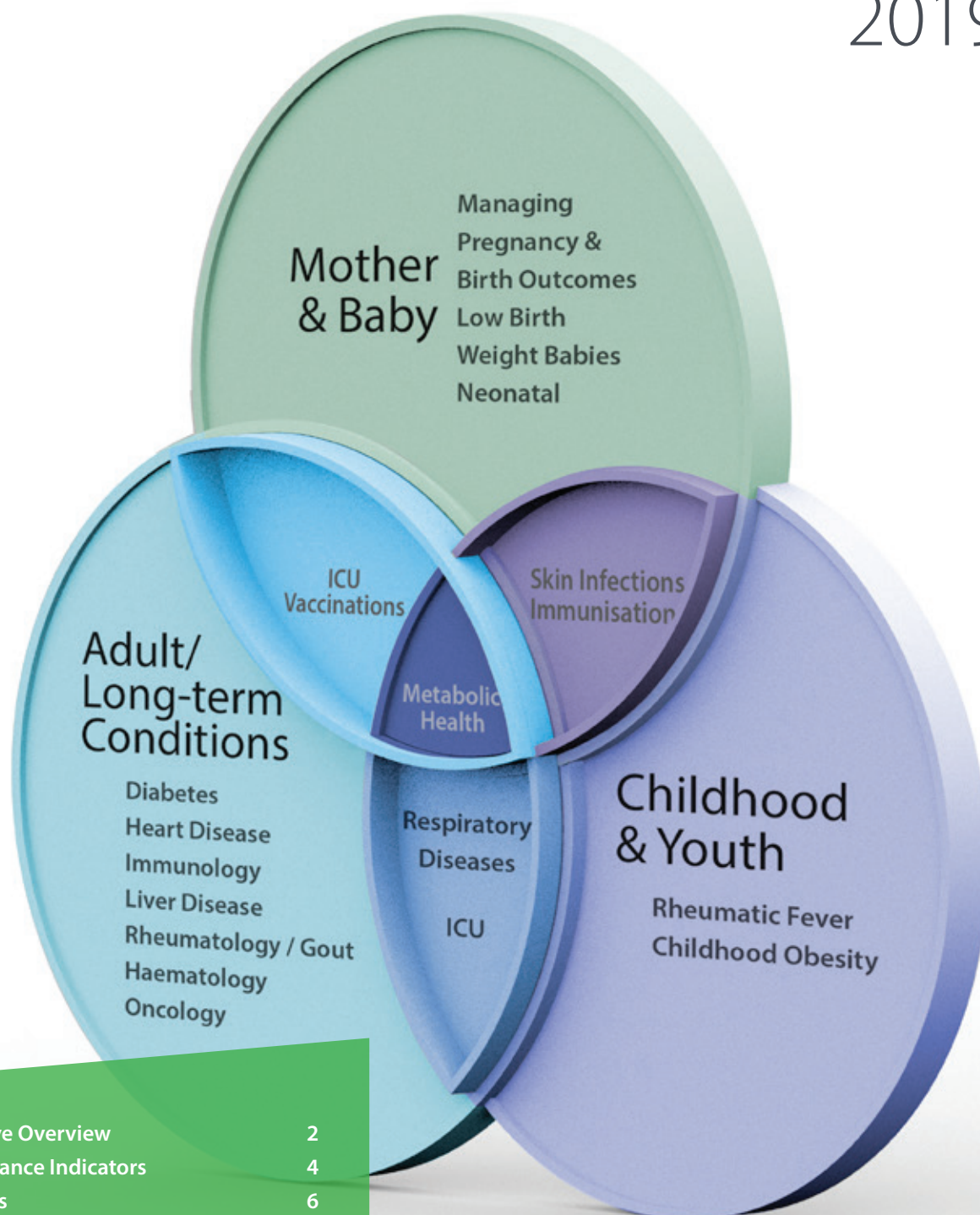


Annual Report 2019



MMCT Research Strategy - simplified for presentation

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MMCT Chair's foreword

Dear supporters and stakeholders,

The year that ended in June 2019 has been one of change, as Middlemore Clinical Trials evolves and prepares itself for changes in the environment in which it operates.

In November, at the conclusion of the AGM, Michelle Sullivan stood down as Chair and left the Board in February. I wish to thank Michelle for the time and effort that she committed to MMCT over six years, including her time since June 2015 as Chair. She led a transformation at Board level and was deeply involved in the transformation at operational and management level in her early days as Chair.

This July we have welcomed Kevin Wightman to the Board. Kevin brings considerable experience in pharmaceutical, biotech and allied healthcare sectors in Australasia and Asia to the Board. We look forward to sharing the new perspective that Kevin brings.

We also welcomed Dr Edward Watson in August 2018, so this year reflects his first year as CEO of MMCT. Ed has engaged with the Board in a process that has mapped out a strategy designed to position MMCT for the future. Implementation of that plan, which includes greater engagement with our Maaori community, is now underway.

MMCT's primary purpose as a Trust is to generate funds for research grants. Our ambition is to be Australasia's leading clinical trial site, known for clinical excellence, participant experience and trial recruitment. Achieving our ambition will over time generate significant funds in the Trust's designated reserves, which will enable significantly greater amounts to be granted to fund research, ultimately benefiting the community in which MMCT belongs.

Once again MMCT's performance reflects the hard work and dedication of the team, at all levels. The Board is extremely proud of what the organisation has achieved. We look back with satisfaction, but also look forward in anticipation of what the next few years will bring.



Greg Batkin

CHAIR



Greg Batkin was appointed CHAIR in November 2018



Trustees (left to right) – Kevin Wightman, Margie Apa, Marama Parore, Greg Batkin (Chair), Michael James, Gloria Johnson (Deputy Chair)

Chief Executive's report

Dear supporters & stakeholders,

Reflecting on the last 12 months, we see it has been a transformational year. While we have hit our revenue targets we also embarked on evolutionary change, both in how we operate and what we focus on. Along the way we achieved many milestones that will set us up well for future growth.

In clinical research, change is inevitable as the global forces with which we play, varies and adjusts to the perceived needs of the medical landscape. Thus as a research unit we need to be able to understand the ecosystem, pick the trends and adjust our focus and delivery to match our partners' ever-changing needs. We have actively engaged with our sponsor partners to understand their portfolios and where future opportunity lies. We aim to be one of the leading research sites in Australasia and hence world class.

This year we have tightened up our financial model and processes, identified and improved our contracting ability, concentrated on improving our performance metrics and strategically planned for the next 12 months and beyond.

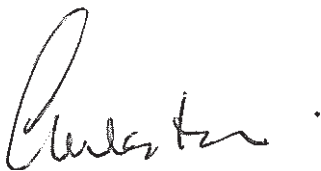
Our continued engagement with mana whenua, commencing with a communication review and numerous meetings, culminated in the co-naming of MMCT as Te Kohinga Ora – the gathering of information/resources to promote wellness. This reflects well the spirit of partnership in everything we do.

Our staff at MMCT have been extremely impressive, willing to engage with novel ideas and concepts, and demonstratively supportive of each other. We all believe that the future we are envisioning is a better one both for the organisation but also for the patients that we serve. Likewise the senior management team has embraced the need for change and the additional responsibility of striving to be the best.

I would also like to thank the Board for being extremely supportive of the changes that have been instituted. Indeed MMCT is very fortunate to have such knowledgeable, committed and capable trustees as its governance.

We haven't got everything right. We are committed to deeper understanding and engagement with our principal investigators and department's research staff and their already busy schedules, but who we see as integral partners in everything we do.

We know that many of the best health outcomes for our patients are derived from their experience in clinical trials. Hence it is our firm commitment to work with our partners to make high quality clinical research more available, both to the clinical staff of the hospital as well as the people of Counties Manukau.



Dr Edward Watson
CEO



Dr Edward Watson was appointed CEO in August 2018

General Performance indicators FY19

40

Total Staff *
*Includes Contractors

26

Research Staff

159

New Trial Participants

514

Total Trial Participants

3728

Outpatient Visits

\$1.1m

Estimated Money Saved.
Service Outpatient Visits

11.8%

Designated/Restricted
Reserves spent

\$1.4m

Grant Revenues

\$6.2m

Total FY19 Revenue

\$8.1m

FY19 Reserves

Commercial trials by department FY19



18

Haematology



12

Gastroenterology



9

Diabetes



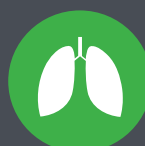
9

Rheumatology



9

Cardiology



5

Respiratory



3

Interventional Radiology



2

Renal



2

Paediatric



1

Emergency Care

70

Commercial Trials in total in FY19

About Us

Middlemore Clinical Trials (MMCT) is now one of the largest research units in New Zealand and aims to be one of the largest in Australasia.

Based in Middlemore Hospital, a large tertiary hospital in South Auckland, MMCT is an independent charitable trust established in 2001 that administers both commercial and grant funded research on behalf of the local District Health Board, Counties Manukau Health. MMCT brings innovative pharmaceutical and device trials to the people of South Auckland, often making available to our patients novel therapies that they otherwise wouldn't have access to. We also provide research facilities and support functions, employ research nurses, and manage the finances of the trials. Surplus funds resulting from successful trials are held in Reserves to enable departments within the hospital to perform more grant and investigator initiated research.

Middlemore Hospital, where MMCT is based, is a large public hospital treating 94,000 inpatients per year and nearly 600,000 outpatients. MMCT works with 22 hospital departments performing research in most therapeutic areas.

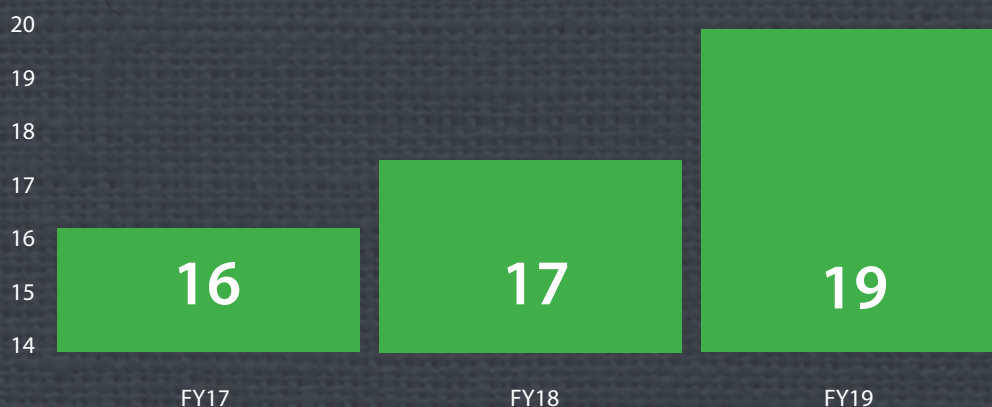
MMCT staff comprise of highly trained research nurses and support staff including finance, management, phlebotomy, dedicated pharmacy and regulatory affairs.

Being part of a large modern hospital is a critical success factor for us, as we are able to partner with research clinicians and nurses, who are often leaders in their field, to try and address some of the many unmet health needs in our diverse local community.

40 Staff and
contractors
in FY19

FY19 was a year of evolutionary change as we ready MMCT for future growth and to meet the needs of our commercial partners and our participants.

Commercial Trials Activated FY17-FY19



What we do

MMCT performs around 140 clinical trial protocols each year. Around half of these protocols are sponsored by commercial companies such as biotech or pharma companies from USA, Europe and China. The other half of our work is in the areas of research grants, trials initiated by researchers at Middlemore or other New Zealand hospitals, or specialist collaborative group studies from around the world. These grants enable our researchers at Middlemore Hospital to be part of the global innovation drive to improve quality of care for patients both throughout the world and in our region.

Working with our global partners we work hard to attract world leading companies to perform research in this country. We appreciate they can choose any hospital anywhere in the world, but we believe the unique characteristics that MMCT offers encourages them to partner with us.

In partnership with our local Primary Care Organisations (PHOs) we often lead the recruitment of participants into many of the clinical trials that we undertake.

Our staff manage all aspects of the clinical trial process ensuring solid recruitment to our trials, high compliance rates, rigorous pharmacy and laboratory management, and the production of high quality clinical data from the trials.

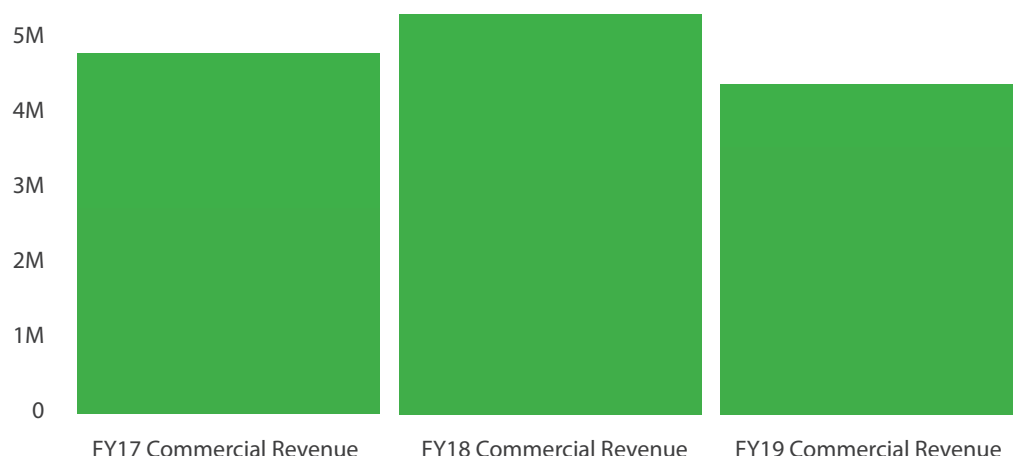
Clinical Trial Recruitment Performance FY19



MMCT Commercial Revenue

Commercial Revenues in FY19 were \$4.35m, 15% down on FY18.

Clinical Trial Commercial Revenue FY17-19



Our Commercial Clinical Trials 2019

Clinical trials are becoming more complex and require a skilled and experienced workforce to obtain the best results.

Due to our relationship with Middlemore Hospital we can perform complex Phase 1 and Phase 2 trials. These trials require considerable medical research experience and sophisticated health care systems to make them successful.

Clinical Trials Activated FY19 - Overview



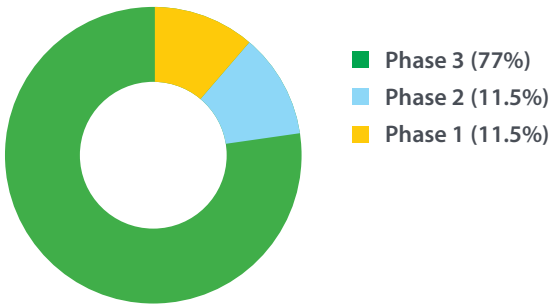
Commercial Trials by Department at CM Health in FY19

Department	Number of Active trials	Number of Participants
Diabetes	9	103
Paediatrics	2	102
Cardiology	9	63
Gastroenterology	12	55
Renal	2	53
Respiratory	5	47
Rheumatology	9	43
Haematology	18	36
Emergency Care	1	7
Radiology	3	5
Grand Total	70	514

Investigators

Our investigators are CM Health senior medical consultants. In FY19, we had 58 investigators engaged in research activities with MMCT representing 19 departments within the hospital.

2019 commercial trials by study phase



58 Active investigators in FY 2019

19 Hospital departments represented in trials in FY 2019



Alice Sika
MMCT
Administrator

WAITING
ROOM

Grant funded trials

Many hospital departments engage in grant funded research trials. The majority of these trials are initiated elsewhere, either as international network studies or as public-good Health Research Council (HRC) funded studies and Middlemore Hospital operates as a collaborating site.

FY19 Grant funded trials - centre of initiation breakdown

Department	Initiated at CM Health	Initiated elsewhere	Total Grant funded trials	% of grand total
Diabetes	1	1	2	4%
Haematology	-	8	8	14%
Respiratory	3	1	4	7%
Cardiology	1	2	3	5%
Paediatrics	4	10	14	25%
Renal	3	1	4	7%
Women's Health	-	2	2	4%
Emergency Dept.	1	1	2	4%
Intensive Care	-	8	8	14%
Histology	1	-	1	2%
Home Health	-	1	1	2%
Infectious Disease	-	1	1	2%
Neonatal	3	1	4	7%
Plastics	2	-	2	4%
Stroke	-	1	1	2%
Grand Total	19	38	57	100%

SHIVERS

SHIVERS is a long-term surveillance study beginning in 2012 that investigates patients admitted to hospital in metro Auckland with severe acute respiratory infections caused by influenza and other respiratory pathogens. Funded by a grant from the Centres for Disease Control (USA), SHIVERS is locally administered by Institute of Environmental Science and Research (ESR). Additional funding has been received from GlaxoSmithKline. Lead local investigators are Dr Conroy Wong (Respiratory Physician), Dr Adrian Trenholme (Paediatrician), and Dr Susan Taylor (Microbiologist). This SHIVERS study has helped the government to decide to give free immunisation to certain children and given us the knowledge that Maaori, Pasifika, and people with low socioeconomic status carry the burden of this disease. The serology survey also showed that

neuraminidase antibodies are quite important, and has led to a further prospective cohort study being carried out in Wellington looking at evolution of antibodies against influenza.

KIWI

KIWI is a multi-centre, single-arm, open-label, network study of kyprolis (carfilzomib) and dexamethasone followed by autologous bone marrow transplant and carfilzomib, thalidomide and dexamethasone consolidation in newly diagnosed patients with multiple myeloma. Sponsored by the Waitemata District Health Board, KIWI is led by local haematologists. The Principal Investigator is Dr David Simpson, North Shore hospital, and Dr Rajeev Rajagopal is lead local investigator. The study drug (carfilzomib) is supplied free of charge by the sponsor. As a result, participating in this study provides significant savings of up to \$1.4 million in treatment related costs to CM Health.

PICASSO

The PICASSO study is funded by a feasibility grant from the Health Research Council of New Zealand (HRC) awarded to Mr Jon Mathy. The PICASSO study evaluates the efficacy and safety of preoperative locally-infiltrated incisional antibiotics for decreasing surgical site infections in patients undergoing skin cancer surgery (the most common cancer affecting New Zealanders). Findings from this study will inform a larger RCT filling a gap in evidence-based clinical guidelines around the treatment of skin cancer, both regionally and internationally.

Safe Sleep Calculator

The Safe Sleep Calculator is a risk assessment tool being implemented in CM Health to objectively assess sudden unexpected death in infancy (SUDI) risk in babies, the leading cause of post neonatal death in New Zealand. It provides individualised SUDI protection advice and accurate targeting for a SUDI protection care programme to the babies at highest risk. Dr Christine McIntosh has been awarded a grant from ProCare Charitable Trust to determine if the Calculator is also a good predictor of respiratory infection, which shares a number of risk factors with SUDI and which causes hospitalisation of around 1200 babies each year. Thus, the research findings will determine if there is opportunity to expand the current SUDI prevention programme to include targeted proactive preventative respiratory care in infants nationwide.

19 Grant funded trials initiated at CM Health in FY19

New Trial Feasibilities Received in 2019

Therapeutic Area	Phase I	Phase I/II	Phase I/II	Phase II	Phase II/III	Phase III	Phase IV	Phase Unknown	Total
Cardiology	1	1	-	-	-	3	-	1	6
Clinical Lipidology	2	-	-	-	-	-	-	-	2
Dermatology	-	-	-	2	-	2	-	1	5
Diabetes	-	1	-	5	-	3	-	-	9
Emergency Dept	-	-	-	-	1	-	-	-	1
Endocrinology	-	-	-	1	-	-	-	-	1
Gastroenterology	6	1	-	12	1	3	1	-	24
Haematology	-	2	-	3	1	12	-	3	21
Infectious Disease	-	1	-	-	-	-	-	1	2
Intensive Care	-	-	-	1	-	1	-	1	3
Mental Health	-	-	-	1	-	-	-	-	1
Neonatal	-	-	-	1	2	-	-	-	3
Neurology	-	-	-	-	-	2	-	-	2
Oncology	-	1	-	-	-	3	-	1	5
Ophthalmology	2	-	-	3	-	-	-	-	5
Orthopaedics	-	-	-	1	-	-	-	-	1
Otorhinolaryngology (ENT)	-	-	-	1	-	-	-	3	4
Paediatrics	2	1	-	3	-	1	1	1	9
Renal	1	-	-	3	-	7	-	1	12
Respiratory	-	-	-	2	-	4	1	1	8
Rheumatology	-	-	1	2	-	5	-	-	8
Surgery	-	-	-	1	-	-	-	-	1
Women's Health	3	-	-	1	-	-	-	-	4
Grand Total	17	8	1	43	5	46	3	14	137

137 Total feasibilities received in FY 2019

New Trial Feasibilities received from 54 different Sponsors and 16 CROs

Sponsor		CRO
AbbVie	GlaxoSmithKline	Allergan
Acerta Pharma	Janssen-Cilag	Chiltern International
Actelion Pharmaceuticals	Kalbe Genexine Biologics	Clinical Network Service (CNS)
Advaccine Biotech	Kaleido Biosciences	Covance
Akebia Therapeutics	Lyra Therapeutics	DrugDev
Amgen	Maruho	George Clinical
Aravax	MedImmune	ICON Clinical Research New Zealand
Arbutus Biopharma	Merck	IQVIA (Quintiles)
Arena Pharmaceuticals	Momenta Pharmaceuticals	Medpace
Arrowhead Research	MRINZ	Novotech
ArTara Therapeutics	Pfizer	Pharmaceutical Solutions
Asahi Kasei Pharma	Pharmacyclics	PPD
Aveo Oncology	Pharm-Olam	PRA International
AWAK Technologies	PolyPid	PSI-CRO
Bayer HealthCare	Regeneron	Syneos Health
BeiGene	resTORbio	Worldwide Clinical Trials (WCT)
Boehringer Ingelheim	Retrophin	
Brii Biosciences	Rhizen Pharmaceuticals	
Checkpoint Therapeutics	Roche	
CHO Pharma	SanBio	
CTC North	Sanofi-Aventis	
Dimerix	Tobira Therapeutics	
Douglas Pharmaceuticals	Tricida	
Eidos Therapeutics	VIR Biotechnology	
Elixir Medical Corporation	Zambon	
Enyo Pharma		
Fisher & Paykel Healthcare		
Galderma		
Gilead		

54 Unique sponsors requested trial feasibilities in FY19

Benefits of what we do

Health outcomes for participants in clinical trials are often better than those for patients receiving the usual 'standard of care' treatment.

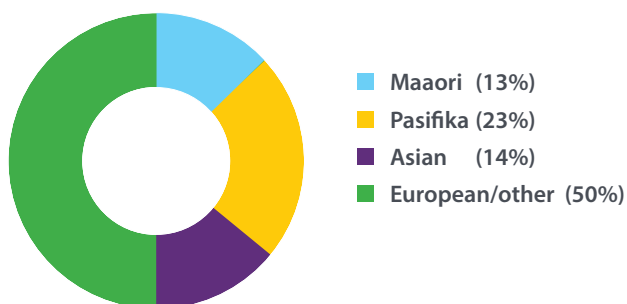
There are many reasons for this including the rigorousness of documented protocol driven care and robust patient education about their disease. Additionally our participants get access to cutting edge novel medications that are unavailable through the public health system.

When a patient is in a clinical trial the cost of the majority of their care including the medications is not paid for by the hospital, meaning considerable savings to the New Zealand public healthcare system.

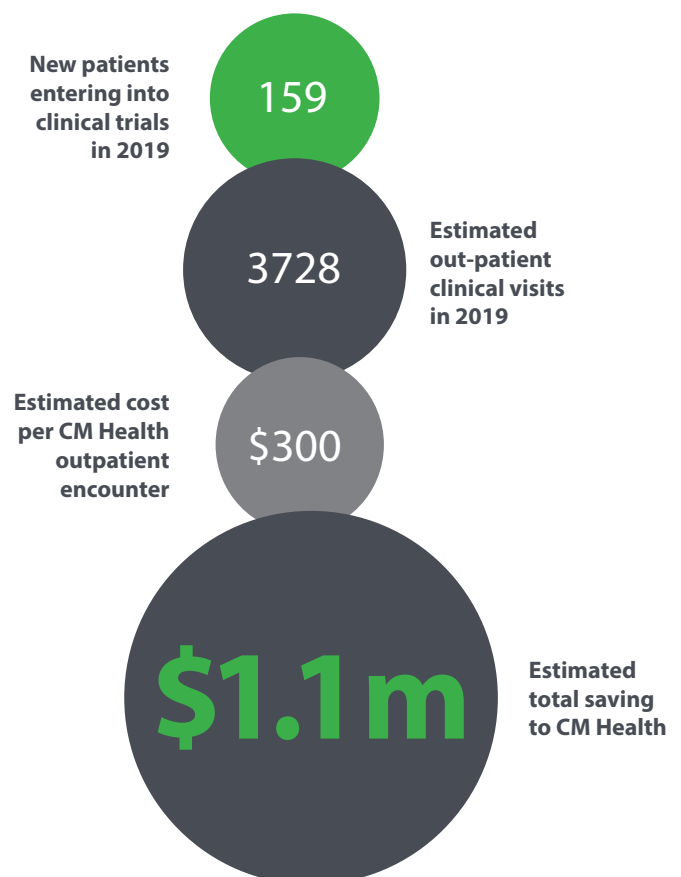
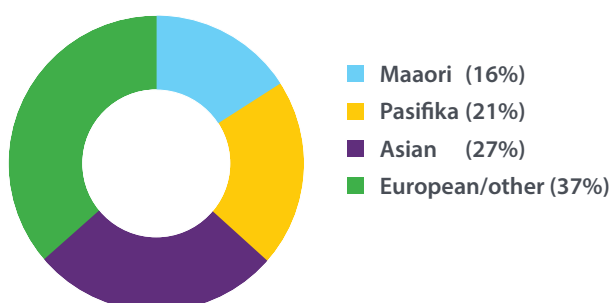
It is important to us, and written into our Trust deed, that our local population sees the benefits of participating in clinical trials. CM Health has the second largest Maaori and Asian population, and largest Pasifika population in New Zealand. A significant number of Maaori and Pasifika people live in socioeconomic deprivation (quintile 5) which contributes to overall poorer health compared to the wider New Zealand community.

Thirty six percent of our participants are Maaori and Pasifika, which closely reflects the ethnic breakdown of the CM Health resident population.

2019 Ethnicity Mix of Trial Participants



2019 Ethnicity of CM Health Resident Population





Mary Paul

MMCT
Research
Nurse



MMCT - Key areas of research by value 2019



Paediatric

The Paediatric team led by Dr Adrian Trenholme had another outstanding year, completing a large highly successful commercial maternal vaccine clinical trial and engaging with a portfolio of grant-funded studies.

MMCT – Fay Sommerville (research nurse).

CM Health – Dr Rebecca Thompson (sub-investigator), Dr Yiing Yiing (sub-investigator), Dr Flo Mow (sub-investigator), Marie Wilson (midwife), Naomi Apel (midwife), Evi van der Weigen (midwife), Adrienne Priday (contractor), Emma Collis (research nurse), Mandy Retter (research nurse), Judith Johnson Niuelua (midwife), Shirley Lawrence (research charge nurse).

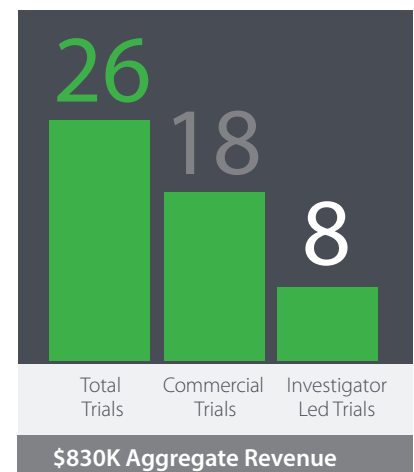


Haematology

The Haematology team led by Dr Sharon Jackson continues to maintain a highly active research program that provides a good blend of commercial trials and investigator-initiated network studies. These trials provide patients with access to medicines that otherwise are not available in New Zealand.

MMCT – Alice Cassidy (research nurse), Chris Giffney (research nurse), Anne Kendall (research nurse), Ella Liang (research nurse).

CM Health – Dr Samar Issa (investigator), Dr Gordon Royle (investigator), Dr Hilary Blacklock (investigator), Dr Rajeev Rajagopal (investigator), Dr James Liang (investigator).



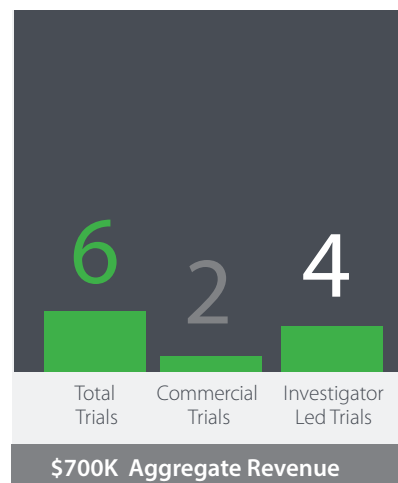


Renal

There continues to be strong interest in commercial trials in renal medicine in 2018/2019 under the leadership of Dr Christopher Hood.

MMCT – Lea Charlesworth (research nurse), Jamie Duckworth (research nurse), Penelope Eadie (research nurse), Brenda Luey (research nurse) .

CM Health – Dr Christopher Hood (investigator), Dr Daniel Lin (sub-investigator), Dr Viliami Tutone (sub-investigator), Dr Jonathan Hsiao (sub-investigator), Dr Hari Talreja (sub-investigator), Dr Noella Ahn (sub-investigator), Dr Dixon Lui (sub-investigator), Dr Jamie Kendrick-Jones (sub-investigator), Dr Elene Ly (sub-investigator), Dr Hla Thein (sub-investigator), Dr Michael Lam (sub-investigator), Dr Mark Marshall (investigator), Dr Rachel Walker (investigator).



Gastroenterology

This year has seen continuing increase in hepatology research at MMCT focusing on non-alcoholic steatohepatitis and chronic hepatitis B under the leadership of Dr Paul Casey. Dr Tien Huey Lim (hepatologist) is working closely with Professor Ed Gane (Auckland Clinical Studies) to attract more early-phase trials to MMCT.

MMCT – Eulyee Ahn (research nurse), Maryam Apat (research nurse), Sarah Baresic (research nurse), Ruth Cammell (research nurse), Lauren Fernyhough (research Nurse), Johanna van der Kolk (research nurse).

CM Health – Dr Tien Huey Lim (investigator), Dr Ashok Raj (sub-investigator), Dr Judy Huang (sub-investigator), Dr Cameron Schauer (sub-investigator), Dr Sum Tram Lo (sub-investigator), Dr Hannah Giles (sub-investigator), Dr Afrasyab Khan (sub-investigator), Dr Ming Han Lim (sub-investigator), and Dr Henry Wei (sub-investigator).





Rheumatology

Rheumatology research continues to be very active at MMCT and CM Health under the leadership of Dr Sunil Kumar. There has been a paradigm shift in standard care of many conditions such as rheumatoid arthritis with a number of innovative new treatments.

MMCT – Lea Charlesworth (research nurse), Mary Paul (research nurse), Cecilia Paul (research nurse), Sandy McGreevy (charge nurse manager).

CM Health – Dr Sunil Kumar (investigator), Dr Rajir Gupta (sub-investigator), Dr Mathew Reynolds (sub-investigator), Dr Sujatha Kamalaksha (registrar).



Diabetes

The diabetes team led by Dr Brandon-Orr Walker works closely with DHB clinicians to undertake a number of commercial sponsored clinical trials. A number of long-term events in 2017/2018, they started several new trials in diabetic kidney disease and a large privately sponsored diabetes in pregnancy registry project.

MMCT – Dr John Baker (investigator), Eulyee Ahn (research nurse), Maryam Apat (research nurse), Sarah Baresic (research nurse), Ruth Cammell (research nurse), Jamie Duckworth (research nurse), Penelope Eadie (research nurse), Lauren Fernyhough (research nurse), Susan Ross-Heard (midwife), Liz Walker (research nurse),

CM Health – Dr Brandon Orr-Walker (investigator), Dr Renate Koops (investigator), Dr Ian Rosen (sub-investigator).





Michael Naylor

MMCT
Finance Manager

Spotlight on Paediatrics

Adrian Trenholme – Principal Investigator (Paediatrics)

Firstly, we would like to acknowledge Professor Diana (Dinny) Lennon who died last year. Dinny led Paediatric research in South Auckland even though her brief was national. She was internationally recognised as an expert in acute Rheumatic Fever and Rheumatic Heart disease and led the development of the meningococcal vaccine which has benefitted South Auckland significantly. It was a sad loss for Kidz First.

Paediatric Research at Kidz First

We have a number of current areas of research in child health in South Auckland.

- Acute Rheumatic Fever research is currently led by Dr Rachel Webb who is an acknowledged expert in Rheumatic Heart Disease, 2D echo investigation and group A Strep disease. Rachel's current active research, both nationally and internationally, includes major collaborative studies about Group A Strep and vaccine development.
- Dr Jocelyn Neutze Paediatric FACEM (Fellow of the Australasian College of Emergency Medicine) is part of the PREDICT collaborative network for Australasia which is internationally recognised as a leading research group.
- Our neonatal unit is extremely active in research. Associate Professor Michael Meyer is an active researcher, working with Fisher and Paykel in the development of neonatal equipment. We are fortunate that Dr Chris McKinlay has joined the team, with his expertise in the nutritional impact of the perinatal period on neonatal welfare and factors impacting on respiratory illness in infancy. His knowledge is particularly relevant with the current PIPPA Tamariki study of the impact of Paracetamol on asthma.
- Dr Christine McIntosh, a General Practitioner with the Auckland University, and is the national expert on Sudden Unexpected Death in Infancy (SUDI). Christine is leading a national program in the development of a SUDI tool which assesses risk factors, particularly for Maaori and Pasifika infants.
- I (Dr Adrian Trenholme) have been involved in research of acute and chronic respiratory illness and in conjunction with Professor Cass Byrnes from Starship Hospital, led the Health Lungs Study, which was an HRC funded study. Currently the Lungs for Life program is in development, this study aims to identify children at risk of bronchiectasis in the early stages.
- Our team also has a strong history of involvement in commercial research, particularly with immuno-prophylaxis of RSV (Respiratory Syncytial Virus) disease, having worked with various sponsors on five studies in the past. We are currently engaged in ongoing immuno-prophylaxis research. A major study we have been involved with over the last 5 years has been a maternal vaccine in pregnancy against RSV where we enrolled 150 local women and were major contributors to the world-wide study which has shown an effective vaccine.

Paediatrics in the local community

Our local population has significant issues with equity of healthcare. Sixty per cent (60%) of our birth cohort are born into quintile 5 and a majority of those are Maaori and Pasifika. This is a huge issue for Maaori health, so our aim is to develop a Maaori child health research collaboration strategy where Maaori have governance of the research agenda, a shared approach to research and development of Maaori and Pasifika research staff. We acknowledge that in the past the Maaori and Pasifika world view has not been acknowledged and has not led the process, and this must change. This Strategy will be developed through a process involving Middlemore Clinical Trials, South Auckland Clinical School, University of Auckland and CM Health.

The Paediatric team are pleased to share that through our participation in commercial research it has enabled us to accrue funds for a Kidz First Research Fund. Dinny was quite clear, and the team all agreed, that the aim of doing commercial research was to involve local people in research that would help them. Hence the Rheumatic Fever and RSV research studies provided expensive treatment which was not available locally. Additionally, commercial research would help develop a fund which could be used for local research to benefit the local population.

So far those funds have employed a Paediatric Research Fellow for the past 3 years looking at post Streptococcal Glomeronephritis, acute Rheumatic Fever and Meningococcal Disease. Additionally, a Midwifery Research Fellow, a Physiotherapy Research Fellow and a Nursing Research Fellow looking at chronic lung disease and immunisation in pregnancy. The team is very proud of this and part of our research program goal going forward will be to employ Maaori and Pasifika Research Fellows and PhD students. To this end Dr Shanti Ameratunga has been employed from the same resource. Shanti is a world recognised public health medicine specialist with expertise in grant applications and PhD supervision. The future looks very exciting. The Paediatric team are in the process of appointing the next Professor of Paediatrics who, of course, cannot replace Dinny but will move forward our research with a focus on Maaori and Pasifika child health.



KIDNEY FIRST

Visitor's Entrance



COUNTIES
MANUKAU
HEALTH

I was also part of the SHIVERS team (headed by Sue Huang at Institute of Environmental Science and Research (ESR)). The team were awarded the New Zealand Association of Scientists (NZAS) Shorland Medal for 2019. The Medal is awarded in recognition of major and continued contribution to basic or applied research that has added significantly to scientific understanding or resulted in significant benefits to society.

The SHIVERS study was a Centre for Disease Control sponsored study looking at respiratory virus surveillance as a Southern Hemisphere initiative. This study has helped the government to decide to give free immunisation to certain children and given us the knowledge that Maaori, Pasifika and poor people carry the burden of this disease. The serology survey also showed that neuraminidase antibodies are quite important, and has led to a further prospective cohort study being carried out in Wellington looking at evolution of antibodies against influenza.



1: Awards presentation showing the SHIVERS team receiving the NZAS Shorland Medal for the Institute of Environmental Science and Research. 2: Sue Huang, Adrian Trenholme with certificates celebrating the Shorland Medal 3: Adrian Trenholme at Kidz First Hospital.

6 Medical Publications came from the Paediatric team in FY19

MMCT Trust outcomes

Middlemore Clinical Trials is a Charitable Trust. Our Charitable Trust status requires that we demonstrate ongoing investment in Public Good activities.

Trust funds are held as either general reserves or departmental funds.

General Reserves

As at 30 June 2019, total general reserves were \$1.44 million (30 June 2018, \$2.07 million).

Granting spend from General Reserves in FY19

Spend Category	\$	%
Diabetes in Pregnancy Registry*	66,294	42.3 %
Evaluation of Research Projects*	30,000	19.1 %
WORTH - Diabetes 2 glycaemic response	25,000	16.0 %
Research Administrator trainee (Jul - Jan)	27,251	17.4 %
Sponsorships / Scholarships / Donations	8,147	5.2 %
Total	156,692	100 %
* Metabolic Health		

Designated / Restricted Reserves

While commercial / grant trials are in progress, the aggregate surplus in both segments is deemed part of total departmental funds. However, these amounts do not formally vest into a Department's Designated Reserve until a trial closes, hence they are unavailable for granting spend until that time. As at 30 June 2019, commercial / grant trials in progress showed an aggregate net surplus of \$1.84 million (30 June 2018, \$1.59 million).

Designated / restricted reserves may be spent at the discretion of department heads on research and academic activities consistent with the Trust Deed. In May 2016 the Trustees decided that department heads should spend at least 10% of departmental reserves each year.

As at 30 June 2019, total designated / restricted reserves were \$4.79 million (30 June 2018, \$4.94 million).

Granting spend from Designated / Restricted Reserves in FY19

Spend Category	\$	%
Research Fellows	265,194	45.6 %
Research Nurses / Co-ordinators / Physios	183,096	31.4 %
Research Costs	28,823	5.0 %
Conferences / Courses / Training	85,243	14.7 %
Equipment / IT	11,428	2.0 %
Publishing	7,524	1.3 %
Total	581,308	100 %

Departmental Breakdown of Granting from Designated / Restricted Reserves

Clinical Speciality	Opening Balance	FY19	
	01-Jul-18 \$	Granting \$	Used %
Paediatrics	466,115	273,832	58.7 %
Dermatology	18,829	5,000	26.6 %
Hand / Upper Limb	186,059	48,135	25.9 %
Neonatal	45,774	9,772	21.3 %
Gastroenterology	167,253	26,986	16.1 %
Rheumatology	167,663	26,429	15.8 %
Renal	176,698	26,909	15.2 %
Intensive Care Unit	383,403	48,911	12.8 %
Diabetes	24,061	2,422	10.1 %
Cardiology			
- Designated / Restricted	1,579,196	75,448	4.8 %
Respiratory	618,216	21,246	3.4 %
Home Health	27,677	517	1.9 %
Haematology	842,550	15,701	1.9 %
Other*	240,214	-	-
Total	4,943,708	581,308	11.8 %
*Infectious Diseases, Emergency Care, Stroke, Spinal Radiology, Microbiology, Oropharyngeal, Women's Health			

Diabetes in Pregnancy Registry (DiPR)

The Freemasons Roskill Foundation donated \$105,832 to support the establishment of the program in 2016 and a further grant of \$41,916 in November 2017. The program involved a 1-year pilot study and collection of retrospective data on 2,500 women who attended diabetes in pregnancy clinic in the previous 5 years. In FY19, total spend on this program was \$66,294.

The Middlemore Foundation provided a grant of \$40,250 in April 2018 for the evaluation and cost benefit analyses of the DiPR and a Diabetes Care Support Service Audit of Primary Care. Both evaluations are conducted by Professor David Simmons of Western Sydney University. In FY19, total spend on these evaluations was \$30,000.

Research week

The MMCT Board of Trustees donated \$5,000 to CM Health Research Office to support Research Week.

Nurse/Midwifery Conference Sponsorship Award

Fortune Ngwenya (Renal Access Coordinator) was granted \$3,100 to attend the Australian and New Zealand Society of Nephrology (ANZSN) and Australia and New Zealand Society of Interventional Nephrology (ANZSIN) Conference in Sydney in September 2018.

Research Administrator Trainee (July-January)

In 2018, the Board of Trustees approved funding for a 1-year trainee role to provide a career development pathway for graduates of the University of Auckland Masters of Bioscience Enterprise programme. Chaewoo Jun was appointed in April 2018 and was made a fulltime member of MMCT's staff in January 2019.

Which One is Right Here? (WORTH)

This Grant study (300 participants, of whom 60 are MMCT) is sponsored by University of Auckland, and two CMDHB PIs and several MMCT nurses / coordinators are working on it. WORTH is a Phase IV type 2 Diabetes trial, seeking to test the response to two new medications on patients with sub optimal glycaemic control on current standard therapy, and to analyse participant glucose response to each test medication according to key baseline characteristics such as ethnicity (Maaori/Pasifika v non-Maaori/Pasifika), genetics, obesity and lipid levels.

WORTH fits with MMCT's granting priority, in funding research that benefits our South Auckland / Counties Manukau communities. Accordingly, our Trustees granted \$74,000 funding in 2018 to cover medication dispensing fees, database development and statistical analysis of results. Of this total, \$25,000 was disbursed in FY19 based on study milestones met through to June 2019.



Chaewoo Jun. MMCT Business Analyst

\$738K

Was distributed from the Trust in FY19



Ella Lang

MMCT
Research Nurse



FY19 Medical Publications from research funded by MMCT Trust

- 1 **Hershnerger et al.** Safety and efficacy of monoclonal antibody VIS410 in adults with uncomplicated influenza A infection: results from a randomised, double-blind, phase-2, placebo-controlled study. *EBioMedicine*, Feb 2019, 40: 574-582.
- 2 **Zhang, Yiling.** Audit of FLOT perioperative chemotherapy for resectable gastric or gastro-oesophageal junction adenocarcinoma in Auckland Area - Audit Poster Presentation at NZSO2019 conference.
- 3 **Slavisa Ninkovic, Rajeev Rajagopal et al.** Carfilzomib, Thalidomide and Dexamethasone (KtD) is safe and effective in RRMM: Interim analysis of the single arm, multicentre phase II ALLG MM08/AMN002 study – Poster Presentation at International Myeloma Workshop.
- 4 **Rajagopal R, Bennett R et al.** Refractory postallogeic stem cell transplant pure red cell aplasia in remission after treatment with daratumumab. *American Journal of Hematology*, May 2019, DOI: 10.1002/ajh.25515.
- 5 **Bigby SM, Blenkiron C, Murhukarrupan A.** Vulval Cancer: Investigation the molecular link between primary cancers and background skin – Poster Presentation at Middlemore Research Week.
- 6 **Mascarenhas J, Blacklock H et al.** Outcomes of patients with myelofibrosis treated with compassionate use pacritinib: a sponsor-independent international study. *Ann Hematol.* 2018 Aug;97(8):1369-1374. doi: 10.1007/s00277-018-3309-6. Epub 2018 Apr 3.
- 7 **Ho PJ, Moore EM, Blacklock H et al.** Renal Impairment at diagnosis in Myeloma: Patient characteristics, treatment, and impact on outcomes. Results from the Australia and New Zealand Myeloma and Related Diseases Registry. *Clin Lymphoma Myeloma Leuk.* 2019 Aug;19(8):e415-e424. doi: 10.1016/j.clml.2019.05.010. Epub 2019 May 16.
- 8 **Mateos MV, Blacklock , KEYNOTE-183 Investigators et al.** Pembrolizumab plus pomalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma (KEYNOTE-183): a randomised, open-label, phase 3 trial. *Lancet Haematol.* 2019 Sep;6(9):e459-e469. doi: 10.1016/S2352-3026(19)30110-3. Epub 2019 Jul 18.
- 9 **Usmani SZ, KEYNOTE-185 Investigators et al.** Pembrolizumab plus pomalidomide and dexamethasone for patients with treatment-naïve multiple myeloma (KEYNOTE-185): a randomised, open-label, phase 3 trial. *Lancet Haematol.* 2019 Sep;6(9):e448-e458. doi: 10.1016/S2352-3026(19)30109-7. Epub 2019 Jul 18.
- 10 **Foo FS, Kerr A, Gabriel R, Heaven D, Looi JL, Lund M, Voss J, Sutton T.** Early direct current cardioversion or ablation for atrial fibrillation or atrial flutter and acute decompensated heart failure. *New Zealand Medical Journal.* 2019; 132:39-46.
- 11 **Kerr A, Wells S, Moffitt A, Lund M, Kreichbaum J, Harwood M, Jackson R.** A unified national cardiovascular disease (CVD) risk generator is required to address equity in the management of CVD risk in clinical practice in New Zealand. *New Zealand Medical Journal.* 2019; 132:89-94.
- 12 **Looi JL, Lee M, Grey C, Webster M, To A, Kerr AJ.** Seasonal variation in Takotsubo syndrome compared with myocardial infarction: ANZACS-QI 16. *New Zealand Medical Journal.* 2018; 131:21-9.
- 13 **Looi JL, Lee M, Webster MWI, To ACY, Kerr AJ.** Postdischarge outcome after Takotsubo syndrome compared with patients post-ACS and those without prior CVD: ANZACS-QI 19. *Open Heart.* 2018; 5:e000918.
- 14 **Wong LL, Lund M, et al.** Combining Circulating MicroRNA and NT-proBNP to Detect and Categorize Heart Failure Subtypes. *J Am Coll Cardiol.* 2019 Mar 26;73(11):1300-1313. doi: 10.1016/j.jacc.2018.11.060.

- 15 **Tan ESJ, Lund M et al.** Ethnic differences in atrial fibrillation in patients with heart failure from Asia-Pacific. *Heart*. 2019 Jun;105(11):842-847. doi: 10.1136/heartjnl-2018-314077. Epub 2019 Jan 19.
- 16 **Kluger N, Doughty R, Poppe K, Earle N, Aish S, Cameron V, Rolleston A, Kerr A.** Factors Affecting Blood Sampling in Acute Coronary Syndromes: Relationship to Patient and Logistic Factors- A MENZACS Substudy. *Heart, Lung and Circulation*, Vol. 28, S20.
- 17 **Wong SP, Jacobsen K, Signal N, Chan C, and Voss J.** Validation of the Samsung S-Patch - A Novel Ambulatory ECG Monitoring Device Circulation. 2018;138:A15566.
- 18 **Prasad N, Trenholme AA, Huang QS, Thompson MG, Pierse N, Widdowson MA, Wood T, Seeds R, Taylor S, Grant CC, Newbern EC; SHIVERS team.** Interactive effects of age and respiratory virus on severe lower respiratory infection. *Epidemiol Infect*. 2018 Jul 26;1-9. doi: 10.1017/S0950268818002017.
- 19 **Huang QS, Bandaranayake D, Wood T, Newbern EC, Seeds R, Ralston J, Waite B, Bissielo A, Prasad N, Todd A, Jelley L, Gunn W, McNicholas A, Metz T, Lawrence S, Collis E, Retter A, Wong SS, Webby R, Bocacao J, Haubrock J, Mackereth G, Turner N, McArdle B, Cameron J, Reynolds G, Baker MG, Grant CC, McArthur C, Roberts S, Trenholme A, Wong C, Taylor S, Thomas P, Duque J, Gross D, Thompson MG, Widdowson MA; SHIVERS investigation team.** Risk factors and attack rates of seasonal influenza infection: results of the SHIVERS seroepidemiologic cohort study. *J Infect Dis*. 2018 Jul 17. doi: 10.1093/infdis/jiy443.
- 20 **Bissielo A, Pierse N, Huang Q, Thompson M, Kelly H, Mishin V, Turner N, SHIVERS.** Effectiveness of seasonal influenza vaccine in preventing influenza primary care visits and hospitalisation in Auckland, New Zealand in 2015: interim estimates. *Euro Surveill*. 2016;21(1);pii=30101. DOI: <http://dx.doi.org/10.2807/1560-7917.ES.2016.21.1.30101>.
- 21 **Turner N, Pierse N, Huang QS, Radke S, Bissielo A, Thompson MG, Kelly H, on behalf of the SHIVERS investigation team.** Interim estimates of the effectiveness of seasonal trivalent inactivated influenza vaccine in preventing influenza hospitalisations and primary care visits in Auckland, New Zealand, in 2014. *Euro Surveill*. 2014;19(42);pii=20934. Article DOI: <http://dx.doi.org/10.2807/1560-7917.ES2014.19.42.20934>.
- 22 **Trenholme AA, Best EJ, Vogel AM, Stewart JM, Miller CJ, Lennon DR.** Respiratory virus detection during hospitalisation for lower respiratory tract infection in children under 2 years in South Auckland, New Zealand *J Paediatr Child Health*. 2017 Jun;53(6):551-555. doi: 10.1111/jpc.13529. Epub 2017 Apr 21.PMID:28430397.
- 23 **McIntosh C, Trenholme A.** Evaluation of a sudden unexpected death in infancy intervention programme aimed at improving parental awareness of risk factors and protective infant care practices 2017 Nov *Journal of Paediatrics and Child Health* DOI: 10.1111/jpc.13772 Internal Article ID: 14677692.



Te Kohinga Ora

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