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CEO's Foreword

Welcome to the 2016/17 St John of God Subiaco Hospital Health and Medical Research Annual Report

Research is at the very core of our hospital. Through engaging in research, we are better positioned to provide our patients with exceptional patient care informed by the latest technologies, techniques and information available.

With more than 40 per cent of St John of God Health Care research undertaken at our hospital, we are leading the way in clinical research and improved health outcomes.

Accomplishments

The progress within our research department over the past year has been tremendous. We have been involved in 79 projects, published 142 papers, presented at 40 conferences and have 15 external collaborations underway.

Other notable highlights include the establishment of the WA Thoracic Research Group due to funds generously donated by the Bendat Family. In addition, we opened the Breast Cancer Survivorship Clinic to assist patients.

The Research Management Committee was also set up this year to bring together our lead investigators and hospital executive and further extend our research capabilities.

Research team

I would like to commend our research caregivers, lead investigators and clinicians for their dedication and commitment to all research undertaken at the hospital. This report is a testament to their brilliant achievement and showcases their many activities which will have a positive impact on our patients.

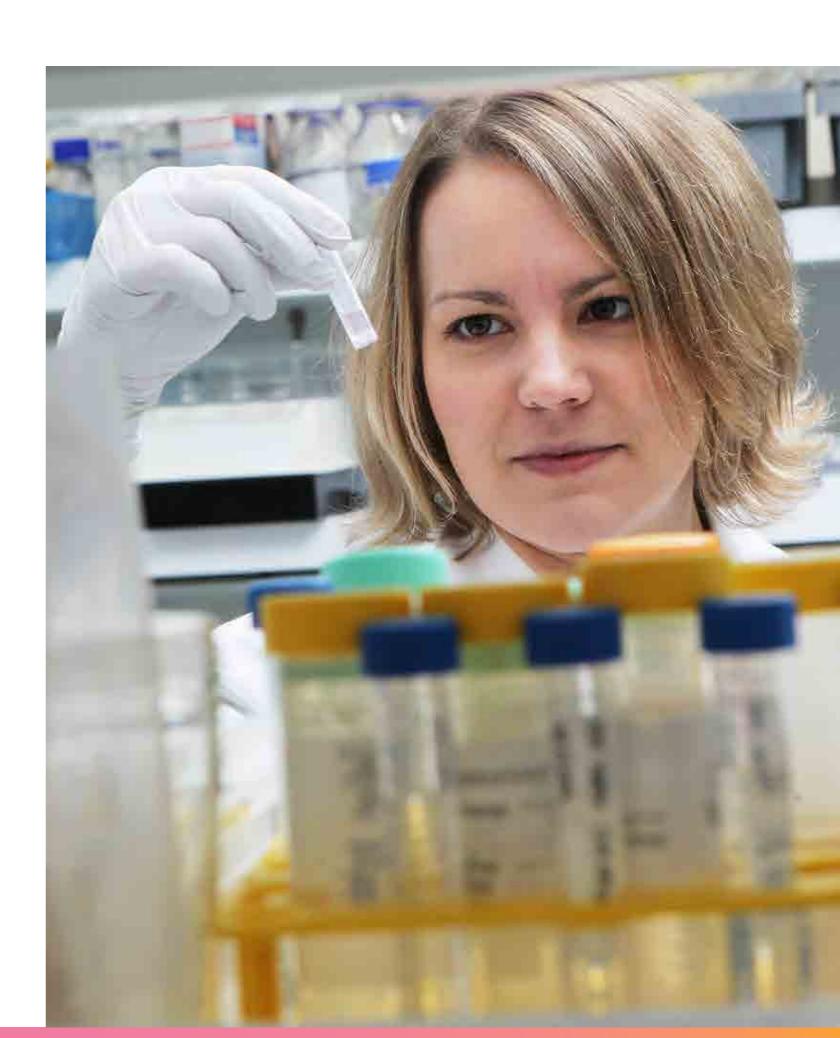
Partnerships

We see partnerships as vital to continuing the innovative research undertaken at the hospital. Strong partnerships with local universities, including Murdoch University, The University of Western Australia, University of Notre Dame Australia (Fremantle) and Curtin University, enable collaborations between academics and clinicians to be fostered and strengthened.

The hospital's 2015-2019 strategic plan places a priority on research to ensure the provision of exceptional person-centred care, informed by research and delivered with compassion, will continue to be implemented over the next few years. Our vision is to build on these foundational research blocks and become a world class academic medical centre of excellence.

Professor Shirley Bowen

Chief Executive Officer St John of God Subiaco Hospital



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Research Highlights



Anaesthesia and Pain Unit

- The top recruiting site in the world for the PADDI study.
- The top recruiting site in Australia for BALANCED trial.



Breast Cancer Research Unit

• The Continuous Improvement in Care – Cancer Project has received \$750,000 per annum over five years in funding from the Cancer Research Trust to implement an innovative program of research that places cancer patients first.



Gynaecological Cancer Research Group

• The EXCISE Study lead by Dr Paul Cohen is the first study the hospital has been a lead site for an international clinical trial.



Inflammatory Bowel Diseases

- Appointment of three IBD nurses and the first IBD fellow in the Western Australian private sector.
- More than 200 patients receiving biological therapies for IBD and our site is the largest user of vedolizumab and stelara medications in the country.

Intensive Care Unit Research Program

 Collaborated with the ANZICS Centre for Outcome and Resources Evaluation on the effects of ICU admission time on outcomes.



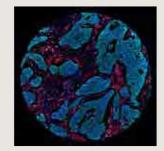
Nursing, Midwifery and Allied Health Research Program

 A successful funding application has enabled an inaugural research project by the Dietetics Department.



Colorectal Cancer Research Group

- Dr Melanie McCoy was awarded a Suzanne Cavanagh Early Career Investigator Grant of \$34,279 by the Cancer Council WA for a project entitled 'Could immune checkpoint blockade improve response to chemoradiotherapy in locally advanced rectal cancer?'
- Successfully established laboratory methods for identifying multiple types of cells in the same tissue section. This will allow further cuttingedge research into the immune response to colorectal cancer. The Group's image entitled 'The World of Tumour Immunology' (right), which showcases this technique, won first prize in the 2017 Australasian Society of Immunology 'Snapshots of the immune system' national scientific photography competition.



This image shows a circular piece of colon cancer tissue (1mm in diameter), stained with fluorescent markers to highlight immune cells (red), surrounding and infiltrating the tumour (light blue). The small green cells visible among the red cells are regulatory T cells that suppress immune responses

Oncology Clinical Trials

 A number of clinical trial safety and compliance initiatives have been implemented that focus on training and teaching including research investigator-initiated research study safety and risk mitigation programs, pre-audit programs, internationally accredited transcelerate Good Clinical Practice (GCP) and research ethics on-site training.

Orthopaedic Surgery Research Group

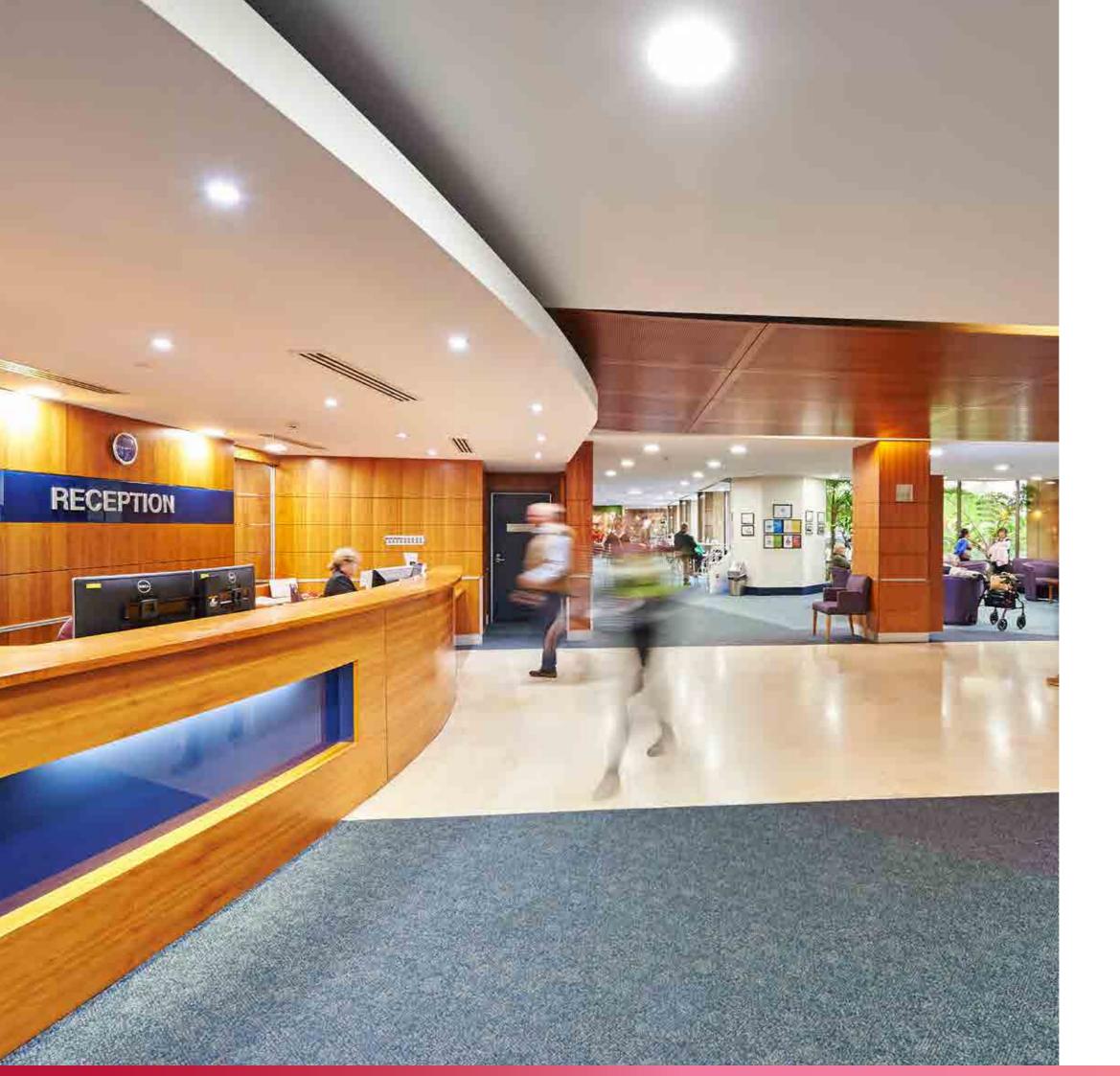
- The first MAKO total knee replacement was performed in December 2016.
- 120 patients have received a total knee replacement using the an orthopaedic surgical arm.



Thoracic Research Group

 Established a tissue biobank of all patients with primary lung malignancy who have been diagnosed or managed at the hospital.





About Us

St John of God Subiaco Hospital has been a leading facility in Western Australia for nearly 130 years. With about 580 beds and more than 800 highly qualified medical practitioners, the hospital covers a range of medical and surgical specialty areas.

The hospital undertakes oncology clinical trials and extensive research in the areas of anaesthesia, pain, cardiology, intensive care, neurosurgery, nursing, midwifery and allied health, respiratory, breast, colorectal and gynaecological cancers.

The latest techniques and technologies are undertaken at the hospital, including operating room robots in gynaecology, orthopaedics and urology and intraoperative CT scanners for some spinal procedures.

St John of God Subiaco Hospital is the flagship hospital of St John of God Health Care, one of Australia's largest private hospital operators and Australia's largest Catholic hospital operator.



HREC Chairperson's Report



The St John of God Health Care Human Research Ethics Committee (SJGHC HREC) and Scientific Review Sub-Committee (SRC) review and support all of the research projects conducted across the organisation.

The SJGHC HREC and SRC provide a range of advice to researchers to facilitate project design and methodology.

More than 40 per cent of the new studies approved by the committees over the past year have been based at St John of God Subiaco Hospital. This includes 30 per cent in medical oncology, 25 per cent in nursing and 25 per cent in respiratory medicine and gastroenterology. Other growing areas of research are intensive care and orthopaedics.

The submission and review process has been streamlined in recent times to comply with National Statement and National Health and Medical Research Council requirements.

There have been some movement with members on our committees this past year. I would like to acknowledge Professor Jack Goldblatt who retired from the SRC after 10 years of service.

We also thank former SRC member and former co-chair Dr Nikolajs Zeps, who is now pursuing other opportunities interstate.

Our thanks also extends to Professor Catherine Cole who retired from the HREC.

Over the past year, we welcomed Dr Ben Carnley who joined the HREC and Professor Kevin Croft who joined the SRC.

We look forward to seeing an increasing range of the excellent research undertaken at St John of God Subiaco Hospital.

Clinical Professor Dr Simon Dimmitt

Human Research Ethics Committee Chairperson St John of God Health Care

St John of God Health Care Human Research Ethics Committee Membership

Chair: Clinical Professor Dr Simon Dimmitt - BMedSc (Hons) MBBS FRACP FCSANZ

Deputy Chair: Mr Colin Keogh - BSW MAPP GCLCC

Members: Ms Tracey Piani - RN BA (Hons) Psychology MBA (in progress)

Fr Joe Parkinson - STL PhD

Mr Eric Heenan - BLaws (Hons) The Honorary Q.C (Retired Judge Supreme Court WA)

Dr Ben Carnley - MBBS FRACP FRCPath
Dr Janie Brown - BNurs MEd PhD

Sr Leonie O'Brien - BEd Master Pastoral Services

Mr Hamish Milne - BA (Hons) GradCertEthics MPhil MBA GAICD FAIM

Professor Sally Sandover - BSc MPH

Mr Patrick O'Connor - MPsych (clinical) MBA

Mr Jeffrey Williams - RN BSc

Ms Mary Rigby - BSc (Nurs) Diploma Management Master of Bioethics (in progress)

SRC Membership

Chair: Professor Sally Sandover - BSc MPH

Members: Clinical Professor Michael Byrne - BMedSci (Hons) MBBS MRCP FRACP

Dr Paige Tucker - BSc (Biomedical Science) BMedicine/BSurgery (Hons) PhD (in progress) AHPRA Dr Kylie Russell - Master Health Science (Education) BNurs PhD Grad Cert Human Resource

Management (in progress)

Mr John Taylor - FRCP FRCS FRCS(Ed) FRACS FRCOG FRANZCOG Ms Gemma McGrath - BNurs BLaws (Hons) Master of Laws

Professor Leanne Monterosso - BNurs (Hons) RN RM NNT GCert TerTeach, PhD FACNA

Professor Kevin Croft

Committee Managers

Gorette De Jesus, Executive Officer Karen Roberts, Research Ethics Officer

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St John of God Foundation CEO's Report

Over the past year St John of God Foundation, through the generous support of the community, has provided funds to assist with clinical research, social outreach programs, purchasing medical equipment and developing hospital infrastructure.

At St John of God Subiaco Hospital, this has included the support of ongoing clinical research and oncology clinical trials, as well as looking at new treatments in breast, melanoma, prostate, pancreatic, colorectal and lung cancers.

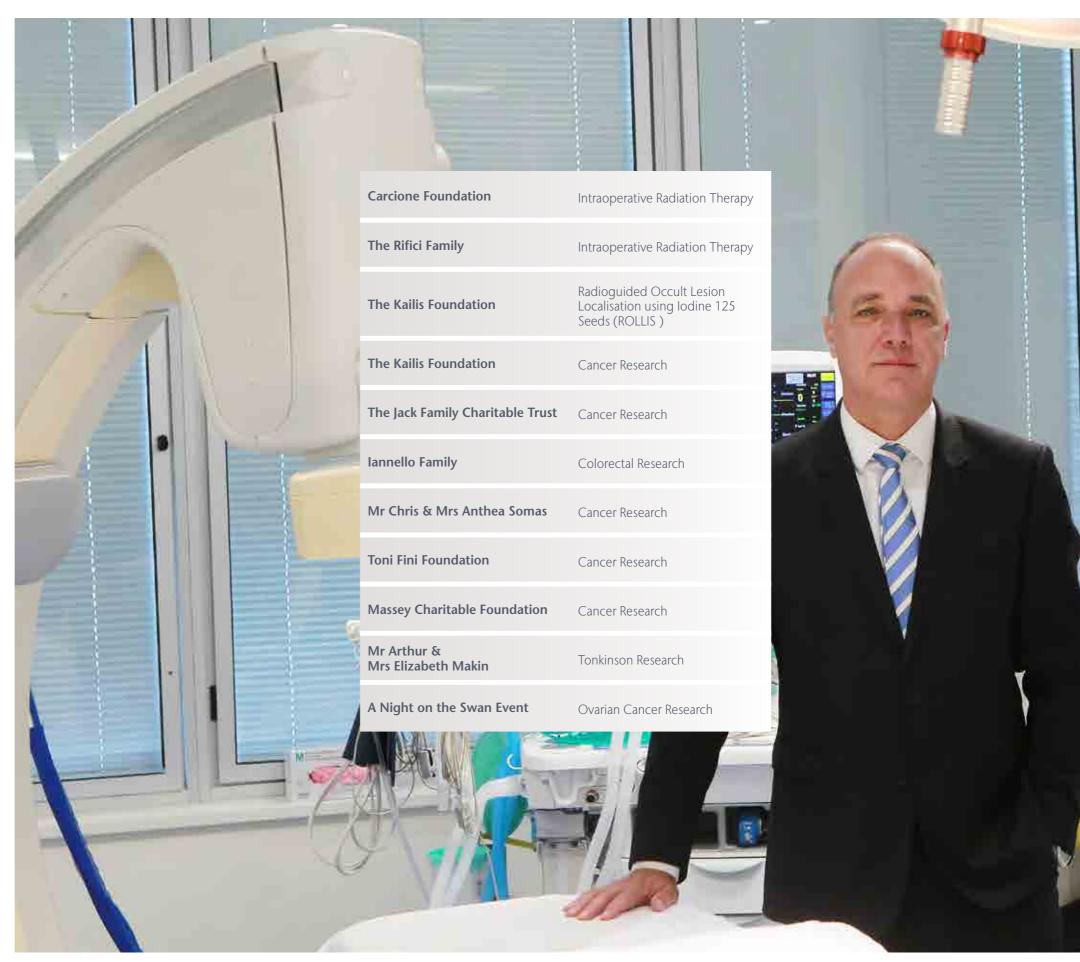
Clinical research plays a crucial role in delivering improved health outcomes. In the past financial year, St John of God Foundation received more than \$3 million through philanthropic donations and pledges. Of this, more than \$510,000 was committed to clinical research at St John of God Subiaco Hospital, with an additional \$79,000 raised for research across St John of God Health Care.

As a leader in the Australian health sector, St John of God Foundation contributes to research projects and clinical trials across more than 25 key health areas, that have the greatest potential to improve patient health care.

We thank and are truly grateful for the support from the individuals, families and communities that contribute to our lifesaving mission.

Nick Harvey

Chief Executive Officer
St John of God Foundation





Research Operations Manager's Report



The past 12 months has seen some change to research management at St John of God Subiaco Hospital.

Following the departure of the Director Medical Research Network, a Research Management Committee (RMC) was established (see page 17).

The RMC provides research leadership and ensures the management of research funds and delivery of quality patient care is in accordance with the mission, philosophy and values of St John of God Health Care.

As the Research Operations Manager, I have continued to focus on enhancing the operational aspects of the research and clinical trial units and ensure they align with the hospital's strategic priorities.

Comprehensive and robust financial stewardship is paramount to the ongoing growth and success of research at the hospital. Our relationship with St John of God Foundation, along with the generous philanthropic support from our donors, is key to the achievement of our strategic objectives.

Over the past year, we have improved and streamlined our research governance processes. As part of this, we successfully reduced the legal approval timelines to align with industry standards.

In addition, we have continued to partner with key stakeholders to enhance our research projects. A range of new service level agreements and collaborations have been established, providing our researchers with opportunities to expand their programs.

Our researchers are committed to providing patients the best possible care and outcomes, and this remains our core value of research management at the hospital.

Dino Cercarelli

Research Operations Manager St John of God Hospital Subiaco

Clinical Trials Safety and Compliance



Catherine MayManager Clinical Trials Safety
and Compliance

Focus continued this year on enhancing the standard of ethical conduct, data reliability and embedding scientific integrity into the hospital's research units.

New risk management programs were established by Catherine May, Manager Clinical Trials Safety and Compliance, to ensure high safety standards are maintained for study participants, researchers and institutions. They are also designed to ensure researchers are trained in accordance with guidelines and laws that mandate safe and ethical research conduct. In addition it ensures best practice, scientific integrity and data reliability are incorporated into research.

New initiatives include:

- Research project assessment and planning services for research study proposals relating to proposed study infrastructure, resource and budget requirements
- Pre-audit study, department inspections and interview preparation, pre study sponsor and international regulatory agency audits
- GCP Training conducted at other St John of God Health Care hospitals throughout Australia
- Monthly education sessions are now available post presentation for caregiver via the intranet research portal

The hospital's research service provision has grown over the past 12 years, due to the increase in investigator initiated clinical research trials being proposed and implemented.

Prior and ongoing current programs include:

- Orientation and mentoring for new researchers
- Monthly research and ethics presentations by scientists, lead researchers and experienced local caregivers
- Bi-annual Good Clinical Practice (GCP) transcelerate credentialed research and ethics training days
- Internal auditing and monitoring services



Research Management Committee Chairperson's Report



Health and medical research is a key area of focus for St John of God Subiaco Hospital.

Research can be significantly beneficial to patients, as it provides access to cutting edge and innovative therapies only available through clinical trials. For clinicians, it generates vast intangible benefits, as well as the delivery of high quality care. A culture of research facilitates awareness of current best practice, willingness to explore new options and reflects commitment to continuous improvement and best outcomes for patients.

Looking back

The past year has been one of transition for our research department. I would like to acknowledge the wonderful work undertaken by Dr Nikolajs Zeps, the former Director Medical Research Network. St John of God Subiaco Hospital is one of the most research active hospitals, both public or private, in Western Australia, largely because of Nik's leadership. Following Nik's departure, a Research Management Committee was formed to provide strategy and leadership for research. I would like to acknowledge all members of the committee, as well as the executive leadership, all of whom have been fully engaged and committed to supporting high quality research.

Looking forward

Our ongoing vision is to be an academic hospital that provides the highest quality care with research embedded and integrated into the delivery of healthcare to ensure the best possible outcomes.

The hospital already has world-leading researchers and conducts leading research, and our ambition is to grow our research substantially. This will include providing further research training and opportunities to junior doctors, as well as nursing and allied health caregivers. We also plan to expand our partnerships with universities and medical research institutes, with a focus on supporting post-graduate students undertaking higher education.

This report outlines the extraordinary amount of work that is being undertaken at St John of God Subiaco Hospital to contribute to better outcomes for patients. The number and quality of projects is a testament to our researchers and collaborators, as well as all those who support and contribute to research activities, including clinical staff, operating theatres and laboratories, as well as those who review projects for ethical and other approvals.

Professor Steve Webb

Research Management Committee Chairperson St John of God Hospital Subiaco

Research Management Committee



Professor Shirley Bowen *Chief Executive Officer*



Dr Eva DenholmActing Director of Medical Services



Dino Gercarelli Research Operations Manager



Dr Paul GohenDirector Gynaecological Cancer
Research Group

Dr Paul Cohen is the Director Gynaecological Cancer Research Group at St John of God Subiaco Hospital. He also is a gynaecologist at King Edward Memorial Hospital and works with the Western Australia Gynaecological Cancer Service, where he is actively involved in research and teaching.

Dr Cohen is a Clinical Senior Lecturer at The University of Western Australia and Adjunct Professor at the Institute of Health Research, University of Notre Dame Australia (Fremantle), where he supervises PhD and Masters' students.

Dr Cohen is the principal investigator for an international multicentre prospective randomised pilot study to compare excisional treatments (cone biopsy vs. LEEP) for adenocarcinoma-in-situ of the uterine cervix. He is an investigator on a number of clinical trials investigating quality of life in cancer survivors and in women at high risk of gynaecological cancers. His pre-clinical research interests include miRNA expression profiling of high-grade serous tubo-ovarian carcinomas, an analysis of the FOXL2 gene mutation in metastatic recurrent adult granulosa cell tumours and the role of circulating tumour DNA in ovarian cancer screening. Dr Cohen is also actively involved in several population-based research studies and his work into outcomes following treatment for screen-detected cervical adenocarcinoma in situ has influenced new practice recommendations in the 2017 revised National Cervical Screening Guidelines.

Dr Cohen is Chair of the 2018 ANZGOG Annual Scientific Meeting Organising Committee and is a member of the Scientific Committee of the International Gynaecological Cancer Society Meeting in Kyoto, Japan 2018.

He organised Western Australia's inaugural BRCA Information Day in May 2016, which was attended by 140 carriers of the BRCA1 and BRCA2 gene faults and their families. These gene faults confer a significantly elevated lifetime risk of breast and ovarian cancer and the event provided these individuals with an opportunity to hear from local experts and to meet others with similar conditions. Dr Cohen organised the subsequent follow up BRCA Information Day in May 2017.





Research Management Committee

Dr Andrew DeanHead of Department Cancer Services

Dr Andrew Dean is the Head of Department, Cancer Services at St John of God Subiaco Hospital. He originally trained in internal medicine and palliative care, before establishing the palliative care service at Sir Charles Gairdner Hospital and St John of God Subiaco Hospital in 1994. Dr Dean also set up VirtualMedicalCentre. com (myvmc.com), Australia's busiest health information site, which won the Prime Minister's Award in 2003.

Dr Dean now works full time in medical oncology and is the principle investigator on numerous studies. His articles have been published in a number of journals, including Lancet and Journal of Clinical Oncology, and his major research interests in pancreatic and ovarian cancer.

Under his guidance, the resident medical officers and fellows at St John of Subiaco Hospital have presented original research at a number of national and international conferences.



Professor Eli Gabbay Lead Investigator of the Thoracic Research Group

Professor Eli Gabbay has an established career as a clinician, researcher, mentor, teacher, administrator and public health advocate. He has a substantial publication record and history of grant success and is an accomplished supervisor of higher degree by research, particularly in the fields of pulmonary hypertension, exercise physiology, advanced lung disease and lung transplantation.

Professor Gabbay has 20 years' experience as a respiratory physician, specialising in pulmonary hypertension and interstitial lung disease. He is the Chair of Research and the Cardio-Respiratory Research Group at the University of Notre Dame Australia (Fremantle) School of Medicine, sits on the Academic Governance Committee of Notre Dame University, is the chair of the Bendat Respiratory and Lung Cancer Research and Development Fund and the Western Australian Health Translational Network. In addition, Professor Gabbay sits on the Board of the University of Notre Dame Institute for Health Research, which oversees health related research across the University's four campuses.

Professor Gabbay is an Adjunct Professor of Medicine at The University of Western Australia and an Adjunct Associate Professor at Curtin University, School of Physiotherapy.



Dr Zi Ng Junior Medical Doctor Research Representative

Dr Zi Ng graduated from The University of Western Australia with a Bachelor of Medicine and Bachelor of Surgery Honours in 2014.

He is currently a resident medical officer of the SMART programme at St John of God Subiaco Hospital and has a strong interest in general surgery. His current research areas include minimally invasive surgery, hernias and high output stoma.



Professor Gameron Platell
Director Colorectal Cancer
Research Group

Professor Cameron Platell is an academic colorectal surgeon. He is a Professor at The University of Western Australia, and is currently seconded to work at St John of God Subiaco Hospital as the Director Colorectal Cancer Research Group and the Scientific Director for the Bendat Family Comprehensive Cancer Centre.

Professor Platell's principal research interests include cancer survival outcomes, the immune response to cancer, the epigenetics of colorectal cancer and the identification of prognostic and predictive markers in colorectal cancer. He has published 125 peer-reviewed manuscripts in cited journals on PubMed.

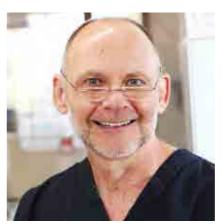


Professor Christobel SaundersDirector Breast Cancer Research Unit

Professor Christobel Saunders is internationally recognised as one of Australia's most prominent research orientated cancer surgeons. She was recently named the joint WA Scientist of the Year for 2017.

Professor Saunders has substantially contributed to many clinical aspects of breast cancer research, including clinical trials of new treatments, psychosocial, translational and health services research and is active in several areas of surgical oncology cancer research, with a particular emphasis on breast cancer.

She has been involved in research for more than 25 years, and in the past five years published more than 150 peer-reviewed journal articles (including two in The Lancet), six letters to the editor, two research reports, three book chapters and one book.



Professor Steve WebbResearch Management Committee
Chairperson and Director Clinical Trials

Professor Steve Webb is a senior staff specialist in Intensive Care Medicine at St John of God Subiaco Hospital and Royal Perth Hospital, a Professor of Critical Care Research at Monash University, a Clinical Professor at The University of Western Australia and the Director Clinical Trials at St John of God Subiaco Hospital.

Professor Webb is a past chair of the Australian and New Zealand Intensive Care Society Clinical Trials Group, a founding Director of the Australian Clinical Trials Alliance, a foundation Fellow and a member of Council of the Australian Academy of Health and Medical Sciences and a member of the National Health and Medical Research Council Health Translation Advisory Committee. He has published more than 140 journal articles, including manuscripts in the New England Journal of Medicine, Journal of the American Medical Association, Lancet and BMJ. He is a recipient of more than \$85 million in grant funding and has conducted multiple clinical trials that provided definitive guidance on optimal management for patients with various forms of critical illness.



Our Lead Investigators

Our Research Management Committee members are also Lead Investigators.



Mr Gavin ClarkOrthopaedic Surgeon

Mr Gavin Clark specialises in hip and knee joint replacement surgery. He is currently undertaking a PhD study in optimising outcomes in knee replacements.

Mr Clark has been involved in the use of computer assisted surgery for more than 15 years and has been at the forefront of assessing and introducing robotic technology for joint replacements in Australia.

His current research studies look at individualising the position of knee replacement based on intra-operative soft tissue tensions and the effect on outcomes. He is also investigating robotically assisted partial and total knee replacement with the potential benefits of optimised balance and alignment to the outcome of these procedures.



Mr Dermott Collopy Orthopaedic Surgeon

Mr Dermott Collopy is a Perth-based surgeon specialising in hip and knee replacement, revision arthroplasty, and pelvic and acetabular trauma. He is well-respected nationally and internationally.

Mr Collopy completed his residency and advanced surgical training at Royal Perth Hospital. After gaining FRACS Ortho in 1994, he undertook three years of overseas fellowship training in the area of hip and knee arthroplasty and revision surgery.

His research interests are in hip and knee implant design and fixation, and was one of the design surgeons on the Emperion revision hip system, the Triathlon knee system and the Accoladell hip system. He, together with one of his partners, Mr Gavin Clark, is involved in developing robotics in knee and hip replacement.

Mr Collopy is the immediate Past-President of the Arthroplasty Society of Australia, and is currently the Chairman of the WA State branch of the AOA. He sits on numerous committees, including the AOA Scientific Committee, the COE Committee and the NJRR Committee. Mr Collopy works as a consultant at St John of God Subiaco and Murdoch Hospitals.



Professor Ian LawranceHead of the Centre for Inflammatory
Bowel Disease

Professor Ian Lawrance is a consultant gastroenterologist, a Professor in the School of Medicine and Pharmacology, Faculty of Medicine and Dentistry, at the Harry Perkins Institute of Medical Research, The University of Western Australia, Murdoch University and the head of the Centre for Inflammatory Bowel Diseases (IBD) at St John of God Subiaco Hospital.

Professor Lawrance is the former head of the Department of Gastroenterology and Hepatology at Fremantle Hospital and the Director of Endoscopic Services at Kaleeya Hospital. In 2000 he developed the Centre for Inflammatory Bowel Diseases at Fremantle Hospital and was its director until the hospital closed and the service was moved to St John of God Subiaco Hospital.

Professor Lawrance was a founding committee member of a physician-initiated interest group IBD Australia in 2002 and was its secretary from 2005 to 2008. He is currently a committee member of the Australian and New Zealand IBD Consortium, a board member of the Australian IBD Association, a board member of Crohn's Colitis Cure, a member of the Western Australian Drug Evaluation Panel and a committee member of the International IBD Genetics Consortium.

Professor Lawrance currently sits on numerous pharmaceutical IBD drug advisory committees. He has published more than 100 peer-reviewed papers into the management of the IBDs and outcomes of the chronic intestinal inflammation, including intestinal fibrosis and carcinogenesis. He continues to review papers, abstracts and research grants for numerous scientific organisations, is a member of nine editorial boards and was the Genetics Section Editor for IBD.



Professor Gabriel LeeHead of Department Neurosurgery/
Spinal Surgery

Professor Gabriel Lee received his medical degree with honours from the University of Adelaide in 1996. His Master of Surgery thesis was centred on research to identify the origin of macrophages in syringomyelia.

Professor Lee became a Fellow of the Royal Australasian College of Surgeons in 2003 after completing his neurosurgery training in Western Australia. He holds dual post-graduate Clinical Fellowships in spinal surgery (Toronto Western Hospital, Canada) and epilepsy surgery (Yale-New Haven Hospital, Connecticut, USA).

Professor Lee has been performing brain and spine surgeries at St John of God Subiaco Hospital since 2006.

He is a Clinical Professor affiliated with The University of Western Australia and Curtin University, and is extensively involved in undergraduate medical student and post-graduate neurosurgery teaching.

Professor Lee has published extensively and collaborated with other researchers on basic science and clinical projects. His research interests include neuro-oncology, spinal disorders and development of medical technologies, such as spinal instrumentation and neurosurgical navigation.



Dr Edward LittonClinical Research Fellow, Intensive Care Unit

Dr Edward Litton is a staff specialist in Intensive Care Medicine at St John of God Subiaco Hospital, Director of ICU Research at Fiona Stanley Hospital and a senior lecturer at The University of Western Australia.

Dr Litton is the recipient of more than \$5 million in research support. His principle areas of research include sepsis and pneumonia, high-risk patients undergoing cardiac surgery, iron metabolism in critical illness, red blood cell transfusion in critical illness, acute lung injury and sleep in critical illness.





Professor Nolan McDonnell Senior Research Fellow Anaesthetics and Deputy Head of Department Anaesthesia Obstetrics

Clinical Associate Professor Nolan McDonnell is a specialist anaesthetist who holds adjunct appointments with the School of Women's and Infants Health and the School of Medicine and Pharmacology at The University of Western Australia.

He is heavily involved in the care of complex obstetric and gynaecology patients and conducts local and multicentre research across these specialties. His particular areas of interest include the optimisation of epidural analgesia in labour, vasopressors and regional anaesthesia in obstetrics, post-operative analgesia, acquired bleeding disorders and rare disorders of pregnancy.

In addition to his research interests, Clinical Associate Professor McDonnell is extensively involved in the education and promotion of high quality anaesthetic and obstetric care in Australia and globally through his involvement as a committee member with the World Federation of Societies of Anaesthesiologists.



Professor Eric Visser Churack Chair of Chronic Pain Education and Research

Professor Eric Visser is a specialist pain medicine physician and anaesthesiologist at St John of God Subiaco Hospital and Joondalup Health Campus. He has wide-ranging interests, including pain education, acute pain service applications, spinal pain, migraine, pharmacological pain management and peripheral neural blockade for chronic pain.

In 2015 the University of Notre Dame Australia (Fremantle) and St John of God Subiaco Hospital appointed Professor Eric Visser as the inaugural Churack Chair of Chronic Pain Education and Research in the School of Medicine. As the Chair, Professor Visser is tasked with reducing the impact of chronic pain, one of the biggest unrecognised health problems in the community, through furthering research and the education of medical students in the area of chronic pain management.



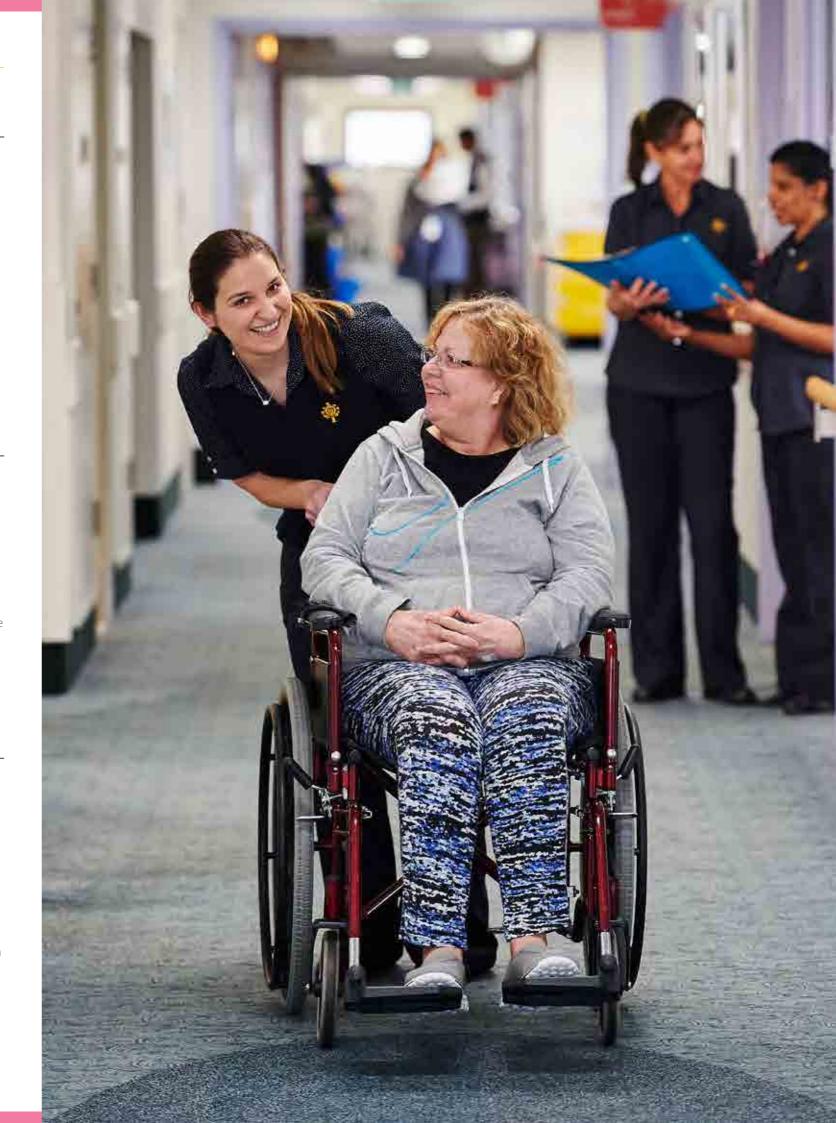
Dr Allan Wang *Orthopaedic Surgeon*

Dr Allan Wang is an orthopaedic surgeon with a special interest in shoulder and upper limb surgery.

Following orthopaedic training, Dr Wang undertook fellowship training in the United States of America, completed a RACS Research Fellowship and was awarded a PhD in 1998.

Currently, Mr Wang is a Clinical Professor of Orthopaedic Surgery and Adjunct Professor in the School of Sports Science and Exercise and Health at The University of Western Australia. He is the President of the Shoulder Elbow Society of Australia and the past Chairman of Continuing Education for the Australian Orthopaedic Association (2007-2010) and Scientific Secretary for the AOA (2011-2015).

Mr Wang continues to lecture and publish in international journals. Current research interests include innovative cellular therapies to enhance healing after elbow and shoulder tendon surgery and rehabilitation protocols after shoulder arthroplasty.







Anaesthesia and Pain Research Unit

Anaesthesia and Pain

Research Unit



The Anaesthesia and Pain Research Unit was established in May 2012 to foster multicentre clinical trials to answer important clinical questions in anaesthesia, pain and perioperative medicine.

The unit aims to deliver high quality, evidence based research and guidance to improve clinical practice, patient care and become a leader in the private sector for clinical excellence.

PROJECTS

ODDS study: A prospective audit of opioid analgesia use, pain scores and adverse clinical events during the first seven days after discharge from day-procedure surgery.

Prof Eric Visser, Jill Kelly, Nisha Sikotra

Commenced 2017, estimated completion 2018

Problems have surfaced in recent years with overprescribing of opioids following surgery, leading to adverse events, risk of overdose and vast numbers of leftover drugs in the community. The ODDS study will prospectively audit opioid analgesia consumption, pain scores and adverse clinical events in 300 patients in the first week after day-case surgery.

This will establish baseline analgesia use following surgery, which in turn will guide development of our one for the road rule' initiative (one opioid, maximum four hourly, four times daily, four day's supply) targeted at RMOs surgeons, anaesthetists and GPs, for safe discharge prescribing of opioids.

BALANCED Anaesthesia Trial

Prof Tomas Corcoran

Commenced 2014, estimated completion 2018

A prospective, randomised clinical trial of two levels of anaesthetic depth on patient outcome after major surgery. It is a large multicentre trial with about 4500 patients recruited so far of a total 6500 patients needed.

(EPITOMISE: Phase 1) A survey of current labour epidural analgesia practices across Australian and New Zealand

Clinical A/Prof Nolan McDonnell, Nisha Sikotra

Commenced 2017, estimated completion 2018

This study involves a survey of maternity hospitals across Australia and New Zealand. The study will provide up to date information on current labour analgesia practices in Australia and New Zealand. This data is not currently readily available and will help inform clinicians and consumers.

The data from this survey will be used to help design a large, multicentre trial to examine the best method of epidural analgesia delivery, which will have significant worldwide practice implications.

PADDAG Study

Prof Tomas Corcoran

Commenced 2015, estimated completion 2016

A multicentred, prospective, stratified-randomised controlled trial to determine if the use of intraoperative Dexamethasone is associated with an increased blood glucose concentration and whether this increase is greater in patients with diabetes than in those without.

PADDI Anaesthesia Trial

Prof Tomas Corcoran

Commenced 2016, estimated completion 2020

A large multicentre, prospective, randomised, double-blind, placebo controlled trial to determine whether the use of intraoperative Dexamethasone is associated with an unacceptable increased risk of postoperative infection in surgical patients. Patients will be stratified according to whether or not they are known to have diabetes. Recruitment for this trial commenced mid-2016.

Reduction of chronic postsurgical pain with ketamine – ROCKet trial

Prof Tomas Corcoran

Commenced 2017, estimated completion 2021

This study is a definitive, large, multicentre, double-blind, placebocontrolled, randomized phase 3/4 trial of the effect of perioperative intravenous ketamine on the incidence and severity of chronic post-surgical pain.

The primary hypothesis is that an intravenous ketamine infusion (commenced with a loading dose prior to incision and run for 24 hours postoperatively) in patients undergoing general anaesthesia for abdominal, thoracic or major orthopaedic surgery, will reduce the incidence of chronic pain related to the surgical wound at 12 months after surgery, compared with placebo.

The treatment effects on chronic pain severity and character, associated psychological and quality of life indices, acute pain and analgesic requirements, quality of postanaesthetic recovery and cognitive function, hospital stay and longer-term healthcare utilisation costs will also be measured.

The study expects to recruit 4884 patients.

The MIGRANT Migraine Study

Prof Eric Visser, Eamon McDonnell

Migraines affect 15% of the population and are a leading cause of pain, suffering and disability in our community. Research suggests that inflammation of the brain's coverings (meninges) by nerve cells releases 'oxygen free radicals', which may cause migraine attacks. This study seeks to enroll 90 migraine patients to see if N-acetylcysteine, Vitamin E and Vitamin C may lessen brain inflammation and in turn reduce the frequency and severity of migraines. This vitamin-based therapy has never been studied before and, if effective, may play an important role in migraine prevention. A grant was received from the Fremantle Hospital Medical Research Foundation to help with the study, which is also an honours project for the University of Notre Dame Australia (Fremantle) Medical Student Eamon McDonnell.

Churack Virtual Headache Research Diary

A cutting edge online headache research tool named the Churack Virtual Headache Research Diary, is currently being finalised.

The PAINCHECKER Pain Management Checklist System

Prof Eric Visser

An online best-practice checklist system for GPs and medical students is being developed to help manage chronic back pain. It will then be developed for neck pain, nerve pain, fibromyalgia and headaches. Chronic low back pain (CLBP) affects 10% of the population and is one of the world's top 10 disease burdens, associated with pain, disability and massive healthcare and economic costs. CLBP can be difficult to manage. No single mode of treatment is usually sufficient and instead requires a multimodal, multidisciplinary approach. Checklists have long been used in industries such as aviation and engineering to promote best-practice and safety. A practical online checklist tool is being developed for low back pain which can be used by GPs during consultations. The tool will also provide links to help people with self-managing pain. The launch of the Churack PainChecker website early next year will integrate education and research and act as a 'one stop shop' for pain management for medical professionals, students and consumers.

The long term outcomes of lignocaine infusions used for postoperative pain study – PILOT [LOLIPOPS]

Prof Tomas Corcoran

Commenced 2017, estimated completion 2018

Chronic post-surgical pain (CPSP) is a common and debilitating condition estimated to cost \$11,000 per patient annually. The incidence is procedure-specific, approximating 12 per cent after major surgery and up to 47 per cent after breast surgery. Perioperative interventions that reduce the incidence of CPSP are the subject of intense interest, but none are currently established in routine practice either globally or in WA.

LOLIPOPS-Pilot is a multicentre prospective, double blind randomised controlled trial, and will explore the hypothesis that perioperative lidocaine



infusions can significantly reduce the incidence of CPSP six months after surgery. A positive finding would have enormous clinical and economic implications. Additional safety, efficacy and feasibility data will inform national funding applications for a larger, multicentre trial exploring lidocaine and CPSP across a range of surgical procedures.

The study expects to recruit 280 patients.

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McDonnell NJ, 'Amniotic Fluid Embolism-An Update', 16th World Congress of Anaesthesiologists, August 2016, Hong Kong

McDonnell NJ, 'Modern Coagulation Management in Obstetric Haemorrhage', Malaysian Society of Anaesthetists National Scientific Congress, August 2016, Kuala Lumpur, Malaysia

McDonnell NJ, 'The EPITOMISE Trial: A randomised, multicentre platform trial of patient controlled epidural analgesia in labour', ANZCA Clinical Trials Network Meeting, August 2016, Coogee

KEY STAFF



Professor Eric Visser Churack Chair for Chronic Pain Education and Research, in partnership with the University of Notre Dame Australia (Fremantle)



Clinical A/Professor Nolan McDonnell Senior Research Fellow and Specialist Anaesthetist



Clinical Professor Tomas Corcoran Chief Investigator and Specialist



Jill Kelly *Nurse Practitioner*



Yvonne Buller Research Nurse



Natalie Hird Research Nurse



Nisha Sikotra





Breast CancerResearch Unit



St John of God Subiaco Hospital provides a range of diagnostic and surgical services for breast cancer. This includes innovative reconstruction surgery, medical oncology, supportive care through dedicated breast nurses and specialist physiotherapy and psychology care.

In 2016, the hospital received funding to open a Breast Cancer Survivorship Clinic to help patients treated for breast cancer. It assists patients who are within one year post-chemotherapy or radiotherapy and includes free wellness programs to help patients thrive.

Led by Professor Christobel Saunders, the breast cancer research unit covers four major aspects to assist and guide patient care. They include:

- Translational research driven by the hospital's Biobank, in collaboration with national and international researchers.
- Medical and surgical oncology clinical trials from prevention through to survivorship. They cover all aspects of cancer, including prevention, diagnosis, treatments, post treatment, survivorship, fertility, end of life care, development of drugs and translation of research into practice.
- Supportive care research, such as exercise intervention and enabling young breast cancer survivors to start a family.
- Health services research that can help deliver more equitable and effective cancer care to Western Australians.

Medical oncologists run a large number of investigator driven and industry sponsored cancer drug trials (see the Oncology Clinical Trials section).

PROJECTS

Healthy living after cancer trial

Prof Christobel Saunders, Dr Sandi Hayes (QUT), Liz Eakin (UQ) and Cancer Council WA

Commenced 2015, expected completion 2018

This telephone intervention trial promotes exercise and healthy living using the Cancer Council WA helpline telephone service. It is for all adult patients with non-advanced cancer.

Funding has been received from the National Health and Medical Research Council Partnership Project.

Mechanical modulation of bone metastases in advanced breast cancer patients: Can targeted exercise suppress osteolytic tumour progression?

Prof Christobel Saunders, Prof Robert Newton, Associate Prof Daphne Tsoi, Dr Nicolas Hart, Prof Daniel Galvão, Prof Nigel Spry, Prof Vincent Low, Prof Dennis Taaffe, Dr Favil Singh, Mrs Kylie Corbett

Commenced 2016, expected completion 2018

Bone is the most common location for metastatic breast carcinoma, with skeletal lesions identified in more than 80 per cent of advanced breast cancer patients. This pilot study aims to establish the feasibility, safety and efficacy of individually tailored, modular multi-modal exercise programs with spinal isometric training (M3EP-SIT) in advanced breast cancer patients with bone metastases to reduce tumour growth and activity in bones with osteolytic lesions.

This project crucially focuses on patients with high disease burden. If successful, this will provide a non-invasive, low-cost therapy in the management of advanced breast cancer and bone metastases,

to improve survivorship and quality of life, which can be immediately translated into practice within community exercise clinics under supervision, nationally and worldwide.

National Tissue Bank of matched primary breast tumours and metastases obtained at autopsy (BROCADE study)

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

Estimated commencement 2017, expected completion 2019

This study will collect tissue to examine molecular and genetic changes in breast cancers from 'warm autopsy' specimens.

Funding has been received from the National Breast Cancer Foundation.

The study is currently under ethics review for commencement in Western Australia at the end of 2017.

POSITIVE study

Prof Christobel Saunders, Dr Daphne Tsoi, Dr Ru-Wen Teh, Dr Tim Clay and International Breast Cancer Study Group

Commenced 2015, expected completion 2032

The POSITIVE study evaluates the safety of interrupting endocrine therapy for young women with hormone-sensitive breast cancer

who wish to become pregnant. SJG Subiaco Hospital is the first Australian site to be actively involved in this large international research effort, coordinated by the International Breast Cancer Study Group under the umbrella of the Breast International Group.

POSNOC

Prof Christobel Saunders, Mr Lee Jackson, Dr Wen Chan Yeow, Dr Yvonne Zissiadis, Dr Eugene Leong

Commenced 2016, expected completion 2023

As part of a bigger international trial, we are the first Western Australian site involved in 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.

ROLLIS Randomised Controlled Trial

Prof Christobel Saunders, Dr Donna Taylor, Dr Anita Bourke, Mr Lee Jackson, Dr Wen Chan Yeow

Commenced 2014, expected completion 2020

SJG Subiaco Hospital is trialling a new method called Radioguided Occult Lesion Localisation (ROLLIS), which uses low activity lodine 125 seeds to identify impalpable breast cancers.

"In WA we have such great collaborative teams which not only can do world class research, but help change the way we practice medicine by implementing this research - and so improve the lives of people affected by cancer."

Professor Christobel Saunders



Sexuality and quality of life of breast cancer survivors after bilateral salpingooophorectomy: a case-control cross-sectional study

Dr Paige Tucker, Dr Paul Cohen, Professor Christobel Saunders, Mr Lee Jackson

The removal of the ovaries and fallopian tubes is a major surgical procedure with both short and long-term potential adverse effects. Several studies have investigated the psychological and menopausal effects of bilateral salpingo-oophorectomy, and have reported high rates of sexual issues following the surgery.

The primary aim of this observational study is to compare sexual function and quality of life in women with breast cancer who have undergone the removal of their ovaries and fallopian tubes with those who have intact ovaries. The clinical rationale of this study is to gain a greater understanding of the effects of bilateral salpingo-oophorectomy in women with breast cancer, to assist in the counselling of women who may be considering the procedure.

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"Thank you for your time, informative talk and your prompt and useful Wellness Plan. It will be an excellent reference."

"This is all wonderful. Thank you so much for the follow up advice and recommendations I think this program is a wonderful initiative and will benefit all that are involved, especially we patients!"

Patient feedback (Breast Survivorship Clinic)

KEY STAFF



Professor Christobel Saunders Director of Breast Cancer Research Unit

Dr Andrew Dean



Mr Lee Jackson Breast Surgeon/Senior Clinical Lecturer



Dr Wen Chan Yeow Breast Surgeon/Senior Clinical Lecturer

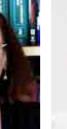


Perth Breast Survivorship Clinic

Dr Sarah Richardson

Dr Daphne Tsoi Medical Oncologist





Dr Tim Clay *Medical Oncologist*



Dr Bridget Cooke



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Positive Trial Delivers Babies After Breast Cancer

"I love being a mum... it's absolutely wonderful."

Breast cancer can put baby plans on hold, so when Kirby was diagnosed at 26 she had to face the prospect that she may never realise her dream of being a mum.

Three years later, Kirby became the first Australian woman to plan, conceive and deliver a healthy baby as part of the international POSITIVE trial. Today, she and husband Chris are the proud parents of five-month old Easton, and they couldn't be happier.

"I love being a mum," Kirby said.

"It's absolutely wonderful."

Led by the International Breast Cancer Study Group, POSITIVE was launched globally in 2014 and is only offered in Australia through St John of God Subiaco Hospital, under the guidance of St John of God Subiaco Hospital Director of Breast Cancer Research Unit and Surgical Oncologist Professor Christobel Saunders. It aims to recruit about 500 women from around the world who wish to interrupt hormone therapy for up to two years to attempt conception.

To be eligible for this trial, women need to have oestrogen receptor positive (ER+) breast cancer, be aged 18 to 42 and premenopausal. Participation involves brief quarterly clinic visits, blood tests at three, six and 12 months and a pelvic ultrasound performed at three and six months, as well as optional questionnaires.

Kirby said she found the lump in her breast after significant weight loss, and within a week of diagnosis was scheduled for a lumpectomy. This was followed by six rounds of chemotherapy and a series of radiotherapy treatments. Like many patients with ER+ cancer, she was then put onto tamoxifen to reduce the risk of recurrence.

"Before my treatment we tried fertility preservation, but they couldn't get any eggs, so unfortunately we had no backup plan," Kirby said.

"When Professor Saunders asked if I wanted to take part in this trial, we jumped at the opportunity.

"Although there is a minor risk with interrupting the tamoxifen, we decided it was a risk worth taking and we couldn't be happier with the result."

Kirby fell pregnant within a year of interrupting her tamoxifen treatment, without intervention. She is now about to re-start the tamoxifen and said without the support of Professor Saunders and the POSITIVE trial she and Chris may never have realised their dream of becoming parents.

Professor Saunders said about 15 per cent of patients with breast cancer are diagnosed during their reproductive years.

"As more women tend to delay childbearing, increasingly, breast cancer occurs before they have completed their families," she said.

"This international study evaluates the pregnancy outcomes and safety of interrupting endocrine treatment. It will also improve our scientific understanding of issues related to conception and pregnancy in young women who have had breast cancer by helping us obtain solid data."



Making breast cancer surgery safer and more effective

"...ongoing research into drugs, detection and supportive care had led to a significant improvement in cure rates and less side effects from treatment."

One of the greatest challenges facing breast cancer surgeons is their own humanity.

Currently, performing a successful lumpectomy relies largely on a surgeon's ability to feel or see a tumour during surgery. This is a subjective process and, unfortunately, up to one in three women are forced to undergo further treatment because some microscopic cancer cells may have been left behind.

Western Australian engineers have joined forces with cancer specialists to start developing a surgical glove fitted with tiny optical fibres that will allow real-time microscopic detection of tumour cells during surgery.

This research is being led by St John of God Subiaco Hospital Director of Breast Cancer Research Unit and Surgical Oncologist Professor Christobel Saunders, The University of Western Australia's Dr Brendan Kennedy (also an engineer at Harry Perkins Medical Research Institute) and Professor David Sampson. Launched six years ago, the research is bridging the gap between engineering and clinical practice.

"This state-of-the-art technology is based on the principles of Optical Coherence Tomography – a non-invasive imaging test using light waves traditionally used to take cross-section pictures of a retina," Professor Saunders said.

"As a surgeon I can't see or feel microscopic disease. This technology provides high-resolution images and we hope it will lead to cleaner surgical margins during breast conservation surgery. It will also significantly reduce the number of repeat surgeries for breast cancer patients and may prove useful in other cancer surgery such as prostate cancer."

Dr Kennedy said the research team had already undertaken successful clinical

studies of this technology using a benchtop unit and a probe. It's been tested as a 'thimble' and they are now focusing on how it can be incorporated into a standard surgical glove for ease of use in the operating theatre.

"Combining this technology into a glove will allow the surgeon to simply 'swipe' across the tissue with their finger to generate a high-resolution image," Dr Kennedy said.

"This will detect if any cancer is left behind in the breast after the lump has been removed."

Breast cancer affects one in eight women in Australia and approximately 1.6 million women worldwide are diagnosed each year.

While these figures are staggering, Professor Saunders said ongoing research into drugs, detection and supportive care had led to a significant improvement in cure rates and less side effects from treatment.

"In the 1980s we were curing about 70 per cent of women," Professor Saunders said.

"In the developed world this is now sitting at about 90 per cent, but we believe we can push the envelope a bit further."

Professor Saunders' research team has been key in developing an instrument to deliver intraoperative radiotherapy to patients during an operation, which means many women no longer have to endure a five-week course post-surgery.

This latest collaboration with the 'engineering department' is another example of innovative research that will improve the mortality rate in breast cancer patients.

"This colliding of different disciplines is one of the great joys of research," she said.

AWARD FOR SCIENTIST OF THE YEAR



Professor Christobel Saunders, Director Breast Cancer Research, at St John of God Subiaco Hospital, has been named the joint recipient of 2017 Premier's Science Award for Scientist of the Year.

The prominent cancer surgeon and internationally regarded cancer researcher has a particular research interest in breast cancer, including clinical trials of new treatments, supportive care and translational and health services research, which have led to better treatments and improved survival for people with cancer.

Professor Saunders said she is appreciative of the award and how it highlights the excellent research being undertaken in Western Australia, which is having a global impact.

"Winning this award is a real win for recognising the importance of clinical medical research in science. It also highlights how in WA we have such great collaborative teams which not only can do world class research but help change the way we practice medicine by implementing this research – and so improving the lives of people affected by cancer," Professor Saunders said.

PROFESSOR SAUNDERS AWARDED JOINT SCIENTIST OF THE YEAR

"Certainly from my point of view this is not an award to an individual but to the team that do cancer research here in WA and across Australia."

St John of God Subiaco Hospital CEO Professor Shirley Bowen said we are delighted that Professor Saunders has been recognised for the incredible work she is undertaking in breast cancer research and assisting the lives of people with cancer.

"The hospitals' breast cancer research group is thriving under Christobel's strong leadership and skills," Professor Bowen said.

"Christobel has greatly expanded the research undertaken by our breast cancer research unit, which now includes the full spectrum of breast cancer, from prevention through to survivorship."

Professor Saunders is a consultant surgeon at St John of God Subiaco, Royal Perth and Fiona Stanley Hospitals, a Professor of Surgical Oncology and head of The University of Western Australia's School of Surgery.

Professor Saunders received the Scientist of the Year award alongside Professor Harvey Millar from The University of Western Australia's School of Molecular Sciences and National Director of the ARC Centre of Excellence in Plant Energy Biology.

The awards were established by the State Government in 2002 to honour the outstanding achievements of WA's science and innovation community.



Cardiology Research Group



The Cardiology Research Group was established in July 2015 and focuses on cardiovascular conditions that are public health priorities in Australia.

The group targets major causes of cardiovascular morbidity and mortality, especially those affecting the majority of patients, and those with the highest burden of disease. The Cardiology Research Group aims to provide the most advanced care for patients to address the need of continuous improvement in cardiology treatment and contribute to the greater body of research in this field.

PROJECTS

Cardiology data base

Dr Brendan McQuillan

Commenced 2016, ongoing

The cardiology database initially collected data from cardiology admissions at SJG Subiaco and Murdoch Hospitals during 2015, based on diagnosis and intervention. Since 2016, data from cardiology patients who admitted to the coronary care unit and ward 41 at SIG Subiaco Hospital is collected prospectively. The data is then used to evaluate patterns of cardiology admissions, which can be used as a platform for future feasibility studies and cardiology clinical trials.

Bempedoic acid (ETC-1002)

Principal Investigator: Dr Brendan McQuillan

This multicentre, multinational phase III cardiovascular outcome trial will assess the impact of bempedoic acid, a novel

reducing the risk of major cardiovascular events among patients with, or at high risk for, cardiovascular disease who are statin intolerant. This trial is expected to enroll more than 12,600 patients globally, who will be followed for up to four years. Academic coordination of the trial is provided through the Cleveland Clinic Coordinating Centre for Clinical Research.

EMPEROR- preserved- BI 1245.110

Principal Investigator: Dr Brendan McQuillan

Submitted to ethics, will be commenced soon

This phase III randomised, double-blind trial will evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo in patients with heart failure with preserved ejection fraction (HFpEF – EF > 40%). The study is set to recruit more than 4100 patients across 400 sites, in 17 countries.

Victoria- MK-1242 (Vericiquat)

Principal Investigator: Dr Brendan McQuillan

Recruiting now

This phase three randomised, double-blind clinical outcome trial will assess the efficacy and safety of oral sGC stimulator vericiquat in subjects with heart failure with reduced ejection fraction. The global study aims to evaluate if the drug is superior to placebo for patients with the condition.

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KEY STAFF



A/Professor Brendan McQuillan Cardiologist



Dr Devind Bhullar



Dr Philip Cooke



Dr Tim Gattorna Cardiologist



Dr Stephen Gordon Cardioloaist



Dr Mark Hands Cardiologist



Dr Johan Janssen



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Under site evaluation

LDL cholesterol lowering agent, on

Cardiologist



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Colorectal Cancer Research Group



The Colorectal Cancer Research Group was established in 2006 to help improve survival outcomes for patients with colorectal cancer. The unit focuses on providing optimal medical and surgical management to colorectal cancer patients, integrated with bench top and clinical research activities to provide evidence based care. The group provides a unique opportunity for clinicians, research and laboratory staff to work closely together to maximise care for patients.

PROJECTS

A comparison of the complete clinical response rate in patients with rectal cancer receiving either oral Capecitabine versus infusional 5-FU as neoadjuvant treatment

Dr Ravish Jootun, Prof Cameron Platell

Commenced 2016, completed 2016

This project involved an audit of outcomes of patients with rectal cancer who received neoadjuvant (preoperative) chemo-radiotherapy. It compared the complete clinical response rate for those patients receiving oral Capecitabine chemotherapy *versus* infusional 5-FU chemotherapy.

Assessment of CD47 and calreticulin gene expression in archived tumour tissue

Dr Melanie McCoy, Dr Chidozie Anyaegbu, Ms Tracey Lee-Pullen, Ms Stephanie Austin, A/Prof Chris Hemmings (Clinical Labs), Prof Cameron Platell

Commenced 2013, estimated completion 2017

This project is using novel technology to investigate the expression of CD47 and calreticulin in colorectal cancer. Calreticulin acts as an 'eat me' signal, tagging cells for destruction by the immune system. Conversely, expression of CD47 acts as protective 'don't eat me' signal. Increased calreticulin expression is associated with higher numbers of

tumour associated immune cells and better prognosis colorectal cancer, whereas higher levels of CD47 have been associated with poorer long-term outcome in some cancers. This project is investigating CD47 and calreticulin gene expression in colorectal cancer and whether this correlates with treatment response.

Cancer stem cells as prognostic markers in colorectal cancer

Mr Timothy Miller, Dr Melanie McCoy, A/Prof Chris Hemmings (Clinical Labs), Prof Barry Iacopetta (UWA), Prof Max Bulsara (University of Notre Dame), Prof Cameron Platell

Commenced 2014, estimated completion 2017

This study aims to determine the prognostic significance of cancer stem-like cells in colon cancer. Prognostic markers are important tools in the clinical management of colorectal cancer patients, as they identify patients at a higher risk of disease progression, which allows appropriate treatment to be given.

Cancer stem-like cells (CSC) are a small proportion of highly resistant cancer cells thought to have the capacity for unlimited self-renewal and the ability to form entire tumours. Markers of CSC may provide valuable prognostic information, but are yet to be validated in clinical samples of colon cancer. This project will assess the prognostic value of a number of markers associated with cancer stem-like cells in colon cancer so that patients with a higher chance of a poor outcome can be accurately identified for treatment.

This study is supported by The University of Western Australia, a John Clauscen Murray Postgraduate Scholarship and the Tonkinson Foundation for Colorectal Cancer Research.

Could immune checkpoint blockade improve response to chemo-radiotherapy in locally advanced rectal cancer?

Dr Melanie McCoy, Ms Tracey Lee-Pullen, Dr Chidozie Anyaegbu, Ms Stephanie Austin, A/Prof Chris Hemmings (Clinical Labs), Prof Anna Nowak (UWA), Prof Richard Lake (UWA), Prof Cameron Platell

Commenced 2017, estimated completion 2018

Drugs that stimulate immune cells to attack cancer are routinely used in melanoma and lung cancer treatments. Many of these drugs target molecules known as 'immune checkpoints', which are found on immune cells and can lower immune responses.

One such checkpoint molecule is PD-1, which is triggered by a molecule called PD-L1. It is known that bowel cancer cells can make PD-L1 and that radiotherapy and chemotherapy sometimes increase the amount of PD-L1 they make. This study aims to determine whether the PD-1/PD-L1 interaction influences response to chemo-radiotherapy in rectal cancer.

This study is supported by the Cancer Council WA and the Tonkinson Foundation for Colorectal Cancer Research.

Detecting bacterial species in archived colorectal tissue – a pilot study

Dr Melanie McCoy, Dr Marie Rye, Dr Kerryn Garrett, A/Prof Chris Hemmings (Clinical Labs), Dr Robert Holt (BC Cancer Agency, Canada), Prof Cameron Platell

Commenced 2016, estimated completion 2018

This pilot study aims to measure whether certain bacteria and their associated toxins can be found in archived

colorectal tumour tissue. The data will then be used in a subsequent study to investigate the association between the presence and abundance of bacterial species and treatment response.

Do regulatory T cells inhibit the response of rectal carcinomas to neoadjuvant chemo-radiotherapy?

Dr Melanie McCoy, A/Prof Chris Hemmings (Clinical Labs), Ms Tracey Lee-Pullen, Ms Stephanie Austin, Dr Chidozie Anyaegbu, Mr Timothy Miller, Prof Max Bulsara (University of Notre Dame), Prof Anna Nowak (UWA), Prof Richard Lake (UWA), Mr Greg Makin, Ms Cheryl Penter, Prof Cameron Platell

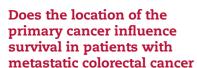
Commenced 2013, estimated completion 2018

This project is investigating whether the immune system plays a role in how well people with rectal cancer respond to chemo-radiotherapy (CRT). Approximately one in five patients who receive CRT before having surgery for rectal cancer have no tumour left at the time of scheduled surgery. Known as a complete response, this is a very good long-term prognosis.

Not all patients benefit from CRT and it is currently impossible to predict who will and will not respond to the treatment. This project is investigating the role of the immune system in CRT response, with a particular focus on regulatory T cells, a subset of immune cells that suppress immune responses. The main aim is to enable better prediction of treatment response, which would allow selection of the most appropriate treatment for individual patients.

This study is supported by the Cancer Council WA, the Raine Medical Research Foundation, the Colorectal Surgical Society of Australia and New Zealand and the Tonkinson Foundation for Colorectal Cancer Research.





Dr Arul Edward. Prof Cameron Platell

Commenced 2016, completed 2016

This study evaluated various prognostic variables in patients with metastatic colorectal cancer to determine whether the location of the primary cancer (right colon versus left colon versus rectum) has an independent influence on survival outcomes.

Rectal cancer stem cells, the stroma and inflammation

A/Prof Chris Hemmings (Clinical Labs), Mr Timothy Miller, Dr Melanie McCoy, A/Prof Nik Zeps, Prof Cameron Platell

Commenced 2010, estimated completion 2017

This study aims to identify predictors of rectal cancer response to chemo-radiotherapy, which can be translated into everyday clinical practice in diagnostic oncology and histopathology. Response to neoadjuvant (preoperative) chemoradiotherapy for advanced rectal cancer varies widely depending on the patient. Currently, there are no well-defined histologic markers or clinical predictors of response. This study is investigating the importance of cancer stem cells, fibrosis and stromal phenotype in relation to treatment response.

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"I have always been interested in how the body works and, in particular, how the immune system works. Looking at how the immune system interacts with cancer is an emerging and very exciting area of research that has the potential to change how well treatments work for cancer patients."

Dr Melanie McCoy, Postdoctoral Research Fellow

KEY STAFF



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Exploring the myths of colorectal cancer

If you were diagnosed with colorectal (bowel) cancer 20 years ago, you had a 50 per cent chance of surviving five years.

Today, thanks to improved treatment informed by innovative research, almost three in every four patients (75 per cent) with colorectal cancer at St John of God Subiaco Hospital celebrate this milestone.

Colorectal cancer is the third most commonly diagnosed cancer in Australia, affecting about one in every 25 Australians. Treatment depends upon the location of the cancer in the bowel. Cancers in the rectum (the last 17cm of the bowel) are usually treated with a combination of chemotherapy and radiotherapy, followed by surgery to remove the tumour. Cancers higher up in the bowel, in the colon, are usually treated with surgery and sometimes chemotherapy.

Understanding why some patients with rectal cancer respond to this standard treatment regime and some don't is a primary focus for St John of God Subiaco Hospital's Colorectal Cancer Research Group.

They currently have 150 patients enrolled in a research program which is looking at how stem cells grow and divide in colorectal cancer patients and how the body's own immune system fights cancer. By the end of the year they hope to have increased this patient cohort to 200.

St John of God Subiaco Hospital's Colorectal Research Group Director Professor Cameron Platell said the study team followed these patients from



diagnosis to at least five years postsurgery, collecting data from biopsies as well as blood and stool tests.

"What we are doing is looking at a range of factors that may help us to predict a response to treatment," Professor Platell said.

"If we can get it right in terms of managing colorectal cancer and encouraging an immune response, we may get to a point where some people may not need surgery.

"Eventually, we hope this study will help us select treatment options and improve survival rates."

Professor Platell said the incidence of bowel cancer internationally remained fairly stable, although he noted there had been a slight but unexplainable increase among Australians aged under 50 more recently.

"Being overweight or sedentary, genetic factors and pre-existing inflammatory conditions such as colitis do appear to have a link to colorectal cancer, but in many people it appears to be a random mutation," he said.

"By allowing us to follow their journeys, the patients in our trial are contributing to a better understanding of this disease, which will hopefully lead to better outcomes for everyone."

Emma helps researchers de-riddle colorectal cancer treatment

Emma Fletcher is no stranger to cancer.

As a young adult she was diagnosed with Hodgkins Lymphoma and treated with radiotherapy to kill a tumour wrapped around a nerve in her lower back.

Now 42, she has just completed a year's treatment for colorectal cancer, which included a six-week course of radiation and chemotherapy, followed by surgery to remove the rectum and 30cm of the large intestine.

As part of her treatment Emma agreed to donate blood and tissue samples to St John of God Subiaco Hospital's Colorectal Cancer Research Group, which is investigating why some patients have a better response to the standard treatment regime.

This information will eventually be used to identify patients who don't need surgery, thereby reducing recovery time and minimising other lifestyle disruptions.

Understanding why some patients respond to standard treatment and some don't is a primary focus for St John of God Subiaco Hospital's Colorectal Cancer Research Group.

"What we learned from my samples is that I had a complete response to the initial round of radiation and chemotherapy and there were no visible or pathological cancer cells left," Emma said.

"While this theoretically could mean that I didn't need the surgery, current research shows that it is still the best treatment regime.

"However, if the information gained from this research means that some people won't have to have surgery one day, and I can help dispel the myth that this is an old person's disease, then at least some good will come from this."

Emma said despite her earlier brush with Hodgkins Lymphoma, cancer was the last thing on her mind when she began experiencing changes in her bowel movements at the age of 41. Initially diagnosed with a bacterial parasite, she was given antibiotics, but when things didn't improve she insisted on a referral to a gastroenterologist. Thinking Emma may have ulcerative colitis, the gastroenterologist sent her for a colonoscopy which revealed a far more serious problem.

"I remember waking up from the colonoscopy and the gastroenterologist was as white as a sheet saying they had found a cancerous tumour in the rectum," Emma recalled.

"This was a lot to process, but thankfully, scans showed the tumour was slow-growing and had not spread, so we were able to get to it quickly."

Her treatment now complete, Emma is enjoying time at home with her husband Kevin and 16-year-old son while planning a gradual return to work later this year. She is also planning to join a cancer survivor's exercise program at Edith Cowan University, which will be contributing to further research.

"Understanding why some patients respond to standard treatment and some don't is a primary focus for St John of God Subiaco Hospital's Colorectal Cancer Research Group."



Gynaecological Cancer Research Group



Gynaecological Cancer Research Group

The Gynaecological Cancer Department at St John of God Subiaco Hospital has provided care for Western Australian women with gynaecological cancers for more than 30 years. The service offers the latest surgical techniques and innovations, medical oncology services and supportive cancer care.

Gynaecological Cancer Research Group

The hospital is a leading national recruiting site for surgical trials and novel chemotherapy drug trials to treat women with gynaecological cancers. The hospital hosts the state wide multidisciplinary gynaecological tumour conference.

The St John of God Subiaco Hospital Gynaecological Cancer Research Group includes scientists, clinical researchers and clinicians who are members of the multidisciplinary team that delivers statewide comprehensive patient care.

The group is actively engaged in laboratory-based translational research using tissue specimens obtained through the Western Australian Gynaecologic Oncology Biospecimen Bank, clinical trials, novel interventions in supportive care, health behaviour change in cancer survivors, and statewide epidemiologic and population-based health research.

PROJECTS

Screening for sexual health concerns in gynaecological cancer survivors

Dr Paul Cohen, Ms Karen Roberts, Prof Max Bulsara, Dr Jason Tan, Dr Stuart Salfinger and Dr G. Raj Mohan

Commenced 2016, expected completion 2017

A gynaecological cancer diagnosis and its treatment may have a significant negative impact on a woman's sexuality. The issue of sexual health in cancer survivors is rarely addressed in clinical practice yet discussion of sexual issues can lead to better sexual outcomes. Improved care can only occur if a patient's concerns are elicited and the clinician then reviews and acts on her response.

This study aims to determine the prevalence of sexual health concerns in gynaecological cancer survivors using the 'brief sexual symptom checklist for women,' which is a recommended primary screening tool for this purpose. A secondary aim is to assess the impact of routine sexual health screening on referrals to appropriate sexual health practitioners.

Behavioural intervention trial to improve physical activity in cancer survivors at cardiovascular risk

Chloe Maxwell, Dr Sarah Hardcastle, Dr Cameron Platell, Dr Paul Cohen, Dr Nik Zeps

Commenced 2017, expected completion 2018

The objective of this study is to determine whether a behavioural intervention increases physical activity in cancer survivors who are at increased risk of cardiovascular disease.

This project invites cancer survivors to participate in a 12-week behavioural intervention to increase physical activity levels. Participants will be randomised into intervention and control groups. The intervention group will be required to attend two group sessions to help them set goals, plan and monitor their behaviour. Each participant in this group will also receive a device to monitor their physical activity for the 24-week trial.

The control group will receive physical activity recommendations. Physical activity, health indicators and attitudes will be measured at 12 weeks (end of intervention), and at 24 weeks. It is expected that cancer survivors will be more physically active when their support and self-monitoring needs are met.

A secondary aim is to assess the feasibility of the administration of this intervention in a clinical setting that could be incorporated into routine after-care for cancer survivors who have completed active treatment.

A pathological and molecular analysis of POLE mutations in grade 3 endometrial carcinoma

Dr Adeline Tan, Dr Yee Leung, Dr Ben Amanuel, Dr Paul Cohen, Dr Stuart Salfinger, Dr Jason Tan

Commenced 2017, expected completion 2018

Endometrial cancer (EC) is classified by its microscopic appearance with the majority of cases being endometrioid subtype (EEC). Most are low-grade and have a favourable prognosis. Poorly differentiated (grade 3) carcinomas are aggressive and treated with more extensive surgery and adjuvant radiotherapy. Recent studies have established a subgroup of EC characterised by mutations in DNA polymerase epsilon (POLE). These appear to have a good prognosis even though they are 'high-grade' by conventional histopathology. POLE mutation testing could be required in all grade 3 EEC, to identify women who may benefit from less radical treatment.

Investigating barriers to genetic counselling and germline mutation testing in women with suspected hereditary breast and ovarian cancer syndrome and Lynch syndrome.

Josephine Shaw, Caroline Bulsara, Paul Cohen, Madeleine Gryta, Cassandra Nichols, Lyn Schofield, Sarah O'Sullivan, Nicholas Pachter and Sarah Hardcastle

Commenced 2016, expected completion 2017

For women with gynaecological cancers who are at high risk of carrying a germline mutation such as BRCA1/ BRCA2 or the known Lynch syndrome mutations, genetic testing may help them understand their level of risk of developing other primary cancers, and their family members understand their risk of developing cancer. Genetic counselling and testing may also help patients and their families decide about specific treatment options and cancer prevention strategies. Genetic counselling is offered to patients before they undergo testing so they can better understand the process and the implications of potential results.

Despite the benefits of genetic counselling and testing, some women choose to decline genetic services. A recent study in Western Australia found that of those patients with ovarian cancer who were eligible for BRCA testing, 19 per cent either declined their genetic counselling appointment or declined testing. Most research into the reasons for declining genetic services has focused on breast cancer patients. There are a limited number of studies that have assessed the reasons for declining genetic services in ovarian and endometrial cancer patients who are specifically at high risk for breast or colon germline mutations. Most studies have been conducted in the USA and to our knowledge, no similar studies have been conducted in Australia. There are significant differences between clinical practice, policies/laws and referral procedures in the USA compared to Australia and it would therefore be helpful to gain an understanding of the specific issues that are relevant in an Australian context.

In this retrospective and prospective case study, we are conducting in-depth qualitative interviews with approximately 20 gynaecological cancer patients who have declined genetic counselling or testing in the past five years.

We aim to investigate perceived barriers to genetic counselling and testing. Our findings will inform a larger national multicentre study, which will improve our understanding of barriers which may facilitate appropriate interventions aimed at increasing patient uptake of genetic services. Such interventions have the potential to identify more

individuals with germline mutations for whom there are effective cancer risk reducing treatments/surveillance.

EXCISE Study

Dr Paul Cohen, A/Prof Alison Brand, A/ Prof Peter Sykes, Dr David Wrede, A/ Prof Orla McNally, Dr Lois Eva, Dr Archana Rao, Michael Campion, Prof Martin Stockler, Dr Aime Munro, Prof Jim Codde, Prof Max Bulsara, A/Prof Lyndal Anderson, Prof Yee Leung, Dr Louise Farrell, Ms Pennie Stoyles, Dr Rachael van der Griend

Commenced 2017, expected completion 2018

SJG Subiaco Hospital is the lead site for a pilot study to compare loop electrosurgical excision procedure (LEEP) to 'cold knife cone biopsy' for treatment of cervical adenocarcinoma in situ (AIS).

The objective of the proposed pilot study is to demonstrate the feasibility and safety of LEEP compared to cone biopsy for the treatment of cervical AIS with the aim of conducting a much larger randomised international multicentre non-inferiority trial.

Recruitment is open to woman aged between 18 and 45 years who have been diagnosed with cervical AIS on a pap smear or cervical biopsy with lesions amenable to single pass excision.

The study is comparing these two treatments as cone biopsy is considered the 'gold standard' in Australia, but no prospective trials have been conducted to inform clinical practice. In many countries, LEEP is considered an equivalent treatment and may have fewer post-procedure complications.

The objectives of the study are to:

- 1. Compare LEEP to cone in terms of margin status and specimen dimensions.
- 2. Compare rates of early complications to six weeks, e.g. pain, infection, primary and delayed haemorrhage, readmission to hospital, return to the operating theatre after the two treatment modalities.
- 3. Assess patient satisfaction following LEEP and cone biopsy.
- 4. Determine costs of treatment.

This study is being conducted by SJG Subiaco Hospital in conjunction with the Institute for Health Research at the University of Notre Dame Australia Fremantle, the School of Medicine at The University of Western Australia and clinical researchers at six hospitals across Australia and New Zealand.

The study has been funded by the Australian and New Zealand Gynaecological Oncology Group.

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Munro A, Codde J, Cohen C, 'Outcomes of accessing and utilising Western Australian linked data for the management of cervical abnormalities', **Credentialed Pap Smear Provider** Professional Development Day, WA Cervical Cancer Prevention Program, June 2016, Perth, Australia

KEY STAFF



Dr Paul Cohen Director Gynaecological Cancer Research Group, supported by the lako Groun



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Dr Martin Buck Medical Oncologist



Dr Tarek Meniawy Medical Oncologist



Sanela Bilic Project Manage



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WA Gynaecologic Oncology (WAGO) Biospecimen Bank

The WAGO Biospecimen Bank was developed to provide ethically obtained biospecimens for research, cross-referenced with the health information database.

This infrastructure enables researchers to define the clinico-pathological, molecular and therapeutic factors impacting on morbidity and mortality of patients presenting to gynaecologic oncologists operating within Western Australia.

Patients are recruited into the WAGO Biospecimen Bank across four hospitals:
St John of God Subiaco Hospital, St John of God Murdoch Hospital, Hollywood Private Hospital and King Edward Memorial Hospital.

Active recruitment for the study began on 1 January 2013 and about 450 subjects are recruited annually.

Approximately two thirds of subjects are estimated to be presenting with gynaecological malignancies and one third are estimated to be presenting with benign disease. Between 1 January 2013 and 30 June 2017 a total of 4616 people have been recruited. St John of God Subiaco Hospital and St John of God Murdoch Hospital have recruited 66% of these cases.

Pathology reports were obtained for 4429 patients.
A summary of these cases is shown below:

2,600 BENIGN 1,502

MALIGNANT (GYNAECOLOGICAL ORIGIN) 173

Y

NON-GYNAECOLOGICAL ORIGIN 67

NORMAL HOSPECIMENS

One step closer to screening test for ovarian cancer

Ovarian cancer is the eighth most common cancer and the sixth most common cause of cancer death affecting women in Australia.

Often undiagnosed until it has spread to other organs and tissue, early detection is the key to survival, and a team of researchers is launching a new study they are confident will help develop a blood-screening test for early-stage ovarian cancer.

Led by Dr Elin Gray and Professor Mel Ziman at Edith Cowan University, in collaboration with St John of God Subiaco Hospital Head of Gynaecological Cancer Research Dr Paul Cohen and medical oncologist Dr Tarek Meniawy, this study will build on earlier research which shows that early stage ovarian cancer can be detected by a non-invasive pre-natal blood test (NIPT).

Normally used to screen for Down Syndrome in early pregnancy, this test may also detect circulating tumour DNA in the blood stream.

Dr Cohen said this latest study will test the blood of newly-diagnosed ovarian cancer patients at several stages, including diagnosis, pre-surgery, post-surgery, pre-chemotherapy and post-chemotherapy to determine whether it contains the DNA from malignant ovarian tumours.

"Our aim is to recruit 30 Perth women by the end of the year for this study," Dr Cohen said. "Once the pilot is complete in Perth, there will be a need for more funding for national clinical trials, but the St John of God Foundation has got us off to a good start. Without this support, we wouldn't be where we are now with this important research."

Ovarian cancer is hard to detect, as its symptoms are non-specific and may mimic other conditions.

Dr Cogen said "It's often diagnosed after the disease has spread."

"If it hasn't spread – which is the case in about 20 to 30 per cent of diagnoses – the chances of a cure are high, although there may be some

recurrence. In the remaining 70 to 80 per cent of cases, the disease is already outside the ovary and only half of these women are likely to survive," he said.

"The earlier ovarian cancer can be detected, the earlier treatment can begin and the greatest chance we have of stopping the cancer spreading to surrounding tissues and organs."

Dr Cohen said it was possible that blood tests for circulating DNA could also be used to detect recurrence of ovarian cancer, which may prolong survival.





Inflammatory Bowel Disease Research Unit

The St John of God Subiaco Hospital's Centre for Inflammatory Bowel Disease (IBD) manages patients suffering from Crohn's disease (CD)

and ulcerative colitis (UC).

The unit is involved in international clinical trials investigating novel therapies for the treatment of IBD. It encompasses basic science research, clinical research and clinical trials. The basic science research focuses on the chronic inflammation-induced intestinal changes that occur in IBD and the subsequent complications of fibrosis and carcinogenesis. Investigation has been undertaken in both human and animal models.

The unit has local investigator lead studies into new medications, including rectal tacrolimus for use in resistant proctitis and perianal CD. The research covers clinical outcomes to management, improvement of patient care and clinical outcomes.

The unit comprises three IBD nurses, an IBD research and clinical fellow, clinical trial research staff, specialist gastroenterologists, colorectal surgeons, pharmacists, dietician, physiotherapist, clinical psychologist, histopathologists and radiologists.

Other clinically based research that is being undertaken by the IBD unit includes;

- the sub classification of IBD through serological assays and Toll-like receptor activity
- the cancer risks and surveillance in IBD
- skin cancer risk in IBD patients on azathioprine
- risk of sperm DNA fragmentation
- nutritional problems in IBD patients including vitamin D
- the efficacy of rectal tacrolimus in resistant proctitis
- outcomes of vedolizumab in real-life IBD management

PROJECTS

A multicentre double blind randomised placebocontrolled study of the use of rectal tacrolimus in the treatment of resistant ulcerative proctitis

An investigation into the natural history and genetics of inflammatory bowel disease

My aid - a cluster randomised controlled trial of a decision aid for ulcerative colitis patients: enhancing patients' quality of life, empowerment, quality of decision making and disease control

Vedolizumab real life outcomes to therapy

INTERNATIONAL CLINICAL TRIALS

- A phase 2, randomized, double-blind, placebo-controlled, parallel group, multi-center study to investigate the safety and efficacy of apd334 in patients with moderately to severely active ulcerative colitis an extension study of apd334-003 in patients with moderately to severely active ulcerative colitis
- Combined phase 2b/3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the induction and maintenance of remission in subjects with moderately to severely active ulcerative colitis
- A long-term extension study to evaluate the safety of filgotinib in subjects with ulcerative colitis
- Combined phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the induction and maintenance of remission in subjects with moderately to severely active Crohn's disease
- A long-term extension study to evaluate the safety of filgotinib in subjects with Crohn's disease
- A phase 2b randomised, double-blind, placebo-controlled, parallel adaptive 2-stage, multicentre study to evaluate the safety and efficacy of oral ptg-100 induction in subjects with moderate to severe active ulcerative colitis
- A phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of vedolizumab subcutaneous as maintenance therapy in subjects with moderately to severely active Crohn's disease who achieved clinical response following open-label vedolizumab intravenous therapy
- A phase 3b open-label study to determine the long-term safety and efficacy of vedolizumab subcutaneous in subjects with ulcerative colitis and Crohn's disease

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CONFERENCE PRESENTATIONS

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Lawrance IC, 'UC what do we have now?', 21 July 2016, Perth, Australia

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Intensive Care Unit Research Program

The Intensive Care Unit (ICU) is a 10-bed unit admitting more than 1500 patients a year from a range of specialties, including cardiothoracic, upper and lower gastrointestinal surgery, bariatric surgery, spinal and orthopaedic surgery, obstetrics and oncology.

As part of the busiest private ICU in Western Australia and one of the busiest nationally, the ICU Research Unit places great focus on quality assurance and delivering the best, evidence-based practices.

The ICU is an established contributor to the Australia and New Zealand Intensive Care Society Adult Patient Database and Point Prevalence Programme, enabling benchmarking of activity and outcomes against similar ICUs. The unit is also a member of the Australia and New Zealand Intensive Care Society Clinical Trials Group, which is dedicated to promoting excellence in collaborative clinical research and one of the most successful critical care trial groups internationally.

ICU research activity has continued to grow in the past 12 months through contribution to National Health and Medical Research Council-funded multicentre research as well as studies designed and led by St John of God Subiaco Hospital ICU clinicians and researchers.

PROJECTS

Attitudes and belief of clinicians regarding barriers and enablers in conducting perioperative clinical trials: a qualitative study

Dr Edward Litton, Prof Steve Webb, Janet Ferrier

Commenced 2016, expected completion February 2018

This qualitative study aims to assist



in understanding clinician attitudes towards clinical research in the setting of a large, busy private hospital.

Outcomes following elective out-of hours intensive care admissions to a large private Australian hospital

Dr David Morgan, A/Prof KM Ho

This active research project has already yielded important published results using a retrospective, observational nested case-control design looking at the comparison of patients electively admitted to the SJG Subiaco Hospital ICU after elective surgery, either inhours or out-of-hours.

PROMEDIC Study: Prophylactic melatonin for the prevention of delirium in intensive care

Dr Ed Litton

Commenced 2017, expected completion January 2019

This study is part of a multicentre randomised controlled trial of melatonin

as a therapy to improve sleep in patients admitted to the ICU. The study is currently under active recruitment.

ROCIT Trial: Restoration of the Gut Microflora to Improve Outcomes in ICU

Dr Ed Litton

Commenced 2017, expected completion November 2019

The SJG Subiaco Hospital ICU is playing a leadership role in this multicentre, randomised controlled trial of probiotics compared with placebo to reduce hospital-acquired infection in patients admitted to the ICU. In addition, the study will provide novel insights into the changes that occur in the gut microflora during early critical illness and in the recovery phase.

The SIQ Study

Dr Ed Litton

Commenced 2017, expected completion July 2018

This study is investigating the sources of health information used by surrogate decision makers of patients admitted in the ICU. It will also explore the understanding, trust and satisfaction associated with the surrogate decision makers use of the internet and other sources of health information for patients admitted to the ICU.

The study is being led by SJG Subiaco Hospital, where it is actively recruiting. It is planned to recruit 500 patients at 12 centres across Australia.

The SPICE III Study: Sedation practices in intensive care evaluation.

Dr Edward Litton, Prof Steve Webb Commenced 2016, expected completion February 2018

The use of sedative drugs in intensive care is ubiquitous. Despite this, high quality evidence to guide the choice of commonly used sedative medications is lacking and definitive studies on sedation practice are required. The SPICE III RCT is a large multinational trial of 4000 patients to investigate whether a strategy of early goal directed sedation (EGDS) is superior to the current standard of care with respect to sedation practices.

If a strategy of EGDS is found to be superior, this would benefit a large portion of future patients with critical illness, as it would then be incorporated into standard care. If no improvement is found, there will be a financial benefit from not incorporating a potentially expensive intervention into standard clinical practice.

PUBLICATIONS

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CONFERENCE PRESENTATIONS

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Litton E, 'The Microbiome: targeted therapy in the ICU', Australia and New Zealand Intensive Care Society Singapore, 22 April 2017, Singapore (Invited Speaker)

Litton E, 'Platform Trials in ICU: Who, what, why?', Australia and New Zealand Intensive Care Society Singapore, 22 April 2017, Singapore (Invited Speaker)

Litton E, 'Sleep in the Intensive Care Unit', **World Congress of Anesthesiologists**, 30 August 2016, Hong Kong (Invited Speaker)

"Being involved in research allows me to reflect on my clinical practice, question what I do and ask myself if I could do better."

Dr Ed Litton

Research Fellow and Consultant Intensivist

KEY STAFF



Dr Ed LittonResearch Fellow and Consultant
Intensivist



Professor Steve Web Consultant Intensivist



Janet Ferrier Research Officer



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Junior Doctor Research Projects

Junior Doctor Research Projects



"St John of God Subiaco Hospital encourages its junior doctors to identify research opportunities in the hospital and develop these into research outcomes, in partnership with our specialists." An important component of junior doctor training is undertaking a research project. Most advanced training fellowship positions require evidence of research activity for eligibility and research is increasingly becoming a vital component of the training itself.

St John of God Subiaco Hospital encourages its junior doctors to identify research opportunities in the hospital and develop these into research outcomes, in partnership with our specialists.

PROJECTS

'Artery First, Vein Second' Approach for vascular anastomosis in kidney transplantation

Dr Zi Qin Ng, Assoc Prof Wai Lim, Assoc Prof Bulang He

Commenced 2016, completed 2017

The conventional vascular anastomotic technique for kidney transplant has been well adopted as renal vein first followed by renal artery. Alternatively, the renal artery can be anastomosed first, then renal vein for kidney transplantation. However, there is a lack of data on this alternative approach.

This single-centre experience has shown that an alternative 'artery first, vein second' anastomotic technique for kidney transplant is associated with low rates of early post-transplant complications. The kidney graft function is satisfactory and comparable to those with conventional vascular anastomosis.

This is also the first cohort study to provide the evidence that renal artery anastomosis first has comparable outcome in comparison with customary renal vein anastomosis first in kidney transplantation. The utilisation of this technique could be considered in minimally invasive techniques for kidney transplantation such as robotic-assisted kidney transplantation and laparoscopic-kidney transplantation, where minimal manipulation of the kidney allograft is often desirable.

Cancer in pouches and after an ileorectal anastomosis

Dr Samba Siva Reddy Pulusu

Chemo in the home vs infusions within an infusion lounge – Quality of life project

Dr Michelle Madden

The recurrence rates of CD post rhemicolectomy and factors that contribute to long-term remission without medication use post surgery

Kirstin Griffin and Linda Vu

Total colectomy with ileorectal anastomosis for slow transit constipation – highly effective in carefully selected patients

Ram Shrestha

Commenced 2017, completed 2017

Total colectomy with IRA in carefully selected patients is highly effective in relieving the principal pre-operative symptoms and is associated with high rates of patient satisfaction. It almost certainly remains under-utilised in the management of severe, slow colonic transit constipation.

Vedolizumab real life outcomes to therapy in CD

Dr Samba Siva Reddy Pulusu

Vedolizumab real life outcomes to therapy in UC

Dr Samba Siva Reddy Pulusu

PUBLICATIONS

Shrestha R, Levitt M, 'Total colectomy with ileo-rectal anastomosis for slow transit constipation – highly effective in carefully selected patients'

CONFERENCE PRESENTATIONS

Shrestha R, Levitt M, 'Total colectomy with ileo-rectal anastomosis for slow transit constipation – highly effective in carefully selected patients', RACS Annual Scientific Congress 2017, May 2017, Adelaide, Australia.

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Neurosurgery Research Unit



Neurosurgery Research Unit

Neurosurgeons provide lifesaving surgery to people with a range of nervous system conditions, including trauma, tumour removals, clipping haemorrhages and aneurysms, as well as treat infection.

Neurosurgery research focuses on improving care and treatment options for patients needing surgery on the nervous system, particularly the brain or spine. The research unit also helps develop new medical technologies to improve the safety of surgery.

While there have been many advances in this area, more research needs to be done to ensure diseases and conditions affecting the nervous system can be treated safely and with good outcomes.

Neurosurgery research at the hospital focuses on projects that have the potential to enhance clinical outcomes for patients. For example, analysing why spinal conditions can cause weakness in the foot and ankle and the development of new surgical equipment to aid patient recovery.

The unit have been selected to participate in ON Prime, a preaccelerator to help validate its research and determine its real world application.

Many projects are undertaken in collaboration with researchers at Curtin University, The University of Western Australia and the Harry Perkins Institute of Medical Research.

PROJECTS

Development of expandable bone/spine fastener

Matthew Oldakowski, Intan Oldakowska, Brett Kirk, Philip Hardcastle, Markus Kuster, Robert Day, Timothy Sercombe, Garry Allison, Allen Goodship, Gordon Blunn, Prof Gabriel Lee

In conjunction with Curtin University mechanical engineers, the group has developed an expandable spinal fastener which allows stronger bone fixation than a traditional threaded screw. This device has proven to be superior in laboratory testing. The novel design allows the device to be removed if required, which sets it apart from other expandable devices in the current market. The fastener will be further tested in human cadaveric bone with eventual plans for clinical studies.

Improving navigation technology

Lei Cui, Prof Gabriel Lee

This study aims to improve the accuracy of the computer navigation technology which is used when performing surgeries in the brain and spine.

The foot drop study

Dhakshinamoorthy Gurumoorthy, Peter Silbert, Shiva Sharif, Iain Murray, Prof Gabriel Lee

This study will be one of the biggest prospective studies performed on the topic, which objectively documents the surgical outcomes of patients where a spinal condition has resulted in a foot drop. The aim is to identify the factors which may predict neurological recovery. In collaboration with computer engineers from Curtin University, novel 3D printable devices are being developed to analyse the gait patterns of these patients.

Vascular peptide binding capacity in brain tumours

Ruth Ganss, Prof Gabriel Lee

This study is assessing vascular peptide binding capacity in brain tumours. The goal is to identify and develop targets for chemotherapy agents and drugs which could be used for treating brain tumours. The primary focus is on patients with gliomas and meningiomas. This study involves collaborating with researchers from the Harry Perkins Institute of Medical Research.

PATENT CITATION

A Component AU2016901032 filed 18th March 2016.

PUBLICATIONS

Sharif SH, Murray I, Lee G, 'The application of Inertial Measurements Unit for the clinical evaluation and assessment of gait events among foot drop patients', Journal of Medical Engineering & Technology (Accepted for publication, 12 June 2017).

Sharif SH, Murray I, Lee G, 'Validation of Foot Pitch Angle Estimation Using Inertial Measurement Unit against Marker-Based Optical 3D Motion Capture Systems, in Medical Applications', IEEE Transactions on Neural Systems & Rehabilitation Engineering Journal (Under review, submitted 18 June 2017).



CONFERENCE PRESENTATIONS

Sharif SH, Murray I, Lee G, 'Utility of Inertial Measurement Units for portable gait analysis in patients with foot drop of lumbar spine origin', 2017
Annual Scientific Meeting of the Neurosurgical Society of Australasia, Adelaide (Invited for verbal presentation)

Sharif SH, Murray I, Lee G, 'Inertial Measurement Units for portable gait analysis and clinical assessment of gait events among foot drop patients', 2017 One Curtin International

Postgraduate Conference, Malaysia

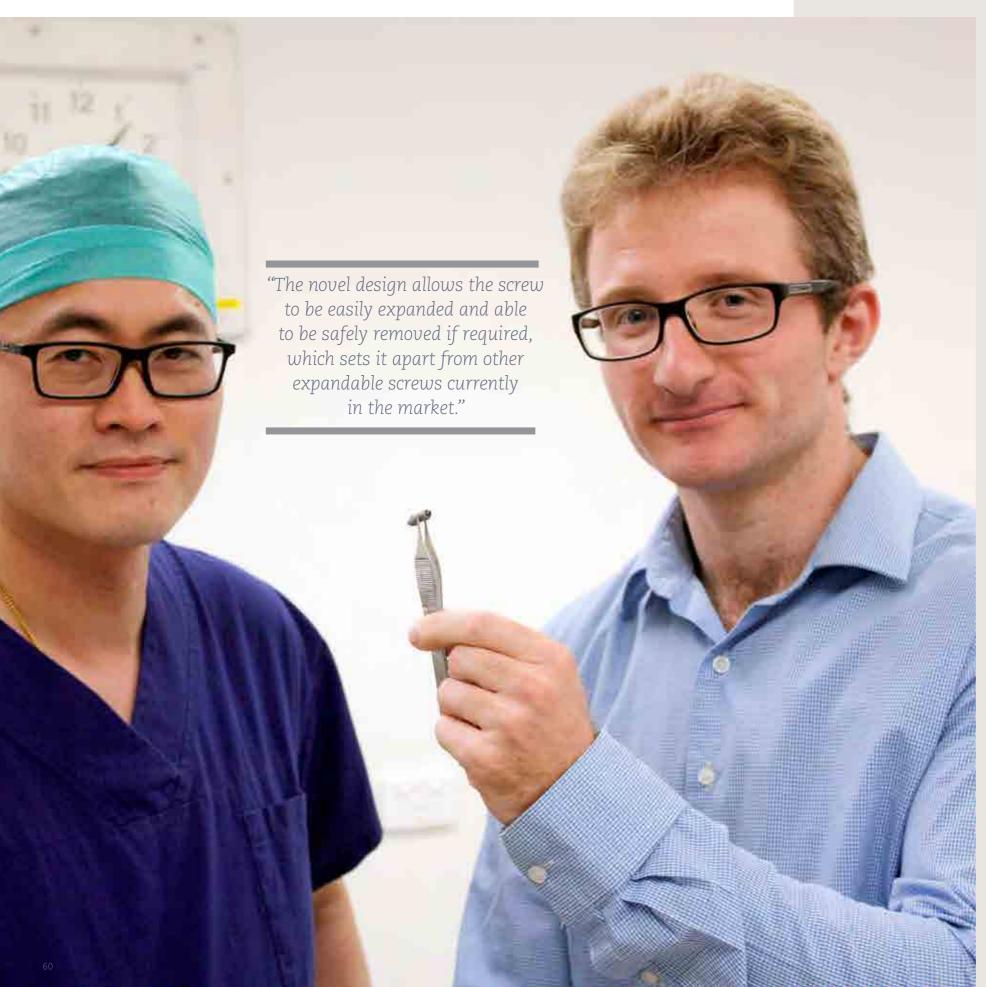
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Oldakowski M, Oldakowski I, Lee G, Kuster M, 'A removable expandable screw to reduce screw related complications'- Paper presented at the Australian Orthopaedic Association (WA) Annual Scientific Meeting, August 2016, Perth, Australia.

KEY STAFF



Professor Gabriel Lee



New 3D bone screw set to revolutionalise spinal surgery

An innovative device being developed by a team of surgeons and researchers at St John of God Subiaco Hospital, Royal Perth Hospital and Curtin University could greatly improve the safety of complex spine surgery which requires stabilisation and fusion procedures.

St John of God Subiaco Hospital Head of the Neurosurgery and Spinal Surgery Department Professor Gabriel Lee said that using 3D printing technology the group had created a titanium expandable bone screw, which allows stronger bone fixation than a traditional screw.

"A spinal stabilisation and fusion may be required to treat a variety of conditions, including traumatic fractures, spinal degeneration, deformity and tumours," Professor Lee said.

"During these procedures, a number of bone screws are typically implanted to stabilise the spine. These screws need to be placed carefully as they are often millimetres from critical blood vessels or nerve structures, and they need to be interconnected by plates or rods.

"However, elderly and osteoporotic patients may have quite weak bone, which causes screws to loosen or pull out over time. This significant complication can result in worsened pain and neurological disability – often requiring further surgery. This is costly and adds to the burden of the health system."

Researchers from Curtin University are working closely together with surgeons at St John of God Subiaco Hospital and Royal Perth Hospital to solve this problem. Collaborators at The University of Western Australia and University College London are also assisting with developing the expandable screw.

Matthew Oldakowski, a PhD student from Curtin University, who is developing the expandable screw, said the patented design of the screw is at the heart of its functionality and has been made possible in part by the development of 3D printing with titanium.

"The novel design allows the screw to be easily expanded and able to be safely removed if required, which sets it apart from other expandable screws currently in the market."

Indeed, this new screw design is seen as platform technology, which may be translated for use in orthopaedic surgeries throughout the skeleton.

Orthopaedic surgeon Professor Markus Kuster is leading an investigative study to evaluate the use of these new screws in hip surgery.

Recently the group was awarded a National Health and Medical Research Council Development Grant of \$414,000, to take the research to the next stage of development. The funding will allow additional safety testing in the laboratory to strengthen its commercial potential, with the hope that a clinical trial will start in three years.

The work has been made possible in part by financial support from St John of God Subiaco Hospital and Curtin University, who are co-funding Matthew Oldakowski's postdoctoral research fellowship and Kickstart funding from Curtin University in support of commercialisation activity.



Nursing, Midwifery and Allied Health

Research Program



St John of God Subiaco Hospital embraces an evidenced based approach to clinical care and culture that actively encourages nurses, midwives and allied health caregivers to investigate and trial new processes that could enhance patient care.

The Nursing, Midwifery and Allied Health Research Program investigates projects across a variety of specialities, including maternity, oncology, colorectal surgery and workforce.

Such projects aim to improve clinical outcomes and enhance service delivery, while at the same time build research capacity amongst nurses, midwives and allied health professional.

PROJECTS

An intervention to improve patient understanding and use of preoperative chlorhexidine washes

Julie Salathiel, Lyn Balinski, Elizabeth Boucher, Fiona Childs, Toni Dennis, Sally Gollner, Danielle Morris, Kaylene Riches, Brian Riggall-Southworth, Felicity Timmings, Dr Janie Brown, Alannah Cooper

Commenced 2017, estimated completion 2018

Builds on the work from a previous research project which surveyed patients experience of preoperative chlorhexidine washes. An intervention has been developed which aims to improve patient understanding and compliance with preoperative chlorhexidine washes.

The intervention includes improved delivery of information to patients through both written materials and standardising pre-admission phone calls. Once these interventions have been in place for four months all adult patients who are admitted to the hospital for an inpatient surgical procedure will be invited to participate in a survey about their experience and understanding of preoperative CHG washes.

In total 200 surveys will be collected across all surgical specialities. This will be the same survey employed in the original study, so results can be compared with the original study, with the addition of questions about the materials and information patients received on CHG.

Improving post-operative nutrition education outcomes of colorectal surgery patients

Dr Roslyn Giglia, Senior Research Dietitian, Mrs Charlene Grosse, Manager Allied Health, Ms Sascha McMeekin, Clinical Dieitian

Commended June 2017, estimated completion December 2017

Approximately 300 people are seen by the dietitian each year for education after bowel surgery. The surgery often involves removal of the diseased part of the bowel, followed by either fusing the bowel together, or formation of an ileostomy or colostomy. The surgery and resulting outcomes creates both anxiety and significant challenges for patients in dealing with their condition and then managing changes to normally private bodily functions.

At SJG Subiaco Hospital post-operative nutrition education is routinely provided to patients and includes detailed information regarding their disease and treatment so they can have a better understanding of their medical nutrition therapy related to their procedure.

This research project aims to determine the effectiveness of nutrition education processes for patients undergoing bowel surgery.

Ultimately, the success of this research depends on providing optimal nutrition education and setting goals and expectations, including the concept of patients being partners in their care and taking part-ownership of post-operative medical nutrition therapy.

Improving the clinical skills and knowledge of midwives and nurses caring for late preterm neonates in postnatal ward setting.

Therese O'Connor, Siobhan Eccles, Alannah Cooper, Dr Janie Brown

Commenced 2017, estimated completion 2018

The aim of this study is to measure any enhancement in the clinical knowledge and clinical skills of nurses and midwives

caring for late preterm neonates outside of the neonatal unit following the delivery of a targeted education intervention.

Changes to health funding has resulted in some late preterm babies being cared for on postnatal wards rather than in the neonatal unit. The needs of late preterm babies are more complex than their full term counterparts and they have a higher risk of complications. It has been identified that extra support and education is maybe needed to facilitate the care of late preterm babies outside of the neonatal unit.

An educational intervention was designed for the research study. Caregivers were invited to complete a pre-intervention survey prior to the educational intervention and a minimum of eight weeks post intervention. Pre and post intervention data for the study has now been collected and the data is being analysed.

Neonatal admission to a high dependency unit and its impact on maternal pain scores and analgesic requirements: a pilot study

Suzanne Kelly, Siobhan Eccles, Dr Janie Brown, Alannah Cooper

Commenced 2015, estimated completion 2017

The aim of this research is to determine if postnatal women whose babies are admitted to the neonatal unit (NNU), self-report lower postpartum pain scores and require decreased administration of post-delivery analgesia, compared to women whose babies remain with them.

In order to achieve this, an audit of pain scores and analgesia requirements will be undertaken to compare women whose babies are admitted to the NNU and women whose babies are not admitted to NNU. The required sample size has been obtained and data for the study is being analysed.

Patient satisfaction and selfreported adverse events associated with peripherally inserted central catheters (PICC) in patients receiving chemotherapy at St John of God Subiaco Hospital: A pilot study

Claire Kelly, Alannah Cooper, Dr Janie Brown

Commenced 2016, completed 2017

The aim of this pilot study was to explore patient experience and satisfaction including self-reported adverse events of PICC line use for chemotherapy in the outpatient oncology centre. A prospective survey was utilised to gain an understanding of patients' experiences of living with PICCs.

The survey included self-reported pain, comfort and ease of managing activities of daily living. Participants were surveyed at two points over one month. The positive aspects of PICCs included ease of treatment and little pain being associated with the PICC site. However, PICCs did hinder patients in a number of activities, including work, leisure and exercise.

Preoperative chlorhexidine gluconate washes: a survey of patient experience in a private hospital setting

Julie Salathiel, Lyn Balinski, Elizabeth Boucher, Fiona Childs, Toni Dennis, Sally Gollner, Danielle Morris, Kaylene Riches, Brian Riggall-Southworth, Felicity Timmings, Dr Janie Brown, Alannah Cooper

Commenced 2016, completed 2017

This study explored patient experience, understanding and compliance with using Chlorhexidine Gluconate (CHG) preoperative washes. A cross-sectional survey was conducted over a ten week period with adult inpatients who had undergone a surgical procedure.

A 74 per cent (n = 194) sample response rate was attained. The sample obtained was representative of the wider hospital surgical patient population. Although 85 per cent (n = 159) of participants reported they used CHG prior to their surgical



procedure, only 63 per cent (n = 101) used the wash the recommended two times. Across all age groups in the survey 20 per cent (n = 36) of participants reported they received too little information about CHG washes.

The effectiveness of a preoperative consult with a breast care nurse in women undergoing breast surgery in a private tertiary hospital

Gay Refeld, Dr Janie Brown, Alannah Cooper

Commenced 2015, estimated completion 2017

The study is examining the effects of a pre-operative face-to-face consultation by a breast care nurse before admission to hospital for breast cancer treatment. It is primarily focussed on whether patients feel less anxious following the consultation.

The consultation is used to provide early recognition of any psychosocial, practical, cultural and communication issues which may require referral onto appropriate health professionals.

Additionally, the research hopes to determine if the consult affects length of stay post operatively. A sufficient sample has been obtained and data analysis is now being conducted.

The forgotten puncture site:

patient awareness of spinal and epidural complications

Jennifer Fraser, Dr Janie Brown, Alannah Cooper

Commenced 2016, completed 2016

This quality improvement project evaluated the effectiveness of a new discharge information sheet on patient knowledge, symptoms to seek attention and use of a contact number.

General surgical patients who underwent single shot spinal or epidural analgesia had a discussion with their nurse relating to their discharge and given the information sheet. A confidential self-report questionnaire was given to patients to complete while in hospital. The results demonstrated that patients found the discharge information sheet improved their knowledge and awareness of potential complications from epidural and spinal analgesia and they valued the additional information provided.

PUBLICATIONS

Cooper A, Brown J, Salathiel J, Gollner S, Childs F, Boucher E, Morris D, Riggall-SouthworthB, Baliniski L, Riches K, Dennis T, Timmings F, 'Exploring patient experience and understanding of Chlorhexidine Gluconate preoperative washes: A cross-sectional survey', Infection, Disease & Health, 2017, 22, 51-56. doi:10.1016/j.idh.2017.02.002

Cooper A, Kelly C, Brown J, 'Exploring the patient experience of living with

a periperally inserted central catheter (PICC): A pilot study', Australian Journal of Cancer Nursing, 2017, 18(1), 10-14.

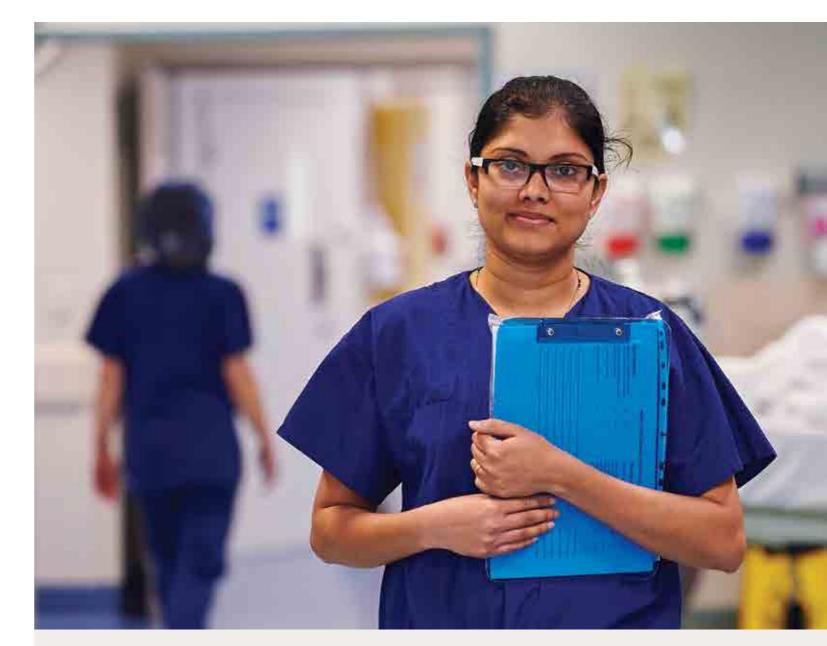
CONFERENCE PRESENTATIONS

Salthiel J, Cooper A, Brown J,
'Preoperative chlorhexidine gluconate
washes: A survey of patient experiences
in a private hospital in Western
Australia', Paper presented at the
8th International Congress on
Innovations in Nursing, 2016, Perth,
Australia

Kelly S, Eccles S, Cooper A, Brown J, 'Neonatal admission to a high dependency unit and its impact on maternal pain scores and analgesic requirements', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia

Cooper A, Brown J, Colvin L, Boyd L, Wong K, 'A point prevalence study of peripheral intravenous cannulation (PIVC) and therapy', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia

Fraser J, Brown J, Cooper A, 'The forgotten puncture site: Patient awareness of spinal and epidural complications', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia



"Food as medicine is an essential component of each person's journey to recovery and health. We are passionate about having our clinical dietitians incorporating research as part of their everyday clinical practice. With the constant changes around us and the changing horizon of medicine, it is important that we look at the gaps and challenge our thinking. This allows us to be innovative in our clinical practice and leaders in our profession."

- Charlene Grosse

KEY STAFF



Alannah Cooper Research Nurse



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Oncology Clinical Trial Unit



In 1999 St John of God Subiaco Hospital established the Western Australia Clinical Trial Oncology Group and was one of the first sites to have a dedicated oncology clinical trial unit (OCTU) in the state.

The unit was managed as a joint venture with the Cancer Council WA until 2008 when it transferred entirely to the hospital.

The OCTU is committed to integrating research into standard of care treatment options for patients and strengthening the hospital's position as one of the nation's top research institutes.

The OCTU is one of the largest oncology clinical trial units in Australia, with 30 active trials in various phases of recruitment and follow up and several more trials currently pending.

Great focus is placed on providing outstanding research-based health care to patients by offering comprehensive and integrated evidence-based treatment options, whilst upholding the mission and core values of the organisation.

To ensure the unit can facilitate future growth, the OCTU has streamlined its processes to expedite the start-up phase to enable earlier site activation and to maximise the recruitment period. This has improved its service and increased the total number of trials from 46 to 51.

The OCTU works in partnership with key service providers, including SKG Radiology, Western Cardiology, Genesis Cancer Care and Australian Clinical Labs. It also works closely with key departments within the hospital, particularly nursing and pharmacy.

KEY STAFF



Angela Baird Acting Senior Clinical Trial & Data Management Officer



Skye Ridley Senior Clinical Trial & Data Management Officer



Kathryn Jajko Clinical Trial & Data Management Officer



Amanda Taylor Clinical Trial & Data Management Officer



Luke Hanrahan Clinical Trial & Data Management Officer



Laura Debry
Clinical Trial & Data
Management Officer



Martha Jaworski Clinical Trial & Data Management Officer



Rebecca Weselman Clinical Trial & Data Management Officer



Grace Till
Clinical Trial & Data
Management Officer



Angelika Kimble Research Assistant



Dr Niloufer Johansen, Phd *Research Officer (Breast)*



Stephanie Jeffares *Research Officer* (*Gynaecology Cancer*)



Dr Andrew Dean *Medical Oncologist*



Dr Martin Buck *Medical Oncologist*



Dr Daphne Tsoi *Medical Oncologis*



Professor Christobel Saunders Surgical Oncologist



Dr Tim Clay *Medical Oncologist*



Dr Tarek Meniawy *Medical Oncologist*



Dr Thomas van Hagen *Medical Oncologist*



Medical Registrar



Dr Joanne Youd Project Manager – Clinical Trial Development



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PROJECTS

Trials open to recruitment July 2016 - June 2017

Principal Investigator	Study Titles	"Opened to recruitment"
Dr Daphne Tsoi	A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 with Concurrent Chemoradication and Adjuvant Temozolomide in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification	Sep-16
Dr Tom Van Hagen	A Randomised Phase II Study of nab-paclitaxel in Combination with Carboplatin as First Line Treatment of Gastrointestinal Neuroendocrine Carcinomas.	Jan-17
Dr Tom Van Hagen	A Randomised Phase III Double-Blind Placebo-Controlled Study of Regorafenib in Refractory Advanced Oesophago-Gastric Cancer (AOGC)	Mar-17
Dr Tom Van Hagen	A Phase 3, Randomized, Open-Label Study Comparing Pexa-Vec (Vaccinia GM-CSF/Thymidine Kinase Deactiavted Virus) Followed by Sorafenib versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) without prior systemic therapy	Apr-17

Trials due to be opened before end of 2017

Principal Investigator	Study Titles	Pending site activation
Dr Tim Clay	A Phase 1, Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATK™ (Coxsackieviorus A21, CVA21) alone and in Combination with Pembrolizumab in Patients with Late Stage Solid Tumours (NSCLC, Prostate Cancer, Melanoma and Bladder Cancer)	Jul-17
Dr Daphne Tsoi	A Phase III, Randomized, Double-Blind Study to Evaluate Pembrolizumab Plus Chemotherapy vs. Placebo Plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs. Placebo as Adjuvant Therapy and Pembrolizumab vs. Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)	Jul-17
Dr Daphne Tsoi	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 Early Stage Hormone Receptor Positive, Human Epidermal Receptor 2 Negative Breast Cancer	Aug-17
Dr Tim Clay	Three-arm Study of Carboplatin, Pemetrexed Plus Placebo vs Carboplatin, Pemetrexed plus 1 or 2 Truncated Courses of Demcizumab in Subjects with First Line Non-Squamous NSCLC (Phase II)	Aug-17
Dr Tom Van Hagen	A Phase II, open-label, multicentre trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in subjects with Merkel Cell Carcinoma (PART B)	Aug-17
Dr Daphne Tsoi	A Phase 3 open-label, randomized, multicentre study of NKTR-102 versus treatment of physician's choice (TPC) in patients with metastatic breast cancer who have stable brain mestastases and have been previously treated with an anthracycline, a taxane, and capecitabine.	Aug-17
Dr Tim Clay	Pattern of use and safety/effectiveness of Nivolumab in routine oncology practice	Aug-17
Dr Tim Clay	A Multicentre, Open-label Phase 2 Study of Rucaparib in Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency	Aug/Sept 2017
Dr Tom Van Hagen	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 pembrolizuman or nivoluman treatment	Sep-17
Dr Tim Clay	A Multicenter, Randomized, Phase 3 Study of Rucaparib versus Physician's Choice as 2nd Line Treatment Following Androgen Receptor Directed Therapy for Patients with Metastatic Castration- Resistant Prostate Cancer Associated with a Deleterious BRCA or ATM Mutation	Oct-17
Dr Tim Clay	A randomised phase 2 trial of nivolumab and stereotatic ablative body radiotherapy in advanced non-small cell lung cancer, progressing after first or second line chemotherapy	Oct-17
Dr Andrew Dean / Dr Tim Clay	Phase 1b Multi-indication Study of Anetumab Ravtansine (BAY 94-9343) in Patients with Mesothelin Expressing Advanced or Recurrent Malignancies	Oct-17
Dr Andrew Dean	Phase III randomized study for the treatment of recurrent or mestastic platinum-refractory cervical carcinoma with a new Anti-PD-1 therapy	Oct-17
Dr Tim Clay	A randomised trial of durvalumab and tremelimumab ± platinum-based chemotherapy in patients with high-risk, (metastatic stage IV) squamous or non-squamous non-small cell lung cancer	Nov-17

Ongoing trials currently open to recruitment

Principal Investigator	Study Titles
Dr Andrew Dean	A randomized, open-label phase 2 study of Nanoliposomal Irinotecan (nal-IRI)-containing regimens versus nabpaclitaxel plus gemcitabine in patients with previously untreated, metastatic pancreatic adenocarcinoma (Part 2)
Dr Tom Van Hagen	Aspirin for dukes C and high risk dukes b colorectal cancers: an international, multicentre, double blind, randomised placebo controlled phase III trial
Dr Andrew Dean	A randomized, open-label study comparing the combination of YONDELIS and DOXIL/CAELYX with DOXIL/CAELYX Monotherapy for the treatment of advanced-relapsed epithelial ovarian, primary peritoneal, or fallopian tube cancer
Dr Daphne Tsoi	A Phase III Study of Pembrolizumab (MK-3475) vs. chemotherapy in microsatellite instability-high colorectal adenocarcinoma
Dr Daphne Tsoi	Phase III, Randomised, Double-Blind, Placebo-Controlled Study to Investigate Efficacy & Safety of MPDL3280A (anit-PD-L1 Antibody) in combination with NAB-Paclitaxel vs. PDL3280A Placebo with NAB-Paclitaxel in Patients with Previously Untreated Metastatic Triple Negative Breast Cancer
Dr Andrew Dean	A Phase 2 open-label, single-arm, multicentre study to evaluate efficacy and safety of Pembrolizumab monotherapy in subjects with advance recurrent ovarian cancer
Dr Daphne Tsoi	A Phase III study of Pembrolizumab vs. physicians' choice Paclitaxel or Docetaxel in 2L subjects with advanced/metastatic adenocarcinoma and squamous cell carcinoma of the esophagus (PN 181)
Dr Andrew Dean	A randomised controlled trial of online versus telephone-based information and support. In collaboration with the University of Newcastle and the Cancer Council New South Wales, endorsed by the Australasian Lung Cancer Group
Dr Tim Clay	A phase 3, randomized, double-blind, placebo-controlled study of ramucirumab plus docetaxel versus placebo plus locally advanced or unresectable or metastatic urothelial carcinoma who progressed on or after platinum-based therapy
Dr Andrew Dean	A phase 3, multicentre, open-label, randomized study of nab®-paclitaxel plus gemcitabine versus gemcitabine alone as adjuvant therapy in subjects with surgically resected pancreatic adenocarcinoma
Dr Andrew Dean	A multicentre, randomised, 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
Dr Daphne Tsoi	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
Dr Andrew Dean	A prospective randomized phase III trial of carboplatin/gemcitabine/bevacizumab vs. carboplatin/pegylated liposomal doxorubicin/bevacizumab in patients with platinum-sensitive recurrent ovarian cancer
Dr Chistobel Saunders	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy
Dr Daphne Tsoi	Denosumab/placebo for Adjuvant Breast Cancer with High Risk of Recurrence (Phase III)
Dr Daphne Tsoi	A Randomised, Multicentre, Double-Blind, Placebo-Controlled Phase II study of the Efficacy and Safety of Traztuzumab Emtansine in Combination with Atezolizumab or Atezolizumab-Placebo in Patients with HER2-positive Locally Advanced or Metastatic Breast Cancer who have Received prior Trastuzumab and Taxane Based Therapy

Oncology Services

Oncology Services



The St John of God Subiaco Hospital holistic oncology service supports patients' physical, emotional and psychological wellbeing, including surgical and medical needs.

The Oncology Services department provides education, clinical expertise and support for patients and their loved ones in the prevention, diagnosis and treatment of cancer.

Clinicians are brought together from a range of disciplines associated with cancer treatment, including oncology, haematology and palliative care. The team pride themselves on providing a high standard of professional and multidisciplinary care with compassion and expertise at the onsite Bendat Family Comprehensive Cancer Centre.

Services include:

- cancer-related surgery
- chemotherapy treatment
- targeted and immunotherapies
- cancer research and clinical trials
- cancer specific multidisciplinary team meetings

- allied health support including social workers, dietitians, case occupational therapists, physiotherapists and pharmacists
- pain management
- pastoral services
- specialist nurses in breast care, palliative care and oncology.

PUBLICATIONS

Angelov S, Dean AP, 'Cancer associated thrombosis in patients taking direct oral anticoagulants (DOACs): Retrospective review of a single institutional series', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e14080)

Blanc JF, Hubner R, Li CP, Wang-Gillam A, Bodoky G, Dean A, Shan YS, Jameson G, Macarulla T, Lee KH, 'Subgroup analysis by prior non-liposomal irinotecan therapy in NAPOLI-1: A phase 3 study of nal-IRI±5-fluorouracil/leucovorin in patients with metastatic pancreatic ductal adenocarcinoma previously treated with gemcitabine-based therapy', Annals of Oncology,

Volume 28, Issue suppl_3, 1 June 2017, mdx263.017

Clarke E, George J, Dean AP, 'Metastases from lobular breast cancer as an unusual source of GI bleeding', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e12557)

Dean AP, Higgs D, James A, Van Gemert T, James AT, 'Modified FOLFIRINOX (mFOLFIRINOX) as second-line chemotherapy in pancreatic adenocarcinoma', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e15747)

Dean AP, Higgs D, Robins P, Stobie P, Craven P, Daly C, Carija S, 'Fluoropyrimidine-associated myocardial toxicity as a global metabolic effect compared to vascular spasm and visibility on FDG PET scanning', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e14013)

Dean A, Higgs D, Robins P, Stobie P, Craven P, 'PET scanning suggests that 5FU myocardial toxicity is metabolic, rather than ischaemic', Annals of Oncology, Volume 28, Issue suppl_3, 1 June 2017, mdx261.163,

Dean A, Higgs D, Yusoff I, Johansson M, Tang C, 'Resecting the unresectable - long course gemcitabine/nab-paclitaxel followed by chemoradiation to downstage locally advanced pancreatic adenocarcinoma', Annals of Oncology, Volume 28, Issue suppl_3, 1 June 2017, mdx261.206

James AT, James A, Pinto do Nascimento M, Higgs D, 'Rogers- Seeley, Madeline. Dean, Andrew Peter. 2017. Pneumocystis infection during first-line chemotherapy for solid tumours: Increased virulence or better diagnosis?' Journal of Clinical Oncology 35, 2017 (suppl; abstr e18277)

Macarulla TM, Siveke JT, Wang-Gillam A, Li CP, Bodoky G, Dean AP, Yanshen S, Jameson GS, Lee KH, Blanc JF, Chiu CF, Schwartsmann G, Braiteh FS, Cunningham D, Chen LT, Von Hoff DD, Mamlouk KK, Bhargava P, de Jong FA, Hubner R, 'Subgroup analysis by prior lines of metastatic therapy (mtx) in NAPOLI 1: A global, randomized phase 3 study of liposomal irinotecan (nal IRI) ± 5 fluorouracil and leucovorin (5 FU/LV), vs. 5 FU/LV in patients (pts) with metastatic pancreatic ductal adenocarcinoma (mPDAC) who have progressed following gemcitabine-based therapy', Journal of Clinical Oncology 35, 2017 (suppl; abstr 4127)

Van Gemert T, James A, 'Expanded analysis of mFOLFIRINOX as secondline chemotherapy in pancreatic adenocarcinoma', Annals of Oncology, Volume 28, Issue suppl_3, 1 June 2017, mdx261.204, doi.org/10.1093/ annonc/mdx261.204 Wang-Gillam A, Chen LT, Li CP, Bodoky G, Dean A, Lee KH, Cunningham D, Hubner R, Braiteh, et al, 'The prognostic value of baseline neutrophil-to-lymphocyte ratio (NLR) and platelet- to-lymphocyte ratio (PLR) for predicting clinical outcome in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with liposomal irinotecan (nal- IRI; MM-398) + 5- fluorouracil and leucovorin (5-FU/LV) vs 5-FU/LV', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e15795)

Wang-Gillam A, Li CP, Bodoky G, Dean AP, Lee KH, Cunningham D, Hubner R, Siveke JT, Braithwaite FS, Pipas m, Belanger B, De Jong F, Mody PD, Chen Li-Tzong, Von Hoff D, 'Characteristics of long-term survivors in a randomized phase III trial (NAPOLI-1) of patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with liposomal irinotecan (nal-IRI; MM-398) + 5-FU/LV', Journal of Clinical Oncology, 35, no. 4_suppl (February 2017) 293-293.

PREVIOUS PUBLICATIONS

Wang-Gillam A, Li CP, Bodoky G, Dean A, et al, 'Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial', Lancet, February 2016, 387 (10018): 545-57

Demetri GD, et al, 'Efficacy and Safety of Trabectedin or Dacarbazine for Metastatic Liposarcoma or Leiomyosarcoma After Failure of Conventional Chemotherapy: Results of a Phase III Randomized Multicenter Clinical Trial', Journal of Clinical Oncology, March 2016, 10;34(8):786-93.

Oncology Services

Dean A, et al, 'Nab-paclitaxel plus gemcitabine followed by radiotherapy with concurrent 5-FU in locally advanced unresectable pancreatic cancer: A Western Australian experience', Journal of Clinical Oncology, 34, 2016 (suppl 4S; abstr 430)

Dean A, et al, 'A randomized, openlabel phase II study of nanoliposomal irinotecan (nal-IRI)-containing regimens versus nab-paclitaxel plus gemcitabine in patients with previously untreated metastatic pancreatic adenocarcinoma', Journal of Clinical Oncology, 34, 2016 (suppl 4S; abstr TPS482)

Wang-Gillam A, Li CP, Bodoky G, Dean A, et al, 'Updated overall survival analysis of NAPOLI-1: Phase III study of nanoliposomal irinotecan (nal-IRI, MM-398), with or without 5-fluorouracil and leucovorin (5-FU/LV), versus 5-FU/LV in metastatic pancreatic cancer (mPAC) previously treated with gemcitabinebased therapy', Journal of Clinical Oncology, 34, 2016 (suppl 4S; abstr 417)

Chen L, Von Hoff DD, Li CP, Wang-Gillam A, Bodoky G, Dean AP, et al, 'Expanded analyses of napoli-1: Phase 3 study of MM-398 (nal-IRI), with or without 5-fluorouracil and leucovorin, versus 5-fluorouracil and leucovorin, in metastatic pancreatic cancer previously treated with gemcitabine-based therapy', Journal of Clinical Oncology, 33, 2015 (suppl 3; abstr 234)

KEY STAFF



Dr Andrew DeanHead of Department Cancer
Services



Dr Joanne Youd Project Manager – Clinical Trial Development



Libby Walker Administrative Officer

Improving survival rates for pancreatic cancer patients

The Bendat Family Comprehensive Cancer Centre (BFCCC) at St John of God Subiaco Hospital is carving out a niche as a leader in global pancreatic cancer research, trialling new treatments that are significantly improving survival rates for Western Australian patients.

Pancreatic cancer is one of the less common cancers, but one of the leading causes of death, because it usually presents when well-advanced and is difficult to treat.

Eight years ago, the BFCCC was only the second cancer treatment centre in the world to introduce a new combination of chemotherapy drugs – Gemcitabine and Abraxane – with stunning results.

St John of God Subiaco Hospital's Head of Medical Oncology Dr Andrew Dean said Gemcitabine had traditionally been used to treat pancreatic cancer, while Abraxane was a new breast cancer treatment yet to be released for widespread use. It was generously provided by the suppliers so that more than 200 patients could be treated with the combination before it became widely available.

"This combination was the first significant advance in many years and resulted in a doubling of the survival rate among patients with widespread (metastatic) pancreatic cancer," Dr Dean said.

"It also had a dramatic effect on those with locally advanced cancer, which is usually considered inoperable. At least a quarter of these patients went on to have successful surgery."

The Abraxane was made available to patients at no charge as part of this ground-breaking access program, made possible by a 'can-do' attitude by all involved.

The analysis of the results and impact of this innovative approach have since been presented at many international meetings, including The American Society of Clinical Oncology and The World Gastrointestinal Congress, cementing the centre's reputation as a global leader.

Dr Dean said the BFCCC was also the first in the world to use modified Folfirinox as a second-line treatment for pancreatic cancer, when it had previously been dismissed as too toxic.

"Our results showed that this can be a very successful treatment when previous treatment options have failed," Dr Dean said.

"Because of this published experience, we have since been invited to participate in a number of major international studies."

Dr Dean said the BFCCC is now the leading global site for the Yosemite study, which is trialling a new antibody in conjunction with chemotherapy, and the first centre in the world to offer a pancreatic cancer study, using a newer, more potent version of Folfirinox.

"Being involved in trials like this gives our patients access to innovative new drugs, often many years before they become available on the open market," Dr Dean said.

"As a result, our five-year survival rate for patients with locally advanced pancreatic cancer is among the best in the world."



Orthopaedic Surgery Research Group

Orthopaedic Surgery Research Group



At St John of God Subiaco Hospital clinical orthopaedic research is being developed in partnership with universities and medical device companies, and is conducted within a highly regulated and ethical research environment.

The Orthopaedic Surgery Research Group's goal is to translate research findings to clinical practice, so patients can receive the best and most up to date treatments available.

Orthopaedic research is conducted to audit clinical outcomes, better understand disease and injury and investigate new technologies which may lead to further improvements in treatment.

The unit has been established to capture and analyse ongoing patient clinical and surgical outcomes utilising the latest technology in order to maintain and enhance patient care.

Patient data is collected preoperatively, intra operatively and post operatively for future comparative analysis

PROJECTS

A study on the 3D Microstructure of Tendons with different physiology

Wang, Wu, Xin, Mackie, Allison, Kirk

Tendon sampling during surgery has commenced, with analysis performed by The University of Western Australia and Curtin University.

Analysis of benefits of undertaking all pre-admission procedures and education within a specialists private rooms

Mr Dermot Collopy, Mr Gavin Clark Commenced 2015, ongoing

This study is analysing the benefits of undertaking all pre-admission procedures and education within the specialist's private rooms. The study

aims to demonstrate any differences in patient satisfaction and length of stay for total knee replacement and total hip replacement with coordinated patient education and pre-operative assessment together with discharge planning from private rooms.

Comparative radiographic study of robotic hip replacement compared to conventional technique

Mr Gavin Clark, Mr Dermot Collopy Commenced July 2016, ongoing

This randomised controlled trial is comparing robotically assisted total hip replacement with standard surgical technique. The aim is to investigate any clinical benefit of robotically assisted total hip replacement and to investigate health economics of the procedure Australia wide.

Defining a randomised controlled study of Ortho-ATI vs corticosteroid injection for treatment of rotator cuff tendonopathy and tear

Wang, Breidahl, Ebert, Zheng

Exercise rehabilitation and functional recovery following reverse total shoulder arthroplasty: a prospective randomised controlled trial

Edwards, Wang, Ebert, Ackland, Honey Estimated completion 2019

Initial Mako Registry-15

Mr Gavin Clark, Mr Dermot Collopy Commenced March 2015, estimated completion 2018

A prospective enrolment of patients undergoing a uni-compartmental knee arthroplasty, bi-compartmental (bi-comp) or total knee replacement performed using Stryker's robotic arm assisted surgery into a registry database.

Whilst the initial registry has ceased after two years of follow up, data is still being collected. Currently 135 patients have undergone bi-comp or partial knee replacements in this registry.

Gait analysis for bicompartmental OA trial

Mr Gavin Clark

Commenced January 2016, ongoing

This is a sub-study of the Mako Randomised Clinical Trial MAKORCT-15. It involves 40 patients undergoing gait analysis at The University of Western Australia preoperatively and 12 months post operatively to determine any difference in gait function.

Mako MRCT-15 clinical trial

Mr Gavin Clark, Mr Dermot Collopy Commenced September 2015,

Commenced September 2015, estimated completion 2019

A prospective, randomised control trial evaluating total knee replacement with the Stryker Triathlon Primary Total Knee System, compared to the bi-compartmental knee replacement with the MCK Restoris Multicompartmental Knee System performed using Stryker's robotic-arm assisted surgery system, Mako.

Pilot study of celgro collagen scaffold to augment surgical repair of rotator cuff tears

Wang, Breidahl, Ebert, Zheng Ongoing

Currently nine patients have completed 12 months post-surgical follow-up.

Morphological assessment of knees that have demonstrated different kinematic patterns during total knee arthroplasty Mr Gavin Clark

Commenced 2014, estimated completion 2018

This study aims to investigate the anatomical basis for observed differences in preoperative and post-operative knee kinematics utilising gait lab technology.

PUBLICATIONS

Wang, Ebert, Breidahl, Ackland, Zheng, 'Postoperative platelet rich plasma injections following arthroscopic supraspinatus tendon repair – mid-term clinical and radiological outcomes', American Journal of Sports Medicine

CONFERENCE PRESENTATIONS

Clark G, 'Physiological alignment and balance matching; the sensible compromise?', Australian Orthopaedic Association Scientific Program, March 2017, Perth, Australia

Collopy D, 'Outcomes and are we really as good as we think? (Registry vs true fn and satisfaction)', Australian Orthopaedic Association Scientific Program, March 2017, Perth, Australia

Collopy D, 'Major bone loss about the knee; reconstructive options' Australian Orthopaedic Association Scientific Program, March 2017, Perth, Australia

Clark G, Australian Knee Society Meeting, October 2016, Port Douglas, Australia

KEY STAFF



Mr Gavin Clark Principal investigator



Mr Dermot Collopy Principal investigator



Mr Sani Erak Principal investigator



Mr Allan Wang Principal investigator

Orthopaedic Fellow
Dr Daniel
Bianco-Adames
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Exploring the benefits of robotic-assisted knee replacement surgery

Orthopaedic surgeons at St John of God Subiaco Hospital are leading the way when it comes to using robotic technology to assist with joint replacement surgery.

The hospital was the first in Australia to use this technology in partial knee replacements two years ago, since December 2016 they have been researching its potential long-term benefits in total knee replacements.

Orthopaedics is one of the biggest surgical departments at St John of God Subiaco Hospital, with more than 45 surgeons, and one of the busiest joint replacement units in Australia.

Head of Department Orthopaedics, Mr Peter Campbell said the outcomes of this research would help to ensure that robotic technology was used effectively and that patients had access to the best and most up-to date treatments.

"Although it is being used in many places around the world, robotic equipment and technology in orthopaedic surgery is still quite new and the overall effect on patients is relatively unknown," Mr Campbell said.

Mr Gavin Clark and Mr Dermot Collopy are spearheading this study. Mr Clark said robot-assisted surgery allowed for a more individualised approach to total knee replacements, which could lead to improved long-term outcomes for patients.

"For the past 30 years, there has been a one-alignment-fits-all approach to knee replacement surgery," Mr Clark said.

"But we know from our research that there is a variation in alignment among the normal population.

Robot-assisted surgery allows us to replicate an individual's personal alignment during a knee replacement, and our study is aiming to determine whether this variation leads to better outcomes and improved patient satisfaction."

Mr Clark said the process begins with a CT scan of the patient's leg, which is used to create a three-dimensional model of the knee. During the operation, the knee is manipulated to see how the surrounding soft tissue behaves, then a 'virtual' operation is undertaken on the computer.

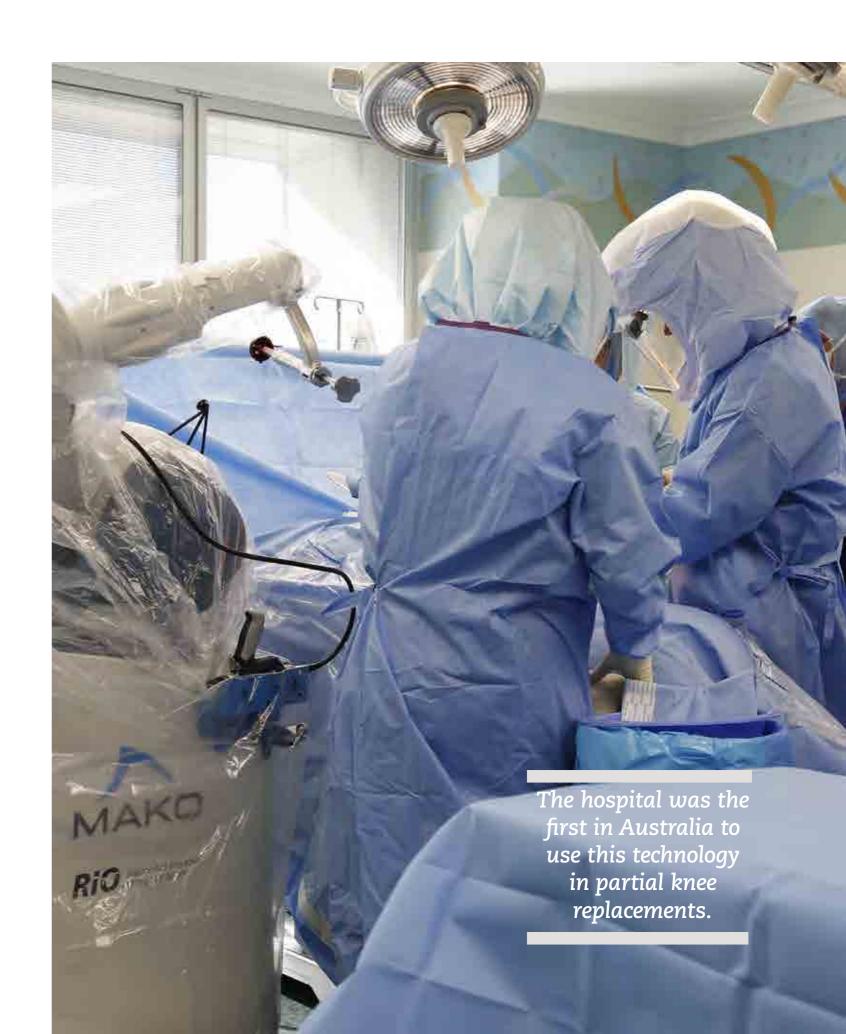
The results of this 'virtual' surgery are then refined and the robotic technology is activated by the surgeon to complete the final operation.

"The robot allows you to plan and execute an operation to within one degree of accuracy, removing any inaccuracy you might experience with standard instruments," Mr Clark said.

Early results from this study, which analyses data on patient outcomes, recovery times, complications and time in hospital, look promising, but will be confirmed within the next few months.

The next step will be to undertake a randomised, controlled trial comparing the outcomes of robot-assisted surgery with standard practice.

Long-term, Mr Clark said there was exciting potential for this technology to be informed by the experience of the world's best orthopaedic surgeons, improving global outcomes for knee replacement surgery.



WA Thoracic Research Group WA Thoracic Research Group

WA Thoracic Research Group

The St John of God Subiaco Hospital Thoracic Research Group is the largest respiratory and respiratory oncology research group in Western Australia's private health sector.

The group have broad interests across the respiratory and thoracic oncology landscape, including primary lung malignancy, mesothelioma, pulmonary hypertension and pulmonary thromboembolic disease, respiratory complications of connective tissue disorders and respiratory issues in bariatric surgery.

The group works closely with the University of Notre Dame Australia (Fremantle), where Professor Gabbay is the Head of Research for the School of Medicine, as well as the medical school at The University of Western Australia.

A very generous donation from Mr Jack Bendat enabled the group to recruit two Bendat Research Fellows and a research nurse. This group is coordinating several multicentre studies throughout Western Australia, Australia and internationally and has commenced six research projects.

PROJECTS

IVC Filters use at SJG Subiaco Hospital 2014 -2016

Prof Eli Gabbay, Dr Tim Clay, Dr Phil Craven, Dr Ciara Daly, Ms Nisha Sikotra

Commenced 2017, ongoing

Inferior vena cava filters are a form of mechanical thromboembolic prophylaxis, their sole purpose is the prevention of pulmonary emboli, by impeding the propagation of emboli from the deep venous system of the lower limbs to the pulmonary vasculature. Conflicting international

guidelines and lack of good randomised control trial evidence and concerns over their long-term safety warrants a review of their use. A single centre retrospective observational study is investigating inferior vena cava filter use at SIG Subiaco Hospital over three years. The study is looking at indications for insertion, appropriateness of insertion, retrieval rates, complication rates and long-term outcomes of their use.

Pneumocystis Jirovecii Pneumonia, a review of presentation, diagnosis, treatment and outcome at a single centre

Prof Eli Gabbay, Dr Tim Clay, Dr Phil Craven, Dr Ciara Daly, Ms Nisha Sikotra

Commenced 2017, ongoing

Pneumocystis Jirovecii Pneumonia (PJP), previously known as Pneumocystis Carnii Pneumonia (PCP), is a devastating opportunistic fungal infection of the lung that primarily affects immunocompromised patients, with a mortality rate of 10 to 20 per cent.

As a large oncological centre, with a large cohort of immunocompromised patients, 19 patients have been diagnosed with PIP over a 29-month period. Each case has been individually analysed for key information, including but not limited to, underlying diagnosis, risk factors, clinical presentation, biochemistry, microbiology, radiological findings, time to appropriate treatment, time to sputum PCR, response to therapy, complications and duration of therapy. Prompt recognition and prompt appropriate treatment are associated with better outcomes, warranting further investigation of management strategies.

Analysing novel methodology for assessing lung function in health and disease

Prof Eli Gabbay, Dr Craven, Mr Peter Franchina, Mr Avi Lazar

Commenced 2017, ongoing

Pulmonary function tests (PFTs) are used to diagnose pulmonary disorders, indicating the underlying aetiology, categorising disease severity and monitoring disease progression.

At present, there are several accepted methods of measuring lung volumes (LV). Most commonly the measurement of LV is performed by whole body plethysmography (WBT), which requires cumbersome equipment, is costly, involves expensive maintenance and is only available in hospitals and specialist centres.

A novel device now exists (PulmOne Minibox®), which claims to be as accurate as WBT, while only being the size of a desktop computer. This study is examining the accuracy and reproducibility of this device, against the WBT in patients with obstructive physiology, restrictive physiology and normal pulmonary physiology.

Preliminary results to date have been promising, with good correlation between the two devices and accurate reproducibility.

The role of tumour markers lung malignancies

Dr Phil Craven, Dr Ciara Daly, Ms Nisha Sikotra

Lung cancer is the leading cause of cancer related mortality in Western

Australia. Tumour, node and metastasis (TNM) stage at diagnosis is an independent predictor of prognosis and up to 75% of lung cancers are diagnosed at an advanced stage where surgical resection is impossible. Low dose CT screening is recommended for high risk individuals, however, this has a high false positive rate and often leads to unnecessary invasive interventions.

This research is reviewing the role of tumour markers in the assessment of primary lung malignancy with particular focus on circulating tumour DNA, a novel "liquid biopsy" as a screening tool to aid in the detection of lung cancer at an earlier and potentially curable stage. The group is collecting its own biobank of liquid biopsy samples to study this.

Mesothelioma – a patient journey

Prof Eli Gabbay, Dr Tim Clay, Dr Phil Craven, Dr Ciara Dalv. Ms Nisha Sikotra

Commenced 2017, ongoing

Malignant Pleural Mesothelioma (MPM) is a malignancy that arises from the pleura of the lungs. It has a very poor prognosis with a median survival of six to 12 months, less than a five per cent,

five-year survival and is recognised as being chemo-resistant.

A significant number of patients with MPM attend the public sector for access to clinical trials, while a substantial cohort of MPM patients attend SJG Subiaco Hospital. This retrospective observational study is examining the patients admitted to the Hospital with MPM between 2012 to 2016, to review their epidemiology, presentation, diagnosis and management, including referral elsewhere. This data will then be compared with guidelines set out by the Lung Foundation Australia for the diagnosis and treatment of MPM, to assess the hospital's adherence to national standards.

Clinical trials in primary lung malignancy

Dr Tim Clav. Dr Andrew Dean Commenced 2011, ongoing

This program continues work by oncologists in non-small cell lung cancer for early stage disease and metastatic disease.

The epidemiology of cardiorespiratory complications in systemic sclerosis

Prof Eli Gabbay, Ms Tara Hannon, Dr Megan Harrison

Commenced 2013, ongoing

The group is leading a multicentre study which explores cardiorespiratory complications in systemic sclerosis. It is the largest database of systemic sclerosis in the world, which commenced in 2008, and has been run out of SJG Subiaco Hospital over the past three years.

The management of pulmonary arterial hypertension

Prof Eli Gabbay, Ms Tara Hanon

Commenced 2008, ongoing

The group has an established a record of clinical trials in pulmonary hypertension exploring new therapies and new combinations of therapies. This study has been supported by the National Health and Medical Research Council grant.

KEY STAFF



Professor Eli Gabbay



Dr Tim Clav Oncologist



Dr Andrew Dean Oncologist



Nisha Sikotra Research Nurse



Dr Phil Craven Research Fellow

in the assessment of primary

Prof Eli Gabbay, Dr Tim Clay,

Commenced 2017, ongoing

Intensivist

Dr Ciara Dalv

Respiratory Physician **Dr Miranda Smith**

Dr David Morgan

Junior Doctor Dr Megan Harrison

Research nurse Tara Hannon

External Collaborations



External Collaborations

COLORECTAL CANCER RESEARCH GROUP

External Collaborations

Behavioural intervention to improve physical activity in colorectal and gynaecological cancer survivors at increased cardiovascular risk

Collaborator: *Dr Sarah Hardcastle* (*Curtin University*)

External authors: Dr Sarah Hardcastle, Chloe Maxwell-Smith, Dr Terry Boyle, Dr Robert Kane (all Curtin University), Dr Raj Mohan (Hollywood Private Hospital)

SJGSH authors: Prof Cameron Platell, Mr Michael Levitt, Mr Greg Makin, Mr Patrick Tan, Mr Paul Salama, Dr Paul Cohen, Mr Stuart Salfinger, Mr Jason Tan

Commenced 2017, estimated completion 2018

This trial aims to recruit colorectal and gynaecological cancer survivors at heightened cardiovascular risk and provide them with Fitbits and behavioural techniques (i.e. goal setting, action planning, self-monitoring and problem solving) based on the Health Action Process Approach Model to increase physical activity and promote improved psychological wellbeing.

Morphology and molecular profiling on interval colorectal cancers: Is procedural quality or molecular biology responsible?

Collaborator: Dr Claire Harma (Sir Charles Gairdner Hospital)

External authors: Dr Claire Harma, Dr MunaSalama (Sir Charles Gairdner Hospital), Dr Spiro Raftopoulos (Sir Charles Gairdner Hospital), Dr Priyanth Kumarasinghe (PathWest), Dr Bastiaan DeBoer (PathWest), Dr Benhur Amanuel

(PathWest), Prof Wendy Erber (UWA), Hooi Ee (Sir Charles Gairdner Hospital)

SJGSH authors: A/Prof Chris Hemmings (SJG Pathology/Australian Clinical Labs)

Commenced 2014, estimated completion 2017

Cancers diagnosed following a complete colonoscopy that is negative for cancer are frequently termed interval colorectal cancers (ICC). Limited data exists regarding the morphology and molecular profile of ICC. The aim of this study is to determine whether the histopathology and molecular biology of ICC differs from that of non-interval colorectal cancers.

Whole Exome sequencing and phenotyping in families with serrated polyposis

Collaborator: Dr Douglas Taupin (ACT Health)

External authors: Dr Douglas Taupin, Dr Matthew Cook (Australian National University)

SJGSH authors: A/Prof Chris Hemmings (Australian Clinical Labs), A/Prof Nik Zeps, Prof Cameron Platell

Commenced 2015, completed 2016

This project aimed to better understand the genetics of serrated polyposis, a disorder with apparently variable inheritance where multiple polyps occur in the colon and may give rise to cancer. However, the genetic basis for serrated polyposis has not been established. This study investigated previously identified genetic variations potentially associated with colorectal cancer development in a large cohort of patients with serrated polyposis.

Survey of health behaviours, barriers, and motives for health behaviour change in gynaecological and colorectal cancer survivors

Collaborator: Dr Sarah Hardcastle (Curtin University)

External authors: Ms Chloe Maxwell-Smith, Dr Sarah Hardcastle, Prof Martin Hagger, Dr Robert Kane (all Curtin University)

SJGSH authors: Dr Nik Zeps, Prof Cameron Platell, Dr Paul Cohen, Mr Jason Tan, Mr Greg Makin

Commenced 2016, completed: 2016

This study surveyed physical activity levels, dietary patterns and readiness and motivation to change in gynaecological and colorectal cancer survivors. Survey findings will be used to evaluate the feasibility of approaching health behaviour change for cancer survivors based on patient profiles.

GYNAEGOLOGICAL CANCER RESEARCH GROUP

A phase II randomised clinical trial of Mirena® ± Metformin ± weight loss intervention in patients with early stage cancer of the endometrium

Collaborator: Prof Andreas Obermair (Queensland Centre for Gynaecological Cancer, Royal Brisbane and Women's Hospital, University of Queensland)

External authors: Prof Andreas Obermair

SJGSH authors: Dr Paul Cohen, Dr Stuart Salfinger, Dr Jason Tan, Dr Raj Mohan Endometrial cancer is a cancer arising from the endometrium (the lining of the uterus). Endometrial hyperplasia with atypia is the medical term for unusual or excessive growth in the inner lining of the uterus of cells that look different from normal, but do not have all the features of cancer cells.

Currently the standard treatment for cancer or endometrial hyperplasia with atypia is a total hysterectomy and removal of both ovaries. While highly effective, this surgery carries significant side effects for young women who still wish to have children and who would lose fertility and women with significant comorbidities who are at risk of surgical complications.

This study aims to investigate whether endometrial cancer and endometrial hyperplasia with atypia can be effectively treated either with a Mirena intrauterine system, Mirena with Metformin or Mirena with weight loss, thus sparing patients major surgery.

A phase III randomised clinical trial comparing laparoscopic or robotic radical hysterectomy versus abdominal radical hysterectomy in patients with early stage cervical cancer

Collaborator: Prof Pedro T. Ramirez

External authors: Prof Pedro
T. Ramirez, The University of Texas MD
Anderson Cancer Center, Houston,
Texas, USA.

SJGSH authors: Dr Ganendra Raj Kader Ali Mohan, Dr Stuart Salfinger, Dr Jason Tan, Dr Paul Cohen

The standard treatment for early cervical cancer is a radical hysterectomy, which may be performed by laparotomy or laparoscopic surgery.

Preliminary data has shown that laparoscopic treatment of early cervical cancer may have potential advantages for patients, and that no difference exists in the prognosis of patients with cervical cancer whether they had laparoscopic or open surgery. However, no formal comparison has been made between these two surgical techniques.

This study will compare both techniques to see if they are equally effective in

terms of prognosis, but that laparoscopy is superior with respect to quality of life, treatment-related morbidity of surgery and disease status. Without such a clinical trial final treatment, recommendations cannot be made.

A prospective audit of sentinel node biopsy for vulval carcinoma in Australia and New Zealand

Collaborator: A/Prof Peter Sykes, University of Otago, Christchurch, New Zealand

External authors: A/Prof Peter Sykes, Dr Bryony Simcock, Dr Lois Eva, Dr Simone Petrich, Dr Cecile Bergzol, A/Prof Alison Brand, A/Prof Orla McNally, A/ Prof Penny Blomfield, Dr Lewis Perrin, Dr Diane Kenwright, Dr Ole Mogenson, Dr Rachael van der Griend, A/Prof Peter Sykes (University of Otago)

SJGSH authors: Dr Paul Cohen

This study aims to document the utility and safety of sentinel node dissection for vulval cancer in Australia and New Zealand.

The authors of GROINSS study in 2008 concluded that 'sentinel node dissection, performed by a quality controlled multidisciplinary team, should be part of the standard treatment in selected patients with early stage vulvar cancer.' This study revealed a groin recurrence rate of three per cent in the non-dissected sentinel node negative groin at 24 months and 2.6 per cent at a median follow up of 10 years.

In view of the morbidity associated with formal groin node dissection, it has been considered that selected women in Australia and New Zealand women with early vulval cancer should be offered Sentinel node procedures in place of groin node dissection, but it should be performed to agreed protocols and the outcomes carefully monitored. This can only be done as a collaborative multicentre study.

A prospective audit of all women offered this procedure in all centres in Australia and New Zealand has been proposed and that all procedures should be performed in accordance with the method published by the GROINSS collaboration.

A qualitative study exploring perceptions of health and factors influencing physical activity and healthy eating among endometrial cancer survivors

Collaborator: Dr Sarah Hardcastle, Curtin University

External authors: Dr Sarah Hardcastle

SJGSH authors: Dr Stuart Salfinger, Dr Jason Tan, Dr Paul Cohen

Endometrial cancer is the most common gynaecological cancer in Australia, with the incidence increasing due to an ageing population and growing obesity rates. The adoption of healthy lifestyle habits, such as increased physical activity may promote cancer survivors' health, well-being and longevity.

Research demonstrates the need for health behaviour change in this unique population group who often have poor lifestyles and co-morbidities. Endometrial cancer survivors are twice as likely to die from cardiovascular disease as to die from cancer. Obesity and metabolic syndrome are risk factors for both endometrial cancer and heart disease and are likely to contribute to cardiovascular related death.

In one study 43 per cent of endometrial cancer survivors were obese and 35 per cent were physically inactive. Obesity poses one of the greatest health threats to endometrial cancer survivors but despite the wishes of survivors to lose weight, increase physical activity and eat a better diet, few are achieving these health goals post treatment.

The aim of this study is to determine:

- How cancer survivors perceive and make sense of their current health status?
- Do they consider their health at risk having made a successful recovery?
- What are the attitudes, motives and barriers towards lifestyle behaviour change, including physical activity and healthy eating among endometrial cancer survivors?
- Do participants know the government recommendations for physical activity and healthy eating?
- What are the main influences on their physical activity and eating behaviours?

External Collaborations

Blood based markers to predict recurrence in ovarian cancer patients

Collaborator: Dr Yu Yu (Curtin University)

SJGSH authors: Dr Paul Cohen, Sanela Bilic, Dr Sturt Salfinger, Dr Jason Tan, Dr Raj Mohan, Dr Adeline Tan

Commenced 2017, estimated completion 2024

Ovarian cancer is one of the most lethal female cancers with 239,000 new cases worldwide in 2012. It is estimated that 1580 Australian women will be diagnosed with ovarian cancer in 2017. Thus, ovarian cancer is one of the deadliest gynaecological malignancies with 39 per cent and 17 per cent five-year survival for stages three and four, respectively.

The majority of patients have advanced disease at time of diagnosis, and despite best treatment including cytoreductive surgery and platinumbased adjuvant chemotherapy, most will relapse and ultimately die of their disease. Recent epidemiological and clinical data suggest that ovarian cancer is immunogenic. There is a clear relationship between a declining anti-tumour immune response and cancer recurrence. However, a lack of understanding in chemoresistance mechanisms and the immune system in mediating these processes has limited the development of effective prognostic biomarkers and therapies.

Our hypothesis is that increasing immune dysfunction plays a significant role in ovarian cancer recurrence and that appropriate immune activation using immunotherapy will promote favourable responses to chemotherapy. This study will examine tumour specific autoantibody and cytokine profiles to identify 'immune signatures' as potential prognostic biomarkers, and select specific targets for development of a novel immunotherapy approach.

Identification of markers for diagnosis and prognosis of ovarian cancer

Collaborator: Dr Mel Ziman (Edith Cowen University), Prof Mel Ziman, Prof Michael Millward, Prof. Mark Shackleton, Dr Tim Isaacs, A/Prof Fred Chen, Dr Adnan Khattak, Dr Samantha Bowyer, Dr Chris Lomma, Dr Tim Cooper, Dr Ben Wood, Dr David Prentice, Dr Tersia Vermeulen, A/Prof Jacqueline Bentel, A/Prof Benhur Amanuel, Ms Anna Reid, Mr James Freeman, Dr Elin Gray, Ms Pauline Zaenker, Dr Carlos Aya-Bonilla, Mr Aaron Beasley, Ms Ashleigh McEvoy, Ms Michelle Pereira, Mr Ali Didan, Ms Karen Shakespeare, Dr Lydia Warburton, Dr Prasad Kumarasinghe.

SJGSH authors: Dr Tarek Meniawy, Dr Paul Cohen, Prof Christobel Saunders, Dr Mark Hanikeri, Dr Mark Lee

Commenced 2015, estimated completion 2019

Ovarian cancer is the eighth most common cancer and the sixth most common cause of cancer death affecting women in Australia. Often undiagnosed until it has spread to other organs and tissue, early detection is the key to survival and a team of researchers is launching a new study to investigate circulating tumour cells, immune cells, gene expression and proteins in the peripheral blood of patients with cancer relative to these markers in tumour tissue.

It is anticipated that changes in these markers may be used to identify changes in the blood of patients that are indicative of tumour presence (diagnostic) or may provide information on patient outcome or tumour progression (prognostic) or response to treatment.

Impact of clinical genetics at gynaecologic oncology MDT

Collaborator: A/Prof Nick Pachter, Head of the Familial Cancer Program, Genetics Services of Western Australia, King Edward Memorial Hospital, School of Paediatrics and Child Health, University of Western Australia; and School of Medicine and Pharmacology, University of Western Australia.

External authors: Cassandra B. Nichols, Lyn Schofield, Steven Van Der Werf, and Nicholas Pachter

SJGSH author: Dr Paul Cohen

Germline mutations in the BRCA1 and BRCA2 genes underlie the hereditary

breast and ovarian cancer syndrome. Women with germline mutations in BRCA1 have up to a 59 per cent lifetime risk for breast cancer and up to a 40 per cent risk for epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. Similarly, women with germline mutations in BRCA2 have lifetime risks of breast and ovarian cancer of 49 per cent and 18 per cent, respectively.

BRCA mutations are associated with improved progression-free and overall survival in women with ovarian cancer compared to mutation-negative patients. Currently there are no effective screening tests for ovarian cancer but there are effective strategies aimed at cancer prevention, therefore it is clinical imperative to identify women with germline BRCA mutations.

Gynaecologic cancer services in Western Australia (WA) are centralised. and 98 per cent of women diagnosed with gynaecologic malignancies in the state are discussed at the weekly WA Gynaecologic Oncology Tumor Board. Since July 1 2014, the manager of the WA Familial Cancer Registry and an associate genetic counsellor from Genetics Services WA have attended the weekly gynaecologic oncology tumor board as members of the multidisciplinary team. They play a key role in identifying women presented at the tumor board who are eligible for genetics referral.

The group hypothesized that attendance of the WA clinical genetics service at the Gynaecologic Oncology Tumor Board would increase the referral rate of eligible patients with ovarian cancer for genetic counselling and BRCA mutation testing.

The objectives of this study are:

- to determine the proportion of eligible patients with ovarian cancer discussed at a gynecologic oncology tumor board who were referred for counseling and BRCA mutation testing
- to compare referral rates before genetics attendance at the tumor board to referral rates after genetics attendance
- to ascertain the proportions of women with germline BRCA mutations.







External Collaborations

Mindfulness based cognitive behavioural therapy to treat fear of recurrence in ovarian cancer survivors (FROCS): a pilot study

Collaborator: A/Prof Kellie Bennett, Behavioural Science Unit, Queen Elizabeth II Medical Centre, The University of Western Australia

External authors: Prof Kellie Bennett, Dr Toni Musiello, Dr Suzie Brans, Dr Anna Petterson, Prof Yee Leung, Dr Valda Duffield

SJGSH authors: Dr Paul Cohen, Dr Nik Zeps, Dr Stuart Salfinger, Dr Ganendra Raj Kader Ali Mohan, Dr Jason Tan

This study aims to determine the acceptability and efficacy of mindfulness based cognitive therapy as a treatment for fear of cancer recurrence in ovarian cancer survivors. This study also will ascertain the prevalence and severity of fear of cancer recurrence in ovarian cancer survivors in Western Australia, and assess whether there is a correlation between this fear and psychological wellbeing.

The study is funded by a St John of God Foundation grant.

Non-invasive detection of early stage ovarian cancer (NEO) study

Collaborator: Prof Stephen Tong (Translational Obstetrics Group, Mercy Hospital for Women, Department of Obstetrics and Gynaecology, University of Melbourne)

External authors: Prof Stephen Tong (Translational Obstetrics Group, Mercy Hospital for Women, Heidelberg, Melbourne, Victoria, Australia; Department of Obstetrics and Gynaecology, University of Melbourne, Parkville, Victoria, Australia), Dr Mark Pertile (Victorian Clinical GeneticsServices, Parkville, Victoria, Australia), Dr Lisa Hui (Department of Perinatal Medicine, Mercy Hospital for Women, Heidelberg, Melbourne, Victoria, Australia; Translational Obstetrics Group, Mercy Hospital for Women, Heidelberg, Melbourne, Victoria, Australia; Department of Obstetrics and Gynaecology, University of Melbourne,

Parkville, Victoria, Australia; Murdoch Children's Research Institute, Parkville, Australia), Dr Natalie Hannan, Dr Claire Whitehead

SJGSH author: Dr Paul Cohen

Ovarian cancer is now the leading cause of gynaecological cancer related deaths in Australia. Unfortunately, most women with ovarian cancer are diagnosed when the disease is advanced and cure is not possible. There is an urgent need to develop an acceptable, accurate screening test that can detect ovarian cancer at an early, curable stage in the general population.

The non-invasive detection of early ovarian cancer study is a multicentre collaboration between the St John of God Subiaco Hospital Gynaecological Cancer Research Group, the Mercy Hospital for Women Translational Obstetric Group and the Victorian Clinical Genetics Service.

The proposal draws on recent advances in molecular biology and non-invasive methods of monitoring health to develop promising biomarkers of ovarian cancer. It will explore two approaches to screening for ovarian cancer using blood samples. The first approach is based on next generation sequencing of cell free DNA in plasma. The recent introduction of cell-free DNA-based non-invasive prenatal testing (NIPT) for Down Syndrome in antenatal care has unexpectedly demonstrated its ability to detect asymptomatic maternal malignancies. This serendipitous finding has opened a new approach for noninvasive cancer screening based on the detection of chromosome abnormalities in circulating tumour DNA.

The second proposed approach is based on the detection of another type of circulating tumour-derived cell-free nucleic acid - micro RNA (miRNA). These miRNAs are small non-coding RNAs that regulate gene expression. miRNA expression is dysregulated in ovarian cancer, suggesting that it may play a key role in malignant transformation and tumour progression. As these tumour-associated miRNAs circulate in blood, they are another source of potential ovarian cancer biomarkers.

If successful, this project may form the foundation of larger prospective studies that have the potential to advance the

scientific knowledge in non-invasive techniques in oncology and improve patient care and survival.

This study is funded by a Norman Beischer Medical Research Foundation Grant.

Targeting mTOR signaling in human ovarian cancer

Collaborator: Dr Pradeep Tanwar

External authors: Dr Pradeep Tanwar **SIGSH authors:** Dr Paul Cohen

This study aims to analyse the status of mTOR signalling in serous ovarian cancer and investigate the functional evidence

for the role of mTOR signalling in the

pathogenesis of serous ovarian cancer.

An improved understanding of the involvement of mTOR in serous ovarian carcinogenesis will provide a rationale for using mTOR inhibitors in patients with alterations in this signalling pathway and may be immensely beneficial for ovarian cancer patients.

This study has been funded by an ARC Future Fellowship.

MURDOCH UNIVERSITY

Centre for Comparative Genomics

In 2015/16, SJG Subiaco Hospital engaged Professor Matt Bellgard and his team at the Centre for Comparative Genomics (CCG), Murdoch University to design and develop a patientcentric registry that functions as a Multidisciplinary Team Registry (MDT-R) that possesses biobank Laboratory Information Management System (LIMS) functionality. Importantly, this allows patients to have their biospecimens and any molecular analyses done as part of routine care integrated into this registry. This is an alternative approach to the many past unsuccessful attempts to deploy/build a biobank LIMS in close alignment with an MDT.

The MDT-R has a powerful querying engine and can track study groups. The system is designed with interoperability in mind to better link clinical information coming from external sources, such as pharmacy, imaging and

medical oncology with the a patient's tissue samples. The system has been live for more than 15 months supporting the Colorectal MDTs for both SIG Subjaco and Murdoch Hospitals. The improved data handling speeds up the hospitals ability to undertake and support medical research that links detailed clinical data with biological analysis that is integrated into the MDT itself. It is ideally placed to support the intentions of improving healthcare through Precision Medicine. We will continue to work closely with Professor Bellgard and his team to roll out the MDT-R to other cancer types and disease subspecialties.

The hospital has also worked closely with the CCG to audit other related data sources within the hospital. This work has identified the need for more standardised electronic record management in medical oncology. An inventory of all data sources, including their governance and the ability to link, import and export data is underway.

NEONATOLOGY UNIT

Publications

Buchiboyina A, Jasani B, Deshmukh M, Patole S, 'Strategies for managing transient tachypnoea of the newborn - a systematic review', Journal Maternal Foetal Neonatal Medicine, October 2016, 20:1-9

Chawla N, Deshmukh M, Sharma A, Patole A, 'Strategies for medical management of pediatric eosinophilic esophagitis - a systematic review', Journal of Peadiatric Gastroenterology Nutrition, December 2016, 63(6):e152-e157

Deshmukh M, Patole *S, 'Antenatal* corticosteroids for neonates born before 25 Weeks-A systematic review and meta-analysis', **PLoS One**, 9 May 2017, 12(5):e0176090. doi: 10.1371

Deshmukh M, Balasubramanian H, Patole S, 'Meconium evacuation for facilitating feed tolerance in preterm neonates: a systematic review and meta-analysis', Neonatology, 2016, 110(1):55-65. doi: 10.1159/000444075

WA THORACIC RESEARCH GROUP

The incidence and impact of obstructive sleep apnoea in patients undergoing bariatric surgery

Collaborator: Taunton Hospital, United Kingdom

SJGSH authors: Prof Eli Gabbay, Dr Miranda Smith and Dr David Morgan

Commenced 2017, estimated completion 2019

This multicentre study will explore the cardiorespiratory impacts of bariatric surgery across three sites in Western Australia and the United Kingdom.

List of Publications



List of Publications

Anaesthesia and Pain Research Unit

- McDonnell NJ, Paech MJ, Muchatuta N, Hillyard S, Nathan EA, 'A randomised double-blind trial of phenylephrine and metaraminol infusions at the time of spinal anesthesia for elective caesarean section', Anaesthesia, May 2017, 72:609-617
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- 3. Mu Y, McDonnell NJ, Li Z, Liang J, Wang Y, Zhu J, Sullivan E, 'Amniotic fluid embolism as a cause of maternal mortality in China between 1996 and 2013: a population-based retrospective study', BMC Pregnancy and Childbirth, October 2016, 19:16:316.
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Breast Cancer Research Unit

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- Chin L, Latham B, <u>Saunders CM</u>, Sampson DD, Kennedy BF, 'Simplifying the assessment of human breast cancer by mapping a micro-scale heterogeneity index in optical coherence elastography', J Biophotonics, 12 September 2016, doi: 10.1002/ bio.201600092.
- 7. Cohen PA, Brennan A, Marino JL, Saunders CM, 'Managing menopausal symptoms after breast cancer A multidisciplinary approach,' Maturitas, 2017, doi.org/10.1016/j. maturitas.2017.04.013

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Inflammatory Bowel Disease Research Unit

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Intensive Care Unit Research Program

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Junior Doctor Research Projects

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Neurosurgery Research Unit

- 126. Sharif SH, Murray I, Lee G, 'The application of Inertial Measurements Unit for the clinical evaluation and assessment of gait events among foot drop patients', Journal of Medical Engineering & Technology (accepted for publication, 12 June 2017).
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Nursing, Midwifery and Allied Health research Program

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Oncology Services

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 first-line chemotherapy for solid tumours:
 Increased virulence or better diagnosis?'
 Journal of Clinical Oncology 35,
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- 138. Macarulla TM, Siveke JT, Wang-Gillam A, Li CP, Bodoky G, Dean AP, Yanshen S, Jameson GS, Lee KH, Blanc JF, Chiu CF, Schwartsmann G, Braiteh FS, Cunningham D, Chen LT, Von Hoff DD, Mamlouk KK, Bhargava P, de Jong FA, Hubner R, 'Subgroup analysis by prior lines of metastatic therapy (mtx) in NAPOLI 1: A global, randomized phase 3 study of liposomal irinotecan (nal IRI) ± 5 fluorouracil and leucovorin

List of Publications

- (5 FU/LV), vs. 5 FU/LV in patients (pts) with metastatic pancreatic ductal adenocarcinoma (mPDAC) who have progressed following gemcitabine-based therapy', Journal of Clinical Oncology 35, 2017 (suppl; abstr 4127).
- 139. Van Gemert T, James A, 'Expanded analysis of mFOLFIRINOX as second-line chemotherapy in pancreatic adenocarcinoma', **Annals of Oncology**, Volume 28, Issue suppl_3, 1 June 2017, mdx261.204, **doi.org/10.1093/annonc/mdx261.204**.
- 140. Wang-Gillam A, Chen LT, Li CP, Bodoky G, Dean A, Lee KH, Cunningham D, Hubner R, Braiteh, et al, 'The prognostic value of baseline neutrophil-to-lymphocyte ratio (NLR) and platelet- to-lymphocyte ratio (PLR) for predicting clinical outcome in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with liposomal irinotecan (nal- IRI; MM-398) + 5- fluorouracil and leucovorin (5-FU/LV) vs 5-FU/LV', Journal of Clinical Oncology, 35, 2017 (suppl; abstr e15795)
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Orthopaedic Surgery Research Group

142. Wang, Ebert, Breidahl, Ackland, Zheng, 'Postoperative platelet rich plasma injections following arthroscopic supraspinatus tendon repair – mid-term clinical and radiological outcomes', American Journal of Sports Medicine.



List of Conference Presentations

Anaesthesia and Pain Research Unit

- McDonnell NJ, 'The EPITOMISE Trial: A randomised, multicentre platform trial of patient controlled epidural analgesia in labour', Collaborative Clinical Trials in Anaesthesia Prato Conference, June 2017, Prato, Italy.
- Corcoran T, 'PADDAG Study preliminary results', ANZCA ASM May 2017, Brisbane, Australia.
- 8. McDonnell NJ, 'Amniotic Fluid Embolism-An Update', 16th World Congress of Anaesthesiologists, August 2016, Hong Kong.
- McDonnell NJ, 'Modern Coagulation Management in Obstetric Haemorrhage', Malaysian Society of Anaesthetists National Scientific Congress, August 2016, Kuala Lumpur, Malaysia.
- McDonnell NJ, 'The EPITOMISE Trial: A randomised, multicentre platform trial of patient controlled epidural analgesia in labour', ANZCA Clinical Trials Network Meeting, August 2016, Coogee.

Cardiology Research Group

 McQuillan BM, 'Echocardiographic Pulmonary Left Atrial Ratio (ePLAR): Is it a Clinically Useful, Noninvasive Measure to Help Identify Patients with Left-Heart Causes of Pulmonary Hypertension?' Cardiac Society of Australia and New Zealand, August 2016

Colorectal Cancer Research Group

 Ang S, Cook M, Austin SJ, Zeps N, Fletcher N, Whiting P, Fadia M, Taupin DR, 'High frequency of RNF43 R117H missense mutations in SSA/PS predisposes to truncating R117FS in microsatellite unstable colorectal cancer', American Gastroenterological Association Digestive Diseases Week Meeting, June 2017, Bethesda, United States of America.

- Miller TJ, McCoy MJ, Hemmings C, Bulsara MK, lacopetta B, Platell CF, 'The prognostic value of the cancer stem-like cell marker SOX2 is modified by expression of the immune-related factors Foxp3 and PD-L1 in stage III colon cancer' - poster presentation, International Academy of Pathologists Australia Annual Scientific Meeting, June 2017, Sydney, Australia.
- P. Miller TJ, McCoy MJ, Anyaegbu C, Cheah K, Hemmings C, Bulsara MK, lacopetta C, Platell CF, 'Clinical utility of the cancer stem-like cell marker SOX2 is influenced by expression of the immune-cell related markers Foxp3 and PD-L1 in colon cancer patients' oral presentation, Australian Society for Medical Research Scientific Symposium, June 2017, Perth, Australia.
- McCoy MJ, Hemmings C, Anyaegbu CC, Lee-Pullen TF, Austin SJ, Miller TJ, Bulsara MK, Nowak AK, Lake RA, Platell CF, 'Identifying immune biomarkers of response to chemo-radiotherapy in rectal cancer using digital image analysis' - poster presentation, Global Engage Ltd Digital Pathology Congress; December 2016, London, United Kingdom.
- 11. McCoy MJ, Hemmings C, Anyaegbu CC, Lee-Pullen TF, Austin SJ, Miller TJ, Bulsara MK, Zeps N, Nowak AK, Lake RA, Platell CF, 'Immune biomarkers of response to chemo-radiotherapy in locally advanced rectal cancer' poster and oral presentation (Awarded Best of Posters Runner-Up), Australasian Gastro-Intestinal Trials Group Annual Scientific Meeting, September 2016, Melbourne, Australia.
- 12. MJ McCoy MJ, C Hemmings C, CC
 Anyaegbu CC, TF Lee-Pullen TF, SJ
 Austin SJ, TJ Miller TJ, M K Bulsara MK,
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 of response to chemo-radiotherapy in
 locally advanced rectal cancer' poster
 presentation, International Congress
 of Immunology, August 2016,
 Melbourne, Australia.

Gynaecological Cancer Research Group

- Tucker P, Cohen P, Mohan G, Tan J, '3D Reconstruction from Diagnostic Imaging in Gynaecological Oncology – is Virtual Reality Ready for Prime Time?' – poster presentation, Australian Society of Gynaecologic Oncologists Annual Scientific Meeting, May 2017, Broome, Australia.
- 14. Coghlan E, Meniawy TM, Munro A, Bulsara M, Stewart CJ, Tan A, Koay MH, MaGee E, Codde J, Tan J, Salfinger SG, Mohan GR, Leung Y, Nichols CB, Cohen PA, 'Prognostic Role of Histological Tumour Regression in Patients Receiving Neoadjuvant Chemotherapy for High-Grade Serous Tubo-ovarian Carcinoma', Australian and New Zealand Gynaecological Oncology Group Annual Scientific Meeting, April 2017, Melbourne, Australia.
- 15. Meniawy TM, McCoy MJ, Coghlan E, Anyaegbu CC, Austin SJ, Munro A, Tan A, Koay E, MaGee D, Nichols C, Tan J, Salfinger SG, Mohan GR, Leung Y, Cohen PA, Stewart CJ, 'Higher PD-L1 expression predicts poor prognosis in patients with tubo-ovarian high-grade serous carcinoma treated with neoadjuvant chemotherapy' (Winner of the Best Abstract Prize), Australian and New Zealand Gynaecological Oncology Group Annual Scientific Meeting, April 2017, Melbourne, Australia.
- Codde E, Munro A, Stewart JRC, Spilsbury K, Bowen S, Codde J, Steel N, Leung Y, Tan J, Salfinger GS, Mohan R G, Cohen P, "Pure' adenocarcinomain-situ of cervix vs. adenocarcinomain-situ mixed with high grade cervical neoplasia: does the distinction matter?', Australian Society for Cervical Colposcopy and Pathology Scientific Meeting, March 2017, Sydney, Australia.
- 17. Coghlan E, Meniawy TM, Munro A, Bulsara M, Stewart CJR, Tan A, Koay MH, MaGee E, Coode J, Tan J, Salfinger SG; Mohan GR, Leung Y, Nichols CB, Cohen PA, 'Prognostic Role of Histological Tumour Regression in Patients Receiving Neoadjuvant Chemotherapy for High-Grade



Serous Tubo-ovarian Carcinoma', International Gynaecological Cancer Society Bi-annual Scientific Meeting, November 2016, Lisbon, Portugal.

Note: This work was also presented at the Royal Australia and New Zealand College of Obstetricians and Gynaecologists Annual Scientific Meeting in Perth, Western Australia in October 2016 and at the RANZCOG Combined South Australia/Northern Territories/Western Australia Regional Scientific Meeting in Adelaide, South Australia in April 2017, where it won the Tony McCartney Prize for Best Oral Presentation

- Standen P, Cohen P, Salfinger S, Tan J, Pang C, Leung Y, 'Recurrence Rates of Cervical Cancer Following Radical Hysterectomy for Early Stage Cervical Cancer in Western Australia From 2010 to 2014' Winner of Best Oral Presentation Prize, Royal Australia and New Zealand College of Obstetricians and Gynaecologists Annual Scientific Meeting, October 2016, Perth, Australia.
- Tucker P, 'Sexuality and Risk Reducing Salpingo-oophorectomy', "Rising Stars Event", Women and Infants Research Foundation, September 2016, Perth, Australia.
- Munro A, Codde J, Cohen C, 'Outcomes of accessing and utilising Western Australian linked data for the management of cervical abnormalities', Credentialed Pap Smear Provider Professional Development Day, WA Cervical Cancer Prevention Program, June 2016, Perth, Australia.

Inflammatory Bowel Disease Research Unit

- 21. Lawrance IC, Baird A, Lightowler D, Radford-Smith G, Andrews JM, Connor S, 'A multicentre double blind randomised placebo-controlled study of the use of rectal tacrolimus in the treatment of resistant ulcerative proctitis', European Crohn's and Colitis Organisation, February 2017, Barcelona, Spain.
- 22. Lawrance IC, 'UC what do we have now?', 21 July 2016, Perth, Australia.

Intensive Care Unit Research Program

23. Ong S, 'Out-of-office hours' elective surgical intensive care admissions and their associated complications', ANZCA, May 2017, Brisbane, Australia.

- 24. Litton E, 'The Microbiome: targeted therapy in the ICU', Australia and New Zealand Intensive Care Society Singapore, 22 April 2017, Singapore (Invited Speaker).
- Litton E, 'Platform Trials in ICU: Who, what, why?', Australia and New Zealand Intensive Care Society Singapore, 22 April 2017, Singapore -(Invited Speaker).
- 26. Litton E, 'Sleep in the Intensive Care Unit', World Congress of Anesthesiologists, 30 August 2016, Hong Kong - (Invited Speaker).

Junior Doctor Research Projects

- Shrestha R, Levitt M, 'Total colectomy with ileo-rectal anastomosis for slow transit constipation – highly effective in carefully selected patients', RACS Annual Scientific Congress 2017, May 2017, Adelaide, Australia.
- Ng ZQ, He B, 'A Proposed Classification System and Therapeutic Strategy for Chyle Leak after Laparoscopic Live Donor Nephrectomy: A Single-centre Experience and Review of Literature', RACS Annual Scientific Congress 2017, May 2017, Adelaide, Australia.

Neurosurgery Research Unit

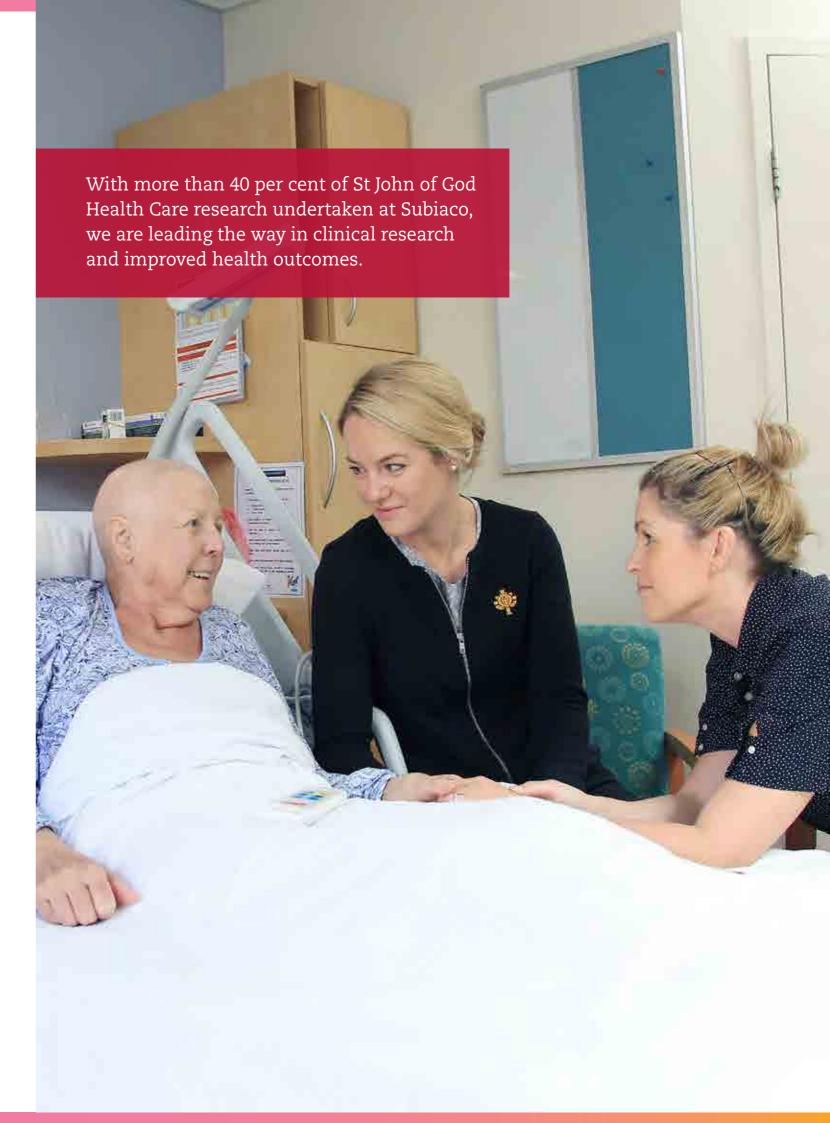
- Sharif SH, Murray I, Lee G, 'Utility of Inertial Measurement Units for portable gait analysis in patients with foot drop of lumbar spine origin',
 2017 Annual Scientific Meeting of the Neurosurgical Society of Australasia, Adelaide (Invited for verbal presentation).
- Sharif SH, Murray I, Lee G, 'Inertial Measurement Units for portable gait analysis and clinical assessment of gait events among foot drop patients', 2017 One Curtin International Postgraduate Conference, Malaysia.
- Oldakowska I, Oldakowski M, Day R, Sercombe T, Kirk B, Lee G, 'Redesigning the traditional screw: Development of a novel spinal fixation device', Neurosurgical Society of Australasia Annual Scientific Meeting, September 2017, Adelaide, Australia
- 32. Oldakowski M, Oldakowski I, Lee G, Kuster M, 'A removable expandable screw to reduce screw related complications'- Paper presented at the Australian Orthopaedic Association (WA) Annual Scientific Meeting, August 2016, Perth, Australia.

Nursing, Midwifery and Allied Health research Program

- 34. Kelly S, Eccles S, Cooper A, Brown J, 'Neonatal admission to a high dependency unit and its impact on maternal pain scores and analgesic requirements', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia.
- Cooper A, Brown J, Colvin L, Boyd L, Wong K, 'A point prevalence study of peripheral intravenous cannulation (PIVC) and therapy', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia.
- Fraser J, Brown J, Cooper A, 'The forgotten puncture site: Patient awareness of spinal and epidural complications', Paper presented at the 8th International Congress on Innovations in Nursing, 2016, Perth, Australia.

Orthopaedic Surgery Research Group

- 37. Clark G, 'Physiological alignment and balance matching; the sensible compromise?', Australian Orthopaedic Association Scientific Program, March 2017, Perth, Australia.
- Collopy D, 'Outcomes and are we really as good as we think? (Registry vs true fn and satisfaction)', Australian
 Orthopaedic Association Scientific Program, March 2017, Perth, Australia.
- Collopy D, 'Major bone loss about the knee; reconstructive options' Australian Orthopaedic Association Scientific Program, March 2017, Perth, Australia.
- Clark G, Australian Knee Society Meeting, October 2016, Port Douglas, Australia.





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