; Anyaegbu, C. C.; Lee-Pullen, T. F.; Spalding, L. J.; Platell, C. F.; McCoy, M. J., PD-L1+ dendritic cells in the tumor microenvironment correlate with good prognosis and CD8+ T cell infiltration in colon cancer. Cancer Sci 2021, 112 (3), 1173-1183. <https://doi:10.1111/cas.14781>
- Hardcastle, S. J.; Maxwell-Smith, C.; Hince, D.; Bulsara, M. K.; Boyle, T.; Tan, P.; Levitt, M.; Salama, P.; Mohan, G.; Salfinger, S.; Makin, G.; Tan, J.; Platell, C.; Cohen, P. A., The wearable activity technology and action-planning trial in cancer survivors: Physical activity maintenance post-intervention. J Sci Med Sport 2021, 24 (9), 902-907. <https://doi:10.1016/j.jsams.2021.04.004>



Project highlights

Getting the MOST out of follow-up: a randomised controlled trial to compare three-monthly nurse-led telephone follow-up, including monitoring serum CA125 and patient reported outcomes using the MOST (Measure of Ovarian Symptoms and Treatment concerns) with routine clinic-based follow-up, following completion of first-line chemotherapy in patients with epithelial ovarian cancer.

We were awarded competitive funding (WAHTN-MRFF Translational Research Grant application - \$240,000 - with matched funding from ANZGOG, the Ladybird Foundation, and an NHMRC Program Grant of Prof Michael Friedlander, to a total of \$480,000) to lead a national phase II trial that will investigate the feasibility of a novel approach to the follow-up of women with ovarian cancer after completion of surgery and chemotherapy. Patients will have nurse led follow-up with three-monthly telephone calls and will complete a patient-reported symptom assessment called the Measure of Ovarian Symptoms and Treatment concerns (MOST) questionnaire at home on a personal computer or mobile device, and also have a blood test for the ovarian cancer tumour marker CA125 to diagnose ovarian cancer recurrence. Many patients, particularly those living in rural and remote locations and the elderly, may find it difficult and costly to travel to their hospital clinic appointments. We will assess the health-related quality of life of women undergoing this novel type of follow-up compared to conventional hospital clinic-based follow-up that includes completion of the MOST. Secondary aims include comparing nurse-led telephone follow-up with conventional clinic-based follow-up by investigating patient satisfaction, quality of life and fear of cancer recurrence, the proportions of women diagnosed with recurrence, the number of patients referred for treatment of symptoms such as anxiety and fear of recurrence, and whether the nurse led follow-up method is more cost-effective than the conventional model. St John of God Subiaco Hospital is the sponsor for this study. The study opened for recruitment in Perth in February 2021 and is now open in sites in WA, Queensland, New South Wales and Victoria.

TRACEBACK

In February 2017, the Australian Government announced \$2.96 million to fund TRACEBACK, a world first program that is a collaboration with Prof. David Bowtell at the Peter MacCallum Cancer Centre and Ovarian Cancer Australia. Ovarian cancer is a sentinel cancer for BRCA mutations. These mutations substantially increase a person's lifetime risk of breast and ovarian cancer. Identification of a mutation in an ovarian cancer patient provides opportunities for cancer prevention in at-risk family members. Mutations in patients

whose diagnosis predated revised testing guidelines may have been missed. We assessed the feasibility of detecting mutations in this population, to enable genetic risk reduction in relatives. Deceased patients were identified from cohort studies and oncology clinics. Genetic material (DNA) was extracted from archival tissue for sequencing of ten risk associated genes. Testing of deceased patients was performed with a consent waiver. Familial contacts of deceased patients with mutations received a written notification of results, with verbal contact made in most cases. For many, this was new information and referral to a genetic service was mostly accepted. We overcame ethical and logistic challenges to show that genetic testing in previously untested deceased patients with ovarian cancer is feasible. The St John of God Subiaco Hospital Gynaecological Cancer Research Group was one of the first to contribute to this study and provide an opportunity for current and future generations to adopt strategies to reduce their cancer risk. To date, more than 1000 cases have been tested and many pathogenic gene variants have been identified. The results of TRACEBACK were published in the Journal of Clinical Oncology in March 2022.



PROJECT 1

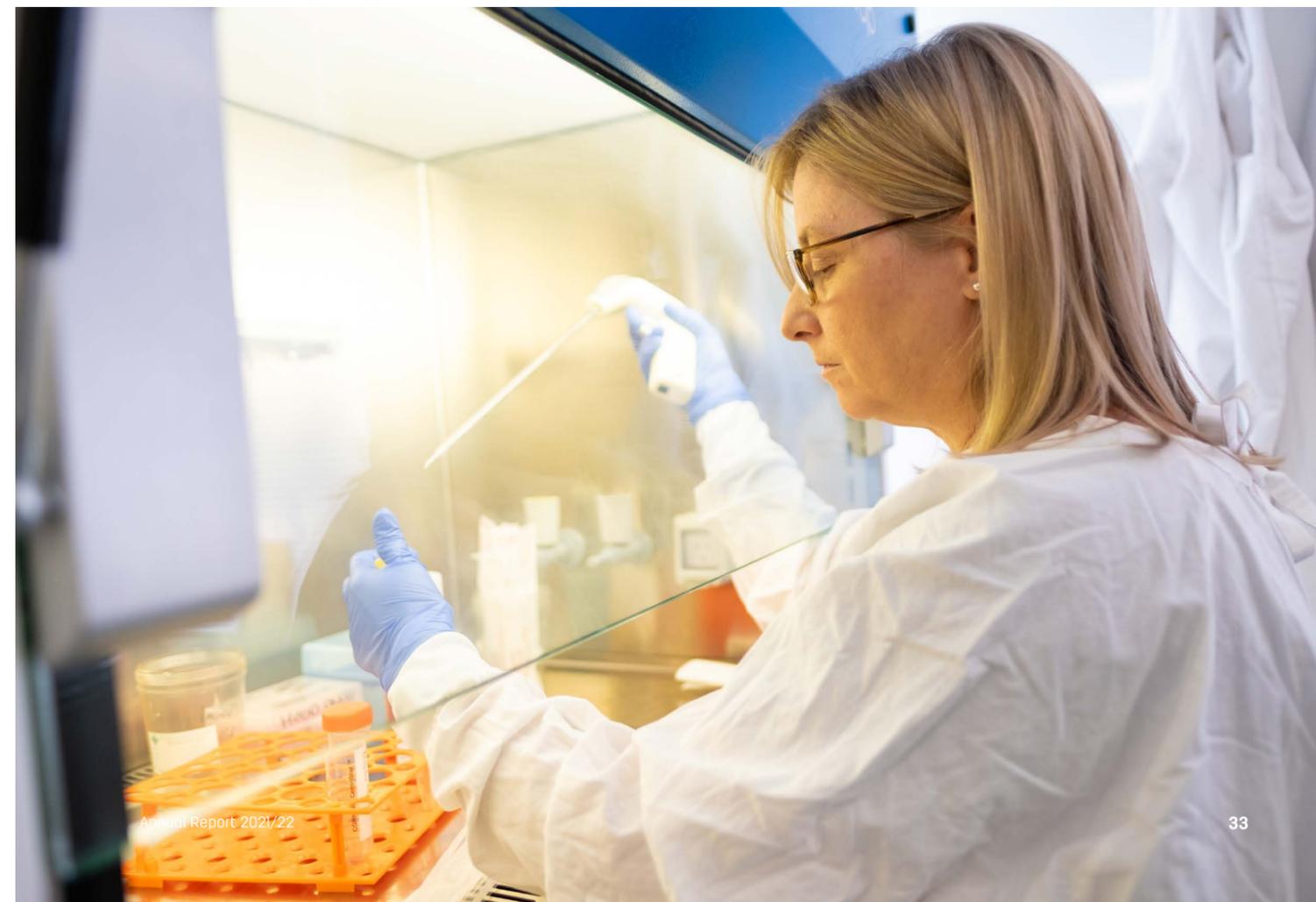
PRE-EMPT - PaRacErvical local anaEthesia to Mitigate post-operative Pain after Total laparoscopic hysterectomy: A single centered, randomised, double-blinded, placebo-controlled, phase II study comparing the use of paracervical block verses placebo

Lead researchers:

- Dr Pippa Robertson
- Dr Jade Acton
- Dr Stuart Salfinger

A hysterectomy is a commonly performed operation with 1 in 800 Australians undergoing the procedure each year. Postoperative pain management is an important aspect of patient care that is shown to have a significant impact on patients' quality of life. Recovery after surgery is important as suboptimal recovery may have a negative effect on physical, emotional, and social wellbeing. Pre-emptive local anaesthetic used prior to vaginal hysterectomy has been demonstrated to

reduce pain scores postoperatively. No trials have investigated the effect of injecting local anaesthetic around the cervix - known as a paracervical local anaesthetic block - at total laparoscopic hysterectomy. We aim to investigate whether a paracervical block with the local anaesthetic bupivacaine prior to incision at total laparoscopic hysterectomy improves patients' quality of recovery compared to the standard of care.



PROJECT 2

PRiMeD - A four arm, multi-centered, randomised, blinded, placebo-controlled phase 2 study in gynaecological patients undergoing a total laparoscopic hysterectomy comparing Pulmonary Recruitment Maneuver with closed Drainage vs. closed drainage vs. pulmonary recruitment vs. placebo in reducing shoulder tip pain.

Lead researchers:

- *Dr Ganendra Raj Mohan*

This study is comparing different techniques for reducing the incidence of shoulder tip pain after total laparoscopy hysterectomy. Shoulder tip pain occurs commonly after the procedure, may be mild or severe and can last up to 72 hours. The exact cause is unknown, although it is suspected that the carbon dioxide (CO₂) gas that is introduced into the abdomen to allow laparoscopic surgery to be performed safely may be the cause.

We believe that combining two techniques (closed drainage and the pulmonary recruitment manoeuvre)

after surgery may allow CO₂ gas to be removed more effectively from the abdomen and allow patients to experience less shoulder tip pain than if these techniques are used on their own. The primary outcome measure of the study is shoulder tip pain at 24 to 36 hours post-surgery. Patients are currently being enrolled at hospitals in Perth and 48 participants have been recruited. St John of God Subiaco Hospital is the lead site and study sponsor. The study is funded by a grant from the Australasian Gynaecological and Endoscopy Surgery Society (AGES).



Top publications in 2021/22

1. Delahunty, R., Craig, S., Creighton, B., Ariyaratne, D., Garsed, D. W., Christie, E., Fereday, S., Andrews, L., Lewis, A., Limb, S., Pandey, A., Hendley, J., Traficante, N., Carvajal, N., Spurdle, A. B., Thompson, B., Parsons, M. T., Beshay, V., Volcheck, M., ... Alsop, K. TRACEBACK: Testing of Historical Tubo-Ovarian Cancer Patients for Hereditary Risk Genes as a Cancer Prevention Strategy in Family Members: *Journal of Clinical Oncology*. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology* 2022, 40(8), JCO.21.02108. <https://doi.org/10.1200/JCO.21.02108>
2. COVIDSurg Collaborative. Effect of COVID-19 pandemic lockdowns on planned cancer surgery for 15 tumour types in 61 countries: an international, prospective, cohort study. *The Lancet. Oncology* 2021, 22(11), 1507-1517. [https://doi.org/10.1016/S1470-2045\(21\)00493-9](https://doi.org/10.1016/S1470-2045(21)00493-9)
3. Woopen, H., Sehouli, J., Davis, A., Lee, Y. C., Cohen, P. A., Ferrero, A., Gleeson, N., Jhingran, A., Kajimoto, Y., Mayadev, J., Barretina-Ginesta, M. P., Sundar, S., Suzuki, N., van Dorst, E., & Joly, F. GCIG-Consensus Guideline for Long-term survivorship in Gynecologic Cancer: a position paper from the Gynecologic Cancer Intergroup (GCIG) symptom benefit committee. *Cancer Treatment Reviews* 2022, [102396]. <https://doi.org/10.1016/j.ctrv.2022.102396>

Inflammatory Bowel Disease Research Group



Prof Ian Lawrence
Gastroenterologist

Key research areas:

- Ulcerative colitis
- Crohn's Disease



Overview

Inflammatory bowel disease (IBD) are known as the series of chronic inflammatory disorders that affect the bowel. This includes Crohn's disease (CD) and Ulcerative Colitis (UC) that may have its onset at any stage of life. The incidence of each disease continues to have a marked increase in many countries and different populations.

As the prevalence of patients suffering from these diseases is on the rise, treatments that modify the immune and inflammatory processes of an individual are in greater demand. Due to the severity and symptom management of IBD varying in each patient, what has worked for one before may not necessarily work for another.

These circumstances steer the approach to test fresh and unconventional IBD treatments that bring efficacy, whilst maintaining patient safety and allowing patients to achieve long-term remission both clinically, endoscopically and histologically.

Contact

Telephone: (08) 9382 6205
Email: ibd@sjog.org.au

Highlight

St John of God Subiaco Hospital cares for over 1,000 patients with IBD who are managed by multiple gastroenterologists and the highly qualified IBD team. There are currently four active clinical trials at St John of God Subiaco Hospital - two are for UC patients and two are for Crohn's disease patients.

St John of God Subiaco Hospital was also the first site in Australia to recruit a participant to the UC study, Quasar CNT01959UC03001. This participant continues to be active in the study and is the first one to go ahead in the long-term extension of the study.

PROJECT 1

AURORA Study - an Australia multicentre, prospective observational cohort study to evaluate the real-life experience of Ustekinumab in patients with moderate to severe Crohn's disease

Lead researcher:

- Prof Ian Lawrence

Ustekinumab is a human monoclonal antibody, which targets IL-12/23 pathways in order to treat patients with moderate to severe Crohn's disease. This can be, when other biological agents, such as anti-TNF antagonists or anti-integrin medication has failed or patients have become refractory to them. Ustekinumab can be used to optimize disease control and induce clinical, endoscopic and histological remission.

This observational study looked at clinical remission at 3 and 12 months, defined by CDAI<150 and assessing steroid-free response and remission rates at 3,9,15 and 27 months as well as endoscopic remission, intestinal imaging and histological improvement. We have currently four patients enrolled to this study.

PROJECT 2

ENTYVIO® Real-World Outcomes in Bio-naïve Crohn's Disease Patients in Belgium, Australia, and Switzerland: An EVOLVE Observational Expansion Study

Lead researcher:

- Prof Ian Lawrence

This study compares biologic-naïve Crohn's disease patients who received first line Vedolizumab (VDZ) with those receiving Ustekinumab (UST) long-term (up to 36 months) observing clinical remission, post treatment initiation. Both are biological agents that work differently on the body's immune response. This study compared patients regarding early remission at weeks 6, 10 and 14 and long term clinical response and mucosal healing post-treatment initiation. Safety outcomes (adverse events, serious adverse events and serious

infection) were compared and Crohn's related hospitalisations.

Clinical remission was evaluated by assessing disease activity Simple Endoscopic Score for Crohn's disease (SES-CD), Crohn's disease activity Index (CDAI) and Harvey Bradshaw Index (HBI).

Laboratory assessment and endoscopic assessments were carried out in order to determine which treatment will be more effective for each patient's disease severity.

PROJECT 3

QUASAR: A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis

Lead researcher:

- Prof Ian Lawrance

There is a high, currently unmet, need for new treatment options in Ulcerative Colitis (UC) that are safe, effective and can provide improved long-term efficacy (ie, sustained remission) over currently available therapies. The Phase 2B/3 clinical development program for Guselkumab in UC will evaluate the safety and efficacy of Guselkumab compared with placebo and will be conducted under a single protocol.

Under this single protocol, the following studies will be analysed as 3 separate studies. A Phase 2B induction dose ranging study (Induction Study 1), a Phase 3 induction study (Induction Study 2), and a Phase 3 randomised maintenance study (Maintenance Study). Maintenance participants that have been responding well to treatment have the option to continue with a Long term Extension Study.

Top publications in 2021/22

1. Mashtoub, S., Chartier, L. C., Trinder, D., Lawrance, I. C., & Howarth, G. S. (2022). Emu oil attenuates disease severity and results in fewer large colonic tumors in a mouse model of colitis-associated colorectal cancer. *Nutrition and Cancer*, 74(2), 715-723. <https://doi.org/10.1080/01635581.2021.1909737>
2. Grosse, C., Christophersen, C., Thin, L., Lightowler, D., Lo, J., Devine, A., & Lawrance, I. (2021). A lacto-ovo vegetarian diet in patients with mild to moderate ulcerative colitis improves clinical response: A pilot study. *Journal of Gastroenterology and Hepatology (Australia)*, Supp 3.

Intensive Care Research Group



A/Prof Ed Litton

Clinical Research Fellow,
Staff Specialist Intensive
Care Medicine



Prof Steve Webb

Director Clinical Trials,
Senior Staff Specialist
Intensive Care Medicine,
Chair Research
Management Committee

Key research areas:

The ICU Research Group is involved in a range of quality improvement and research projects. We support Medical Students and Junior Doctors to conduct audits, lead observational and interventional studies, single site initiated studies at St John of God Subiaco Hospital, and contribute to large, national and international investigator-initiated studies.

Key Research Areas for Intensive Care Medicine are improving outcomes for patients undergoing cardiothoracic surgery, reducing the incidence and severity of delirium, measuring and reporting on patient experiences and outcomes, embedding research in Clinical Quality Registries, and the treatment of Community Acquired Pneumonia and COVID-19 related pneumonia.

Consultant Intensivists

- A/Prof Kwok Ho
- A/Prof Ed Litton
Research Fellow and Consultant
Intensivist
- Dr John Lewis
Head of Department ICU and
Consultant Intensivist
- Prof Steve Webb
Director of Clinical Trials St John
of God Healthcare Subiaco and
Consultant Intensivist

Research Officers

- Janet Ferrier RN
- Lesley Kemp RN

Overview

The COVID-19 pandemic remains a major focus of the ICU research group. Group members have led research on the national ICU resources available to meet the needs of critically ill patients in a pandemic, and also the characteristics and outcomes of Australians with severe COVID over the course of the pandemic, as new treatments have been introduced and new challenges have emerged.

The ICU Research Group is also involved in REMAP-CAP, led by Prof Steve Webb as the Principal investigator. This is a highly successful international adaptive randomised controlled trial recently awarded the Australian Clinical

Trials Alliance (ACTA) Trial of the Year Award. The trial continues to generate pivotal evidence of treatments to improve outcomes for critically ill patients with COVID-19, with findings that have been translated into practice and policy worldwide. REMAP-CAP currently recruits in over 361 sites in 25 countries and has recruited over 10,000 patients with suspected or proven COVID-19 infection.

Beyond COVID-19, the group was successful in acquiring national funding to lead a clinical trial designed to improve outcomes for patients undergoing cardiac surgery (NOTACS).

As the transition to living with COVID-19 continues, these and other studies will ensure that we continue to improve outcomes for all our patients.



Highlights from REMAP-CAP

A/Prof Edward Litton was awarded the Premier's **Early Career Researcher of the Year Award 2021**, in part for his contribution to ICU COVID-19 research.

The Premier's Awards are a keystone in the Western Australian government's efforts to raise the profile of science, technology, engineering and mathematics (STEM) in Western Australia. Over the years, Awards alumni have become important ambassadors for the state, helping to inspire future generations to take up courses and careers in STEM. The Awards cover all fields of science, including natural, medical, applied and technological science, engineering and mathematics.

A/Prof Ed Litton's contribution to the COVID-19 response includes developing and helping to implement a large international clinical trial that has identified effective treatments for severe COVID-19 (the REMAP-CAP Trial), leading a study to inform Australian intensive care COVID-19 preparedness, surge capacity, and evaluating, reporting, and feeding back Australian intensive care COVID-19 outcomes. His research findings have been incorporated into international guidelines, informing intensive care policy and practice, and helping to improve outcomes for more than 10,000 Western Australians who require intensive care treatment each year.

www.youtube.com/watch?v=3Pby50tih2E

REMAP-CAP trial was awarded the Australian Clinical Trials Alliance (ACTA) Trial of the Year Award at the ACTA National Tribute and Awards Ceremony held in May 2022.

The REMAP-CAP trial was also the Runner-up in the Excellence in Trials Statistic Award. These awards were established to celebrate outstanding achievements that advance clinical practice that save or improve the lives of Australians

MRFF Grant

Medical Research Future Fund grant \$1.39m led by A/Prof Litton for a trial of Nasal High Flow Oxygen as a prophylactic intervention to reduce complications in high-risk patients who have undergone cardiac surgery.

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Publications



Studies in 2021/22

1. NOTACS - Effect of Nasal High-Flow oxygen on Patient-Centred Outcomes in Patients at High Risk of Postoperative Pulmonary Complications after Cardiac Surgery: An International Multicentre Randomised Controlled Trial
2. SPICE IV – Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated critically Ill Patients: A Prospective, Multi-centre, Double-Blind, Randomized Controlled Trial
3. BONEZONE - Bone Loss Prevention with Zoledronic Acid or Denosumab in Critically Ill Women – A Randomised Controlled Trial
4. REMAP-CAP - Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia
5. ESO-DICE - A Randomised Controlled Feasibility Study for the Efficacy and Safety Outcomes of Drainage of Pleural Effusions in the intensive care unit
6. PPP - Point Prevalence Program, a bi-national observational study of ICU practice and outcomes conducted in 50+ ICUs
7. EUROBACT II – Publication is pending for the completed international multicentre observational study of critically ill patients with hospital-acquired blood stream infection
8. FASTTRACK – this ongoing research is a collaboration with the Australian and New Zealand Society of Thoracic Surgeons (ANZSTS) Database Program investigating the current use and capacity of cardiac surgical units to decrease patient time in ICU
9. The ICU also contributes and collaborates with the Australian and New Zealand Intensive Care Society (ANZICS) Centre for Outcomes and Research Evaluation
10. CHESTY - Publication is pending for the completed CHESTY project (Chest infection prevalence following surgery)
11. PROMEDIC –A randomised blinded placebo controlled trial of melatonin in Intensive Care patients for the prevention of delirium. The trial completed and was published in February 2022
12. Intensive Care CONSUMER RESEARCH Survey Questionnaire – the survey was conducted to ascertain the beliefs and attitudes regarding health outcomes after ICU (intensive care unit) admission. The survey also assessed the willingness of patients to participate in clinical trials. The publication is pending



PROJECT 1

NOTACS : Effect of Nasal High-Flow Oxygen Therapy on Patient-Centred Outcomes in Patients at High Risk of Postoperative Pulmonary Complications After Cardiac Surgery: An International Multicentre Randomised Controlled Trial.

Lead researcher:

- A/Prof Ed Litton

Enhanced recovery after cardiac surgery is an emerging and important concept in perioperative care, designed to reduce complications, hospital stay and health service and resource use.

Patients undergoing cardiac surgery are at significant risk of postoperative pulmonary complications that may lead to prolonged intensive care unit and hospital stay and increase mortality. The incidence of respiratory complications may be three to four times more common in patients with pre-existing respiratory disease such as asthma or chronic obstructive pulmonary disease (COPD), or obese patients or current heavy smokers. These patients often develop lower respiratory tract infections, with impaired oxygenation/ventilation. They are more likely to require escalation of respiratory support and re-admission to intensive care unit during recovery from surgery.

Nasal high-flow oxygen (NHFO) therapy is increasingly used as a non-invasive form of respiratory support. It delivers low level, flow-dependent positive airway pressure, and is much better tolerated by patients than alternatives such as continuous positive airway pressure (CPAP) or non-invasive ventilation. Patients can talk, eat, drink and walk whilst using NHFO. However, there is equipoise regarding its prophylactic use and effect on important patient-centred outcomes, hence the rationale for this trial. Before the intervention is recommended for routine use in cardiac surgery patients at high risk of pulmonary complications, whether it improves patient-related outcomes and is cost effective needs to be assessed.

If evidence is generated to support the routine use of NHFO, this will inform the development of effective enhanced recovery care bundles after cardiac surgery.

PROJECT 2

REMAP-CAP: Randomised, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

Lead researcher:

- Prof Steve Webb

CAP is a syndrome in which acute infection of the lungs develops in persons who have neither been hospitalised recently nor had regular exposure to the healthcare system. (1) A wide range of microorganisms are capable of causing pneumonia, but bacteria and viruses are responsible for the vast majority of cases where a cause is identified. Severe CAP is defined as pneumonia of sufficient severity to be an immediate threat to life.

Severe CAP is common, case fatality is high, the strength of current evidence is limited, and there is evidence of substantial variation in existing standard care. The combination of these factors provides a strong rationale for the need for better quality evidence about the impact of the different treatment options that are in existing practice, the impact of different combinations of treatment options, and the timely and effective evaluation of new candidate interventions to improve outcomes.

The objective of REMAP-CAP is also to generate evidence that can be applied to clinical practice during the pandemic, regarding the impact of multiple candidate interventions, to reduce mortality or reduce the length of ICU admission or both in critically ill patients with COVID-19 infection.

Top publications in 2021/22

1. Litton, E., Huckson, S., Chavan, S., Bucci, T., Holley, A., Everest, E., Kelly, S., McGloughlin, S., Millar, J., Nguyen, N., Nicholls, M., Secombe, P., & Pilcher, D. (2021). Increasing ICU capacity to accommodate higher demand during the COVID-19 pandemic. *The Medical journal of Australia*, 215(11), 513–517. <https://doi.org/10.5694/mja2.51318>
2. Writing Committee for the REMAP-CAP Investigators, Estcourt, L. J., Turgeon, A. F., McQuilten, Z. K., McVerry, B. J., Al-Beidh, F., Annane, D., Arabi, Y. M., Arnold, D. M., Beane, A., Bégin, P., van Bentum-Puijk, W., Berry, L. R., Bhimani, Z., Birchall, J. E., Bonten, M., Bradbury, C. A., Brunkhorst, F. M., Buxton, M., Callum, J. L., ... Shankar-Hari, M. (2021). Effect of Convalescent Plasma on Organ Support-Free Days in Critically Ill Patients With COVID-19: A Randomized Clinical Trial. *JAMA*, 326(17), 1690–1702. <https://doi.org/10.1001/jama.2021.18178>
3. Webb, S. A., Higgins, A. M., & McArthur, C. J. (2021). Glucocorticoid Dose in COVID-19: Lessons for Clinical Trials During a Pandemic. *JAMA*, 326(18), 1801–1802. <https://doi.org/10.1001/jama.2021.164388>
4. Wibrow, B., Martinez, F. E., Myers, E., Chapman, A., Litton, E., Ho, K. M., Regli, A., Hawkins, D., Ford, A., van Haren, F., Wyer, S., McCaffrey, J., Rashid, A., Keltly, E., Murray, K., & Anstey, M. (2022). Prophylactic melatonin for delirium in intensive care (Pro-MEDIC): a randomized controlled trial. *Intensive care medicine*, 48(4), 414–425. <https://doi.org/10.1007/s00134-022-06638-9>
5. Investigators R-CWCftr-C, Bradbury CA, Lawler PR, et al. Effect of Antiplatelet Therapy on Survival and Organ Support-Free Days in Critically Ill Patients With COVID-19: A Randomized Clinical Trial. *JAMA*, 327(13), 1247–1259. <https://doi.org/10.1001/jama.2022.2910>



Medical Oncology Services Research Group

Key research areas:

Pancreatic, Melanoma, Gynaecological, Breast, Upper Gastro-intestinal, Lung, Prostate, Colorectal and Renal Cancers

Overview

The Subiaco Hospital Clinical Trial Unit has strong record in the delivery and conduct of oncology clinical trials primarily in the areas of pancreatic, ovarian, melanoma, endometrial, cervical, breast, upper GI, lung, prostate and renal cancer. The Unit is committed to providing research-based healthcare to patients at St John of God Subiaco by conducting clinical trials to investigate new treatments and interventions from early to late phase; with a strong focus on areas with unmet need, and an ongoing commitment to patient safety.

The Unit currently has 54 active clinical trials which are comprised of commercially sponsored trials and cooperative research group trials. The Unit continues to collaborate with a number of national and international groups including the Australia New Zealand Gynaecological Oncology Group (ANZGOG), Australasian Gastro-Intestinal Cancer Trials Group (AGITG), Thoracic Oncology Group of Australasia (TOGA), Breast Cancer Trials (BCT) and the NHMRC Clinical Trials Centre.

As with other clinical centres the COVID-19 pandemic has created a need for rapid and marked adjustments in service delivery due to the risk of viral spread. With ongoing restrictions we have had to revise the way in which we operate to minimise the potential rate of transmission of the virus between patients, visitors and caregivers.

Despite the challenging environment, our Site Investigators, together with Clinical, Pharmacy, Laboratory, Data and Study Coordinator teams, have demonstrated a steadfast commitment to continue to operate our trials portfolio in a professional and efficient manner, to ensure that patients can continue to access essential treatment and that critical data continues to be collected and monitored by trial sponsors. This continuing site activity including patient recruitment, managing trials in follow up, initiating new trials and continuing activity around feasibility of future studies for our site reflects our organisational commitment to research-based health care.

10
Clinical trials opened to recruitment 2021/22



57 Active clinical trials

Project highlights

Destiny-Breast12

Recruitment to the confirmatory phase III trials has been completed. Results are awaited pending the maturation of the data. St John of God Subiaco participated in these studies (Trastuzumab DxD vs Trastuzumab emtansine in 2L and Trastuzumab DxD vs SOC in 3L).

Outcomes from the phase II Destiny Breast 01 study showed a substantial progression free survival duration of 16.4 months in the overall population of 253 patients with a median of six prior lines of therapy. This is substantially better than current third line standard of care (eg capecitabine/trastuzumab mPFS 8.2 months; capecitabine/lapatinib 8.4 months). Thus, it is anticipated that the confirmatory phase III study will show a significant benefit given the historical performance of control arms. The ongoing phase 3b/4 Destiny-Breast 12 study will allow West Australian patients treatment with an agent that is unlikely to be on the PBS for sometimes and is not commercially available and in a setting where the evidence for other available regimens is limited.

NAPOLI-3

St John of God Subiaco Hospital was the highest ranking recruitment site in Australia.

RELOCATION OF DEPARTMENT

After months of investigation for suitable premises the St John of God Subiaco Research & Clinical Trials Unit has relocated our Administration and Patient Consultation Rooms.

The new Patient Rooms include a reception and waiting area for patients; in addition to 2 larger consultation rooms fully equipped with all medical equipment. This area is readily accessible by the hospital clinicians, consultants and patients.

The Clinical Trials Unit and Administration Office area includes a reception, administration offices and boardroom as well individual work spaces for our Clinical Trial Data Management Teams. A secure storage area for Study specific Investigator Site Files and participant clinical trial records, and two self-contained workstations for Sponsors and CRAs for onsite monitoring ensures optimal efficiency in this new work space.

Contact

Telephone: (08) 6465 9204
Email: clinicaltrials.subiaco@sjog.org.au

Top publications in 2021/22

- Majem, M., Felip, E., Doger, B., Akay, M., Carcereny, E., Clay, T., Krebs, M., Peguero, J., & Triebel, F. (2020). 1266P Initial results from a phase II study (TACTI-002) of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients with PD-L1 unselected first-line metastatic non-small cell lung carcinoma. *Annals of Oncology*, 31, S818. <https://doi.org/10.1016/j.annonc.2020.08.1580>
- Oza, A. M., Lorusso, D., Aghajanian, C., Oaknin, A., Dean, A., Colombo, N., Weberpals, J. I., Clamp, A. R., Scambia, G., Leary, A., Holloway, R. W., Gancedo, M. A., Fong, P. C., Goh, J. C., O'Malley, D. M., Armstrong, D. K., Banerjee, S., Garcia-Donas, J., Swisher, E. M., Cella, D., ... Coleman, R. L. (2020). Patient-Centered Outcomes in ARIEL3, a Phase III, Randomized, Placebo-Controlled Trial of Rucaparib Maintenance Treatment in Patients With Recurrent Ovarian Carcinoma. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, 38(30), 3494–3505. <https://doi.org/10.1200/JCO.19.03107>
- Dean, A. P., Mulligan, F., Kelly, G., Shaughnessy, E., & Wilson, K. (2021). Updated single institution outcome data from the first-in-human CEND-1 trial in metastatic pancreatic cancer. *Journal of Clinical Oncology*, 39(15_suppl), e16274. https://doi.org/10.1200/jco.2021.39.15_suppl.e16274
- Marsavela, G., Johansson, P. A., Pereira, M. R., McEvoy, A. C., Reid, A. L., Robinson, C., Warburton, L., Khattak, M. A., Meniawy, T. M., Amanuel, B., Millward, M., Hayward, N. K., Ziman, M. R., Gray, E. S., & Calopre, L. (2020). The Prognostic Impact of Circulating Tumour DNA in Melanoma Patients Treated with Systemic Therapies—Beyond BRAF Mutant Detection. *Cancers*, 12(12), 3793. <https://doi.org/10.3390/cancers12123793>
- Brendel K, Bekaii-Saab T, Boland PM, Dayyani F, Dean A, Macarulla T, Maxwell F, Mody K, Pedret-Dunn A, Wainberg ZA, Zhang B. Population pharmacokinetics of liposomal irinotecan in patients with cancer and exposure-safety analyses in patients with metastatic pancreatic cancer. *CPT Pharmacometrics Syst Pharmacol*. 2021 Dec;10(12):1550-1563. <https://doi.org/10.1002/psp4.12725>
- Wainberg ZA, Bekaii-Saab T, Boland PM, Dayyani F, Macarulla T, Mody K, Belanger B, Maxwell F, Moore Y, Thiagalingam A, Wang T, Zhang B, Dean A. First-line liposomal irinotecan with oxaliplatin, 5-fluorouracil and leucovorin (NALIRIFOX) in pancreatic ductal adenocarcinoma: A phase I/II study. *Eur J Cancer*. 2021 Jul;151:14-24. <https://doi.org/10.1016/j.ejca.2021.03.028>



Oncology Research Group

Oncology Clinical Trials Opened to Recruitment FY21/22 (9)

A Global, Phase 2 Study of ARX788 in HER2-positive, Metastatic Breast Cancer Patients whose Disease is Resistant or Refractory to T-DM1, and/or T-DXd, and/or Tucatinib-containing Regimens (ACE BREAST 03)

Principal Investigator: Dr Daphne Tsoi
Opened to recruitment February 2022

An Open-Label, Multinational, Multicenter, Phase 3b/4 Study of Trastuzumab Deruxtecan in Patients With or Without Baseline Brain Metastasis With Previously Treated Advanced/Metastatic HER2-Positive Breast Cancer (DESTINY BREAST 12)

Principal Investigator: A/Prof Tim Clay
Opened to recruitment February 2022

A Phase 1b/2, Protocol Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Sotorasib Monotherapy and in Combination With Other Anti-cancer Therapies in Subjects With Advanced Solid Tumours With KRAS p.G12C Mutation (CODEBREAK 101)

Principal Investigator: A/Prof Tim Clay
Opened to recruitment February 2022

A Randomised, Double-Blinded Phase 2 Study of Gemcitabine and Nab-Paclitaxel with CEND-1 or Placebo in Patients with Untreated Metastatic Pancreatic Ductal Adenocarcinoma (ASCEND)

Principal Investigator: Dr Andrew Dean
Opened to recruitment March 2022

A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Paclitaxel With or Without Bevacizumab for the Treatment of Platinum-Resistant Recurrent Ovarian Cancer (MK-3475-B96)

Principal Investigator : Dr Andrew Dean
Opened to recruitment June 2022

A Phase 3 Randomized, Open-label, Active-comparator Controlled Clinical Study of Pembrolizumab vs. Platinum Doublet Chemotherapy in Participants with Mismatch Repair Deficient (dMMR) Advanced or Recurrent Endometrial Carcinoma in the First-line Setting (MK3475-C93)

Principal Investigator: Dr Tarek Meniawy
Opened to recruitment June 2022

A Phase 1b/2a Study Investigating ATX-101 in Combination with Platinum-based Chemotherapy in Platinum-Sensitive, Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (ATX101-03)

Principal Investigator : Dr Tarek Meniawy Opened to recruitment May 2022

A Study of Coformulated Favezelimab/Pembrolizumab (MK-4280A) Versus Standard of Care in Patients with Previously Treated Metastatic PD-L1 Positive Colorectal Cancer (MK-4280A-007)

Principal Investigator: Dr Andrew Dean
Opened to recruitment December 2021

Study of Telisotuzumab Vedotin (ABBV-399) in Participants with Previously Treated c-MET+ Non-Small Cell Lung Cancer (M14-239)

Principal Investigator: A/Prof Tim Clay
Opened to recruitment December 2021

Cardiology Clinical Trials Opened to Recruitment FY21/22 (1)

A Study of Vericiguat (MK-1242) in Participants with Chronic Heart Failure with Reduced Ejection Fraction (MK-1242-035 VICTOR)

Principal Investigator: Dr Brendan McQuillan
Opened to recruitment March 2022



Oncology Active Studies FY 21/22 (13)

Pattern of use and safety/effectiveness of Nivolumab in routine oncology practice (NIVOPASS)

Principal Investigator: A/Prof Tim Clay

Opened to recruitment October 2017

A multicentre Phase 2, open-label trial of intratumoral pIL-12 plus electroporation in combination with intravenous Pembrolizumab in patients with stage III/IV melanoma who are progressing on either Pembrolizumab or Nivolumab treatment (PISCES)

Principal Investigator: Dr Tom van Hagen

Opened to recruitment October 2017

A phase 3, multicenter, randomized, open-label, active-controlled study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy (DESTINY-Breast 05)

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment April 2021

A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC) (AMPLITUDE)

Principal Investigator: A/Prof Tim Clay

Opened to recruitment May 2021

A Phase II Randomised Study to Evaluate Alpelisib plus Fulvestrant versus Capecitabine in Oestrogen Receptor Positive, HER2-Negative Advanced Breast Cancer Patients with PIK3CA Mutant Circulating DNA (CAPTURE)

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment October 2020

A Phase III, Randomised, Double-Blind, Placebo-Controlled Study of Atezolizumab with or Without Tiragolumab (Anti-Tigit Antibody) in Patients with Unresectable Locally Advanced Oesophageal Squamous Cell Carcinoma (SKYSCRAPER 07)

Principal Investigator: Dr Andrew Dean

Opened to recruitment November 2020

A Randomised Phase III Open Label Study of regorafenib + nivolumab vs standard chemotherapy in Refractory Advanced Gastro-Oesophageal Cancer (INTEGRATE IIB)

Principal Investigator: Dr Tom van Hagen

Opened to recruitment May 2021

A Phase 2 Basket Study of the Oral TRK Inhibitor larotrectinib in Subjects with NTRK Fusion-Positive Tumours (NAVIGATE)

Principal Investigator: Dr Andrew Dean

Opened to recruitment March 2021

A Multicenter, Double-Blind, Randomized Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintilimab versus Placebo in Combination with Chemotherapy for First-Line Treatment for Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15)

Principal Investigator: Dr Andrew Dean

Opened to recruitment October 2020

A Phase II safety and efficacy study of tiragolumab plus atezolizumab and atezolizumab monotherapy in patients with metastatic and/or recurrent PD-L1-Positive cervical cancer (SKYSCRAPER-04)

Principal Investigator: Dr Andrew Dean

Opened to recruitment August 2020

A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy with or without Pembrolizumab for the Treatment of High-risk, Locally Advanced Cervical Cancer (KEYNOTE-A18)

Principal Investigator: Dr Andrew Dean

Opened to recruitment March 2021

A Multicenter, Open-label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants with Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial (KEYNOTE 587)

Principal Investigator: Dr Andrew Dean

Opened to recruitment April 2021

Phase 3 Multicenter, Open-Label, Randomized, Controlled Study of Oral Infigratinib versus Gemcitabine with Cisplatin in Subjects with Advanced/Metastatic or Inoperable Cholangiocarcinoma with FGFR2 Gene Fusions/Translocations (PROOF)

Principal Investigator: Dr Andrew Dean

Opened to recruitment December 2019

Breast Cancer Research Unit – Active Study

Studying the Effect of Denosumab on Preventing Breast Cancer in Women with BRCA1 Germline Mutation (BRCA-P)

Principal Investigator: Dr Helen Ballal

Open to recruitment

Oncology Studies Closed to Recruitment with Active Patients (13)

A Phase 2 Randomized Study of Adjuvant Immunotherapy with the Personalized Cancer Vaccine mRNA-4157 and Pembrolizumab versus Pembrolizumab Alone After Complete Resection of High-Risk Melanoma (mRNA-4157-P201)

Principal Investigator: Dr Tarek Meniawy

Closed to recruitment

A Phase 2, Open-Label, Multicentre, Randomised study of the efficacy and safety of R07198457 in combination with pembrolizumab versus pembrolizumab in patients with Previously Untreated Melanoma (G040558)

Principal Investigator: Dr Tarek Meniawy

Closed to recruitment

A Randomized, Double-Blind, Controlled Phase 3 Study of Cabozantinib in Combination with Nivolumab and Ipilimumab versus Nivolumab and Ipilimumab in Subjects with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma of Intermediate or Poor Risk (COSMIC-313)

Principal Investigator: A/Prof Tim Clay

Closed to recruitment

A Phase III, single arm study of Mirvetuximab Soravtansine in patients with platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor alpha expression (SORAYA)

Principal Investigator: Dr Andrew Dean

Closed to recruitment

A multicentre, open label, Phase 2 study in patients with previously untreated unresectable or metastatic non-small cell lung cancer (NSCLC) or recurrent PD-X refractory NSCLC or with recurrent or metastatic squamous head and neck cancer (HNSCC) receiving the soluble LAG-3 fusion protein Eftilagimod alpha (IMP321) in combination with Pembrolizumab (PD-1 antagonist) (TACTI-002)

Principal Investigator: A/Prof Tim Clay

Closed to recruitment

A Phase 3, multicentre, randomized, open-label, active-controlled study of DS-8201a, an anti-HER2-antibody drug conjugate, versus treatment of investigator's choice for HER2-positive, unresectable and/or metastatic breast cancer subjects pre-treated with prior standard of care HER2 therapies, including T-DMI (DESTINY 2)

Principal Investigator: Dr Daphne Tsoi

Closed to recruitment

A randomized, double-blind, placebo-controlled, Phase 3 study of Fulvestrant with or without Abemaciclib, a CDK4/6 inhibitor, for women with hormone receptor positive, HER2 negative locally advanced or metastatic breast cancer (MONARCH2)

Principal Investigator: Dr Daphne Tsoi

Closed to recruitment

A randomized, open-label, Phase 3 Study of Abemaciclib combined with standard adjuvant endocrine therapy versus standard endocrine therapy alone in patients with high risk, node positive, early stage hormone receptor positive, HER2 negative breast cancer (MONARCH E)

Principal Investigator: Dr Daphne Tsoi

Closed to recruitment

Aspirin for Dukes C and high-risk Dukes B colorectal cancers: an international, multicentre, double-blind, randomized placebo-controlled Phase 3 Trial (ASCOLT)

Principal Investigator: Dr Tom van Hagen

Closed to recruitment

A multicentre, randomised, open-label Phase 3 study of Rucaparib versus physician's choice of therapy for patients with metastatic castration-resistant prostate cancer associated with homologous recombination deficiency (TRITON 3)

Principal Investigator: A/Prof Tim Clay

Closed to recruitment

Phase 1/1b Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Anti-TIGIT Monoclonal Antibody BGB-A1217 in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab (BGB-A317) in Patients with Unresectable Locally Advanced or Metastatic Solid Tumors (Lung cancer) (BGB-900-105)

Principal Investigator: A/Prof Tim Clay

Closed to recruitment



A randomized, multicentre, double-blind, placebo-controlled, phase III study of first line carboplatin and paclitaxel in combination with Durvalumab, followed by maintenance Durvalumab with or without Olaparib in patients with newly diagnosed advanced or recurrent endometrial cancer (DUO-E)

Principal Investigator: Dr Tarek Meniawy
Closed to recruitment

A Multicentre, Double-Blind, Randomized Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination With Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Oesophageal Squamous Cell Carcinoma (ORIENT 15)

Principal Investigator: A/Prof Tim Clay
Opened to recruitment October 2020

Closed to Recruitment – Patients in Follow-Up (16)

An open-label, randomised, multicentre, phase III study of Irinotecan liposome injection, Oxaliplatin, 5-fluorouracil/Leucovorin versus Nab-paclitaxel plus Gemcitabine in subjects who have not previously received chemotherapy for metastatic adenocarcinoma of the pancreas (NAPOLI-3)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A multicentre, randomized, double-blind, placebo-controlled Phase 3 study in ovarian cancer patients evaluating Rucaparib and Nivolumab as Maintenance treatment following response to front-line platinum-based chemotherapy (ATHENA)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 3, Multicentre, open-label, randomized study of nab-Paclitaxel plus Gemcitabine versus Gemcitabine alone as adjuvant therapy in subject with surgically

resected pancreatic adenocarcinoma (APACT)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 2 Study of Durvalumab and Tremelimumab In combination with neoadjuvant Carboplatin and paclitaxel in newly diagnosed women with advanced high-grade serous ovarian, fallopian tube and peritoneal cancers (iPRIME)

Principal Investigator: Dr Tarek Meniawy
Closed to recruitment

A multicentre, randomized, double-blind, placebo-controlled Phase 3 study of Rucaparib as switch maintenance following platinum-based chemotherapy in patients with platinum-sensitive, high-grade serous or endometrioid epithelial ovarian, primary peritoneal or fallopian tube cancer (ARIEL3)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A multicentre, open-label, randomized, Phase 3 trial to compare the efficacy and safety of Lenvatinib in combination with Pembrolizumab versus treatment of physician's choice in participants with advanced endometrial cancer (KEYNOTE 775)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 3 randomized, double-blind, placebo-controlled trial of Pembrolizumab plus chemotherapy versus chemotherapy plus placebo for the first-line treatment of persistent recurrent or metastatic cervical cancer (KEYNOTE 826)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 3, multicentre, randomized, open-label, active-controlled study of DS-8201a, an anti-HER2-antibody drug conjugate, versus ado-Trastuzumab Emtansine (T-DM1) for HER2-positive, unresectable and/or metastatic breast cancer subjects previously treated

with trastuzumab and taxane (DESTINY 3)

Principal Investigator: Dr Daphne Tsoi
Closed to recruitment

A Phase 3 placebo-controlled study of Carboplatin/ Paclitaxel with or without concurrent and continuation maintenance Veliparib (PARP inhibitor) in subjects with previously untreated stages 3 or 4 high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer (VELIA)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

Phase 3 randomized study for the treatment of recurrent or metastatic platinum-refractory cervical carcinoma with a new Anti-PD-1 therapy (EMPOWER CERVICAL 1)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A randomized, open-label, multi-arm, two-part, phase II study to assess the efficacy and safety of multiple LXH254 combinations in patients with previously treated unresectable or metastatic BRAFV600 or NRAS mutant melanoma (CLXH254C12201)

Principal Investigator: Dr Tarek Meniawy
Closed to recruitment

A Phase 2, multicenter, randomized study of trastuzumab deruxtecan in subjects with HER2-mutated metastatic Non-Small Cell Lung Cancer (NSCLC) (DESTINY-Lung 02)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

A Phase 2 Randomized Open-Label Study of Patritumab Deruxtecan (U3-1402) in Subjects with Previously Treated Metastatic or Locally Advanced EGFR-mutated Non-Small Cell Lung Cancer (NSCLC) (HERTHENA-Lung 01)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

A Phase 3 prospective double-blind placebo controlled randomized study of adjuvant MEDI4736 in completely resected non-small cell lung cancer (BR.31)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

Phase 3 adjuvant chemotherapy with Gemcitabine and Cisplatin compared to standard of care after curative intent resection of cholangiocarcinoma and muscle invasive gallbladder carcinoma (ACTICCA-1)

Principal Investigator: Dr Andrew Dean
Closed to recruitment



A Non-interventional Biomarker Study on the Molecular Evaluation of Archival Tumor Tissue in Subjects with Non-Small Cell Lung Cancer (20190294)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

Inflammatory Bowel Disease - Closed to Recruitment with Active Patients

A Study of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis (QUASAR)

Principal Investigator: Dr Ian Lawrance
Closed to recruitment

Breast Cancer Research Unit Closed to Recruitment – Patients in Follow-Up
Psycho-oncological comparison study evaluating psychological distress, fertility concerns and decisional conflict in young women who participate in the Positive Study (POSITIVE)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

A randomised controlled trial of axillary treatment in Women with Early Stage Breast Cancer who have metastases in one of two sentinel nodes (POSNOG)

Principal Investigator: Dr Yvonne Zissiadis
Closed to recruitment

Oncology Studies - Closed Out (12)

A Phase 3, multicentre, randomized, placebo-controlled study of Atezolizumab (anti-PD-L1 antibody) in combination with nab-Paclitaxel compared with placebo with nab-Paclitaxel for patients with previously untreated metastatic triple negative breast cancer (IMPASSION 130)

Principal Investigator: Dr Daphne Tsoi
Closed to recruitment

A Phase 2 open-label, single-arm, multicentre study to evaluate efficacy and safety of Pembrolizumab monotherapy in subjects with advance recurrent ovarian cancer (KEYNOTE 100)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 3 Study of Pembrolizumab versus chemotherapy in microsatellite instability-high colorectal adenocarcinoma (KEYNOTE 177)

Principal Investigator: Dr Daphne Tsoi
Closed to recruitment

A randomized, open-label Phase 2 Study of Nanoliposomal Irinotecan (nal-IRI)-containing regimens versus nab-Paclitaxel plus Gemcitabine in patients with previously untreated, metastatic pancreatic adenocarcinoma (NAPOLI-2)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

An international Phase 3 randomized trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer (ICON8)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

A Phase 2, double-blind, randomized study of BGB-290 versus placebo as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer that responded to platinum-based first-line chemotherapy (PARALLEL)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

Phase 1B multi-indication study of Anetumab Ravtansine (BAY 94-9343) in patients with mesothelin expressing advanced or recurrent malignancies (BAYERS ARCS-MULTI)

Principal Investigators: Dr Andrew Dean
Closed to recruitment

A Phase 3, Double-Blind, Placebo-Controlled, Randomised Study of Ipatasertib in Combination with Atezolizumab and Paclitaxel as A Treatment for Patients with Locally Advanced Unresectable or Metastatic Triple-Negative Breast Cancer (IPAtunity 170)

Principal Investigator: Dr Daphne Tsoi
Closed to recruitment

A Phase 1b/2 multicenter open-label study of CS1001 in combination with Regorafenib in Patients with Advanced or Refractory Solid Tumours (C-Stone-Rego-101)

Principal Investigator: Dr Andrew Dean
Closed to recruitment

Randomized blinded Phase 3 assessment of second or third line chemotherapy with Docetaxel plus Plinabulin compared to Docetaxel alone plus placebo in patients with advanced non-small cell lung cancer with at least 1 large lung lesion (DUBLIN 3)

Principal Investigator: A/Prof Tim Clay
Closed to recruitment

A randomized Phase 3 double-blind placebo-controlled study of Regorafenib in refractory advanced oesophago-gastric cancer (INTEGRATE II)

Principal Investigator: Dr Tom van Hagen
Closed to recruitment

A Phase 3 randomized, double-blind study of adjuvant immunotherapy Nivolumab combined with Ipilimumab versus Ipilimumab or Nivolumab monotherapy after complete resection of Stage 3b/c/d or stage 4 Melanoma in subjects who are at high risk of recurrence (CHECKMATE-915)

Principal Investigator: Dr Tom van Hagen
Closed to recruitment

Orthopaedic – Perth Hip and Knee



Mr Gavin Clark
Consultant Orthopaedic Surgeon



Mr Dermot Collopy
Consultant Orthopaedic Surgeon

Key research areas:

Total knee Arthroplasty and Total Hip Arthroplasty.
Robotically-assisted Arthroplasty Surgery



Overview

Perth Hip and Knee Clinic consists of three experienced Hip and Knee joint replacement surgeons. Together, they provide over 1000 patients a year with joint replacement surgery. Since opening in November 2015, Perth Hip and Knees' research database has been steadily growing with 4,039 patients prospectively enrolled and 4,859 patients retrospectively. The registry is now reaching the point of maturity, with a large number of patients having over two years follow up. This will allow comprehensive analysis and meets the requirements for international publication. Perth Hip and Knees robotic total knee database, has over 2400 patients enrolled, capturing their preoperative, intraoperative and postoperative data and clinical outcomes. This represents one of the most comprehensive databases involving this emerging technology anywhere in the world.

Perth Hip and Knee is focused on ongoing collaboration with national and international likeminded surgical research groups to facilitate and drive orthopaedic research. The Data Acquisition Project, has interest between America, Europe and Australia. This clinical research project was a multicentre study following the outcome of 800 total knee robotic arthroplasty from Perth Hip and Knee that contributed to a database of >5000 patients. The project completed data collection in March 2022 and is expected to be used to enhance the design of future prosthesis, improve surgical outcomes and improve patient satisfaction and performance post total knee replacement.

Our Clinic has a leading role in developing the philosophy of functional alignment in TKA. This alignment technique takes into account a patient's soft tissues

rather than generic bony landmarks when aligning and inserting knee replacement components. The ultimate aim of this continues to be improved outcomes for patients undergoing total knee arthroplasty. An Investigator initiated randomised-control trial is well underway (with 90% of recruitment achieved to date) to look at the use of this alignment technique and its effect on outcome when compared with conventional, mechanically aligned total knee replacement. This study involved two surgeons from Perth Hip and Knee operating out of St John of God Subiaco and will follow 100 Total knee Replacement patients across two years, with recruitment being completed in July 2022.



Contact

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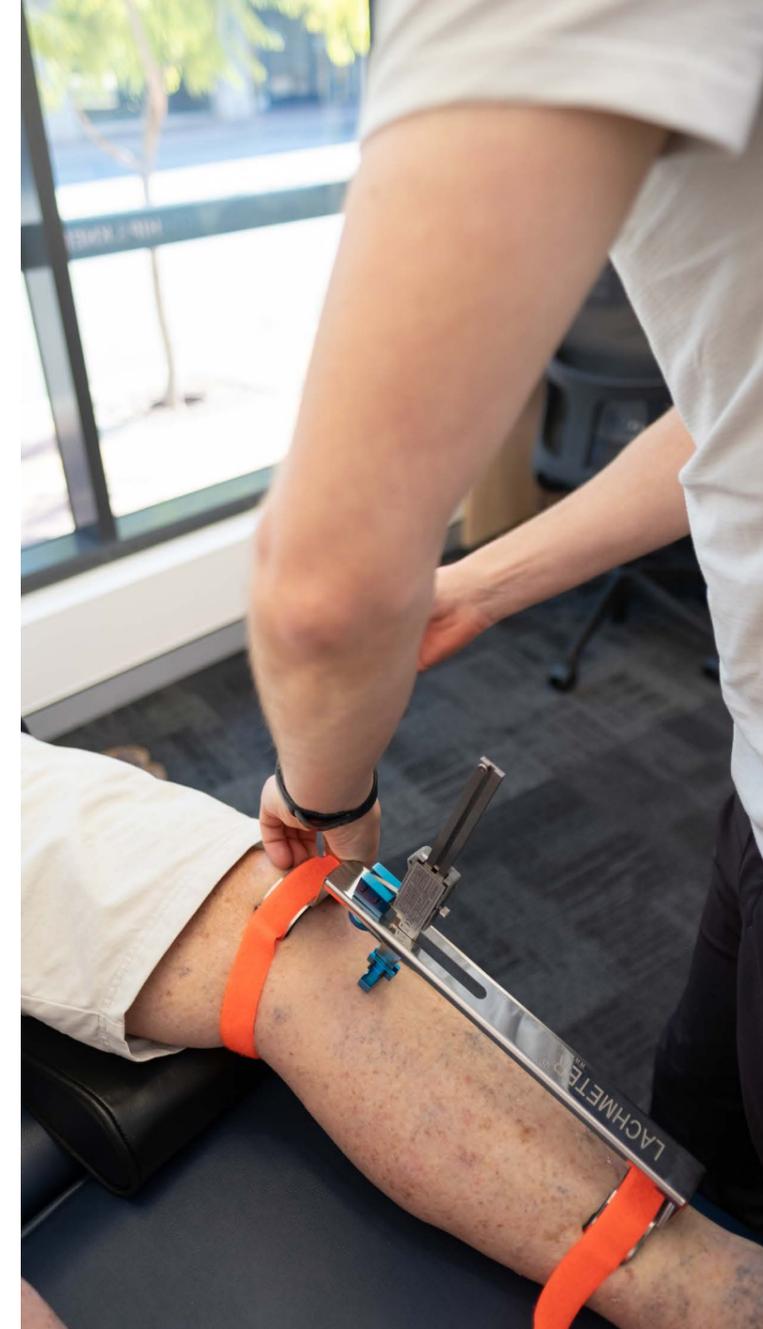
PROJECT 2

A Prospective Randomised-Control Trial Comparing Functional with Mechanical Axis Alignment in Total knee Arthroplasty

Lead researchers:

- Dr Gavin Clark
- Dr Dermot Collopy

This Prospective randomised-control trial is comparing the outcomes of conventional mechanically aligned Total knee Arthroplasty with Functionally kinematic aligned Total Knee Arthroplasty. Functional alignment considers native morphology and soft tissue considerations when positioning prosthetic components. Previous attempts to compare outcomes have shown little difference on gross outcome measures. Our functional testing with incorporate strength, range of motion, anteroposterior stability, intraoperative pressure balancing testing, radiographical considerations and patient reported outcome measures in two, otherwise comparable, patient cohorts. This is one of three studies currently underway internationally, hoping to elucidate any discrepancy in outcomes between approaches.



PROJECT 1

Perth Hip and Knee Research Registry

Lead researchers:

- Dr Gavin Clark
- Dr Dermot Collopy

Perth Hip and Knee's robotic total knee database has over 2400 patients enrolled, capturing their preoperative, intraoperative and postoperative data and clinical outcomes. This represents one of the most comprehensive databases involving this exciting and emerging technology anywhere in the world.



Top publications in 2021/22

1. Steer, R., Tippet, B., Khan, R.N. et al. A prospective randomised control trial comparing functional with mechanical axis alignment in total knee arthroplasty: study protocol for an investigator initiated trial. *Trials* 22, 523 (2021). <https://doi.org/10.1186/s13063-021-05433-z>
2. Clark, G., Esposito, C. I., & Wood, D. (2021). Individualized functional knee alignment in total knee arthroplasty: A robotic-assisted technique. *Techniques in Orthopaedics* (Rockville, Md. <https://doi.org/10.1097/BTO.0000000000000567>
3. Clark, G., Quinn, M., Murgier, J., & Wood, D. (2022). Tibial component rotation alters soft tissue balance in a cruciate retaining total knee arthroplasty. *Computer Assisted Surgery* (Abingdon, England), 27(1), 35–40. <https://doi.org/10.1080/24699322.2022.2078738>
4. Clark, G., Steer, R., Tippet, B., & Wood, D. (2022). Short-Term Benefits of Robotic Assisted Total Knee Arthroplasty Over Computer Navigated Total Knee Arthroplasty Are Not Sustained With No Difference in Postoperative Patient-Reported Outcome Measures. *Arthroplasty Today*, 14, 210–215.e0. <https://doi.org/10.1016/j.artd.2021.11.014>
5. Rebgetz, P., Kovacs, A., Bochat, K., Hayes, A., Clark, G., Blakeney, W., & Pabbruwe, M. (2021). Loosening of tibia baseplates after total knee arthroplasty: Evaluation of pull-out strength of tibia baseplate-cement Interface. *Clinical Biomechanics* (Bristol), 90, 105497–105497. <https://doi.org/10.1016/j.clinbiomech.2021.105497>

WA Thoracic Research Group (WATRG)



A/Prof Tim Clay
Medical Oncologist
Deputy Chair of the Bendat Respiratory Research and Development Fund Committee



Prof Eli Gabbay
Clinical Research Fellow, Respiratory Physician, Chair of the Bendat Respiratory Research and Development Fund Committee

Key research areas:

Respiratory Medicine, Lung Cancer, Oncology

Overview

The generous donation from Mr Jack Bendat has enabled us to continue to undertake research with an aim to improve clinical practice and provide high quality care to our patients.

We continue to collaborate with many national and international teams of prominence including the Australian Scleroderma Cohort Study, the National IPF registry, the WA Silicosis screening project and we are assisting in the development of neural networks to enable earlier detection of Pulmonary Arterial Hypertension.

In addition, we have begun a project where we are supplementing our National Leading Thoracic Biobank with a Thoracic Registry of all Lung cancer related surgery performed at St John of God Subiaco Hospital (with a view to extending this to all St John of God Health Care sites) in collaboration with our Cardiothoracic Surgery Colleagues. This will ensure that surgical times and success are optimised for our patients, and that any barriers to the best therapy for lung cancer are addressed, paving the way for similar projects across other centres in Australia.

Contact

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PROJECT 1

Descriptive observational cohort study of patients with severe asthma on biologic agents

Lead researchers:

- Dr Aine McClean
- Prof Eli Gabbay
- Tara Hannon
- Nisha Sikotra
- Dr Emma Shaughnessy
- Dr Quentin Summers
- Prof Peter Bremner
- Dr Kuan Pin Lim
- A/Prof Tim Clay

Asthma is a common disease of the airways affecting over 300 million people worldwide (1). Approximately 5-10% of these patients have 'severe asthma'. Severe asthma is characterized by increased exacerbations, hospitalizations and impaired quality of life.

The emergence of biologic treatments for asthma over the past decade has

provided new treatment options for patients with severe asthma. We aim to study the experience of biologics in severe asthma in private practice in Australia, to better understand the characteristics, comorbidities and disease patterns of patients in whom biologic agents are prescribed.

PROJECT 2

Scalp cooling for chemotherapy induced alopecia

Lead researchers:

- Dr Emma Shaughnessy
- A/Prof Timothy Clay,
- Ms Nisha Sikotra
- Ms Shauna Gaffey
- Dr Aine McClean
- Ms Tara Hannon
- Prof Eli Gabbay

Chemotherapy induced alopecia (CIA) can be one of the most distressing side effects for both men and women undergoing chemotherapy. There is good scientific evidence behind the mechanism of scalp cooling. The belief is that it works by limiting the blood flow to the scalp and thus the amount of chemotherapy reaching the vessels, which supply the hair follicle.

There are many variables that influence how effective scalp cooling is, including chemotherapeutic agent given, patient ethnicity and hair type, type of device used, length of time the advice is applied for, how well the device fits, as well as many more.

Given its relatively well tolerated side-effect profile, scalp-cooling should be offered, where possible, to patients at risk of CIA. However, this can lead to increasing appointment times for patients, longer waiting times due to machine demand, and increased costs for the hospital.

Our primary aim is to geographically map out the availability of scalp cooling devices across Australia. Secondary aims are to determine the barriers that prevent scalp cooling from being available to patients. Also, to conduct a nursing survey regarding nursing experience in the use of scalp cooling devices, nurses' experience and views regarding the use of scalp cooling.

PROJECT 3

The incidence of brain metastases in patients with upper GI malignancies

Lead researchers:

- Dr Emma Shaughnessy
- A/Prof Tim Clay

The Project involves a retrospective audit of patients with upper GI malignancies known to St John of God Subiaco Hospital and Genesis care. The hypothesis is that patients with upper GI cancers are living longer due to advances in treatment, and therefore there is a higher incidence of brain metastases.

Historically gastrointestinal cancers have poor survival outcomes with only modest effects of systemic therapy. The advent of more effective systemic therapy has led to prolonged survival and more challenging patterns of progression. This paper will report presentations, treatment and outcomes for patients in this cohort managed at St John of God Subiaco Hospital. The paper currently includes outcomes for 42 patients, making it one of the largest case series collated to date on this topic.

PROJECT 4

A systematic review of treatments for metastatic extramammary Paget's disease (EMPD).

Lead researchers:

- Dr Emma Shaughnessy
- A/Prof Tim Clay

EMPD is a primary cancer of the skin that is very rare – it is estimated to occur in 0.6 per 1 million person years in European populations. Distant spread is even less common. Given the rarity of this cancer, descriptions of systemic therapies have been limited to case reports or small series. Emerging data on molecularly targeted strategies are being reported. This review will collate available reports of treatment strategies in the peer reviewed literature and present them in a single manuscript.



PROJECT 5

Artificial Intelligence: Pulmonary Arterial Hypertension Screening Project - stage 2

Lead researchers:

- Prof Eli Gabbay in collaboration with Janssen LTD

The aim of this study is to test an Artificial Intelligence algorithm for PAH, in real primary healthcare electronic medical records (EMR) and to assess the performance of the screening algorithm in identifying the known PAH patient(s) in the EMR database. The study will attempt to identify known PAH patients in primary

healthcare EMR. 'Known positive' PAH patients will be identified by the lead investigator. If 20 of the 20 known PAH patients are ranked as having a high probability of having PAH using the AI algorithm, the study will be considered positive

PROJECT 6

The incidence and characteristics of Interstitial Lung Disease in Scleroderma

Lead researchers:

- Dr Sophia Connor
- Dr Alice Talbot
- A/Prof Tim Clay
- Prof Eli Gabbay

We are leading a multi-centre Australian study in this important disease that disproportionately affects women. Systemic Sclerosis (more commonly known as Scleroderma) is a connective tissue disorder causing collagen formation. Collagen is a protein that has many jobs such as providing structure to skin; and when the production becomes out of hand, it leads to fibrosis (scarring) of multiple organ systems. This research project is specifically concerned with the effect that systemic sclerosis has on the lungs, where it results in diffuse interstitial lung disease, seen in approximately 17-26% of individuals. In other forms of interstitial lung disease

unrelated to systemic sclerosis, it is divided into different categories, including nonspecific interstitial pneumonia and usual interstitial pneumonia. People who have a different type of interstitial lung disease may have a higher chance of complications or death. In our study, we will be looking at lots of individuals with different types of interstitial lung disease within systemic sclerosis and seeing whether any particular type has a higher chance of complications or death. We will also see whether any factors, such as age or gender, are associated with any particular subtype of interstitial lung disease.

PROJECT 7

The impact of the Ukrainian/Russian Conflict on Cancer Clinical Trials

Lead researchers:

- Dr Alice Talbot
- Dr Sophia Connor
- Prof Eli Gabbay
- A/Prof Tim Clay

In recent years, clinical trials have become an essential part of treatment for all oncology patients. Following the invasion of Ukraine on 24 February 2022 the feasibility of maintaining active clinical trial treatment was jeopardised. This study aims to quantify the potential impact of the war on cancer clinical trials with sites in Ukraine or Russia using data from clinicaltrials.gov. Initial data from this study revealed that over 500 clinical trials, most of which were multinational (93%) have sites in Ukraine or Russia. The majority of these trials were active or currently recruiting patients (97%)

and 89% of clinical trials in this study were commercially sponsored. This means that a large number of these studies have the potential to be impacted by economic sanctions placed on Russian imports and limitations to airspace and entry points into Russian and Ukrainian port sites. This humanitarian impact of the Ukraine/Russian conflict is difficult to overestimate. This project focuses on one area of quantifiable impact related to cancer care and clinical trials. This study will be written up for review in a peer reviewed journal following completion of data collection.

PROJECT 8

The landscape of clinical trial activity in Australia using publicly available data trials

Lead researchers:

- Dr. Alice Talbot, Dr. Sophia Nolde, Prof Eli Gabbay and A/Prof Tim Clay

Overall survival for cancer in Australia and worldwide has improved greatly in recent years. This is partly driven by the recent implementation of clinical trial interventions for the diagnosis and management of malignancy into oncology practice. The aim of this study is to explore the characteristics of clinical trials in Australia including study phase, agents used, site locations (public and private) and sponsorship type. This study will also involve data collection from public clinical trial databases and subsequent write up for submission to a peer reviewed journal

PROJECT 9

The inter-relationship between Haematologic Malignancies and Bronchiectasis

Lead researchers:

- Dr Amy Rolston, Dr Tim Whitmore, Dr Simon Kavanagh, A/Prof Tim Clay and Prof Eli Gabbay

Dr Rolston has completed a project examining the interrelationship between chronic haematologic malignancies and bronchiectasis. We are the first group to show that the presence of one of these conditions predisposes to another. The management of both conditions is complex and this seminal study has highlighted how physicians can navigate the care of these patients when both diseases occur together.



Top publications in 2021/22

1. Smith, R., Harrison, M., Lam, K.V., Adler, B., Bulsara, M., Sahhar, J., Stevens, W., Proudman, S., Nikpour, M. and Gabbay, E., 2021. The emerging association between bronchiectasis and systemic sclerosis: assessing prevalence and potential causality. *Internal Medicine Journal*. <https://doi.org/10.1111/imj.15661>
2. Gahungu, N., Trueick, R., Coopes, M. and Gabbay, E., 2021. Paroxysmal atrial fibrillation. *BMJ*, 375. <https://doi.org/10.1136/bmj-2021-058568>
3. Nel, H., Davis, B., Adler, B. and Gabbay, E., 2021. Case report of osteolytic lesions in a patient with multisystem granulomatous disease. *BMJ Case Reports CP*, 14(6), p.e242685.
4. Gahungu, N., Shariar, A., Playford, D., Judkins, C. and Gabbay, E., 2021. Transfer learning artificial intelligence for automated detection of atrial fibrillation in patients undergoing evaluation for suspected obstructive sleep apnoea: a feasibility study. *Sleep Medicine*, 85, pp.166-171. <https://doi.org/10.1016/j.sleep.2021.07.014>
5. Ong, S., Goh, D., Tan, A., Sikotra, N., Hannon, T., Clay, T., Gabbay, E. Pneumonitis in Association with Immune Check Point Inhibitors; *Case Reports in Respiratory Medicine*. 2021 in press
6. Skiba, R., Sikotra, N., Ball, T., Arellano, A., Gabbay, E. and Clay, T.D., 2019. Management of Febrile Neutropenia in a Private Hospital Oncology Unit. *Internal Medicine Journal*.

Allied Health Research Program



Charlene Grosse
Manager of Allied Health



Key research areas:

- The role of diet as an adjunct therapy in mild to moderate Ulcerative Colitis (UC).

Overview

This program supports research investigations by providing and supporting opportunities to build research capacity among Allied Health Care Professionals. The research projects aim to improve clinical outcomes and enhance service delivery to determine evidence based interventions and treatment.

Highlight

In this pilot study we demonstrated a clinically significant improvement in the Partial Mayo, Pro 6, IBD-Q and FRQoL Scores when patients with mild to moderate UC followed a plant-based diet. Microbiome and metabolite analysis is expected to demonstrate a favourable composition change in the gut microbiome, and increased levels of beneficial metabolites after following a plant-based diet. Further dietary analysis is expected to show an increase in resistant starch. The results of this study suggest a plant-based diet may have clinical implications as an adjunct therapy in mild to moderate UC. A limitation of this study is the small sample size.

Contact

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PROJECT 1

Effectiveness of a lacto-ovo vegetarian diet in ulcerative colitis: a proof of concept study

Lead researchers:

- *Charlene Grosse*
- *Advanced Accredited Practising Dietitian*
- *Manager Allied Health*
- *PhD Candidate ECU*

Inflammatory Bowel Disease (IBD) carries a significant burden on an individual's quality-of-life and on the healthcare system. The majority of patients use dietary modifications to manage their symptoms, despite limited research to support these changes. A Westernised diet has been associated with increased IBD risk and relapse. There is emerging data to suggest a plant-based diet will

be beneficial to IBD patients through improving clinical response, reducing inflammation and restoring symbiosis. The aim of this study was to perform a proof-of-concept evaluation of this hypothesis.

Top publications in 2021/22

1. GESA AGW 2021 Poster presentation, September 11-12, 2021 Ulcerative Colitis: what's for dinner? Grosse, C1,2 Lawrance, I2 Devine, A1 Thin, L3 Lightowler, D3 Lo, J1 Christophersen, C1 1. Edith Cowan University, School of Medical & Health Sciences 2. St John of God Subiaco Hospital 3. Fiona Stanley Fremantle Hospitals Group

Nursing and Midwifery Research



Alannah Cooper
Nurse Researcher

Key research areas:

- Improving outcomes for patients, their families and caregivers, by supporting nursing and midwifery research projects across St John of God Subiaco Hospital
- Enabling clinical nurses and midwives to initiate and conduct research projects across a range of specialities including maternity, general medicine and palliative care
- Supporting an active culture of nursing and midwifery research within the hospital
- Sharing our research findings with peers by collaborating, presenting at external conferences and through journal publications



Overview

Our nursing and midwifery research program utilises an evidence-based approach to improving clinical care, service delivery, and health outcomes.

We encourage nurses and midwives to investigate and trial new processes that could benefit patient care, with projects spanning maternity, palliative, and general nursing care. As the profession with the most frequent patient contact, nurses are uniquely placed to identify areas for research to improve patient care and the patient experience.

Highlights

- 'Nurse resilience: A concept analysis' one of the top cited papers for the International Journal of Mental Health Nursing (Wiley Publishing) in 2020/2021
- 'Nurse resilience for clinical practice: An integrative review' of the top cited papers for the Journal of Advanced Nursing (Wiley Publishing) in 2020/2021
- Completion of the research project 'Reducing Midwife and Nurse Paperwork Burden in a Hospital Setting: A mixed methods, action research project'
- Awarded a Curtin Summer Research Scholarship for our project titled, 'A period prevalence study of palliative care need and rate of referral in adult outpatients'

Contact

Nurse Researcher: Alannah Cooper
Email: alannah.cooper@sjog.org.au

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Main research projects



4 Publications in 2021/22

PROJECT 1

A period prevalence study of palliative care need and rate of referral in adult outpatients.

Research team:

- Dr Alannah Cooper
- Jacqueline Mazzer
- Dipna Martin-Robins
- Sarah Tucknott
- Dr Janie Brown

Building on our earlier inpatient point prevalence study, this study aimed to gain an understanding of palliative care need and service utilisation in adult outpatients. There is limited research that investigates unmet palliative care need in an outpatient context. Early access to palliative care services is associated with better symptom management and reduced healthcare costs. Using the Gold Standards Framework, data was collected

prospectively in a period prevalence study to estimate the level of palliative care need in adults attending an outpatient day treatment unit at St John of Subiaco Hospital. By understanding the level of need for palliative care and the characteristics of patients who may benefit from palliative care, and examining the palliative care models currently used, interventions can be developed to improve service access and delivery.

PROJECT 3

Reducing Midwife and Nurse Paperwork Burden in a Hospital Setting: A mixed methods, action research project

Research team:

- Dr Alannah Cooper
- Siobhan Eccles
- Suzanne Kelly
- Kirsten Wild
- Narelle Coope
- Jo Fairclough
- Sarah Ho
- Dr Janie Brown

This project aimed to reduce the paperwork burden nurses and midwives encounter, in order to release time for direct patient care. Most paperwork completed in hospitals related to patient care is completed by nurses and midwives. Issues around the paperwork burden placed upon clinicians in healthcare settings have been recognised in the literature for several decades. There is evidence that direct contact with patients is reducing due to other demands placed upon nurses including paperwork. Excessive documentation is a major predictor

of clinician dissatisfaction which is correlated with patient dissatisfaction. It seems that paperwork that was intended to enhance care can adversely affect clinician and patient satisfaction, reduce time available for direct patient care, and ultimately lower quality of care. This research engaged with clinical-based nurses and midwives to evaluate paperwork burden, and developed and tested an intervention to reduce paperwork burden.

PROJECT 2

A point prevalence study of palliative care need and referral rates in adult inpatients.

Research team:

- Dr Alannah Cooper
- Jacqueline Mazzer
- Dipna Martin-Robins
- Dr Janie Brown

This study aimed to gain an understanding of palliative care need and service utilisation in adult inpatients. Both locally and internationally, there is evidence of a significant unmet palliative care need. Early access to palliative care services is associated with improved outcomes including better symptom management, prolonged survival, improved quality of life, and reduced healthcare costs. Using

the Gold Standards Framework, data was collected prospectively in a point prevalence study to estimate the level of palliative care need among inpatients at St John of Subiaco. Determining the level of palliative care need can help to understand the operational requirements needed to provide palliative care and to improve access to palliative care.



PROJECT 4

Exploring the impact of organisational values on nurses' resilience levels: A Mixed methods study.

Research team:

- Dr Alannah Cooper
- Dr Janie Brown
- Prof Gavin Leslie

This study focused on the impact of organisational values on nurse resilience. Nursing shortages and recruiting and retaining nurses are global issues compounded by an ageing patient population, an ageing nursing population and higher patient acuity and complexity. There is ample evidence that nurses' work places them at risk of negative psychological outcomes including depression, anxiety, secondary traumatic

stress and burnout. In order to protect, retain, and recruit nurses we must seek to promote resilience and prevent negative psychological outcomes such as burnout that lead to individuals exiting the profession. This study contributes further knowledge and understanding of nurse resilience that is needed to determine how to build and maintain resilience in nurses.

PROJECT 6

Patient experiences of attending a specialist Breast Care Nurse led survivorship clinic.

Research team:

- Gay Refeld
- Dr Alannah Cooper
- Professor Christobel Saunders
- Niloufer Johansen
- Liz Sorial

This study aimed to establish if the Wellness after Breast Cancer Clinic at St John of Subiaco Hospital addresses the needs of breast cancer survivors. There is growing recognition of the need for supportive care beyond active treatment. The term survivorship incorporates the timeline from the end of primary treatment to living beyond cancer. A Specialist Breast Nurse-led Wellness after Breast Cancer Clinic was established in 2017. The clinic aims to improve quality of life and to identify and manage issues for breast

cancer survivors following completion of their acute treatment. A multi-method approach including questionnaires, quality of life assessments, and reviews of Wellness Care Plans were used to evaluate the clinic, understand the issues experienced by breast cancer survivors, compare the needs and issues faced by survivors who received chemotherapy with those who did not, and to assess satisfaction with the Specialist Breast Nurse-led clinic.

PROJECT 5

The COVID-19 pandemic: A descriptive, longitudinal, mixed methods study of the professional and personal impact on Nurses, Midwives, Allied Health Professionals and students of these disciplines.

Research team:

- Dr Janie Brown
- Dr Alannah Cooper,
- Associate Professor Lauren Breen
- Dr Matthew Albrecht

An international study with researchers from Australia, the UK, and Hong Kong that aims to explore the impact of the worldwide COVID-19 pandemic on the professional and personal wellbeing of clinically based nurses, midwives, allied health professionals and students of these disciplines. The COVID-19 pandemic is subjecting nurses, midwives and allied health professionals to unprecedented levels of stress as the crisis evolves.

As health services race to ramp up capacity, staff are being redeployed into new roles in unfamiliar specialties that require new skills. New Graduates must rapidly transition to practice amid the sudden surge of the pandemic and potentially with less guidance from senior professionals who are focused on pandemic preparation. This study aims to capture real time data about their professional and personal well-being before, during and after the crisis.

Top publications in 2021/22

1. Cooper, A.L.; Mazzer, J.; Martin-Robins, D.; Brown, J. A. (2021). A point prevalence study of palliative care need and referral rates in adult inpatients. *Journal of Clinical Nursing* 2021. doi.org/10.1111/jocn.16148
2. Cooper, A. L.; Brown, J. A.; Leslie, G. D. Nurse resilience for clinical practice: An integrative review. *Journal of Advanced Nursing* 2021, 77(6), 2623-2640. doi.org/10.1111/jan.14763
3. Cooper, A. L.; Brown, J.A.; Eccles, S. P.; Cooper, N.; Albrecht, M. A. Is nursing and midwifery clinical documentation a burden? An empirical study of perception versus reality. *Journal of Clinical Nursing* 2021, 30(11-12), 1645-1652. doi.org/10.1111/jocn.15718
4. Cooper, A. L.; Brown, J. A.; Leslie, G. D. The impact of organisational values on nurse resilience: A mixed methods study. *Journal of Nursing Management* 2021, 29(7), 2074-2083. doi:10.1111/jonm.13338

Research Data Management



Andrew Mews
Research Data Scientist

Key research areas:

- Management of research and clinical trials data management
- Development of databases and registries to facilitate clinical trials and research project management
- Contributing to the Digital Health Cooperative Research Consortium to develop data tools and methodologies to improve patient care and healthcare outcomes nationwide.

Overview

Access to reliable data means better healthcare. In recent years, there has been an increased awareness of the benefits healthcare providers can provide to patients through refined uses of data collected during routine operations. This includes support for clinical research.

High quality, up-to-date data can enable clinicians and researchers the opportunity to improve patient outcomes by asking research questions which would be otherwise unanswerable - providing insights toward improving patient care.

While the potential for such benefits from data acquired for operational and admissions needs is intriguing, it is frequently not organised or accessible in a way which makes it useful for research purposes. Structured data management, integration, and analytics solutions are necessary to make use of these resources.

As a part of the core research and clinical trials group, we provide data management assistance to our research teams and engage in data science research. This includes assisting research groups by developing registries for clinical trials and research projects, and identifying best practices for data collection, and the development of datasets structured toward maximising meaningful research outcomes.

Contact

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Highlight

Since 2019 St John of God Health Care, through the Subiaco Research and Clinical Trials group, has been a partner in the Australian Digital Health Cooperative Research Centre (DHCRC) Consortium.

The DHCRC is a collaborative taskforce of over seventy research, clinical, industry, government, and academic organisations across multiple disciplines tasked with equipping the Australian health industry with the tools, skills, and infrastructure required to provide improved health outcomes to Australians in a time when transformative changes in technology have drastically impacted requirements for personalised health management, data security and privacy, and patient engagement.

Over the past twelve months the DHCRC has been making progress toward translational outputs from the collaboration, with industry experts from across the Australian healthcare space working with DHCRC-funded PhD students to create a broad body of work to define how providers and clinicians can leverage health data to support reflective practice, Professional Development, and quality improvement.

With a particular focus on the use of health data in private hospitals across Australia, the aim is that over the next 12 months the project can deliver practicable recommendations based on currently pending publications for Australian healthcare providers. This includes insights into the governance, policy, and medicolegal barriers hindering data use for improvement and reflective practice, the current state of data presentation and communication to Australian clinicians, and insights and recommendations for the use of clinical quality indicators for reflective practice and improvement of patient outcomes.

Dedications

Thank you to all of our Research and Clinical Trials caregivers who devote their time and energy into research to provide the best possible care for our patients.

We commend them for their outstanding dedication and contribution.

Unit	Researchers	Unit	Researchers
Allied Health	Charlene Grosse	Medical Oncology	Natalya Beer
	Sasha McMeekin		Shauna Gaffey
Anaesthesia & Pain	Yvonne Buller		Dr Alice Talbot
	Natalie Hird		Jennifer Fraser
	Louise Bowles		Amity Frede
Breast Cancer	Joan Burgess		Angela Garbin
	Gabrielle Jones		Martha Henneberry
	Glenys Longman		Monica Jane
	Gay Refeld		Emilie Linahan
Colorectal	Dr Melanie McCoy		Kirsten Loffel
	Tracey Lee-Pullen	Ignacio Moreno Suarez	
	Dr Ryan Cohen	Sarah Negus	
	Dr Tim Miller	Gemma Peagno	
Gynaecology	Stephanie Austin	Stuart Rayner	
	Sanela Bilic	Elise Rosenberg	
	Maria Beilin	Naomi Van Hagen	
	Stephanie Jeffares	Jessica Whitehouse	
IBD	Issy Black	Jean Wei Welch	
	Dr Siva Pulusu	Orthopaedics	Dr Wil Pretty
	Hayley Stanley		Beth Tippett
	Clarizze Abello		Dr Jonathan Manara
Kerry Smith	Dr Daniel Fisher		
ICU	Janet Ferrier	WATRG	Dr Emma Shaughnessy
	Lesley Kemp		Dr Alice Talbot
			Dr Sophia Connor
		Nisha Sikotra	
		Research Development	Dr Angela Baird
		Research Administration	Heather-Jean McNaught
			Amy Davies

External Collaborators

UWA

Developing blood-based biomarkers of colorectal cancer metastasis

This was a pilot study to optimise laboratory methods for using blood samples to identify patients who may be at higher risk of developing metastasis.

UWA UNDA

Do regulatory T cells inhibit the response of rectal carcinomas to neoadjuvant chemoradiotherapy?

This project is investigating whether the immune system plays a role in how well people with rectal cancer respond to chemoradiotherapy.

UWA UNDA

Could immune checkpoint blockade improve response to chemoradiotherapy in locally advanced rectal cancer?

The aim of this project is to determine whether 'immune checkpoint' molecules, which are found on immune cells and dampen down immune responses, hamper response to chemoradiotherapy.

UWA UNDA ECU

Biomarkers of colorectal cancer metastasis

This study is linking long-term patient data with potential 'biomarkers' of bowel cancer metastasis to better predict risk of disease recurrence.

BCCA

Detecting bacterial species in archived colorectal tissue – a pilot study (BCCA)

This was a pilot study to investigate whether certain bacteria and their associated toxins could be found in archived colorectal tumour tissue.

Telethon Kids Institute (TKI) Novel insights into immune control of dormant tumours

This project is aiming to understand how the immune system can keep cancer cells in a dormant state to help develop new therapies to eliminate cancer.

Telethon Kids Institute

Bee Pain Free

A multi-centre double-blinded, placebo-controlled study to investigate the use of honey to reduce pain in children post-tonsillectomy.

Monash Partners

Compass Logo COMPASS - The Clinical Outcomes Measurement in Perioperative Medicine, Anaesthesia & Surgery Study (COMPASS) Pilot Study: Feasibility of a prospective multi-centre observational study of perioperative risk factors and outcomes in Australia

Monash Uni

LOLIPOP logo LOLIPOP Trial – Long-term Outcomes of Lidocaine Infusions for Post-Operative Pain. This large international randomised controlled trial is targeting women undergoing breast cancer surgery.



The Alfred

TRIGS logo TRIGS Study – This trial aims to investigate whether Tranexamic acid reduces surgical site infection and other healthcare associated infections, along with a reduction in red cell transfusion.

University of Melbourne

ROCKET Trial - This trial aims to provide evidence of a reduction of chronic post-surgical pain with the use of ketamine infusions

VAPOR-C Trial

Volatile Anaesthesia and Perioperative Outcomes Related to Cancer

Peter MacCallum Cancer Centre

BROCADE - (BReast Origin CANcer tissue donated after DEath: The NBCF repository of primary tumours and metastases from breast cancer patients.

This study has been designed to support breast cancer research, and aims to understand how breast cancer spreads and why it becomes treatment resistant.

Monash Uni

Bone Zone Trial

Bone Loss Prevention with Zoledronic Acid or Denosumab in Critically Ill Women

Monash Uni

SPICE IV Trial

Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients

Curtin

NOTACS Trial

Nasal High-Flow Oxygen Therapy After Cardiac Surgery

RWH

MOST (Measure of Ovarian Symptoms and Treatment concerns) Follow-Up Study



Additional publications in 2021/22

Anaesthesia & Pain Research Unit

- Corcoran, T. B.; O'Loughlin, E.; Chan, M. T. V.; Ho, K. M., Perioperative Administration of Dexamethasone And blood Glucose concentrations in patients undergoing elective non-cardiac surgery - the randomised controlled PADDAG trial. *Eur J Anaesthesiol* 2021, 38 (9), 932-942.
- Dubowitz, J., Toner, A., Riedel, B. and Corcoran, T., 2021. The use of intravenous lidocaine for postoperative pain and recovery. *Anaesthesia*, 76(5), pp.719-720 <https://doi.org/10.1111/anae.15400>
- Leslie, K.; Martin, C.; Myles, P. S.; Devereaux, P. J.; Peyton, P. J.; Story, D. A.; Wijeyesundera, D. N.; Cuthbertson, B. H.; Short, T. G.; Corcoran, T. B.; Kasza, J., Inclusion, characteristics, and outcomes of male and female participants in large international perioperative studies. *Br J Anaesth* 2022.
- Myles, P. S.; Corcoran, T., Benefits and Risks of Dexamethasone in Noncardiac Surgery. *Anesthesiology* 2021, 135 (5), 895-903.
- Toner, A.J., Bailey, M.A., Schug, S.A. and Corcoran, T.B., 2021. A pilot multicentre randomised controlled trial of lidocaine infusion in women undergoing breast cancer surgery. *Anaesthesia*, 76(10), pp.1326-1341. <https://doi.org/10.1111/anae.15440>

Breast Cancer Research Unit

- Hersch, J., Nickel, B., Dixon, A., Jansen, J., Saunders, C., Houssami, N., Barratt, A., Spillane, A., Stuart, K., Rutherford, C. and Robertson, G., 2022. 132 Treating (or Monitoring?) Low-Risk Ductal Carcinoma in Situ (DCIS): Focus Groups about Women's Views . <http://dx.doi.org/10.1136/bmjebm-2022-PODabstracts.60>

- Foo, K.Y., Newman, K., Fang, Q., Gong, P., Ismail, H.M., Lakhiani, D.D., Zilkens, R., Dessauvage, B.F., Latham, B., Saunders, C.M. and Chin, L., 2022. Multi-class classification of breast tissue using optical coherence tomography and attenuation imaging combined via deep learning. *Biomedical Optics Express*, 13(6), pp.3380-3400.
- Newton, J.C., O'Connor, M., Saunders, C., Ali, S., Nowak, A.K. and Halkett, G.K., 2022. "Who can I ring? Where can I go?" Living with advanced cancer whilst navigating the health system: a qualitative study. *Supportive Care in Cancer: Official Journal of the Multinational Association of Supportive Care in Cancer*, 30(8), pp.6817-6826. <https://doi.org/10.1007/s00520-022-07107-1>
- Bourke, A.G., Taylor, D. and Saunders, C., 2022. ROLLIS roll out: Pitfalls, errors, lessons learned and recommendations from Australian and New Zealand experience during the randomised controlled trial, implementing a novel localisation method for impalpable malignant breast lesions, radio guided occult lesion localisation with iodine 125 (I25I) seed (ROLLIS). *Journal of Medical Imaging and Radiation Oncology*. <https://doi.org/10.1111/1754-9485.13418>
- Sullivan, E., Safi, N., Li, Z., Remond, M., Chen, T. Y., Javid, N., ... & Saunders, C. 2022. Perinatal outcomes of women with gestational breast cancer in Australia and New Zealand: A prospective population based study. *Birth*. <https://doi.org/10.1111/birt.126422>
- Lloyd, R., Walter, J., Pirikahu, S., Cadby, G., Hickey, M., Sampson, D.D., Karnowski, K., Hackmann, M.J., Saunders, C., Lilge, L. and Stone, J., 2022. Assessment of repeated reference measurements to inform the validity of optical breast spectroscopy. *Review of Scientific Instruments*, 93(4), p.044101 <https://doi.org/10.1063/5.0072223>

- Stafford, L., Sinclair, M., Gerber, K., Saunders, C., Ives, A., Peate, M., Lippey, J., Umstad, M.P. and Little, R., 2022. Experiences of health professionals treating women diagnosed with cancer during pregnancy and proposals for service improvement. *The Breast*, 63, pp.71-76. <https://doi.org/10.1016/j.breast.2022.03.003>
- Slavova Azmanova, N.S., Newton, J.C., Saunders, C. and Johnson, C.E., 2020. 'Biggest factors in having cancer were costs and no entitlement to compensation'—The determinants of out of pocket costs for cancer care through the lenses of rural and outer metropolitan Western Australians. *Australian Journal of Rural Health*, 28(6), pp.588-602 <https://doi.org/10.1111/ajr.12686>
- Laabar, T. D., Auret, K., Saunders, C., Ngo, H., & Johnson, C. E. 2021 Support Needs for Bhutanese Family Members Taking Care of Loved Ones Diagnosed with Advanced Illness. *Journal of Palliative Care*. <https://doi.org/10.1177/08258597211066248>
- Safi, N., Saunders, C., Anazodo, A., Dickinson, J.E., Boyle, F., Ives, A., Wang, A., Li, Z. and Sullivan, E., 2022. Clinical Decision Making in the Management of Breast Cancer Diagnosed During Pregnancy: A Review and Case Series Analysis. *Journal of Adolescent and Young Adult Oncology*, 11(3), pp.245-251. <https://doi.org/10.1089/jayao.2021.0054>
- Hatton, A., Heriot, N., Zalberg, J., Ayton, D., Evans, J., Roder, D., Chua, B.H., Hersch, J., Lippey, J., Fox, J. and Saunders, C., 2021. Factors involved in treatment decision making for women diagnosed with ductal carcinoma in situ: A qualitative study. *The Breast*, 60, pp.123-130. <https://doi.org/10.1016/j.breast.2021.09.007>
- Partridge, A.H., Niman, S.M., Ruggeri, M., Peccatori, F.A., Azim Jr, H.A., Colleoni, M., Saura, C.,

Shimizu, C., Sætersdal, A.B., Kroep, J.R. and Mailliez, A., 2021. Who are the women who enrolled in the POSITIVE trial: a global study to support young hormone receptor positive breast cancer survivors desiring pregnancy. *The Breast*, 59, pp.327-338. <https://doi.org/10.1016/j.breast.2021.07.021>

Colorectal Cancer Research Group

- Lee, C., Extracellular Vesicles as Biomarkers for Colorectal Cancer Metastasis (Thesis presented for the degree of Master of Clinical Research thesis; University of Western Australia, School of Biomedical Sciences) 2021
- Maxwell-Smith, C.; Hagger, M. S.; Kane, R.; Cohen, P. A.; Tan, J.; Platell, C.; Makin, G. B.; Saunders, C.; Nightingale, S.; Lynch, C.; Sardelic, F.; McCormick, J.; Hardcastle, S. J., Psychological correlates of physical activity and exercise preferences in metropolitan and nonmetropolitan cancer survivors. *Psychooncology* 2021, 30 (2), 221-230. <https://doi.org/10.1002/pon.5553>
- Maxwell-Smith, C.; Cohen, P. A.; Platell, C.; Tan, J.; Saunders, C.; Nightingale, S.; Lynch, C.; Sardelic, F.; McCormick, J.; Hardcastle, S. J., "To be there for my family" and "Keep my independence": Metropolitan and Non-Metropolitan Cancer Survivors' Health Behaviour Motives. *Support Care Cancer* 2021, 29 (4), 1969-1976. <https://doi.org/10.1007/s00520-020-05690-9>
- Hardcastle, S. J., Maxwell-Smith, C., Hince, D., Bulsara, M. K., Boyle, T., Tan, P., Levitt, M., Salama, P., Mohan, G. R. K. A., Salfinger, S., Makin, G., Tan, J., Platell, C., & Cohen, P. A. The Wearable Activity

Technology And Action-Planning trial in Cancer survivors: physical activity maintenance post-intervention. *Journal of Science and Medicine in Sport* 2021, 24(9), 902-907. <https://doi.org/10.1016/j.jsams.2021.04.004>

- COVIDSurg Collaborative. Preoperative nasopharyngeal swab testing and postoperative pulmonary complications in patients undergoing elective surgery during the SARS-CoV-2 pandemic. *British Journal of Surgery* 2021, 108(1), 88-96. <https://doi.org/10.1093/bjs/znaa051>
- Meagher, N., Koebel, M., Anderson, L., Tan, A., Bolithon, A., Anglesio, M., Cohen, P., Crowe, P., Doherty, J., Fasching, P., Harris, H., Hogdall, E., Huntsman, D., James, P., Karlan, B., Kelemen, L., Kommoss, S., Konecny, G., Goringe, K., ... Ramus, S. Pattern of invasion in stage I mucinous ovarian cancer is prognostic within 2-years of diagnosis. *Asia-Pacific Journal of Clinical Oncology* 2021, 17, 47-48.
- Perera, C. N., O'Sullivan, S., Pachter, N., Tan, J. J-S., & Cohen, P. A. Patient Satisfaction with Private Genetic Counselling for Familial Cancer in Western Australia: A Prospective Audit. *Asian Pacific Journal of Cancer Prevention* 2021, 22(10), 3253-3259. <https://doi.org/10.31557/APJCP.2021.22.10.3253>
- Cohen, P. A., Musiello, T., Jeffares, S., & Bennett, K. Mindfulness-based cognitive therapy for Fear of Recurrence in Ovarian Cancer Survivors (FROCS): a single-arm, open-label, pilot study. *Supportive Care in Cancer* 2021. <https://doi.org/10.1007/s00520-021-06659-y>
- NBCS Collaborators, & Cohen, P. Mendelian randomisation study of smoking exposure in relation to breast cancer risk. *British Journal of Cancer* 2021, 125(8), 1135-1145. <https://doi.org/10.1038/s41416-021-01432-8>
- Kang, E. Y., Millstein, J., Popovic, G., Meagher, N. S., Bolithon, A., Talhouk, A., Chiu, D. S., Anglesio, M. S., Leung, B., Tang, K., Lambie, N., Pavanello, M., Da-anoy, A., Lambrechts, D., Loverix, L., Olbrecht, S., Bisinotto, C., Garcia-Donas, J., Ruiz-Llorente, S., ... Köbel, M. (2021). MCM3 is a novel proliferation marker associated with longer survival for patients with tubo-ovarian high-grade serous carcinoma. *Virchows Archiv* 2021. <https://doi.org/10.1007/s00428-021-03232-0>
- Gupta, S., Nichols, C. B., Phillips, J., O'Sullivan, S., Ayres, C., Mohan, G. R., Leung, Y., Stewart, C. J. R., Tan, A., Schofield, L., Salfinger, S. G., Kiraly-Borri, C., Pachter, N., & Cohen, P. A. Lynch syndrome associated endometrial carcinomas in Western Australia: an analysis of universal screening by mismatch repair protein immunohistochemistry. *International Journal of Gynecological Cancer* 2021, 31(6), 846 - 851. <https://doi.org/10.1136/ijgc-2020-002299>
- Obermair, A., Beale, P., Scott, C. L., Beshay, V., Kichenadasse, G., Simcock, B., Nicklin, J., Lee, Y. C., Cohen, P., & Meniawy, T. Insights into ovarian cancer care: report from the ANZGOG Ovarian Cancer Webinar Series 2020. *Journal of Gynecologic Oncology* 2021, 32(6), [e95]. <https://doi.org/10.3802/jgo.2021.32.e95>
- COVIDSurg Collaborative. Elective cancer surgery in COVID-19-Free surgical pathways during the SARS-cov-2 pandemic: An international, multicenter, comparative cohort study. *Journal of Clinical Oncology* 2021, 39(1), 66-78. <https://doi.org/10.1200/JCO.20.01933>
- Hollingworth, J., Walsh, L., Tran, S., Ramage, L., Patel-Brown, S., Ambekar, M., Weeks, J., Williams, L., & Cohen, P. A. Does a multidisciplinary menopausal symptoms after cancer clinic reduce symptoms? *Supportive*

Additional publications in 2021/22

- Care in Cancer 2021. <https://doi.org/10.1007/s00520-021-06637-4>
- Campbell, R., King, M. T., Ross, T. L., Cohen, P. A., Friedlander, M. L., & Webb, P. M. Development and validation of the measure of ovarian symptoms and treatment concerns for surveillance (MOST-S26): An instrument to complement the clinical follow-up of women with ovarian cancer after completion of first-line treatment. *Gynecologic Oncology* 2021. <https://doi.org/10.1016/j.ygyno.2021.08.022>
 - STARSSurg Collaborative, & COVIDSurg Collaborative. Death following pulmonary complications of surgery before and during the SARS-CoV-2 pandemic. *British Journal of Surgery* 2021, 108(12), 1448-1464. <https://doi.org/10.1093/bjs/znab336>
 - Hannan, N. J., Cohen, P. A., Beard, S., Bilic, S., Zhang, B., Tong, S., Whitehead, C., & Hui, L. Transcriptomic analysis of patient plasma reveals circulating miR200c as a potential biomarker for high-grade serous ovarian cancer. *Gynecologic Oncology Reports* 2022, 39, [100894]. <https://doi.org/10.1016/j.gore.2021.100894>
 - Cohen, P. A., Webb, P. M., King, M., Obermair, A., GebSKI, V., Butow, P., Morton, R., Lawson, W., Yates, P., Campbell, R., Meniawy, T., McMullen, M., Dean, A., Goh, J., McNally, O., Mileskin, L., Beale, P., Beach, R., Hill, J., ... Friedlander, M. Getting the MOST out of follow-up: a randomized controlled trial comparing 3 monthly nurse led follow-up via telehealth, including monitoring CA125 and patient reported outcomes using the MOST (Measure of Ovarian Symptoms and Treatment concerns) with routine clinic based or telehealth follow-up, after completion of first line chemotherapy in patients with epithelial ovarian cancer. *International Journal of Gynecologic Cancer* 2022, 32(4), 560-565. <https://doi.org/10.1136/ijgc-2021-002999>
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- ### Intensive Care Research Group
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Additional publications in 2021/22

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- ### Orthopaedic Research Group - Presentations
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- Neither Mechanical Axis nor Kinematic Axis Alignment Provide Sufficient Balance in TKA .
 - The Case for Functional Alignment. Presentation. Gavin Clark, Rick Steer Dermot Collopy, David Wood. 2021 AOA Annual Scientific Meeting
 - Restoring Joint Line Obliquity with Functional Alignment Results in Improved PROMs following TKA in Patients with Constitutionally Varus Knees. Presentation. Gavin Clark, Rick Steer Dermot Collopy, David Wood. 2021 AOA Annual Scientific Meeting
 - Haptic Arm Robotics. Presentation. Gavin Clark. AOA Continuing Orthopaedic Education Meetings 2021.
 - Use of pre-operative femoral landmarks in predicting tibial component rotation in total knee arthroplasty. Presentation. George Cunningham, Gavin Clark. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - Neither Mechanical Axis nor Kinematic Axis Alignment Provide Sufficient Balance in TKA. The Case for Functional Alignment. Presentation. Gavin Clark, Dermot Collopy, Richard Steer. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - Restoring Joint Line Obliquity with Functional Alignment Results in Improved Outcomes following TKA. Presentation. Gavin Clark, Dermot Collopy, Richard Steer. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - The use of Planning Software for Robotic Assisted Total Hip Arthroplasty to Adjust Component Position Results in an Increased Virtual Range of Motion Before Impingement. Presentation. Naseer Mohammed Abdul, Richard Steer, Gavin Clark. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - Robotic Assisted Unicompartamental Knee Arthroplasty at Two Years has a Low Revision Rate and Good Functional Outcomes. Presentation. Yue Hao Yang, Gavin Clark. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - Experience and lessons learned from 1718 robotic assisted total knee arthroplasties. Presentation. Dermot Collopy. 2021 AOA 50th WA Branch Annual Scientific Meeting
 - Clinical Results And Patient Reported Outcomes After Robotic-assisted Primary Total Knee Arthroplasty: A Multi-Center Study. Peter Y. Joo; Antonia Chen; Langan Smith; Tsun yee Law; Kelly Taylor; Kevin Marchand; Gavin Clark; Dermot Collopy; Robert Marchand; Martin Roche; Michael Mont; Arthur Malkani –
 - Poster Presentation - ORS 2022 Annual Meeting in Tampa, Florida, Feb 2022
 - What Constitutes Mal-Alignment in Modern Day Total Knee Arthroplasty? Dermot Collopy, Gavin Clark, Jonathan Manara – Presentation - Arthroplasty Society of Australia Annual Meeting - May 2022, Noosa, QLD
 - 2 Year Outcomes on Functionally Aligned Total knee Replacement Gavin Clark, Jonathan Manara, Melanie Marley, – Presentation - Arthroplasty Society of Australia Annual Meeting - May 2022, Noosa, QLD
 - Robotic-assisted TKA allows for accurate prediction of balance prior to bony resection. Gavin Clark, Jonathan Manara, Matthew Goonatillake - Presentation - Arthroplasty Society of Australia Annual Meeting - May 2022, Noosa, QLD
 - Functionally Aligned Total Knee Arthroplasty Restores Native Medial Pivot More Frequently Than Mechanically Aligned Total Knee Arthroplasty Gavin Clark, Jonathan Manara - Presentation - Arthroplasty Society of Australia Annual Meeting - May 2022, Noosa, QLD



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