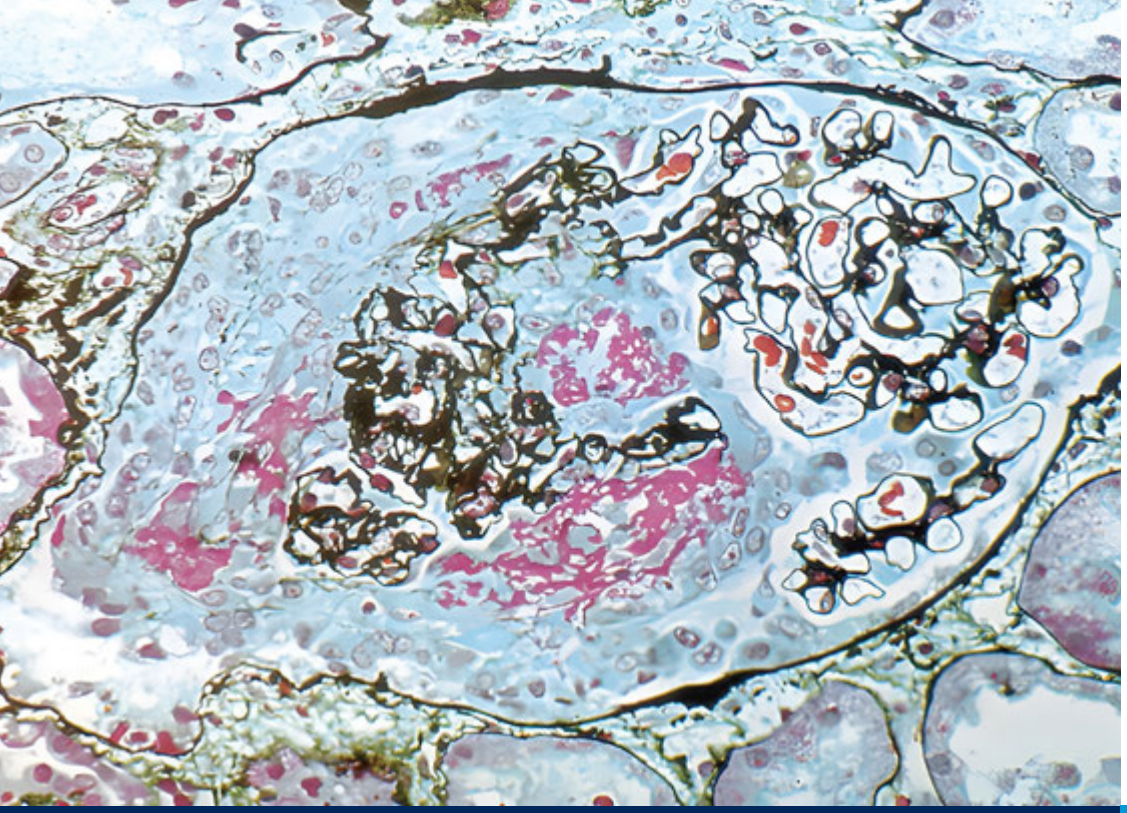


Nephrology Research Report

2021/2022

The Royal Melbourne Hospital

Welcome

On behalf of The Royal Melbourne Hospital, I am pleased to present our 2021/2022 Nephrology Research Report.

The Royal Melbourne Hospital (RMH) Department of Nephrology provides a comprehensive clinical and referral service for patients with acute kidney injury, chronic kidney disease and end-stage kidney failure, including outpatient clinics at various campuses, and a highly successful kidney transplant service. It works in partnership with a dialysis service to provide a complete treatment for patients with kidney disease. This service offers integrated metropolitan, regional satelite and home dialysis services, outpatient clinics, pre-dialysis education and technical services.

Together, the RMH Kidney Care Service is one of the largest national providers of diagnosis and treatment for people with any stage of acute and chronic kidney disease and of kidney replacement therapies for people with kidney failure. We currently treat more than 600 pre-dialysis patients, 550 dialysis patients, and perform more than 120 kidney transplants a year.

Generosity of our donors has enabled us to fund world-class research and infrastructure, develop our workforce and improve patient and family-centered care. We were extremely fortunate to receive a transformational Gift in Will from a grateful patient — Mr John Perrett — who was treated periodically at the RMH for more than 30 years. John's gift of more than $19 million was the largest gift the RMH has ever received.

It will support equipment, research and education and training needs in the Department of Nephrology for many years to come and we are forever indebted to John for his amazing gift.

The RMH Kidney Care Service believes that ongoing research and quality initiatives offer tangible improvements in clinical outcomes. The service is strongly committed to improving patient outcomes through research and innovation. Despite the challenges of 2021/2022, our unit has continued to meet that goal. It is our great pleasure to showcase that research work here.

Professor Nigel Toussaint
Director

The kidney functions as an excretory, biosynthetic, and metabolic organ, vital for maintaining normal health. In healthy adults, the kidneys process about 200 litres of blood a day to remove waste and excess water. In addition, they synthesise hormones to stimulate red blood cell production and regulate blood volume and pressure, affect bone formation, and control phosphate balance.

A sudden loss of kidney function caused by injury, loss of blood flow, or blockage of the urinary tract for example, is referred to as acute kidney injury. More generally, although the kidney has capacity to repair after short or mild injury, severe and ongoing damage for any reason results in chronic kidney disease (CKD), an irreversible, progressive condition characterised by the gradual loss of kidney function over time. Here, kidney replacement therapy (KRT) by dialysis or transplantation remains the only option for end-stage organ failure.

The burden of kidney disease

Acute kidney injury (AKI) is a common clinical diagnosis across many medical specialties within the hospital setting, with international studies suggesting that it can occur in nearly a quarter of hospitalised patients. Likewise, a striking 1 in 10 Australians have biomedical signs of CKD, with kidney disease contributing to 11% of all deaths in 2017[1]. Worryingly, the number of people receiving kidney replacement therapy has more than doubled from 2000 to 2020[1].

The burden and devastating impacts are expected to grow further in parallel with the rising rate of diabetes and high blood pressure, two major contributors to CKD.

Given the kidneys' incredible capacity to compensate for lost function, CKD remains largely asymptomatic in its early stages. This means that in most people, CKD is only detected in the advanced stages of disease, which limits the opportunity for intervention and leads to poorer disease outcomes. This is further highlighted by estimates that earlier detection would over 20 years save $10.2 billion, prevent 32,000 deaths, and delay transplantation or dialysis by an average of five years[2]. Furthermore, inherent inequalities in CKD are starkly highlighted by the fact that Aboriginal and Torres Strait Islanders are almost seven times more likely to require kidney replacement therapies than non-Indigenous Australians[1].

Previous cost benefit analyses in various diseases have consistently shown the enormous disproportionate benefits of targeted investment in medical research[3]. A focused and coordinated approach to kidney research is an imperative for addressing the burden and devastating impact of this under-recognised public health epidemic.

1 Australian Institute of Health and Welfare (AIHW). Chronic kidney disease: Australian Facts, Australian Government 2022.
2 Deloitte, Kidney Health Australia, Access Economics report. Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment. April 2023.
3 Deloitte Access Economics, Returns on NHMRC funded research and development, Australian Society for Medical Research, October 2012.

Research at the RMH Department of Nephrology

Research in the field of nephrology encapsulates a diverse range of specialties, from the basic biology of disease through to specific clinical interventions to improve individuals' health. Each step along this spectrum is critical as they overlap, meaning that progress requires a focus on all aspects of disease development, progression and treatment.

Our collaborative research programme aims to improve the lives of people living with kidney disease in Australia (and globally) by generating high-quality evidence to help inform healthcare decisions made by patients, health professionals, and policy makers.

The department's programme involves biologists, clinical researchers, and clinical services, both internally and externally. Through this commitment we have maintained well-developed infrastructure and support mechanisms for established and novice investigators. We have several major lines of ongoing research within the department which encompass both basic science and clinical research with a strong focus on the translation of findings to clinical practice. A strength of our research programme is that we are able to integrate discovery (basic) science, translational science, clinical trials and health services research studies to achieve these outcomes.

Discovery Science

Basic science research seeks to understand the biological processes that underpin health and disease at the molecular, cellular, organ system and whole body level. Laboratory and early translational studies in our unit are examining the mechanisms of kidney failure, focusing on the pathology, cell biology and biochemistry of kidney disease.

Clinical Medicine and Science Research

Basic science studies are paralleled by an extensive clinical research programme that addresses the mechanisms of progressive kidney failure and their abrogation. Here we are using clinical interactions, diagnostic materials, and patient data to improve the diagnosis, treatment, and prevention of kidney disease.

The unit remains a key centre for conducting clinical trials of new immunosuppressive drugs in transplantation, prevention of complications post-transplantation, and the management of diabetes and genetic kidney disease. Ongoing studies in collaboration with The RMH Department of Cardiology are focused on detecting and understanding cardiovascular events in people on haemodialysis. Recent translational studies, as well as our commitment and participation in clinical trials, have provided patients with early access to new and exciting drugs in development.

Health Services Research

The RMH Department of Nephrology is committed to quality initiatives to understand and improve the effectiveness, quality, social and environmental dimensions of health care. These projects are specifically designed to better understand our health service and improve access, timeliness, and efficiency.

The use of nephrology key performance indicators (KPIs) to measure the performance of nephrology services Australia wide and understand variation in kidney care is now well established. These indicators aim to drive quality improvement and increase efficiency and consistency through transparent comparison of performance. Our studies are using patient-level characteristics to identify factors positively and negatively associated with specific events.

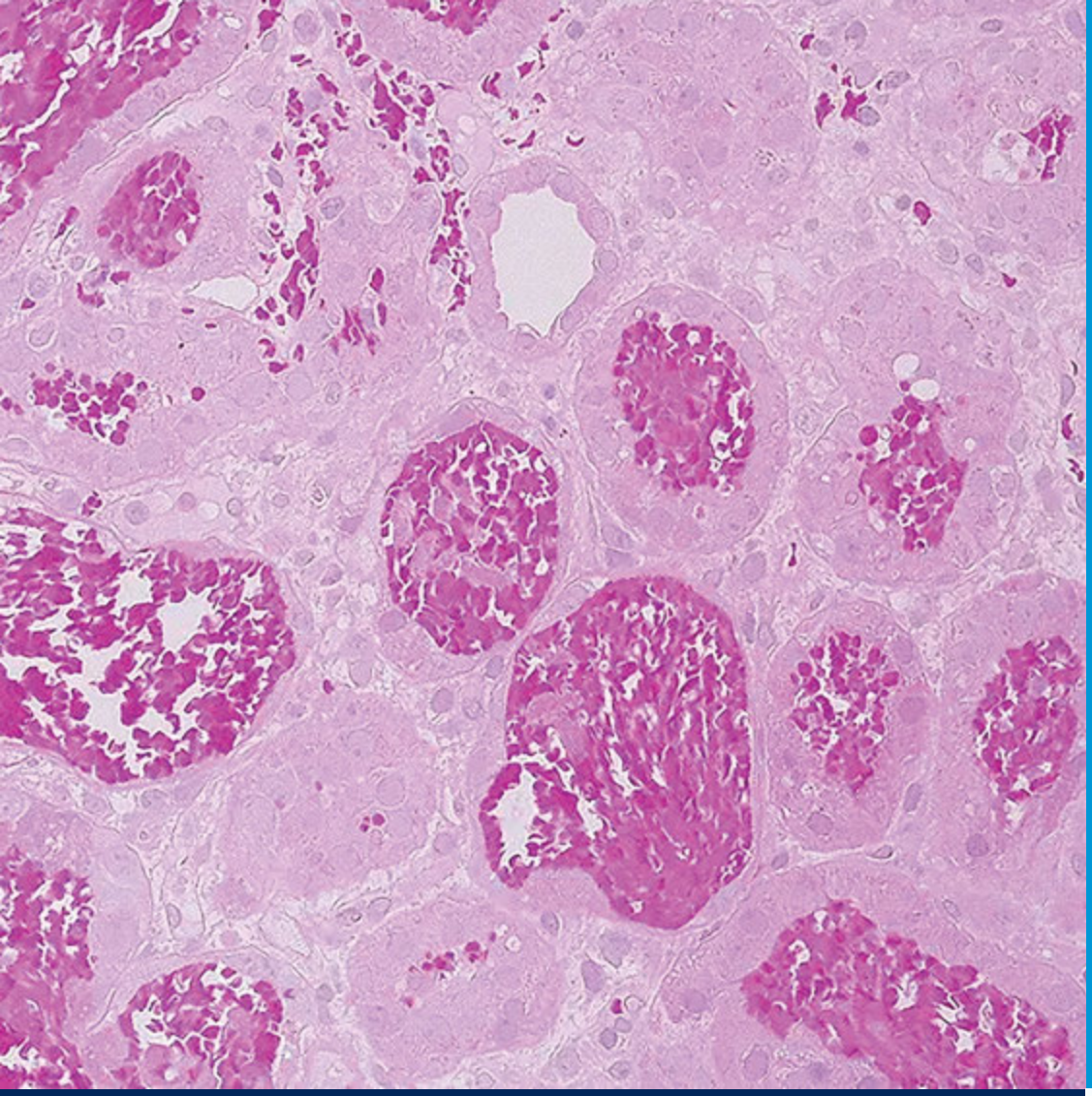
Such studies are being used to identify opportunities to improve patient outcomes.

We also routinely contribute to a variety of patient registries which collect clinical data to document national and international experience. These are often in rare conditions where multicentre data provides a combined sample size not available through any single treatment centre.

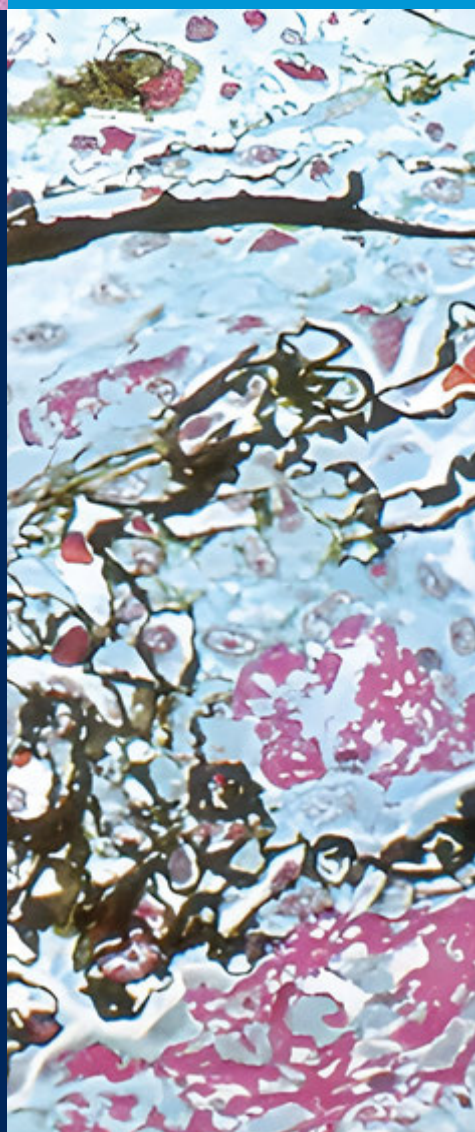
Our PhD fellows

The training of post-graduate students, in particular our physician PhD students, has always been critically important to our research programme. It is through their work that we achieve much of our insight into clinical translation and significance. In 2021, three new fellows commenced their PhD studies: Drs Kylie Martin, Mandy Law, and Stephanie Kuo. They joined Drs Adam Steinberg, Nicole Lioufas and Mark Tiong, all in the second year of their PhD studies. Dr Matt Sypek, supervised by A/Prof. Peter Hughes graduated in 2021 while Dr Emily See, co-supervised by Prof. Nigel Toussaint, delivered her Completion Seminar at the end of 2022.

Pictured: Current PhD fellows with supervisor Prof. Nigel Toussaint. Left to Right: Adam Steinberg, Kylie Martin, Mandy Law, Nigel Toussaint, Stephanie Kuo and Mark Tiong.



Research Highlights



Salt — more than two kidneys

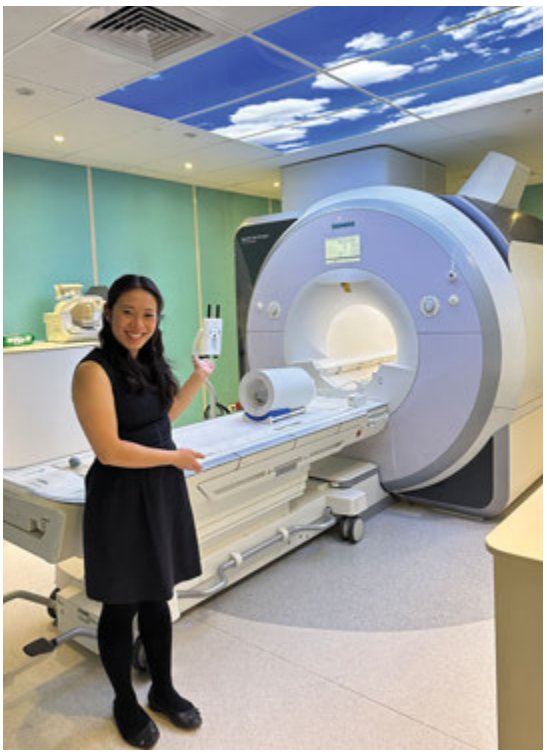
Regulation of sodium, as salt, and water balance in people with CKD becomes challenging as kidney excretory ability declines.

Although the kidney is conventionally thought to be the central regulator of salt, we now recognise that extra-renal regulatory mechanisms exist. Skin and muscle binding of sodium work in concert with the kidneys by acting as a reservoir and buffer during high salt intake. When this system is overwhelmed in CKD, excess tissue sodium is associated with a significant increase in related co-morbidities including worsening hypertension, cardiovascular mortality, and a pro-inflammatory profile. Understanding the tissue distribution of salt and water is therefore increasingly important to our understanding of CKD.

Conventional estimates of sodium balance have been derived mainly from indirect (and imprecise) measurements of sodium intake and excretion including dietary questionnaires and 24-hour urine collections respectively. Unfortunately, more direct measurement of tissue sodium levels has proven problematic. Sampling error is difficult to control for in tissue biopsies, while the necessary sensitivity requires highly specialist equipment usually only available in chemistry research laboratories.

PhD studies being performed by Dr Kylie Martin, in conjunction with the Department of Radiology, are using sodium-hydrogen magnetic resonance imaging (23Na/1H MRI) to dynamically quantify tissue sodium concentration in the lower limb of humans. This method is invaluable for investigating (patho-) physiological conditions associated with tissue sodium deposition and metabolism.

High salt perpetuates CKD. Understanding tissue sodium regulation and exploring new ways to decrease excess sodium binding in tissue, has the potential to be a major advance in managing high blood pressure and cardiovascular disease in CKD.



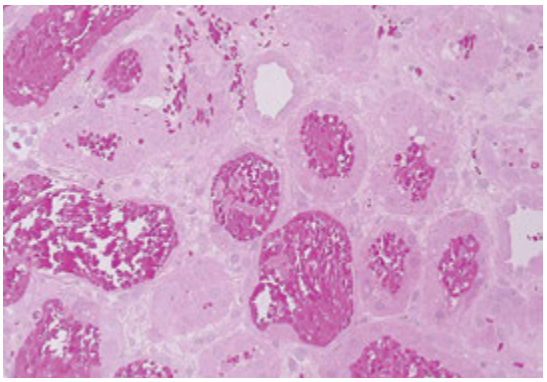
Pictured: Dr Kylie Martin with the MRI machine and a purpose-built knee coil for this study.

Acute Kidney Injury — Clinical translation

Limited Australian research shows that in-hospital deaths of patients with AKI are 17% compared to 2% in those without AKI. This work also highlighted the service gap that exists documenting and under-reporting AKI as well as the underutilisation of inpatient nephrology services for this condition.

Electronic alerts (e-alerts) have been introduced into the clinical care setting in many countries attempting to improve quality of care and provide electronic prompts and reminders to clinicians across many medical disciplines. However, in isolation, e-alerts alone have not improved healthcare outcomes or rationalised the use of kidney replacement therapies in people with this condition. Ongoing work is focused on additional nephrology-based interventions including personalised treatment recommendations coupled with the e-alerts for early detection.

Prof. Nigel Toussaint and colleagues are evaluating the effects of a systematic AKI detection and management package to improve the detection and treatment of AKI at the RMH. A retrospective audit of hospital data has been undertaken to aid the design and implementation of an AKI educational awareness campaign and a service-wide automatic e-alert as part of a systematic “nephrology intervention package” for better diagnosis and management of AKI at RMH. Success of this program will translate into meaningful patient outcomes such as reduced hospital length of stay and reduced medical complications.



Pictured: Renal biopsy of AKI showing characteristic formation of casts in tubules.

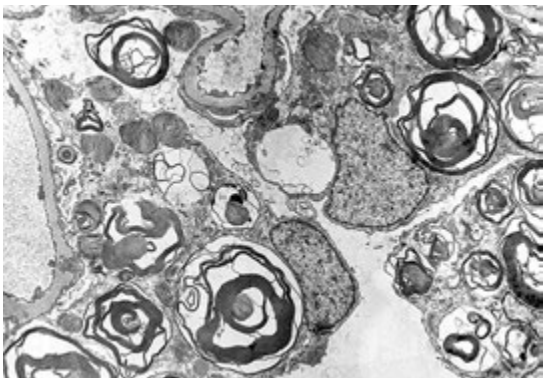
Genetic Diseases

Research into rare kidney disease continues within our Nephrology Unit, where multidisciplinary care for patients with Fabry disease and Tuberous Sclerosis Complex is coordinated.

Fabry disease is an inherited genetic disease where a genetic mutation interferes with the breakdown of biomolecules known as sphingolipids, leading to these substances building up in the walls of blood vessels and other organs, including the kidney. The RMH Nephrology Unit was Australia's first referral centre for the management of Fabry disease and has collaborated with other key global Fabry centres.

In Victoria, all 150 patients with Fabry disease attending RMH clinics for their specialised clinical care also participate in at least one international disease registry. Many also participate in active clinical trials to critically evaluate new therapies. Several gene therapy trials have opened, using new technologies to try to effectively manage the condition with a single treatment. These trials are intensely demanding, but hopefully will bring us closer to "curing" the condition, as well as informing treatment options for other genetic diseases. Other Fabry trials include using specific drugs to limit the impact of the condition, and better replacement therapies to treat more effectively. As in all rare diseases, these trials necessarily involve many international centres, and multiple departments collaborating within RMH.

Basic research involving collaborations with Monash Stem Cell laboratory, the Murdoch Children's Research Institute, and SA Path is using Fabry mutation-specific stem cells, then transforming these into kidney and heart cells. This allows us to study the specific disruptions which the disease induces in target organs. We are very grateful for support via the Honig Research fellowship and industry investigator grants that facilitated this work, and to all patients who generously participate.



Pictured: Renal pathology of Fabry disease showing abnormal build-up of sphingolipids (dark circles) in the kidney glomerulus.

Measuring mineral stress in chronic kidney disease

In CKD, as kidney function declines, there is continuing disruption to normal mineral metabolism.

The term CKD-mineral and bone disorder (CKD-MBD) is used to describe a diverse clinical spectrum of mineral abnormalities found in CKD. CKD-MBD has been broadly defined as disturbances in mineral metabolism, abnormal bone remodelling and accelerated calcification outside of bone leading to increased mortality and morbidity.

The RMH Department of Nephrology remains at the forefront of research into this complex condition, with our laboratory studies examining the cellular, hormonal and physiochemical basis of this disorder. Our interest and expertise in the mechanisms and propensity of CKD-MBD have been recognized internationally with our collaborations in Switzerland, Germany and the Netherlands allowing us to expand our research activity.

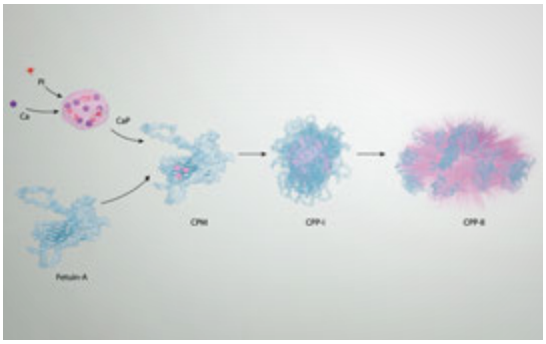
Research led by A/Prof Ed Smith aims to validate a new screening test — the Calciprotein particle (CPP) test — that will identify people who are at higher risk of developing an irreversible condition in CKD. Some people with decreased kidney function see their arteries begin to calcify, resulting in a much higher rate of heart disease and premature death when compared to the general population. Existing imaging tools, such as X-ray or CT scans, aren't sensitive enough to distinguish dynamic changes in calcifying arteries. New tests are urgently needed to help identify patients at high risk for the onset of this irreversible condition. This new CPP test could provide the answer. The CPP test measures the likelihood of calcium phosphate crystallising in blood serum.

A/Prof Smith's Clinical Investigator Award is allowing him to investigate whether measuring CPPs is a new diagnostic tool.

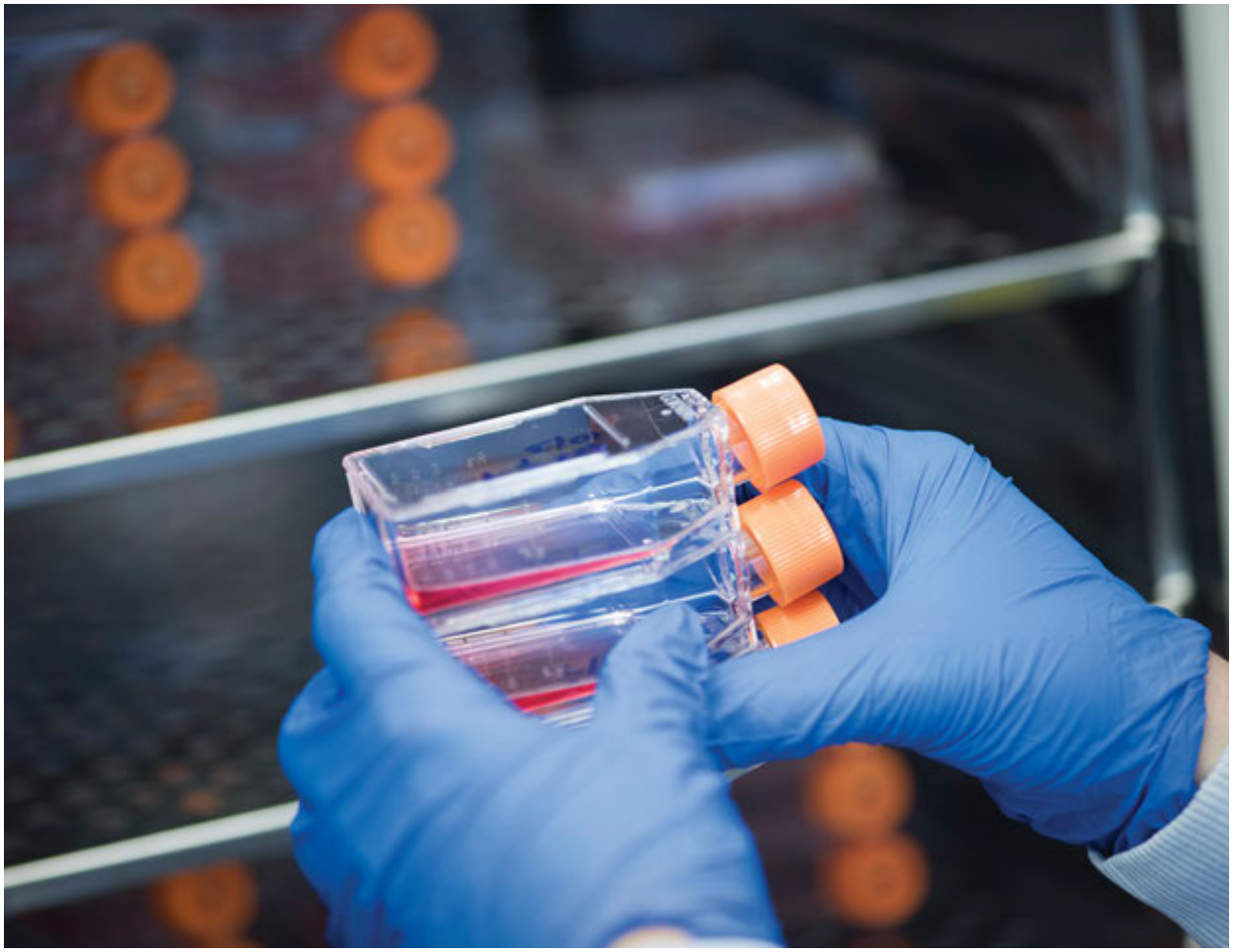
By validating this screening test to identify people at high risk of developing vascular calcification, we can help improve outcomes for people who are at risk of developing cardiovascular disease and other conditions as a result of CKD.

The results will have important implications for clinical care of patients with CKD and for the design of future research studies aimed at reducing the high-risk population.

The Sylvia and Charles Viertel Charitable Foundation was established by Charles Viertel to benefit medical research into diseases along with the alleviation of hardship of the aged and the sick. We are grateful to the Foundation for making this research possible.



Pictured: Calcium (Ca), phosphate (P) clusters bind to Fetuin-A, a protein secreted by the liver, to form calciprotein monomers.



Mineral metabolism in kidney disease

People with CKD develop abnormalities in mineral and bone metabolism, collectively known as Chronic Kidney Disease — Mineral and Bone Disorder (CKD-MBD).

CKD-MBD is almost universally present in advanced stages of CKD and is associated with a range of deleterious patient outcomes, including accelerated cardiovascular disease, increased risk of fracture and all-cause mortality. Dr Mark Tiong's PhD thesis is exploring mineral metabolism in CKD-MBD, including its association with clinical outcomes. Novel markers are being utilised to examine mineral metabolism in health and disease states, including in response to potential therapeutic interventions.

Fibrosis

Although the kidney has capacity to repair after short or mild injury, severe and ongoing damage results in progressive organ failure.

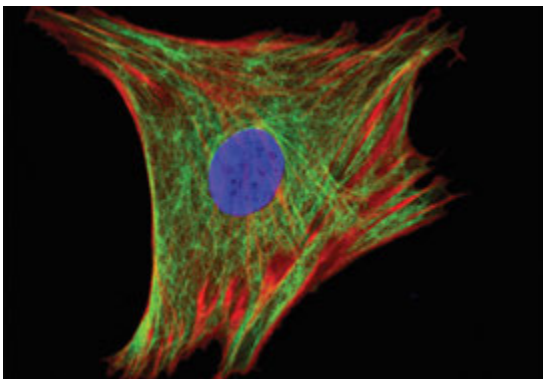
The inability of the kidney to heal itself and the formation of scar tissue, so-called fibrosis, is the hallmark of all CKD. Our interest is focused on the role of a highly specialised cell, the renal fibroblast, in this process. As the major source of connective tissue proteins in the kidney, this cell is largely responsible for the formation of scar tissue that accompanies kidney failure.

A consistent finding in our recent work is that fibroblasts from injured kidneys are more responsive to a molecule called Transforming Growth Factor (TGF) beta1 than their normal counterparts and that these changes are inherited. Our laboratory studies have identified previously unrecognised metabolic changes that occur in fibroblasts for them to synthesise the copious quantities of connective tissue proteins that we see in fibrosis. We are therefore interested in the molecular changes that occur as renal fibroblasts transition from resting to activated states. To examine this, we are having to develop new techniques to measure fibroblast function.

An interesting feature of this process is that it is a final common pathway in kidney failure, regardless of disease. The diabetic microenvironment is one such trigger for fibrosis, yet control of diabetes is often insufficient to prevent progression of scarring. We believe that this is due to a “priming” of fibroblast-like cells by diabetes so that they have an exaggerated response to the chemical pro-sclerotic signals that are released in diabetes.

Through funding from Diabetes Australia, A/Prof. Tim Hewitson and colleagues are investigating this by looking for master regulators of this process in the diabetic environment. These findings are potentially significant because they will help explain the cellular basis of diabetic memory, a phenomenon that severely limits the effectiveness of current treatment strategies in this debilitating condition.

What distinguishes healing from scarring, and when does scarring becomes irreversible, are amongst the fundamental questions in kidney disease, and organ fibrosis in general. Understanding the mechanisms that regulate fibrosis in disease is important, because once scarring is initiated it can be incredibly difficult to switch off or reverse.



Pictured: Fluorescent microscopy of a kidney fibroblast in culture showing features of activation after exposure to TGF-beta1. These include the formation of stress fibres (red) responsible for the contraction that occurs in scarring in the kidney and elsewhere after injury.

Pictured: Department scientists A/Professors Tim Hewitson (left) and Edward Smith (right).

"Medical advances have helped millions of people live longer, healthier lives. We owe these improvements to decades of investment in medical research."

— IKE SKELTON

Transplantation

Kidney transplantation remains the optimal treatment for patients with kidney failure. Nonetheless, many challenges and barriers exist.

RMH Nephrology is one of the largest transplant centres in the country, and consistent with this, we are also a major contributor to a number of international clinical studies aimed at improving outcomes for kidney transplant recipients.

We are currently participating in multicentre, international studies on the use of new medications for the treatment of a type of rejection after transplant and a viral infection which commonly affects transplant recipients and has no specific therapy.

We also have a range of research studies that have been initiated within our unit or in collaboration with other groups, particularly those within the Parkville Biomedical Precinct, to try to address specific clinical problems.

An example is a current project which is attempting to create a new diagnostic test to non-invasively monitor the health of the transplanted kidney. Monitoring kidney transplant recipients remains challenging as rejection is not always detected by routine blood and urine tests. We therefore currently rely on the use of biopsies at certain time points after transplant to detect it. Kidney biopsies are however invasive and costly, and through necessity, are performed on patients despite being well. PhD studies by Dr Stephanie Kuo, in collaboration with the neighbouring Walter and Eliza Hall Institute (WEHI), are exploring the potential of urine proteomics to differentiate between a normal functioning transplant and those with rejection.

This novel approach will potentially lead to a new non-invasive test with great improvements in patient care and experience.

Other research projects include two separate studies investigating the mechanisms of kidney injury at the time of donation and transplantation, being performed in collaboration with CSL and WEHI. Another new study, which has been initiated at the RMH and will start recruiting soon, will investigate the use of a new medication to attempt to allow transplantation in people with high antibody levels.

The transplant team is also reporting some of the areas we are leading clinical practice, including the use of anti-viral medication to reduce the risk of serious illness in transplant recipients who develop COVID-19.

A/Professor Peter Hughes
Deputy Director
Physician in Charge of Transplantation

Redesigning deceased donor kidney transplant allocation in Australia

Kidney transplantation is a life changing event for a person living with kidney failure and the allocation of deceased donor kidneys can have profound impacts on who has access to this treatment, the benefit that is derived from the gift of donation and the long-term outcomes for the individual receiving the organ.

The system that determines the allocation of deceased donor kidneys comprises several interconnected processes and must address a range of competing priorities. Dr Matt Sypek's PhD has examined the current state of deceased donor kidney allocation and investigated the feasibility and effectiveness of redesigning current organ allocation protocols in Australia.

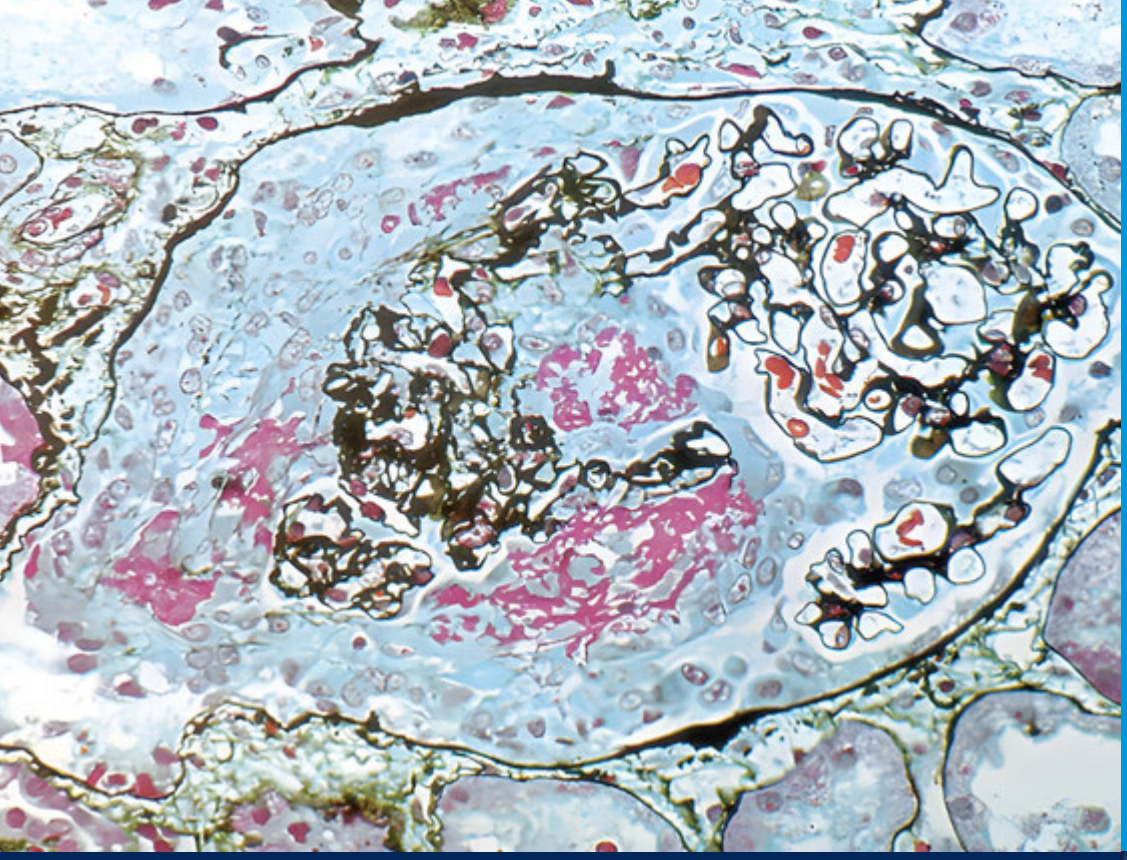
By working closely with the national Renal Transplant Advisory Committee (RTAC), this work has provided proof of concept for the value of simulation models in organ allocation policy development in Australia. The result has been direct and tangible policy improvements that can be implemented.

Industry Trials

We undertake many other clinical trials, ranging from pharmaceutical-sponsored to investigator-initiated, across a range of nephrology conditions including:

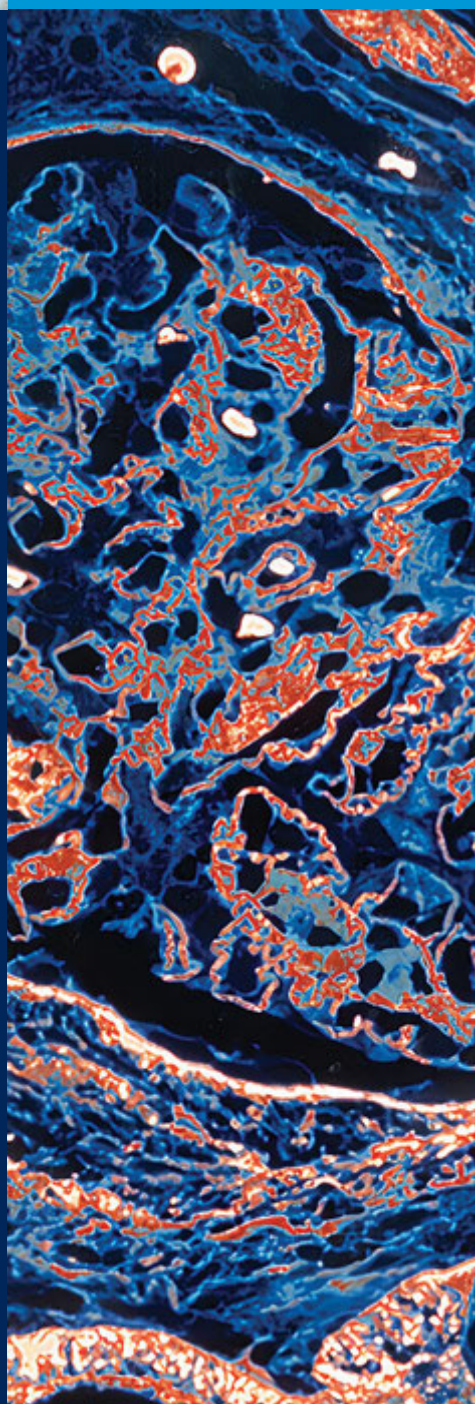
- IgA Disease
- Focal Segmental Glomerulosclerosis
- C3 Glomerulopathy
- Autosomal Polycystic Kidney Disease
- Lupus Nephritis
- Diabetic Kidney Disease
- Metabolic Acidosis
- Anaemia
- Transplantation

The Department is closely aligned with The Royal Melbourne Hospital Office for Research to deliver clinical trials for important new treatments and technical advancements to our consumers.



A transformational gift for the Royal Melbourne Hospital Nephrology Department

In the early 1990s John Perrett had a kidney transplant at the Royal Melbourne Hospital. Back then, the life expectancy for kidney disease wasn't long, but thanks to ongoing research, amazing clinicians and ongoing care, the transplant gave John another 30 years of life — something he never forgot or took for granted.



Pictured: The RMH Department of Nephrology physician team.

John was born in Sunshine and grew up in St Albans, riding horses across the paddocks, playing football and tennis. He never left, spending most of his working life as a pharmacist in Main Road West, and (for a time) also working on his father's small farm in Gisborne. John was a savvy businessman and accepted an offer to sell his pharmacy to Amcal. He wisely invested the proceeds in shares and real estate.

John was very frugal. Jane, one of John's friends and tenants recalls, "He had this old, old television with a green picture, and it had this hum in it and for years we would sit there and I'd say, 'John you would really appreciate the cricket more if you could see it properly'."

Following in his father's footsteps, John was involved in the racing game as part owner of several horses — some were successful, others are still running!

John sadly passed away in September 2020 at the age of 86. At the time of his death he owned five properties in St Albans. He left two properties to his long-time tenants and friends, and the remaining three were donated to the RMH.

"We are forever indebted to John for his transformational gift. His incredible legacy will live on for many generations to come and his vison and generosity will have an enormous impact on all renal patients, particularly in the areas of transplantations, medical and surgical care, equipment, and operating theatre refurbishment. We could not do our vital work without people like John," said Professor Nigel Toussaint, Director of Nephrology at the RMH.

The proceeds from John's gift in Will have been invested. Each year, the Department of Nephrology will identify priority projects and research this legacy gift will fund. This will ensure John Perrett's gift achieves the greatest impact for the RMH, its patients and staff for generations to come. We are eternally grateful to John for his transformational gift.

If you would like more information about how you can make an impact, please contact the RMH Foundation on **03 9342 7111** or email **info@rmhfoundation.org.au**

Research Outcomes

Publications

Acute Kidney Injury

See EJ, Polkinghorne KR, Toussaint ND, Bailey M, Johnson DW, Bellomo R. Epidemiology and outcomes of acute kidney diseases: a comparative analysis. *Am J Nephrol 2021; 52(4):342-350. doi: 10.1159/000515231*

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Book

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Invited Presentations

Toussaint ND. Diet or phosphate binders to control phosphate in CKD, ASN 2021

Toussaint ND. Phosphate in CKD from bench to bedside, EDTA-ERA 2022

Smith ER. Overview of Calciprotein Composition, Isolation, and Quantification Techniques, ASN 2022

See EJ. AKI Genotype, Susceptibility, and the Potential for Personalized Medicine, ASN 2022

Hewitson TD. Animal Models of Kidney Disease, ANZSN 2022

Hewitson TD. KHA-ANZSN Research Collaborative: The Kidney Research Alliance, ANZSN 2022

Steinberg A. Quality Indicators — Variation in Nephrology Care, ANZSN 2022

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"Assessment of mineral metabolism in chronic kidney disease — Mineral and Bone Disorder (CKD-MBD)"

Dr Adam Steinberg
"Variations in nephrology care; and use of quality indicators to promote improvement"

Dr Stephanie Kuo
"Urine proteomics in kidney transplantation"

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"Sodium excess and tissue deposition in chronic kidney disease: Associations with Cardiovascular Disease and Inflammation"

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Funding Sources

The Department of Nephrology is indebted to the many organisations and individuals who have supported our research programme.

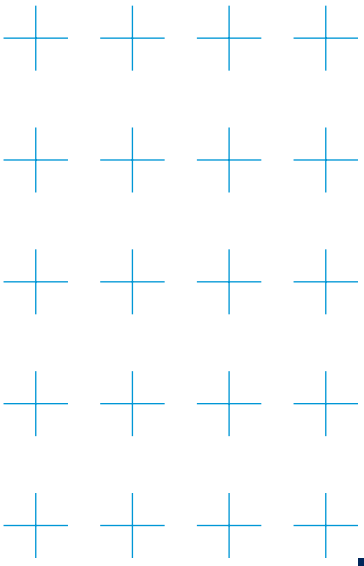
Grants

- University of Melbourne, Research Training Program Scholarship. M. Tiong (2020–2023)
- University of Melbourne, Research Training Program Scholarship. A. Steinberg (2020–2023)
- Diabetes Australia, Metabolic priming and reprogramming of the glomerulus in diabetic kidney disease. T. Hewitson, E. Smith (2020–2022)
- University of Melbourne, Viola Edith Reid Bequest Scholarship. S. Kuo (2021)
- University of Melbourne, Professional and Practice-based RTP scholarship. K. Martin (2021)
- RMH Health Service Improvement Grant, Multifaceted acute kidney injury (AKI) care bundle to improve early detection of AKI and prevent disease progression. N. Toussaint (2021)
- Sylvia And Charles Viertel Charitable Foundation, Clinical Investigator Award. E. Smith (2022)
- RMH Margaret Henderson Women in Research Fellowship, A transcriptome insight into the molecular adaptations of the skin to sodium. K. Martin (2022)
- RMH Grant in Aid. Developing a non-invasive method for the diagnosis and management of kidney transplant rejection. S. Kuo (2022)
- RMH Equipment Grant, Fresenius Medical Care Body Composition Monitor — a small, portable, bedside, non-invasive, objective measure of fluid volume and nutritional status using bioimpedance spectroscopy. N. Toussaint (2022)
- University of Melbourne, David B Rosenthal Memorial Scholarship. M. Law (2022)
- RMH Kearton Conference Grant, T. Hewitson (2022)
- RMH Kearton Conference Grant, S. Bruell (2022)

Donors

The generous support of all our philanthropic partners remains pivotal to our research.

- Estate of John James Perrett
- Katy Honig (Honig Post-doctoral Research Fellowship)
- Haydn & Henrietta Williams Memorial Trust
- The Isabella Pritchard Scholarship for Kidney Research
- Family of the Late Michael J Ball
- Diana Morgan AM
- Family & Friends of Rollo Morgan
- Paul & Francesca Di Natale
- Family & Friends of David Stewart
- Priscilla Kincaid-Smith Festschrift Fund
- Family & Friends of Michael Allan
- Estate of Vicki Peroulis
- DISHA — The Direction of Hope



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