Department of Diabetes and Endocrinology

Research Report

2019-2020

The Royal Melbourne Hospital Foundation

Contents

Director’s message

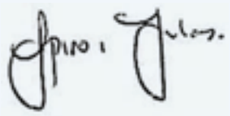
We are delighted to present you with The Royal Melbourne Hospital Department of Diabetes and Endocrinology inaugural biennial research report for the years 2019-2020. The RMH Department of Diabetes and Endocrinology has a long and fine history of fostering investigator driven clinical research and we are excited to present you a summary of our recent large research activities.

In this two year period the department was involved in ninety publications with a continued strong focus on the three endocrine clinical research pillars of diabetes, bone and mineral, and pituitary disorders. The research highlights include screening for type 1 diabetes with newer laboratory assay techniques and clinical risk systems; conducting RAPIDS, the largest cluster- randomised clinical trial of a diabetes model of care in non-critical care; treating obesity prior to conception to improve pregnancy outcomes for mothers; and developing finite element modelling to improve the estimation of bone stiffness.

Of concern, the epidemic of diabetes and other endocrine disease continues to cause major morbidity and mortality in our community, further exacerbated by the challenges of treating people with these endocrine conditions during the COVID-19 pandemic. Our department remains committed to understanding these disorders better, with a view to innovating treatment to improve real life outcomes for people. With this in mind, we remain invigorated in the pursuit of understanding and in our approach to Endocrinology research.

We would like to thank all our committed staff for their contributions, including senior department leaders, staff endocrinologists, registrars, junior hospital medical officers, dietitians and nurses dedicated to research. We also thank the RMH executive, the University of Melbourne, collaborating partners and institutes, funding bodies and generous philanthropists for their kind support of the RMH Department of Diabetes and Endocrinology’s research endeavours. We will continue to seek greater investment into our research program with the steadfast aim of achieving a biologic and health economic return on investment.

Yours sincerely,



A/Prof Spiros Fourlanos
Director, Department of Diabetes and Endocrinology

Our Mission

‘The Royal Melbourne Hospital Department of Diabetes and Endocrinology has a mission to provide individualised, state of the art healthcare for endocrine disorders, via our pursuit of research, education and training to maintain health and well-being.’

The medical expertise of the Royal Melbourne Hospital (RMH) Department of Diabetes and Endocrinology enables the delivery of world leading clinical care and research in a broad range of endocrine conditions, including diabetes, osteoporosis, obesity and pituitary disease. In a recent global survey of over 40 000 medical peers conducted by Newsweek and Statista, the clinical department was ranked the number one Endocrinology hospital department in Australia and 30th in the world.

The RMH Department of Endocrinology and Diabetes provides comprehensive acute and ambulatory clinical care for patients with a wide variety of acute and chronic endocrine disorders. We deliver expert diabetes clinical care in many fields including inpatient diabetes, diabetic foot care, type 1 diabetes and type 2 diabetes. Ambulatory care services have a focus on the use of medical device technologies for diabetes including insulin pumps, continuous glucose monitoring and new subcutaneous insulin and non-insulin diabetes medications. Our endocrinology service also cares for people with other endocrine gland and hormone disorders involving the pituitary, thyroid, parathyroid, pancreatic islet glands, adrenal and sex glands, and also osteoporosis and metabolic bone disease.

We are dedicated to finding new and effective ways to manage endocrine diseases.

Research in the Department of Endocrinology and Diabetes

The Royal Melbourne Hospital Department of Endocrinology and Diabetes is strongly committed to improvement through research and innovation. We have shown that ongoing research and quality initiatives lead to tangible improvements in clinical outcomes.

Our clinical and laboratory research activities integrate basic, translational and health delivery clinical research with clinical services and education of patients. Through this commitment we have developed an infrastructure and support mechanisms for early career and established investigators. A strength of our research program is that we are able to integrate basic science, translational science, and clinical trials to achieve improved health outcomes for patients with endocrine disease.

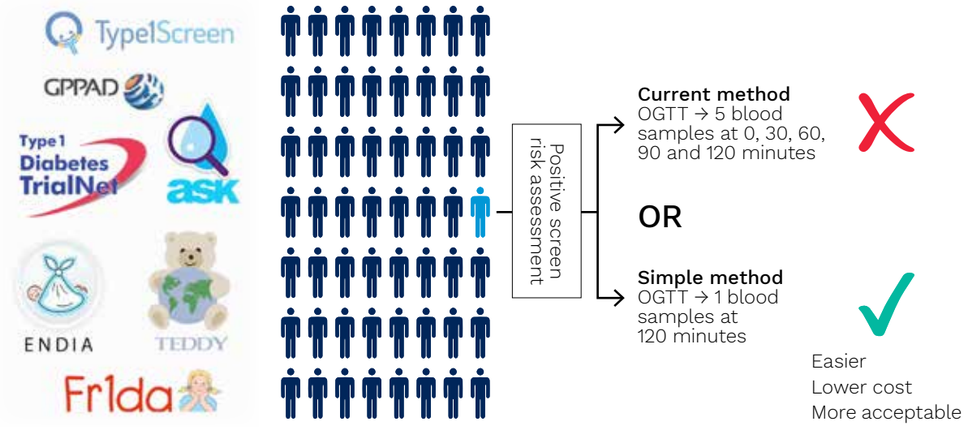
Research Highlights - Basic and Translational Science

Type 1 Diabetes Immunology

John Wentworth

The Department continues to run a research laboratory in pathology with oversight by Professor Peter Colman, A/Prof Cherie Chiang and A/Prof John Wentworth. This laboratory performs diabetes antibody assays for several national projects, including Type1Screen, TrialNet, Environmental Determinants of Islet Autoimmunity (ENDIA), the Baricitinib in New Onset Type 1 Diabetes (BANDIT) trial and the General Population Screening Pilot. The Endocrine Laboratory is the only internationally-accredited antibody facility in the southern hemisphere and continues to refine assays

Type 1 diabetes autoantibody screening programs



John Wentworth and Peter Colman have developed a simpler way to predict how quickly at-risk individuals will develop type 1 diabetes.

methods and introduce new formats, including an agglutination-PCR assay that will allow individuals to self-collect samples in the home and mail them to the laboratory for analysis.

The RMH was the lead clinical site for the BANDIT trial of baricitinib in recent-onset type 1 diabetes; with nearly two thirds of participants recruited since opening in November 2020 and we anticipate it will be fully recruited in early 2022.

The type 1 diabetes research group also recently completed a local study that demonstrated potential for the SGLT inhibitor class of drugs to preserve pancreas function in newly-diagnosed patients. This important finding paves the way for use of these drugs in combination with immune therapies to improve treatment outcomes.

John Wentworth has also recently reported analyses of TrialNet datasets that revealed simpler ways to assess type 1 diabetes risk and to monitor the effects of immune therapy. These innovations will improve the patient experience and decrease treatment costs.

Bones and Mineral Medicine

John D Wark

Finite element modelling: Improved estimation of bone stiffness and strength for clinical application

While dual energy Xray absorptiometry (DXA) can provide clinically-useful measurements of areal bone mineral density (aBMD) in the axial skeleton, there also is a need to reliably quantify bone deficits and loss of bone strength in the peripheral skeleton where fragility fractures are very common. Peripheral quantitative computed tomography (pQCT) may provide such a technique since it is able to measure trabecular and cortical volumetric bone mineral density and bone geometry, hence allowing estimation of bone strength.

Our collaborative studies with biomedical engineers at the University of Melbourne, interested clinicians and Canadian scientists have allowed us to improve the predictive value of these techniques. PhD student Dr Hongyuan Jiang and postdoctoral fellow Dr Dale Robinson have made key contributions. We developed and validated a finite element analysis (FEA) technique to improve the estimation of resistance to fracture and bone stiffness in long bones using pQCT data (1,2). We also obtained pQCT-FEA data in multiple clinically-important settings where fracture risk is increased but DXA does not necessarily reflect the degree of bone fragility. These have included a cohort of low-trauma fracture patients (3), premenopausal women undergoing risk-reducing surgical menopause (4), and young women with type 1 diabetes, whose increased fracture risk is not well understood (5). Further studies are in progress. Based on this work, we envisage that pQCT-FEA is likely to become a valuable tool in the evaluation of bone fragility in a wide range of clinical settings.

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Research Highlights - Clinical Trials

We continue to conduct a range of clinical trials that address the treatment of diabetes and endocrine disorders that aim to ultimately improve the lives of millions of people with diabetes and endocrine disorders.

RAPIDS

Mervyn Kyi
Spiros Fourlanos

Studies within the wards of the RMH are examining the improvements in patient care with close monitoring of blood glucose levels, focusing on minimising patient length of stay and risk of infection.

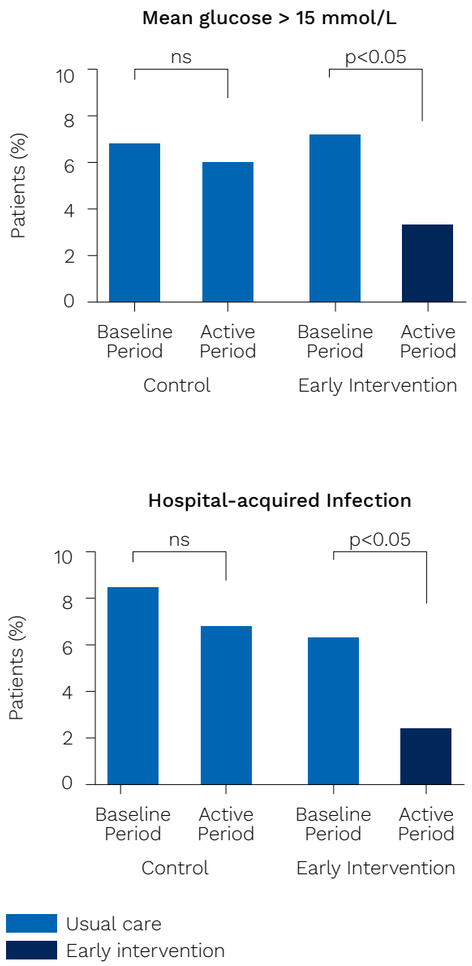
Individuals with diabetes admitted to hospital are more likely to experience unstable glucose levels and related complications such as hospital-acquired infection and longer length of stay. Due to the rising prevalence of diabetes and evolving treatment regimens, optimal diabetes care in hospital is increasingly complex.

To improve the diabetes care in hospital, we developed an *early intervention* model of diabetes care delivered by specialist diabetes clinicians. This model comprised a *proactive inpatient diabetes team* (doctors and nurses specialising in hospital diabetes care), who provided expert management of all individuals with diabetes within 24 hours of admission to hospital. The team used a *networked blood glucose monitoring* system, technology which allowed the team to electronically monitor blood glucose levels, to identify individuals with diabetes and unstable glucose levels.

This early intervention model of care was assessed in the Randomised study of a Proactive Inpatient Diabetes Service (RAPIDS), which is to date, the largest cluster-randomised trial of hospital diabetes in non critical care. This trial recruited over 1000 consecutive individuals with diabetes admitted to one of eight wards over a six-month period. After a 3-month baseline period, the wards were randomised to receive either the early intervention model or usual care.

With the early intervention model most patients with diabetes (92%) had specialist management and more patients received insulin treatment. The early intervention decreased adverse glycaemia (episodes of unsafe hypoglycaemia or hyperglycaemia) by 24%, and decreased severe hyperglycaemia (patient-day with glucose >15 mmol/L) by 55%. Additionally, this intervention decreased hospital-acquired infections by 80%.

The RAPIDS study provides randomised-trial level evidence that early specialist management improves glucose levels and clinical outcomes, and has supported a paradigm shift in hospital diabetes care in Australia and globally. Locally, the outcomes of the RAPIDS study paved the way for the RMH to become the first Australian hospital to implement a hospital-wide networked glucose meter system in 2019, and to implement the first fully-integrated electronic medical record with networked glucose monitoring system in 2020. The inpatient diabetes service is now conducting an electronic-based early intervention randomised controlled trial, whilst providing state-of-the-art diabetes care at the RMH.



Mervyn Kyi, Spiros Fourlanos

Treating obesity prior to conception

Sarah Price
Alison Nankervis

The prevalence of women of child-bearing age with obesity continues to rise at an alarming rate. This has significant implications for both the short-term and long-term health of mother and offspring.

In 2019 we published our systematic review of surgical and non-surgical weight loss options in Obesity Review (*Price et al. 2019*). We explored the impact of surgical and non-surgical weight loss tools on 'time to pregnancy' and pregnancy outcomes in women with obesity. It was evident that there were significant knowledge gaps in the current literature and no ideal tool for the management of obesity in women seeking pregnancy.

After publication of our trial protocol in the journal Trials in 2018 (*Price et al. 2018*), our randomized controlled trial of a very low energy diet vs standard dietary intervention in women with obesity has now been completed.

Our findings of time to pregnancy after preconception weight loss were published in the journal Fertility and Sterility (Price et al. 2020). Maternal weight loss at the end of the 12-week intervention was 3.1% in the standard dietary intervention group and 11.9% in the Very Low Energy Diet group. In completers of the 12-week intervention, time to pregnancy was significantly shorter in the women allocated to the VLED group than in the SDI group. Post hoc analysis showed that this difference in time to conception was particularly overt within 90 days of the intervention.

Our pregnancy outcome data have been accepted for publication in the journal Obesity (*Price et al. 2021*). In completers of the weight loss intervention, a composite of adverse pregnancy outcomes was significantly lower in the VLED group ($p<0{\cdot}001$). However, there was no difference in fasting glucose at 26-28 weeks gestation and mechanistically it is not well understood how weight loss improves pregnancy outcomes in women with obesity.

The results of our study have led to important questions regarding the mechanism of adverse pregnancy outcomes in women with obesity. A recently successful Diabetes Australia Research Program (DARP) grant will provide critical funding to explore changes in glucose metabolism in women with obesity during pregnancy.

Research Outcomes

Publications 2019-2020

Bone

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Our Contributors

Our research objectives are pursued by a multidisciplinary team of clinicians, scientists, nurses, dietitians and trial coordinators based at the RMH. Through close links with the University of Melbourne we provide opportunities for post-graduate research training in Endocrinology. A highlight in 2020 has been two PhD completions.

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3. **Doctor of Medicine Research Project (MDRP)**

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Collaborative Partnerships

We remain committed to expanding our collaborative research network.

Our collaborative partners are listed as follows:

Parkville Biomedical Precinct

- RMH Department of General Medicine
- RMH Department of Nephrology
- RMH Department of Biochemistry
- RMH Department of Genetics
- RMH Department of Cardiology
- RMH Department of Gastroenterology

- RMH Department of Neurosurgery
- RMH Department of Vascular Surgery
- RMH Department of Orthopaedic Surgery
- Victorian Infectious Diseases Service
- Peter Doherty Institute
- University of Melbourne
- Walter and Eliza Hall Institute of Medical Research
- Peter MacCallum Cancer Centre
- Royal Women's Hospital

State

- Royal Children's Hospital
- St Vincent's Hospital
- Austin Hospital
- Western Hospital
- Northern Hospital
- Mercy Maternity Hospital
- Monash University

National

- Australian Diabetes Society
- Endocrine Society of Australia
- Women's and Children's Hospital Adelaide
- Australian Centre for Behavioural Research in Diabetes
- Juvenile Diabetes Foundation

International

- Type 1 Diabetes TrialNet, USA
- Advanced Technologies and Treatment for Diabetes Society, USA
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Your generous support has been instrumental in making the RMH Department of Endocrinology one of the premier departments in Australia.

Future Research Directions

We are committed to expanding our research program in the three major endocrine pillars of diabetes, bone-mineral and pituitary disorders.

Over the next 5 years we intend to prioritise research in the following areas:

Diabetes & Bariatric Medicine

- Type 1 diabetes – immunotherapy to restore and preserve pancreas function
- Type 1 diabetes – medical device technologies
- Type 1 diabetes – early diagnosis and treatment
- Type 2 diabetes – new drug therapies and precision treatment
- Type 2 diabetes – early diagnosis and treatment
- Type 1.5 diabetes/adult-onset type 1 diabetes – outcomes and precision treatment
- Newly-diagnosed diabetes – aiming for remission
- Diabetic foot – evaluating lower limb amputation rates in the COVID-19 pandemic
- Diabetic foot – cognitive and psychological functioning in people with diabetes-related foot complications
- Diabetes in the hospital - improving the acute care and outcomes for people with diabetes admitted to hospital
- Diabetes in the community - improving the chronic care and rapid access for treatment of diabetes exacerbations
- Diabetes in the community - diabetes and mental health
- The role of Diabetes and Obesity in the pathogenesis of Cancer, including Pancreatic Cancer
- The role of Diabetes and Obesity in the pathogenesis of Dementia

Bone & Mineral Medicine

- Osteoporosis treatments
- Clinical role of finite element modelling of bone strength
- Online model of learning in bone health and osteoporosis

Pituitary disorders

- Pituitary tumour treatments

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