



Government of Western Australia  
South Metropolitan Health Service



South Metropolitan Health Service  
**RESEARCH REPORT**  
2019

*Excellent health care, every time*



## Acknowledgement of Country and People

South Metropolitan Health Service respectfully acknowledges the Noongar people both past and present, the traditional owners of the land on which we work. We affirm our commitment to reconciliation through strengthening partnerships and continuing to work with Aboriginal peoples.

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# Forewords

The South Metropolitan Health Service (SMHS) Research Report 2019 highlights research activity undertaken across the Fiona Stanley Fremantle Hospitals Group (FSFHG) and Rockingham Peel Group (RkPG) in the 2019 calendar year.

Research projects listed in this report were collated by reviewing WA Health online Research Governance Service (RGS)

reports to identify new projects approved to commence in the 2019 calendar year i.e. only those that had received site authorisation (governance) were included.

The publications list was collated following detailed searches by the library team on key investigators for published works in 2019 that stated an affiliation with SMHS or a SMHS site.

## From the SMHS Chief Executive

This report highlights the impressive volume of diverse research activity conducted across SMHS sites during 2019 and associated research translation activities occurring via publications. It also details the growth in our research culture, capacity and capability over recent years.

SMHS research projects include sponsored clinical drug trials, national and international collaborative trials and locally initiated projects aimed at improving patient outcomes and quality of life.

Research is critical to SMHS and the community we serve. It is a credit to our investigators that the impact of their research often extends beyond the local setting, with project outcomes having national and international significance for patient quality and safety, clinical and lifestyle outcomes.

The second annual SMHS Research Showcase, with its theme 'Technology in research', celebrated the innovative research happening across our organisation. The event was kindly sponsored by the Harry Perkins Institute of Medical Research and the Commonwealth Scientific and Industrial Research Organisation (CSIRO).



Thank you to all the wonderful presenters for giving their time and expertise to support this event and congratulations to award winners Dr Michael Lim and Nicole Chen.

By involving our research community in delivering activities outlined in the *SMHS Research Operational Plan (2018-2020)* I look forward to building on and improving our research culture during 2020 and creating a research environment of which we can all be proud. I also look forward to setting the research agenda for 2021 and beyond.

**Mr Paul Forden**  
**Chief Executive, SMHS.**

## Executive summary

The SMHS Board has outlined research as a key enabler to deliver on its strategic priority of ***Excellence in the delivery of safe, high quality clinical care.***<sup>1</sup>

It is also recognised that research is a pivotal enabler of the other four strategic priorities of SMHS:

- Provide a great patient experience
- Engage, develop and provide opportunities for our workforce
- Strengthen relationships with our community and partners
- Achieve a productive and innovative organisation which is financially sustainable.

This report captures research activity that occurred in SMHS during the 2019 calendar year.

While the majority of research was conducted at Fiona Stanley Hospital (FSH), a significant number of projects involved collaboration across SMHS sites including Fremantle Hospital (FH) and Rockingham General Hospital (RGH).

Research projects are always at different stages of development during a calendar year.

Some projects have ethics approval and are awaiting governance; some are waiting governance only as they have ethics approval from another lead Human Research Ethics Committee (HREC), or have HREC approval from a prior calendar year; other projects have both ethics and governance approval. However, no research project proceeds in SMHS without a HREC approval and site authorisation (governance).

As a high level summary of research activity:

- **79** projects received SMHS HREC approval, with **12** waivers of consent granted by the SMHS HREC.
- **161** projects were approved to proceed at SMHS sites in 2019 (governance approval), of which:
  - **143** were based at FSH
  - **108** were non-commercial projects
  - **71** were clinical trials
  - **33** were in the broad research area of cancer (refer to Table 3 for more information).
- **479** publications that have an affiliation noted with SMHS or a SMHS site were sourced.

## Acknowledgements

This report was developed with contributions from:

- researchers from multiple departments as detailed within this report
- SMHS Research Advisory Committee
- SMHS/East Metropolitan Health Service Library team
- SMHS Corporate Communications team
- SMHS Research, Support and Development Unit (RSDU) team.

1 [SMHS Strategic Plan 2017-2020 link](#)

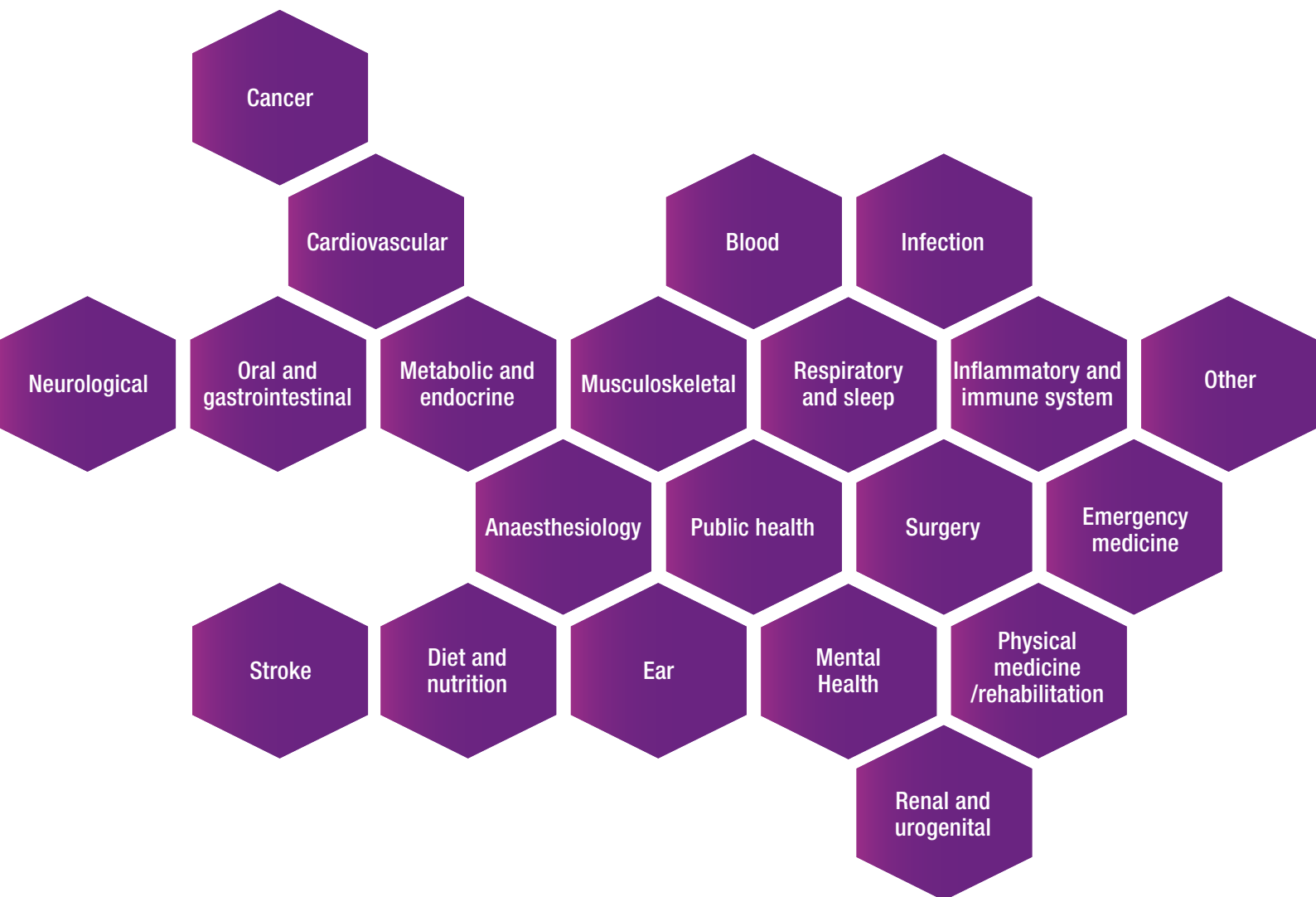


Figure 1: Broad research areas of SMHS research projects / clinical trials

# Research Support and Development Unit

SMHS has a centralised area wide Research Support and Development Unit (RSDU) based at the FSH campus. The RSDU aims to improve the efficiency and quality of ethical and governance reviews, especially for multi-site projects and clinical trials, and to support local clinical researchers to understand and meet their regulatory obligations.

The SMHS RSDU provides ethical and governance review of proposed research projects and monitoring of approved research for all SMHS sites including:

- Fiona Stanley Hospital
- Fremantle Hospital and Health Service
- Rockingham Peel Group
- South Metropolitan Mental Health Service
- South Metropolitan Population Health Unit.

The RSDU team provides support and guidance to researchers in study design, application and approval processes, ongoing monitoring of research projects and associated amendments required to change research projects during the project lifecycle. Throughout the year the team hosts several networking meetings and educational events to facilitate collaborations and enhance the research capability in the organisation.

## Research leadership

During 2019 several key appointments were made to lead research development, support and strategy across SMHS. Although there are now discipline specific research leads, they work together to ensure research is multi-disciplinary, collaborative and harmonised where possible.



*Professor Merrilee Needham, SMHS Clinical Director of Research, works closely with Head of Research and Development, Melanie Wright.*

## Operational team

### **SMHS RSDU Manager, Selina Metternick-Jones**

Selina Metternick-Jones was appointed RSDU Manager in December 2019.

With a background in research administration, medical ethics and public policy, Selina remains abreast of current local, national and international issues surrounding ethics in medicine and research. She is also an active member of the Australasian Association of Bioethics and Health Law.

Her commitment to streamlined and efficient research governance processes has resulted in the RSDU team now conducting research project reviews and approvals well within national key performance indicators (KPIs).

Selina believes that the team's key strength is their dedication to supporting researchers throughout the submission, review and approval process.



“ Our team is here to support researchers every step of the way and help them navigate the process as quickly and painlessly as possible.”

## Medical research

### **SMHS Clinical Director Research Professor Merrilee Needham**

Professor Merrilee Needham was appointed as SMHS Clinical Director of Research in December 2019.

Merrilee provides strategic advice on research-related matters and represents SMHS on State and national research committees. She is committed to raising SMHS's research profile and helping develop a positive, inclusive culture of staff engagement with research.

Merrilee liaises with the innovation and informatics teams and clinicians across SMHS and works closely with Head of Research and Development, Melanie Wright.



“ I see my role as embedding research in day-to-day clinical practice and encouraging all staff to constantly ask: how can we do better?”



## Allied health research

### **FSFHG Allied Health Research Director, Dr Vin Cavalheri**

Dr Vin Cavalheri was appointed inaugural SMHS Allied Health Research Director in October 2019, a position funded jointly by SMHS and the Faculty of Health Sciences, Curtin University.

A senior lecturer within the School of Physiotherapy and Exercise Science at Curtin University, Vin has an extensive clinical and research background and a strong track record of research collaboration across allied health fields and medical specialities.

Vin has substantial experience in systematic review methodology and has mentored several national and international researchers on the process of undertaking systematic reviews and meta-analysis.



“ I look forward to working with staff to make research and knowledge translation core practice for allied health professionals within SMHS.”

## Nursing research

### **FSFHG Nurse Director Practice, Research and Education, Dr Penny Keogh PhD**

The expansion of Penny's role in 2019 to include practice and research facilitates research utilisation and evidence based practice and fosters critical inquiry within nursing and midwifery. This will lead to the identification and investigation of practice based issues, and improved care for patients and their families.

Nurses and midwives can experience barriers to research including a lack of research skills, time to access research and an organisational infrastructure supportive of clinical nursing and midwifery research.

Rather than expecting all nurses to be competent at finding, appraising and utilising research based evidence, a more realistic approach based on the development of research specialists within nursing and midwifery is advocated.



“ Developing a collaborative research effort between nurse researchers and nurse midwifery clinicians and other researchers is critical to generating clinically meaningful nursing and midwifery knowledge.”

# Overview

# SMHS research activity

Table 1 and Table 2 provide an overview of research approval activity in SMHS from 01 January – 31 December 2019.

**Table 1: SMHS HREC approvals and associated sub-data**

Activity	Number of projects
<b>HREC approved – total</b>	<b>79</b>
<b>Type of ethical approval</b>	
WA Health single ethical review	73
NMA single ethical review	6
<b>Risk type</b>	
Negligible risk	11
Low risk	36
More than low risk	31
Not specified	1
<b>Single centre or multi-centre</b>	
Single centre	39
Multi-centre	40
<b>Jurisdiction</b>	
Within WA Health only	53
Intra-jurisdictional (within WA only)	12
Inter-jurisdictional (across Australia)	14

**Table 2: SMHS site authorisation (governance) approvals and associated sub-data**

Activity	Number of projects
<b>Site Authorisation approved – total</b>	<b>161</b>
<b>*Health site</b>	
Fiona Stanley Hospital	143
Fremantle Hospital	16
Rockingham General Hospital	13
Clinical Service Planning and Population Health	1
Community Physiotherapy Service	1
Mandurah Community Health Centre	1
<b>Commercial or non-commercial</b>	
Commercial	53
Non-commercial	108
<b>Clinical trials</b>	
<b>Total number of clinical trials</b>	<b>71</b>
Phase I	6
Phase II	16
Phase III	40
Phase IV	9

\*As one project can be conducted across multiple sites, the sub-data will not always equal the total.

The research projects can also be filtered by 'Broad Research Area' in the RGS data reporting. Table 3 provides an overview of the clinical areas that the research projects are conducted in; the majority (33) being conducted in the area of cancer, followed by 18 in cardiovascular and 12 in blood (haematology).

**Table 3: Broad research area**

Table 3: Broad research area	Number of approved projects
Anaesthesiology	5
Blood	12
Cancer	33
Cardiovascular	18
Diet and nutrition	1
Ear	1
Emergency medicine	4
Infection	11
Inflammatory and immune system	7
Mental health	1
Metabolic and endocrine	9
Musculoskeletal	9
Neurological	10
Oral and gastrointestinal	10
Other	7
Physical medicine/rehabilitation	1
Public health	5
Renal and urogenital	1
Respiratory and sleep	9
Stroke	2
Surgery	5
<b>Total</b>	<b>161</b>

Table 4 provides a comparison of ethics and governance activity, as well as publications sourced from 2017 to 2019.

**Table 4: Comparative data 2017–19**

Descriptor	2017	2018	2019
Ethics approvals	92	79	79
SMHS HREC waiver of consent	30	10	12
Site authorisation approvals	155	152	161
Publications	357	452	479

In 2017, the National Mutual Acceptance (NMA) scheme was introduced, which had an associated minor reduction in projects requiring ethical review from SMHS HREC in 2018/19.

In 2018, the legislative issues around consent to research in WA were reviewed causing a reduction in waivers of consent being issued by the SMHS HREC.

Site authorisation has remained fairly constant with publications increasing year to year.

## SMHS Human Research Ethics Committee (HREC)

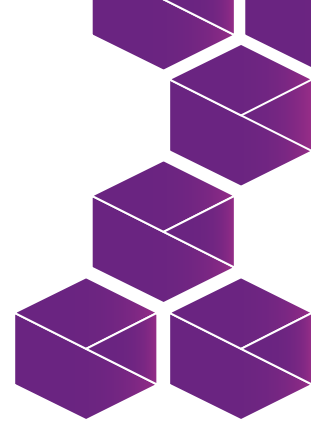
As a certified lead HREC (EC00265), the SMHS HREC can approve any project in Australia regardless of whether it is being conducted at a SMHS site. The HREC conducts eleven meetings per year. Researchers are encouraged to attend meetings to discuss their projects, although this is not compulsory.

The HREC Chair is a pivotal, voluntary position responsible for ensuring HREC members review and approve each research project and substantial amendments. Chair of the SMHS HREC from 2017 to 2019, Mr Richard Wojnor-Horton, was a HREC member for 24 years. As Chief Pharmacist for Fremantle Hospital from 2004 to 2016, his pharmaceutical knowledge was invaluable in reviewing the ethical and scientific integrity of several hundred research projects. On his retirement in 2019 his many contributions to the research community were acknowledged. A new Chair will be appointed in 2020.

In 2019, the SMHS HREC approved 79 projects, of which:

- 11 were negligible risk
- 36 were low risk
- 31 were more than low risk
- 1 was unspecified in RGS.

With the introduction of the National Mutual Acceptance (NMA) Scheme, some projects may have been approved by another certified lead HREC; therefore they do not require SMHS HREC approval, but do require site authorisation via the governance process.



# Waiver of consent

The National Health and Medical Research Council (NHMRC) highlights in the National Statement<sup>2</sup> that, “depending upon the circumstances of an individual project it may be justifiable to employ a waiver of the consent requirement, rather than seeking explicit consent”. In order to apply for a waiver of consent investigators must respond to Section 2.3.10 of the National Statement highlighting the need for a waiver as well as an analysis of the associated risks and benefits of the project.

A waiver of consent can only be granted for low risk projects which pose no more than the risk of discomfort to participants; this does not include any novel interventional research. A waiver can only be granted by a meeting of the full HREC. Table 5 documents **12** waivers of consent granted in 2019, a slight increase from the **10** waivers of consent granted in 2018. The NHMRC requires that a brief description of all projects with a waiver of consent is publically available.

**Table 5: Waiver of consent projects**

PRN	Project title	Brief description of study and rationale for the approval of a Waiver of consent
1373	<b>A randomised trial of palliative dementia care</b> CPI: Assoc Prof Glenn Arendts Sites: FSH, RPH, SCGH	This is a randomised clinical trial, with all eligible and consenting carers receiving educational material, following which half will be randomised through biased coin randomisation to interventional follow up and palliative care access. The waiver of consent is granted to access the medical records of the patients with dementia to clarify aspects of their condition and care.
1439	<b>Impact of body composition response rates on Tumour Necrosis Factor (TNF) alpha treatment in Inflammatory Bowel Disease (IBD)</b> CPI: Dr Zixiang Lim Sites: FSH, RPH	Evidence suggests that outcomes and risk of loss of response in IBD will be improved by intervening at an early inflammatory stage to prevent future complications or identifying if patients with different body compositions have different pharmacodynamic/kinetic effects. The study uses de-identified data with the aim of determining if rates of loss of response is correlated with different body composition parameters and to correlate TNF drug and antibody levels with body composition parameters.
3276	<b>SMILE Study: Serological and clinical correlates in Myositis and Interstitial Lung disease</b> CPI: Dr Brittany Stevenson (SCGH) Sites: FSH, SCGH, PathWest SCGH	Idiopathic inflammatory myopathies are disabling multi-organ autoimmune diseases often presenting with prominent muscle inflammation and weakness, and progressive lung scarring. ‘Myositis-specific antibodies’ (MSAs), found in the blood, are important for diagnosis and prognosis. Currently, over 15 different MSAs are recognised, and clinicians are increasingly reliant on MSA results for diagnosis and patient management. This study aims to improve MSA testing, investigate new MSAs, and compare the clinical presentation and outcomes of our patients with MSA-associated idiopathic inflammatory myopathies and interstitial lung diseases through the use of de-identified samples.

PRN	Project title	Brief description of study and rationale for the approval of a Waiver of consent
1075	<p><b>Clinical characteristics and outcomes of patients receiving outpatient parenteral antimicrobial therapy (OPAT) in Western Australia</b></p> <p>CPI: Dr Paul Ingram Site: FSH, RGH, RPH</p>	<p>Outpatient parenteral antimicrobial therapy (OPAT) is a well-established mode of delivering prolonged courses of intravenous antimicrobials to patients who do not require hospitalisation, and has been shown to be safe, effective and cost beneficial. This is a retrospective observational cohort study which aims to describe the clinical characteristics and outcomes of patients managed by OPAT services in Western Australian public hospitals using de-identified records.</p>
3525	<p><b>Bugs and crystals: a retrospective study evaluating clinical features and outcomes of concomitant septic arthritis and crystal arthropathy compared with septic arthritis alone</b></p> <p>CPI: Dr Laurens Manning (FSH) Sites: FSH, PathWest FSH</p>	<p>This is a retrospective cohort study which aims to describe the clinical features and outcomes of patients with septic arthritis and concurrent crystal arthropathy using de-identified records.</p>
3208	<p><b>Genetic Factors Influencing Transplant Outcome Consent to Storage of DNA</b></p> <p>CPI: Dr Olga Patricia Martinez (FSH), Head of Department Immunology Sites: FSH</p>	<p>The waiver covers the use of stored DNA samples to monitor bone marrow transplant outcomes. All prospective samples will be stored with consent.</p>
3200	<p><b>Exploration of radiological pancreatic and renal density as a risk factor for subsequent cancer development</b></p> <p>CPI: Dr Andrew Redfern (FSH) Sites: FSH</p>	<p>This project will use retrospective CT scans to investigate whether increased radiological density as measured by routine computerised tomography (CT) in the normal organ correlates with an increased risk of cancer development in that organ. It is hoped that the results of this study may be useful to inform the medical community as to those patients that have higher risk factors for developing pancreatic and renal cancers. This could result in targeted screening of those individuals with the potential for earlier diagnosis and treatment resulting in fewer deaths.</p>



PRN	Project title	Brief description of study and rationale for the approval of a Waiver of consent
3152	<p><b>Os intermetatarsium: an analysis of morphology and case reports of Fracture.</b></p> <p>CPI: Dr Timo van Aswegen (FSH)</p> <p>Sites: FSH, FHHS, PCH, RGH, RPH, SCGH, AHS, Broome Health Campus, Derby Hospital, Exmouth Health, Kalamunda District Community Hospital, Murray District Hospital, Osborne Park Hospital, Wyndham Hospital</p>	<p>The foot is well known for its anatomical variations and is the most common site for accessory ossicles in the human body. The incidence of os intermetatarsium reported in radiographic and anatomical literature initially ranged between 2.67 and 12.5%. This is a descriptive study of patients with os intermetatarsium identified on medical imaging plus three case reports of fracture of this accessory ossicle.</p>
3452	<p><b>Traumatic Heterotopic Ossification: Exploring Prevalence, Risk Factors, Prevention and treatment.</b></p> <p>CPI: Miss Nichola Foster</p> <p>Sites: WA – FSH, RPH, SCGH, Osborne Park Hospital; VIC – Alfred Health; QLD – The Royal Brisbane and Women’s Hospital</p>	<p>Heterotopic ossification (HO), defined as the formation of bone outside of the human skeletal structure, is a rare but severely debilitating and excruciatingly painful complication of burn, neurological and orthopaedic trauma. This project involves the collation of a large sample of adult patients in trauma populations with known HO incidence (burn, neurological and orthopaedic populations) admitted to WA tertiary hospitals over a 10 year period.</p>
2288	<p><b>ANZUP co-operative multi-centre cystectomy database (ACCEPT)</b></p> <p>CPI: Prof Dickon Hayne (FSH)</p> <p>Sites: WA – FSH; NSW – John Hunter, Westmead; SA – Lyell McEwin, Royal Adelaide; VIC – Eastern Health, Royal Melbourne; ACT – Canberra Hospital; QLD – Princess Alexandra Hospital</p>	<p>This study utilises de-identified patient records. The primary objective is to create a bi-national (Australia and New Zealand) prospective clinical audit to collect data on outcomes after radical cystectomy surgery. The secondary objective is to hypothesize from acquired data whether specific interventions may achieve improved peri-operative care and outcomes for patients undergoing radical cystectomy in Australia and New Zealand. The hypothesis is that monitoring of outcomes from various interventions may help determine those that actually improve patient recovery after radical cystectomy.</p>

PRN	Project title	Brief description of study and rationale for the approval of a Waiver of consent
3738	<p><b>UV-Signature Mutational Profiling as an Adjunctive Testing Modality in Metastatic Squamous Cell Carcinoma</b></p> <p>CPI: Dr Nathan Harvey (PathWest) Sites: PathWest SCGH</p>	<p>Skin cancer is extremely common in the Western Australian population, and if a skin cancer spreads to other parts of the body it can cause significant illness or even death. Sometimes patients present with a cancer which has already spread (metastatic cancer), but the site at which it first originated (the primary site) is not apparent. Currently this situation necessitates the use of costly extra procedures aimed at identifying the primary tumour to allow for appropriate treatment. This project aims to determine whether a detailed assessment of the genetic mutations within the metastatic cancer can help to ascertain the origin of the tumour.</p>
324	<p><b>A multi-centre, blinded, randomised, controlled trial to determine whether fluid resuscitation and therapy with a “balanced” crystalloid solution (Plasma-Lyte 148®) compared with 0.9% sodium chloride (saline) decreases 90-day mortality in critically ill patients requiring fluid resuscitation</b></p> <p>CPI: Assoc Prof Adrian Regli (FSH) CPI Del: Ms Annamaria Palermo (FSH) Sites: FSH, RKGH</p>	<p>A waiver of consent was granted to access the records of specified deceased participants in the study which compared two accepted standards of care.</p>

## Lead HREC

Table 6 provides a summary of the number of governance approved SMHS projects in 2019 and the associated lead HREC. Of the 161 projects approved to proceed, SMHS HREC was the lead HREC for 64 of the projects (40 per cent). This demonstrates the volume of state and national projects with SMHS collaboration.

**Table 6: Lead HREC for projects approved to proceed at a SMHS site in 2019**

Lead HREC	Number of HREC approved SMHS projects in 2019
Alfred Hospital	6
Austin Health	3
Central Adelaide Local Health Network	9
Child and Adolescent Health Service (CAHS)	7
Department of Health	1
Hunter New England	3
Melbourne Health	4
Metro South	1
Monash Health	7
North Sydney Local Health District	2
Peter MacCallum Cancer Center	6
Royal Brisbane and Women's	3
Royal Perth Hospital (RPH)	7
Sir Charles Gairdner Osborne Park Health Care Group	6
South Eastern Sydney Local Health District	2
South Metropolitan Health Service (SMHS)	64
South Western Sydney Local Health District	1
Southern Adelaide Clinical	1
St Vincent's Hospital	9
St Vincent's Hospital Melbourne	8
Sydney Local Health District (RPAH Zone)	5
Sydney Local Health District - Concord	2
The Royal Children's Hospital	3
Western Sydney Local Health District	1
<b>Total</b>	<b>161</b>

# Research showcase

This is the second year that SMHS has celebrated its researchers and their inspiring work by hosting a research showcase event. The showcase was supported by our event sponsors CSIRO and the Harry Perkins Institute of Medical Research. This year we had more attendees, more events and more presentations.

The annual SMHS Research Showcase was held on 28 November 2019. The theme was 'Technology in Research' and consisted of the following events:

- Breakfast Research Forum (sponsored by CSIRO): 3 presentations
- SMHS Innovation presentation: innovation 'pitches'
- Opening ceremony: 2 keynote addresses
- Podium presentations: 8 presentations
- Consumers in research: 3 presentations
- Technology Expo: 6 displays
- Three Minute Project Competition for novice investigators: 10 presentations
- Evening Gala and Awards Ceremony (sponsored by Harry Perkins Institute of Medical Research): 2 keynote addresses.



## Award winners

### Novice Investigator Three Minute Project Competition

Ten researchers presented their research work in a 'Three Minute Presentation' format, with a judging panel.

**Winner:** Dr Michael Lim, Registrar Gastroenterology, FSH. 'Impact of body composition on outcomes in patients with Inflammatory Bowel Disease'.

**Runner-up:** Anna Scheer, Physiotherapy student, PhD Candidate, Curtin University. 'Water-based exercise training for patients with coronary heart disease'.

### Digital posters competition

Ten researchers submitted a digital poster that was displayed on audio-visual screens during the showcase and judged by a panel.

**Winner:** Nicole Chen, Exercise Physiology student, PhD Candidate, Curtin University. 'Improved daily weighing compliance with telemonitoring in patients with CHF'.

**Runner up:** Dr Shereen Paramalingam, Consultant Rheumatologist, FSH. 'Preliminary validation of shear wave elastography in the diagnostic evaluation of muscle disease'.

*Dr Michael Lim receiving his award from SMHS Clinical Director Research Professor Merrilee Needham and award sponsor, Head of Research and Development SMHS Melanie Wright.*

## Technology in Research



# Projects

# Research projects

Table 7 details 161 research projects approved to commence at a SMHS site during 2019, using site authorisation decision dates from RGS reporting (RGO extract, SMHS, 2020-01-09).

**Table 7: Projects approved to proceed at a SMHS site in 2019**

RGS PRN	Title
75	Assessing the health, economic and wellbeing benefits of Homeless Healthcare services in hospital, primary care and community settings
104	Prothrombinex or Fresh Frozen Plasma for Cardio - Pulmonary Bypass Associated Bleeding
293	Bi-National Colorectal Cancer Audit
356	Australasian Malignant Pleural Effusion Trial - 3. A Randomised Study Comparing Combined Indwelling Pleural Catheter (IPC) and Talc Pleurodesis with Video-Assisted Thoracoscopic Surgery (VATS) for the Management of Patients with Malignant Pleural Effusion
425	The incremental utility of Cardiac Magnetic Resonance Imaging in clinical decision making in Myocardial Infarction with Non-Obstructed Coronary Arteries (MINOCA)
459	CAST / ALLG-BM12: Study of using Cyclophosphamide After Sibling-donor allogeneic stem-cell Transplantation (CAST) in patients with acute leukaemia and myelodysplasia: a randomised study comparing cyclosporin and methotrexate to cyclosporin and post-transplantation cyclophosphamide for graft-versus-host disease prophylaxis
499	MEprobe for improved intraoperative assessment of tumour margins in breast cancer: a pilot study
582	Investigation of a low-risk, non-invasive, low-cost, high-sensitivity method of breast cancer detection based on electromagnetic gradiometry
645	Cost effectiveness of extending the Phase 3 community pulmonary rehabilitation program beyond the recommended 10 weeks
651	Investigation into the prevalence of pompe disease in patients in Australia with asymptomatic or paucisymptomatic hyperCKaemia
737	Evaluation of Ruah-WAPHA Choices Post-discharge Service
804	CHARIOT / BCT 1702: A phase II study evaluating efficacy and safety of Ipilimumab and Nivolumab with neoadjuvant weekly paclitaxel after anthracycline based chemotherapy in high-risk primary triple negative breast cancer, followed by definitive surgery and one year total duration of Nivolumab
806	An open-label single-arm Phase IIb study of F901318 as treatment for infections due to Lomentospora prolificans, azole-resistant Aspergillus spp., and other resistant fungi in patients lacking suitable alternative treatment options.
807	Real world Efficacy of Antiviral therapy in Chronic Hepatitis C
844	Safely Preventing Errors and Complications due to Inappropriate Allergy Labelling (The SPECIAL Study) (Adult Arm)
886	The use of closed loop technology in the management of type 1 diabetes in individuals with poor glycaemic control

RGS PRN	Title
893	Consumers' experiences of goals of patient care: An exploratory study
896	A multicentre, double-blind, parallel group, placebo controlled, randomised, Phase 3/4 trial of the effect of perioperative intravenous ketamine on the risk of development of chronic post-surgical pain
919	Perkins Biobank for Translational Cancer Medicine
925	Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia
954	Cognitive Improvement by Early Restoration of Circadian Rhythms in Very Preterm Infants through Environmental Modification: The CIRCA DIEM Study
956	A phase 3, multicentre randomised double blind placebo controlled study of oral Ozanimod as induction therapy for moderately to severely active Crohn's disease RPC01-3201
957	DICKENS - A randomised controlled trial of DicaCerein to treat KneE osteoarthritis with effusion-Synovitis
972	Restoring Neonatal Gut Biodiversity and Mucosal Immunity After Postnatal Antibiotics Exposure
975	Hyperbaric oxygen therapy for lower limb burns in diabetic patients
1003	Australasian Cardiac Outcomes Registry Ltd -TAVI Registry
1015	A Phase 3, multicenter, open label extension study of oral ozanimod for moderately to severely active Crohn's Disease
1021	A Phase 3, multicenter, randomized, double blind, placebo-controlled study of oral ozanimod as maintenance therapy for moderately to severely active Crohn's Disease RPC01-3203
1050	A Phase 3, randomized, double-blind, active controlled study to compare the efficacy and safety of ridinilazole (200 mg, bid) for 10 days with vancomycin (125 mg, qid) for 10 days in the treatment of Clostridium difficile infection (CDI)
1058	Efficacy, tolerability and predictors of add-on anti-epileptic medications and medical devices in refractory epilepsy: a phase IV pragmatic observational study
1086	Haplo PTCy: A phase II trial of haploidentical peripheral blood stem cell transplantation with post-transplant cyclophosphamide as GVHD prophylaxis
1100	A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis
1117	Patients First: Continuous Improvement in Care - Cancer Project
1137	Peripheral and respiratory muscle function in both preserved and reduced ejection fraction heart failure: the metaboreflex as a novel therapeutic target
1145	Determining the support and education needs of patients diagnosed with head and neck cancer and their carers
1148	Hide and Seek with Hereditary Cancer: Improving detection of colorectal cancer patients with a high risk of Lynch Syndrome
1177	A pilot study of healthy volunteers to compare the performance of standard nasal oxygen cannula at high flows with the "Optiflow" high flow nasal oxygen (HFNO) system
1182	An open -label, multi-centre Phase Ib study of the safety and tolerability of IV infused PG545 in combination with nivolumab in patients with advanced solid tumours with an expansion cohort in patients with metastatic pancreatic cancer



## Making gains in stroke recovery

Today's stroke patients have immediate access to advanced medical treatment and rehabilitation, but there are big gaps in knowledge that researchers like Clinical Associate Professor Darshan Ghia are hoping to fill.

As Head of the Fiona Stanley Hospital (FSH) Stroke Unit, consultant neurologist Dr Ghia is leading ongoing research in a bid to improve recovery after stroke – one of the three top causes of disability.

“We have come a long way thanks to the implementation of 24/7 endovascular clot retrieval services and improvements in secondary prevention, but still stroke care is one area of medicine that has a particularly large evidence-to-practice gap worldwide,” Dr Ghia said.

Dr Ghia and colleagues are working with other organisations, including St John Ambulance, to apply and test pre-hospital scoring methods used to determine whether stroke has occurred due to large artery involvement in which case they will be taken straight to an endovascular treatment capable centre.

A study into the RACE (Rapid Arterial Occlusion Evaluation) scoring method was completed two years ago and results are now being tested on groups of inpatients and outpatients.

The work has already led to improvements in the way patients are triaged by St John Ambulance and in the Emergency Department thereby improving their overall outcomes.

The FSH Stroke Unit has also been part of other projects looking into the role of left atrial enlargement and atrial fibrillation prediction, while being a part of various multi-centre national and international trials.

“We are also participating in nursing and allied health studies, as well as WA's own study into Aboriginal people dealing with neurological injury – Healing the Right Way,” Dr Ghia said.

Dr Ghia is chairing the 2021 Stroke Society of Australasia Conference being held in Perth in July and working to help establish a WA stroke research network.



*Clinical Associate Professor Darshan Ghia*

RGS PRN	Title
1186	DIAmOND / BCT 1703: An investigator-initiated, non-randomised, phase II study of combination CTLA-4 and PD-L1 blockade in combination with HER2 blockade in advanced HER2-positive breast cancers that have progressed on prior trastuzumab-based therapy
1190	Preserving the endothelial glycocalyx in patients undergoing cardiopulmonary bypass. A prospective randomised interventional pilot study of doxycycline and lidocaine
1191	A randomized controlled trial of DIRECT endovascular clot retrieval versus standard bridging thrombolysis with endovascular clot retrieval within 4.5 hours of stroke onset
1195	Evaluation of post-operative care following repair of gastroduodenal ulcer perforation, effect on patient outcomes and development of a new protocol
1200	PeriOperative ISChemic Evaluation-3 Trial
1213	Hepatitis C DAA Treatment Failure with Corresponding Baseline and End-of-Treatment HCV viral variants for Resistance
1229	Multi-Center Clinical Evaluation of the ATTUNE Revision System in Complex Primary Total Knee Arthroplasty (ATTUNE COMPLEX)
1232	The Headache in Emergency Departments study
1260	BELINDA: Tisagenlecleucel versus standard of care in adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma: A randomized, open label, phase III trial
1284	A randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of sarilumab in patients with giant cell arteritis
1314	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Giant Cell Arteritis
1315	A Pilot Study Investigating Physiologic and Timed Responses of Participants in a Simulated Can't Intubate, Can't Ventilate (CICO) Crisis using Standardised Institutional Equipment Versus a CICO Kit
1325	An observational study to investigation the correlation of antibody titres and disease severity in patients with antibody positive myasthenia gravis
1332	Vedolizumab-3035: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Vedolizumab in the Prophylaxis of Intestinal Acute Graft-Versus-Host Disease in Subjects Undergoing Allogeneic Hematopoietic Stem Cell Transplantation
1348	Study of prescribing patterns and effectiveness of Ceftolozane-Tazobactam: real-world analysis (SPECTRA)
1351	A Prospective Non-Interventional Study of Bleeding Episodes, Factor VIII Infusions, and Patient-Reported Outcomes in Individuals with Severe Haemophilia A
1353	fungalAi: Innovative use of fungalAi for antifungal stewardship in haematology-oncology patients
1354	A Prospective Open-Label Study in Subjects With Severe Haemophilia A Who are Currently Receiving a Marketed FVIII Therapy
1356	A StuDy eVALuatiNg the EffiCacy and Safety of RalinEpag To Improve Treatment OUTCOMES in PAH Patients
1357	A StuDy EVALuatiNg the Long-Term EffiCacy and Safety of RalinEpag in Subjects with PAH via an Open-Label EXTENSION
1358	Cluster Randomised Trial of Aspirin versus Low molecular weight heparin (CRISTAL)

## Small device promises big impact for breast cancer patients

A hand-held imaging probe may only be a small device but it promises to have a big impact for women undergoing surgery for breast cancer.

Fiona Stanley Hospital (FSH) consultant breast surgeon and researcher Professor Christobel Saunders is leading a team developing a probe to provide real-time guidance during surgery to delineate cancerous tissue from healthy tissue at a microscopic level.

“It basically translates the surgeon’s sense of touch into a microscale image to get all the cancerous tissue out of the breast in one go,” Professor Saunders said.

About a quarter of breast cancer patients currently require two rounds of surgery because surgeons, working mostly by touch, are unable to detect microscopic tumours during the first operation.

Benchtop trials have shown the device has 96 per cent accuracy in detecting microscopic evidence of cancer.

Professor Saunders said the device would have benefits for both patients and the health system.

“If we can reduce the number of repeat surgeries by removing all of the tumour in the first operation, it will directly impact the lives of patients and reduce the considerable healthcare costs associated with repeat surgeries.

“It will also help women avoid mastectomy as they can choose breast conserving surgery, such as lumpectomy, with the peace of mind all of the cancerous cells will be removed in one operation.”

The research is funded by WA-based OncoRes Medical Pty Ltd, which is funded by the Medical Research Commercialisation Fund, along with other Commonwealth and State funding sources.

While still in the early stages of development, the device will soon be put to the test in clinical trials.



*Professor Christobel Saunders*

RGS PRN	Title
1361	The Appropriateness of Coronary investigation in myocardial injury and Type 2 myocardial infarction "ACT-2"
1368	The clinical and economic impact of a preoperative anaemia and iron deficiency clinic in elective colorectal surgery
1370	Review of Australian prescribing practices of Eribulin (RAPPER STUDY BCRC122)
1373	A randomised trial of palliative dementia care
1378	KEYNOTE 598: A Phase 3, Randomized, Double-Blind Study of Pembrolizumab plus Ipilimumab vs Pembrolizumab plus Placebo in Previously Untreated, Stage IV, Metastatic Non-small Cell Lung Cancer Subjects Whose Tumors are PD-L1 Positive (TPS $\geq$ 50%)
1382	Landscape analyses of hospital-based influenza vaccination programs for children with medical co-morbidities
1387	The epidemiology of fractures conservatively managed from the Emergency Department
1388	The PLANET Registry – An Observational, Multicentre, Non Interventional Programme to Register Patients Diagnosed With Neuroendocrine Neoplasms (NENs) and Monitor Their Patterns of Care in Australian Hospitals
1406	Population pharmacokinetics of intravenous immunoglobulin in adult patients with primary or secondary antibody deficiency
1412	GALAHAD: A Phase 2 Efficacy and Safety Study of Niraparib in Men with Metastatic Castration-Resistant Prostate Cancer and DNA-Repair Anomalies
1413	Ability of older people to access dose administrative aids and standard methods of medication delivery
1415	FeBRILe3 – Fever, Blood cultures and Readiness for discharge in Infants Less than 3 months old
1423	Patient motivation for attending the emergency department with musculoskeletal conditions
1431	Efficacy and Safety of LY3298176 Once Weekly versus Insulin Glargine in Patients with Type 2 Diabetes and Increased Cardiovascular Risk (SURPASS-4)
1439	Impact of body composition response rates on Tumour Necrosis Factor (TNF) alpha treatment in Inflammatory Bowel Disease (IBD)
1441	The Clinical Outcomes Measurement in Perioperative Medicine, Anaesthesia and Surgery Study (COMPASS): THE COMPASS Pilot Study
1443	A Multi-Center, Observational Study in Males with Hemophilia A
1457	LEAP-004. A Multicenter, Open-label, Phase 2 Trial to Assess the Efficacy and Safety of Lenvatinib (E7080/MK-7902) in Combination with Pembrolizumab (MK-3475) in Participants with Advanced Melanoma Previously Exposed to an Anti-PD-1/L1 Agent (LEAP-004)
1458	LEAP-003. A Phase 3 Randomized, Placebo-controlled Trial to Evaluate the Safety and Efficacy of Pembrolizumab (MK-3475) and Lenvatinib (E7080/MK-7902) Versus Pembrolizumab Alone as First-line Intervention in Participants with Advanced Melanoma (LEAP-003)
1461	ALLG AMLM22: The International AML Platform Consortium (IAPC) trial
1463	Cardiovascular risk of Gout
1477	Shear wave elastography and ultrasound in the diagnostic evaluation of inflammatory myopathies

## Gene therapy providing new way forward for treatment of blood diseases

Innovative ways of dealing with cancers and haemophilia, which focus on genetic reprogramming of cells, are revolutionising treatment for patients with haematology cancers and inherited bleeding disorders.

The Fiona Stanley Hospital haematology team has a very busy clinical trials portfolio with participation in 30 active clinical studies including investigator-initiated, collaborative group and commercially sponsored trials.

Haematologist Dr Duncan Purtill said one of the highlights of their recent research was in the area of genetic modified therapy, known as CAR-T Cell therapy.

“This type of treatment genetically modifies white cells to fight against lymphoma and once injected in to the body the reprogrammed cells have the potential to not only fight the existing cancer but also respond to any new malignant cells,” Dr Purtill said.

“Until recently, long term drug treatment was the predominant method of care for most cancer patients.”

“Hopefully what we start to see with gene therapy is a more effective, persisting and cleaner treatment without the side effects associated with taking cancer drugs.”

Led by eight Clinical Trials Coordinators, the team had risen to the challenge to meet the strict guidelines of various research studies to ensure the treatments could be applied to patients with complex medical problems.

Working closely with PathWest, there has also been extensive collaboration with other hospitals through patient referrals, the Charles Day Tissue Bank and support from the WA Cancer and Palliative Care Network in the form of a Fellowship Grant.

“Hopefully what we start to see with gene therapy is a more effective treatment, without the side effects associated with taking cancer drugs.”



*Dr Duncan Purtill*

RGS PRN	Title
1480	A Randomized Open-Label, Phase 1b Study of the Safety of Pirfenidone Solution for Inhalation (AP01) in Patients with Idiopathic Pulmonary Fibrosis
1481	CAPTURE-IO: A non-interventional cross-sectional study to capture the prevalence of cardiovascular disease in patients with type 2 diabetes - an international observation.
1487	ATLAS-OLE: An Open-label, Long-term Safety and Efficacy Study of Fitusiran in Patients with Hemophilia A or B, with or without Inhibitory Antibodies to Factor VIII or IX
1499	A prospective, multi-national, non-interventional study in haemophilia A and B patients with or without inhibitors treated according to routine clinical treatment practice (explorer™6)
2269	Investigation into the Influence of Patient Ambulation and Components Alignment on Medium -Term Patient Outcomes after Total Knee Arthroplasty (APEX)
2988	Choosing Between Biological Agents for Severe Allergic Eosinophilic Asthma
2994	Early treatment following spinal cord injury to prevent long-term susceptibility to urinary tract infection; Safety and feasibility study
3018	Clinical and cost effectiveness of a Fast Track Giant Cell Arteritis (GCA) Clinic in Western Australia compared with standard management of patients clinically suspected to have GCA
3023	The effect of sodium-glucose co-transporter 2 inhibitors on left ventricular diastolic function following acute coronary syndrome
3024	A validation study to predict poor outcomes following mild traumatic brain injury
3033	Tau Pathology in Temporal Lobe Epilepsy
3038	MAGNITUDE: A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for Treatment of Subjects with Metastatic Prostate Cancer
3058	Modified constraint-induced movement therapy after stroke: a process evaluation of implementation within an early-supported discharge rehabilitation service
3068	Optimising uptake of mandated workplace training in the Public Health Sector
3069	Goatcher Gout Cohort Study
3084	The Fitness and Health Study
3089	NATALEE: A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant TriAl with Ribociclib [LEE011]: NATALEE).
3092	Access to Services for the Management of Lymphoedema in Western Australia
3101	Protocol I8B-MC-ITRO. A Prospective, Randomized, Double-Blind Comparison of LY900014 to Humalog in Adults with Type 1 Diabetes Using Continuous Subcutaneous Insulin Infusion PRONTO-Pump-2
3105	Prophylactic early PN in HPT/BMT: Prophylactic early parenteral nutrition in patients undergoing hematopoietic cell transplantation: A multi-centre randomised controlled trial
3127	CANOPY-1. A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab as first line therapy for locally advanced or metastatic non-squamous and squamous non-small cell lung cancer subjects

## Patient-centred research making everyday life better

Most people who attend the Fiona Stanley Hospital (FSH) Rheumatology Department have been referred by their GP after experiencing pain that affects their ability to cope with every day activities.

Head of Rheumatology at FSH, Helen Keen, is leading a raft of research projects aimed at helping to diagnose and treat those patients.

“Making things better for my patients and the wider community is what drives our research,” Dr Keen said.

One of Dr Keen’s projects looks into the cause and treatment of giant-celled arteritis, a condition with symptoms including head, neck, tongue and jaw pain that can result in blood vessel damage and strokes.

Giant-celled arteritis causes blindness in 37 per cent of those who have it.

A patient Dr Keen treated had visited a dentist, had CT scans of his sinuses, and been admitted to hospital with a suspected infection before being referred to the Rheumatology Unit.

“When he finally got to us and we could help him he told me “I feel better than God’ ,” Dr Keen said.

The team is also participating in pharmaceutical trials, because the treatment for giant-celled arteritis usually includes steroids which can be toxic.

“Treatment is an area of interest worldwide – we need better therapies,” Dr Keen said.

With her rheumatology research spanning 20 years, her work has focused on the areas of gout, osteoarthritis and other inflammatory conditions, and includes a PhD in the United Kingdom before she started at FSH in 2009.

Currently working with a team of doctors, research coordinators, PhD and Masters students Dr Keen’s patient-centred research is undertaken in a number of metropolitan clinics, along with some laboratory work.

She is also working on national projects with the National Health and Medical Research Council and the Australian Osteoarthritis Clinical Trials Group.



*Adjunct Professor Helen Keen*

RGS PRN	Title
3132	Enhancing Nationwide Awareness of Cholesterol Treatment in Type 1 Diabetes (ENACT-T1D)
3152	Os intermetatarsum: an analysis of morphology and case reports of fracture
3164	Can self-management group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study
3169	Reason-based approach to completion of cardiac surgery after anaphylaxis
3180	Defining the vaccine preventable burden of lower limb cellulitis: a systems serology approach Study 1: defining the vaccine preventable burden of lower limb cellulitis Study 2: defining the vaccine preventable burden of invasive streptococcal disease
3181	RHAPSODY: KPL-914-C002- A Phase 3, double-blind, placebo-controlled, randomized withdrawal study with open-label extension, to assess the efficacy and safety of rilonacept treatment in subjects with recurrent pericarditis.
3187	The clinical and economic benefits of early use of clozapine in first episode schizophrenia
3192	ESCALATION: Unifying systems for recognition and response to paediatric clinical deterioration in Western Australia
3206	NIVOLUMAB in the treatment of patients with non-small cell lung cancer: The Australian Experience
3210	The EXCEL Study - A comprehensive National Registry on the treatment and outcomes of patients requiring ECMO
3211	Developing and validating research instruments (CI-PEECH and CI-PEECH-Proxy) to measure the experiences of people with cognitive impairments in hospital
3239	A phase 3 Multicenter, Long Term Extension Study to Evaluate the Safety and Efficacy of Upadacitinib (ABT-494) in Subjects with Ulcerative Colitis (UC)
3240	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Ulcerative Colitis
3251	KEYLYNK-010 - A Phase 3, Randomized Open-label Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) Who are Unselected for Homologous Recombination Repair Defects and Have Failed Prior Treatment with One Next-generation Hormonal Agent (NHA) and Chemotherapy (KEYLYNK-010)
3258	The use of electrophysiology as a tool to optimise hearing implants in unilateral and bilateral hearing-impaired recipients
3265	KEYNOTE-641: A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Versus Placebo Plus Enzalutamide in Participants With Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-641)
3268	Feasibility and applicability of a ten metre shuttle exercise stress test for assessing myocardial ischaemia
3272	Non-Technical Skills in Simulation: evaluating multidisciplinary team performance in assessment and treatment of a simulated deteriorating patient
3275	GO40987 A phase I, multicentre open-label preoperative, short-term window study of GDC-9545 in postmenopausal women with stage I-III operable estrogen receptor-positive breast cancer
3288	A phase 3 covariate adjusted, response adaptive, randomised trial to Determine Optimal very early mobility training after stroke. AVERT DOSE



## Masters student aims to translate proven stroke therapy method

A gold-standard rehabilitation therapy for stroke patients isn't widely used in WA, and Ashan Weerakkody wants that to change within his service.

As a community physiotherapist for eight years, Mr Weerakkody said he would not have believed how well and quickly the two-week program worked for people with mild to moderate impairment in one arm unless he had seen it himself.

Known as modified constraint-induced movement therapy, the method requires the patient to be motivated to use the arm that has been most affected after stroke and decide what tasks to do.

Patients need to agree, in partnership with their carer and therapist, to put their good arm in a mitt or sling for between two to six hours a day – a measure aimed at building up the affected arm to improve function.

Mr Weerakkody's research, part of his Masters course at Edith Cowan University, aims to show how the proven and Stroke Foundation-endorsed therapy can be translated into practice.

Physiotherapists, occupational therapists, patients and carers within the Rehabilitation In the Home (RITH) program will be interviewed and invited to take part in focus groups.

RITH caters for stroke survivors who are medically fit to live at home, with some help from carers, but could benefit from rehabilitation.

"I used to see up to six patients in their homes a day and I saw the huge improvements that early, supported discharge services can make compared to recovery as an inpatient," Mr Weerakkody said.

"Rehabilitation is all about allowing people to become more independent, so I want to prove that this method can work in real-life situations and increase the uptake."

Mr Weerakkody said another motivation was to contribute to the body of allied health research.

"New research, including translational research like mine, plays a very important role in allied health to discourage complacency among practitioners about trying new things," he said.



Ashan Weerakkody

RGS PRN	Title
3290	A pilot intervention targeting diabetes self-management and active coping skills to enhance health outcomes, for adults with type 1 diabetes: exploring pathways to psychological and glycaemic outcomes
3291	VFAHF: Ventricle from Atrium Heart Failure Clinical Study
3293	A Phase 3 Open-Label, Single-Arm Study To Evaluate The Efficacy and Safety of BMN 270, an Adeno-Associated Virus Vector Mediated Gene Transfer of Human Factor VIII in Hemophilia A Patients with Residual FVIII Levels $\leq$ 1 IU/dL Receiving Prophylactic FVIII Infusions
3304	Closing the loop for quality improvement in a tertiary public hospital context in Australia - what factors influence on the completion, successful outcome and sustainability?
3335	The NOURISH point prevalence study: Nutritional Outcomes of patients Undergoing Resection for upper gastrointestinal cancer in AuStralian Hospitals
3340	NuTide:121: A Phase III Open-Label, Multi-Centre, Randomised Study Comparing NUC-1031 plus Cisplatin to Gemcitabine plus Cisplatin in Patients with Previously Untreated Locally Advanced or Metastatic Biliary Tract Cancer
3347	ALL09: Phase II Study of Blinatumomab as Induction Therapy in Adolescent and Young Adult Acute Lymphoblastic Leukaemia
3353	Stand up for chronic obstructive pulmonary disease
3366	VESALIUS: A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate the Impact of Evolocumab on Major Cardiovascular Events in Patients at High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke
3372	H19-473 (CURRENT): Real World Treatment Patterns and Clinical Outcomes in Unfit AML Patients Receiving First Line Systemic Treatment or Best Supportive Care
3386	Preventing adverse cardiac events in COPD
3390	Evaluation of the Portico™ NG Transcatheter Aortic Valve in High and Extreme Risk Patients with Symptomatic Severe Aortic Stenosis
3398	The NINJA Clinical Trial: Novel Integration of New prostate radiation therapy schedules with adjuvant Androgen deprivation
3402	Microbiota Profile in Acute Coronary Syndrome
3403	Bladder health in the community after Spinal Cord Injury (SCI); Practicalities of following clinical advice
3404	ATTRIBUTE- CMA Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of AG10 in Subjects with Symptomatic Transthyretin Amyloid Cardiomyopathy
3409	Do Pandemic Influenza discussion exercises facilitate community resilience? Examining the use of discussion exercises as a way to clarify objectives, develop relationships and build stronger, more resilient communities, using established markers of community resilience
3410	An exploration of the factors for supporting a supernumerary return to work program: injury management consultant perspectives
3423	The Lived Experience of Patients Following Total Laryngectomy in Western Australia; a Narrative Inquiry
3430	ARISE: A multi-centre prospective non-interventional study investigating the clinical effectiveness of Ryzodeg® (Insulin Degludec/Insulin Aspart) in patients with type 2 diabetes mellitus in a real-world setting

## Chance patient encounter leads to PhD research project

Working as a nurse in the surgical specialties unit at Fiona Stanley Hospital, Elizabeth Gatonga had her first encounter with a total laryngectomy patient.

“I found the procedure to be overwhelming for the patient and their family members and I was also quite shaken seeing a person breathe through a hole in their neck,” Elizabeth said.

The Clinical Supervisor then began researching total laryngectomy, and identified limited qualitative studies globally, none of which were conducted in Western Australia.

“As I was in the process of identifying a PhD topic, I decided to explore the experiences of these patients following discharge from the hospital,” she said.

“Following total laryngectomy, literature focus is on the biomedical model which concentrates on symptoms rather than the experiences and impact of total laryngectomy, yet they are equally significant.”

The study aims to explore the lived experience from the patients’ perspective and anticipated outcomes include providing evidence for the design of effective interventions to support patients as well as their carers or families following a total laryngectomy, enhancing the psychological wellbeing of patients and improving the quality of post discharge care.

“Research is essential in all fields, as it adds to existing knowledge, identifies and closes gaps, and also ensures delivery of evidence based care to our patients,” Elizabeth said.

“Through my research I really wanted to give a voice to this particular group and also improve their experience post operatively.”

“Through my research I really wanted to give a voice to this particular group and also improve their experience post operatively.”



Elizabeth Gatonga

## Improvements in clinical care driving force behind heart and lung research projects

The Cardiothoracic Anaesthetic Research Group runs multiple research projects examining heart and lung health and disease.

Two current research projects include the Prothrombinex vs Fresh Frozen Plasma (FFP) for bleeding after cardiopulmonary bypass (POPCAB) trial and the Substrate and Oxygen Persufflation of Hearts in Storage for Transplantation (SOPHiST) project.

Staff Specialist Anaesthetist at Fiona Stanley Hospital and Chair of the Heart and Lung Research Institute of Western Australia, Dr Warren Pavey, said both projects involved up to eight co-investigators from multiple disciplines.

“Our projects are inspired by clinical problems that we see while caring for patients having heart or lung surgery or who have heart failure or advanced lung disease,” Dr Pavey said.

“It is motivating and satisfying to be able to investigate these problems looking for causes and possible novel treatments.”

Bleeding requiring treatment in the form of blood transfusions and blood products is common after heart-lung bypass and affects up to 30% of patients. At present when a deficiency in the amount of clotting factors in the blood is thought to be a contributing cause, there are two therapies which may be administered.

The POPCAB trial aims to examine which, if any, of these two blood products is more

effective in treating bleeding after heart lung bypass. The information learnt will help better treat bleeding after heart lung bypass and reduce the amount of blood products that patients are exposed to.

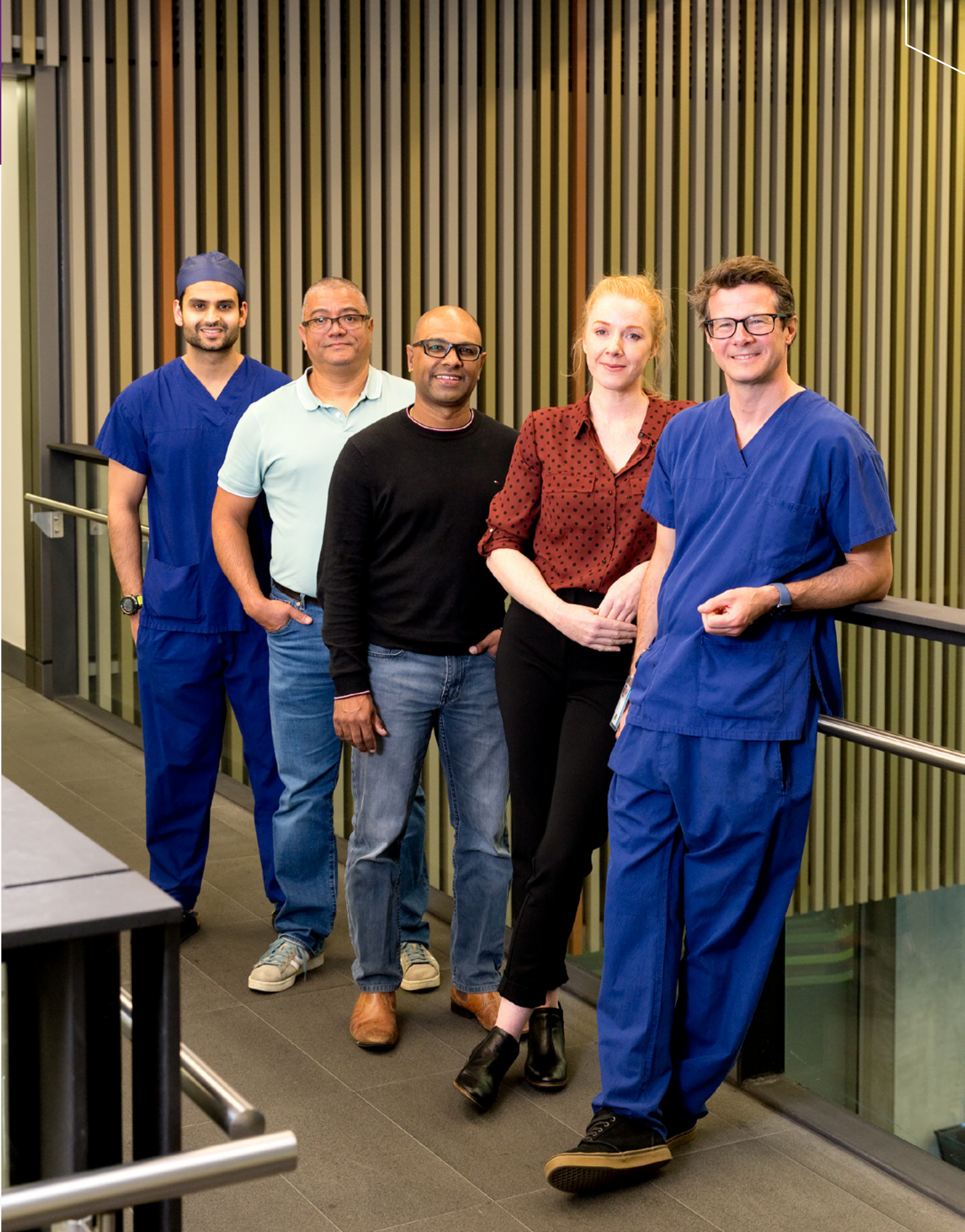
The SOPHiST project investigates the novel technique of using gas instead of blood to resuscitate and support donated hearts before transplantation. Gas may provide a more effective, simpler and cheaper method of resuscitation and storage than machines circulating fluid or blood through the heart while outside the body. Better methods of resuscitating hearts after removal from donors and preserving them while transported to a recipient would allow more hearts to be used and more lives saved.

“Our focus is that once these projects are completed, they are published in the scientific literature and form a basis for improving the clinical care of patients,”

Dr Pavey said.

“It is critical that as part of a tertiary hospital striving to offer quality care for its patients, we systematically strive to improve care and develop innovative solutions to clinical problems through research.”

The POPCAB project has benefitted from a DOH Research translation project (SHRAC) grant and SOPHiST has received a project grant from the Australian and New Zealand College of Anaesthetists (ANZCA).



*SOPHiST and POPCAB research team with Dr Warren Pavey (centre).*



Our projects are inspired by clinical problems that we see while caring for patients having heart or lung surgery or who have heart failure or advanced lung disease.”

RGS PRN	Title
3448	An Australian multicentre, prospective observational cohort study to evaluate the real-life experience of Ustekinumab in patients with moderate to severe Crohn's disease
3452	Traumatic Heterotopic Ossification: Exploring Prevalence, Risk Factors, Prevention and Treatment
3453	Abdominal Functional Electrical Stimulation To Reduce Respiratory Complications in Spinal Cord Injury
3468	Organ Transplant Research Survey
3481	Microbiota Profile in Heart Failure and Heart Transplant
3497	The FSFHG CardioVascular Risk factor Assessment in People with type 1 Diabetes mellitus (CV-RAP1D) study
3506	Integrating Tumour Mutational Burden (TMB) testing for appropriate selection of immuno-oncology therapy in metastatic melanoma
3516	Models of care for airway clearance services in Australia for adults with chronic lung conditions: a descriptive survey
3525	Bugs and crystals: a retrospective study evaluating clinical features and outcomes of concomitant septic arthritis and crystal arthropathy compared with septic arthritis alone
3534	SUBDUE-1: SUBurothelial DURvalumab injection – 1 study. A phase 1 open label dose-escalation study to evaluate the tolerability, safety, and immunological efficacy of sub-urothelial durvalumab injection in adult subjects with muscle invasive bladder cancer or high-risk non-muscle invasive bladder tumours
3545	Cost of hospital admissions and surgical procedures associated with patients who smoke compared with those who don't in Western Australia
3561	Efficacy and Safety of Concizumab prophylaxis in patients with haemophilia A or B with inhibitors
3562	Efficacy and Safety of Concizumab prophylaxis in patients with haemophilia A or B without inhibitors
3565	Can the overall haemostatic potential (OHP) assay predict bleeding in patients with factor XI deficiency?
3566	Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Efficacy and Safety Study with Inhaled RVT-1601 for the Treatment of Persistent Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF)
3590	20180138: Long-term Follow-up of Adult Philadelphia Chromosome-negative Acute Lymphoblastic Leukemia Relapsed Refractory Patients Enrolled in Study 00103311
3624	Barriers to Junior Doctors Seeking Clinical Research Opportunities in WA Hospitals
3646	PrEP in Practice: Clinician Perspectives on Prescribing PrEP in Australia

## Improving outcomes for staff injured in the workplace

Completing her research project as part of her Masters of Occupational Health and Safety, South Metropolitan Health Service (SMHS) Work Health and Safety Manager Michelle Farmer said undertaking the study in her own workplace provided rich and relevant data useful for the development of staff improvement strategies.

“Aside from completing my Masters, I have a genuine interest in my role to improve outcomes for our workers injured in the workplace, the development of injury prevention and management strategies, and a focus on workers’ compensation performance improvement across SMHS,” Michelle said.

The aim of the project was to answer the question, “What are the factors for supporting a supernumerary return to work program from the perspective of injury management consultants?”

Return to work programs are temporary, structured and documented programs developed to support injured staff as a result of a workplace incident in their return to the workplace.

Where medically guided restrictions are difficult to accommodate in the staff member’s pre-injury role, a supernumerary return to work program may be considered to assist the staff member with their return to work.

“Supernumerary return to work programs are based on ad hoc tasks rather than an existing job with staff on a program additional to regular departmental staff numbers, essentially an extra set of hands,” Michelle said.

“I wanted to understand from the perspective of our injury management consultants, what was driving the placement of injured workers back into supernumerary programs, rather than their pre-injury role so we can identify improvement strategies.”

An initiative has been included in the SMHS Work Health and Safety Plan for 2020–21 to consider the findings of the research.

This study was financially supported in-kind by SMHS in conjunction with Edith Cowan University.



*Michelle Farmer*

# Publications



# Publications

The publications list below details **479** published works by SMHS researchers, or researchers who have conducted research at an affiliated SMHS site in 2019.

Further information about SMHS publications can be found online:

- for external staff – please use Google Chrome and visit [Lens.org website](#)
- for SMHS staff – please visit the [Library website](#).

## Publications listing:

Abdullah UYH, Ibrahim HM, Jassim HM, Salleh MZ, Kek TL, Fakhruzzaman Bin Noorizhab MN, Zilfalil BA, Wilairat P, Fucharoen S. **Relative proteome quantification of alpha, beta, gamma and delta globin chains in early eluting peaks of Bio-Rad variant II((R)) CE-HPLC of hemoglobin from healthy and beta-thalassemia subjects in Malaysia.** *Biochem Biophys Rep.* 2019;18:100635.

Abdullah UYH, Ibrahim HM, Mahmud NB, Salleh MZ, Kek TL, Noorizhab M, Jassim HM, Othman I, Zainal Abidin SA, Zilfalil BA, Wilairat P, Fucharoen S. **Quadrupole-Time-of-Flight Mass Spectrometric Identification of Hemoglobin Subunits alpha, beta, gamma and delta in Unknown Peaks of High Performance Liquid Chromatography of Hemoglobin in beta-Thalassemias.** *Hemoglobin.* 2019; 43(3):182-7.

Abraham A, Burrows S, Abraham NJ, Mandal B. **Modified frailty index and hypoalbuminemia as predictors of adverse outcomes in older adults presenting to acute general surgical unit.** *Rev Esp Geriatr Gerontol.* 2019.

Adris N, Hazeldine S, Bentley P, Trinder D, Chua ACG, Powell LW, Ramm LE, Ramm GA, Olynyk JK. **Detection of HFE Haemochromatosis in the clinic and community using standard erythrocyte tests. Blood cells, molecules and diseases.** 2019;74:18-24.

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