ON TRACK NETWORK
BETTER HEALTH FOR MOTHERS AND BABIES
Te Awhi Rito

ON TRACK

Welcome to our October ON TRACK Network newsletter

Kia ora. Welcome to the October edition of ON TRACK news. This month we provide an update on the ON TRACK Network Research Prioritisation Project, we introduce you to one of our Network midwifery leaders engaged in various Network activities and we take a look at the TREAT PARENTS Trial in Update Your Practice.

Research News

Neuroprotection of the perinatal brain

The **MagNUM Study** has shed light on how antenatal magnesium sulphate exerts neuroprotective effects upon the fetus. Antenatal magnesium sulphate is recommended in clinical practice guidelines worldwide for women at risk of very preterm birth to reduce the risk of infant death or cerebral palsy. Despite widespread adoption of its use, we have been uncertain how given prior to preterm birth it exerts neuroprotective effects upon the perinatal brain. **The aim of the MagNUM Study was to assess the effect of exposure to antenatal magnesium sulphate on MRI measures of brain white matter at term equivalent age.** The recently published findings show that **magnesium sulphate prior to preterm birth promotes white matter development in pathways important for motor and cognitive function**. Read more: https://doi.org/10.1016/j.ebiom.2020.102957.

MagNUM was a nested cohort study within the Network supported MAGENTA Trial.

Funding call for research into achieving equitable maternal and infant health outcomes

The **Health Research Council** and Ministry of Health have announced a request for proposals to fund research that will directly inform the development of policy and practice for Aotearoa New Zealand's maternity services to achieve equitable maternal and infant health outcomes, and support a quality improvement culture within maternity services. Further details are available here (or visit the HRC website: https://gateway.hrc.govt.nz/).

Research Prioritisation Project update

The ON TRACK Network Research Prioritisation Project aims to set the future clinical trials research agenda for mothers and babies health in New Zealand. The project's Ranking Group recently met with over 50 members participating via zoom from across the country.

Effective research prioritisation allows the most efficient use of research resources to optimise health and healthcare. A transparent, systematic and equity-focussed framework that reflects the unique social and geographic context of maternal and perinatal health and healthcare in New Zealand has been developed specifically for this project.

We would like to thank all women and whānau, clinicians, researchers, funders and policymakers who contributed their ideas of knowledge gaps and research questions. Our investigator team assisted by a multi-disciplinary national Advisory Group have sorted and developed these research ideas over the last few months in preparation for the ranking process.

The Ranking Group including consumer representatives, policy-makers, funders and clinicians and researchers from a broad range of disciplines met on the 14th September to kick-off the process of ranking questions. They are faced with an exciting but sizeable task with a total of **359 research questions that are amenable to a randomised trial or large prospective cohort study** being developed from the 3,347 knowledge gaps collected.

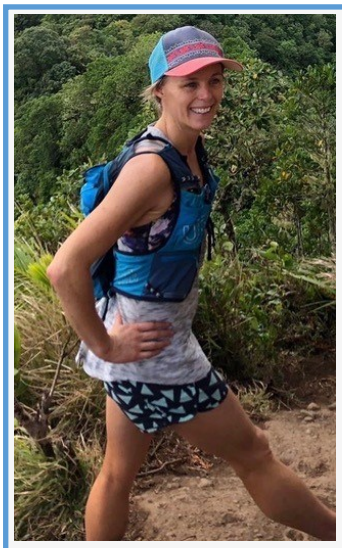
We aim to report New Zealand's top priority clinical trials research questions in mothers and babies health before the end of this year and will be sharing many more research ideas identified during the course of the project.

Trial Development Workshop 2021 - Call for concepts now open!

If you have an idea for a clinical trial in maternal, perinatal or neonatal health, why not bring it along to our 5th annual Clinical Trial Development workshop taking place in Auckland 25th & 26th February 2021? We consistently receive great feedback from all concept lead investigators who have previously taken the plunge. The workshops are informative, fun, supportive and can help connect you with people who share your enthusiasm for improving health of New Zealand mothers and babies through clinical trials research.

Download an application form here
You can register to attend the workshop here
Or visit our website: **https:/ontrack.perinatalsociety.org.nz/**

Apply Now



Interested in getting involved with clinical trials and the Network? One of our Network midwifery leaders explains why she loves to work with the team

This month we caught up with **Phoebe de Jong, Midwife at Tauranga Hospital**. Phoebe wears a number of ON TRACK Network hats. She is involved with recruiting to ON TRACK Network supported clinical trials, is a member of the Network's National Executive Committee, and is a member of the Network's Forum for Women & Whānau Advisory Group. With such amazing commitment to the ON TRACK Network, we wanted to take the opportunity to hear from Phoebe in her own words what motivates her as a midwife to be so involved.

"I find being involved at the coal-face of research a very positive aspect to my work. It allows opportunity to get to know women and their whānau at a very precious moment in their lives."

Please tell us a little about your background. I am a practicing midwife and currently work as the clinical co-ordinator for the antenatal out-patient service at BOPDHB (Tauranga Hospital). I have always had a strong interest in health and wellbeing, in particular women's health. After completing a degree in physical education at Otago University I went onto midwifery which has managed to encapsulate both those interests. I have been fortunate enough to have a diverse and fulfilling career involving LMC, core tertiary and secondary care, co-ordination and more recently research.

What is it that motivates you to be involved with clinical trials research in your midwifery practice? I have always wanted to be guided by evidenced based practice in my work and have also had a natural tendency towards seeking answers and rationales as to why things are done a certain way. Seeing the benefits of research projects that are being carried out here in New Zealand is also hugely motivating. For example, I have worked in both Auckland and Tauranga from the very early pilot trial for hPod (Hypoglycaemia Prevention with Oral Dextrose) (Jane Harding *et al*) right through to its completion as a large trial. The findings have significantly improved outcomes for women and their babies as well as changing practice.

On the Forum for Women & Whānau Advisory Group you work alongside consumers to involve parents in shaping clinical trials research. Why do you think this is so important? Parents are arguably the most important party to involve given the reason we are all contributing to research is to improve outcomes for women and their whānau.

"The insights women and parents can give to shaping research is paramount to ensure women feel confident and willing to participate in trials. It also forces me to challenge the way I think as a practitioner; so it is a really exciting part of the work."

"I see the Network and clinical trials as a real 'door opener' and a way to broaden my career. "

What do you enjoy most about your involvement with clinical trials research and the Network, and why? It is really stimulating being part of such a diverse multidisciplinary team that the Network has attracted. It has allowed me to meet some very interesting and inspiring people. Midwifery can be very demanding and exhausting at times and research is a great option for diversification, whilst still very much providing women-centred care in a clinical setting.

What advice would you give to your colleagues who are interested in getting involved in clinical trials research? Absolutely consider clinical trials research, there are so many options depending on your interests. I would encourage colleagues to ask around about what is happening in your DHB or area. The ON TRACK Network and the Liggins Institute give lots of examples of research opportunities currently available. Research creates opportunities to learn and develop which can be another way to give you enormous fulfilment in your career.

Keeping the ON TRACK Network on track!

A clinical trials network such as ON TRACK requires a committee to develop and ensure compliance with a strategic plan; a committee that builds capacity across the Network and enhances and supports its day to day activities. The ON TRACK Network **National Executive Committee (NEC)** was established in 2016 for this purpose.

The NEC, which is representative across the disciplines of maternal and perinatal health and includes consumer representatives, meets every 2 months. With members across the country, the committee is well accustomed to addressing business via zoom meetings - even prior to COVID! October's virtual meeting was no different to any other NEC meeting with a busy agenda discussing items including the Research Prioritisation Project, Trial Development Workshop, Forum for Women and Whānau and much more.

You can find further details of the committee and its members on our website: https://ontrack.perinatalsociety.org.nz/who-we-are/. If you have any questions about/for the committee, please feel free to email us: ontracknetwork@auckland.ac.nz. Our committee members are always very happy to be of help!

Update Your Practice: Treating Parents to Reduce Neonatal Transmission of *Staphylococcus aureus* (TREAT PARENTS) trial

JAMA. 2020;323(4):319-328. doi:10.1001/jama.2019.20785

Background: *Staphylococcus aureus (S.aureus)* is a leading cause of healthcare associated infections in neonatal intensive care units. Exposing neonates to *S.aureus* colonisation is a well established predisposing factor to invasive *S.aureus* disease, which despite appropriate therapy can have long term consequences including poor neurodevelopmental and growth outcomes. Many infection prevention strategies focus on health care workers and the physical environment as reservoirs for neonatal exposure to *S.aureus*, but parents may also be an important reservoir for *S.aureus* transmission.

Methods: The TREAT PARENTS trial was a double-blind randomised controlled trial designed to test the hypotheses that parents are a primary reservoir from which neonates acquire *S.aureus* colonisation and that treating *S.aureus* colonised parents with intranasal mupirocin and topical chlorhexidine gluconate antisepsis would reduce the spread of *S.aureus* from parents to their neonates. The trial recruited participants from two neonatal intensive care units in the US between 2014 and 2018. Parents were assigned to the active arm of intranasal mupirocin and 2% chlorhexidine impregnated cloths (n=117) or the placebo arm of petrolatum intranasal ointment and non-medicated soap cloths (n = 119) for 5 days.

The primary outcome was concordant *S.aureus* colonisation by 90 days, defined as neonatal acquisition of a *S.aureus* strain the same as a parental strain at time of screening. Secondary outcomes included neonatal acquisition of any *S.aureus* strain and neonatal *S.aureus* infections.

Summary of primary and secondary outcomes

Time-to-Event Outcomes	2% Mupirocin +2% Chlorhexidine Cloths			Placebo			Treatment Effect: HR (95% Bias-Corrected and Accelerated CI)[a]
	No. of Events	Days at Risk	Rate per 100 d	No. of Events	Days at Risk	Rate per 100 d	
Primary outcome							
Concordant *S aureus* acquisition[b]	13	1736	0.75	29	1681	1.73	0.43 (0.16 to 0.79)[c]
Secondary outcomes							
Concordant *S aureus* acquisition[d]	15	1751	0.86	29	1713	1.69	0.50 (0.20 to 0.92)
Any *S aureus* acquisition[b]	28	1736	1.61	46	1681	2.74	0.57 (0.31 to 0.88)
Any *S aureus* acquisition[d]	30	1751	1.71	46	1713	2.69	0.62 (0.34 to 0.95)
S aureus infection[e]	1	1863	0.05	1	1799	0.06	NC[f]
Bloodstream infection, any organism[g]	4	1794	0.22	2	1748	0.11	NC[f]
Binary secondary outcomes	No. of Events	No. at Risk	%	No. of Events	No. at Risk	%	Treatment Effect: Risk Difference, % (95% Bias-Corrected and Accelerated CI)[a]
Concordant *S aureus* acquisition							
By 4 wk	11	89	12.4	27	101	26.7	−14.4 (−31.2 to −4.7)
By 8 wk	13	89	14.6	28	101	28.7	−14.1 (−30.8 to −3.9)
Any *S aureus* acquisition							
By 4 wk	22	89	24.7	38	101	37.6	−12.9 (−29.9 to −1.3)
By 8 wk	28	89	31.5	45	101	44.6	−13.1 (−31.2 to −0.3)
S aureus infection							
By 4 wk	1	89	1	1	101	1	NC[f]
By 8 wk	1	89	1	1	101	1	NC[f]
Mortality	0	101	0	3	107	2.8	NC[f]

Results: Of 236 randomised neonates, 208 were included in the analysis (55% male; 76% singleton births; mean birth weight, 1985 g [SD, 958 g]; 76% vaginal birth; mean parent age 31 [SD, 7] years) with 18 lost to follow-up.

Of 190 neonates included in the analysis 74 (38.9%) acquired *S.aureus* colonisation by 90 days of which 42 (56.8%) had a strain concordant with a parental baseline strain. In the intervention and placebo groups 13 of 89 neonates (14.6%) and 29 of 101 neonates (28.7%) respectively, acquired concordant *S.aureus* colonisation (risk difference, –14.1% [95%CI, –30.8% to –3.9%]; hazard ratio [HR] 0.43 [95.2%CI, 0.16 to 0.79]).

A total of 28 of 89 neonates (31.4%) in the intervention group and 46 of 101 (45.5%) in the control group acquired any *S.aureus* strain (HR 0.57 [95%CI, 0.31 to 0.88]), and 1 neonate (1.1%) in the intervention group and 1 neonate (1.0%) in the control group developed an *S.aureus* infection before colonisation. Skin reactions in parents were common (4.8% in the active arm and 6.2% in the placebo arm).

Interpretation: The authors concluded treatment with intranasal mupirocin and chlorhexidine-impregnated cloths compared with placebo significantly reduced neonatal colonisation with an *S.aureus* strain concordant with a parental baseline strain.

What do these results mean for New Zealand practice and future research? The TREAT PARENTS trial being a preliminary trial based in just two US neonatal units will not change practice here in New Zealand but it does highlight the possibility of future research to see if the findings can be replicated in the New Zealand setting.

New Zealand Trials		New Zealand recruits
C*STEROID	Corticosteroids before planned caesarean section from 35^{+0} to 39^{+6} weeks of pregnancy	2 (92 feasibility)
DIAMOND	DIfferent Approaches to MOderate & late preterm Nutrition	362
FIIX Trial	The Fertility, IVF and Intrauterine Insemination trial in couples with uneXplained infertility	153
LATTE Dosage	The most effective and best tolerated dose of caffeine to reduce intermittent hypoxaemia	117
Little Eye Drop	Phenylephrine and Cyclopentolate Eye Drops in Neonates **ADHB now recruiting!**	61
NeoGluco	Neonatal Glucose Care Optimisation Study (I) **ADHB now recruiting!**	18
OBLIGE	Comparing two methods of starting an induction of labour in pregnant women (balloon at home versus hormone gel in hospital) to assess chance of vaginal birth	858
PAEAN	Preventing Adverse Outcomes of Neonatal Hypoxic Ischaemic Encephalopathy with Erythropoietin	63
PIPPA	Paracetamol and Ibuprofen in Primary Prevention of Asthma	1765
PLUSS	Preventing Chronic Lung Disease in Extremely Preterm Infants Using Surfactant + Steroid	59
PROTECT	IV pentoxifylline as adjunct therapy to improve long-term disability in preterm infants	33
Recruitment completed - follow up to primary outcome ongoing		
C*STEROID Feasibility	C*STEROID Feasibility: Corticosteroids before planned CS form 35^{+0} to 39^{+6} weeks	
ECOBABe	The ECOBABe study (Early Colonisation with Bacteria After Birth)	
GEMS	Gestational Diabetes Mellitus Trial of Diagnostic Detection Threshold	
MAGENTA	Magnesium Sulphate at 30 to 34 weeks' gestational age: Neuroprotection Trial	
PROVIDE	Higher IV protein intake for extremely low birthweight babies in the first week after birth on survival free from neurodevelopmental disability at 2 years' corrected age	
Childhood outcome studies		
hPOD@2YR Follow-up Study	Hypoglycaemia Prevention in newborns with Oral Dextrose	
TARGET Follow up Study	Optimal glycaemic targets for women with gestational diabetes: the randomised trial	

Save the date **ACTA Summit 2020** 30 Nov - 4 Dec 2020 (Virtual) - https://clinicaltrialsalliance.org.au/

PSANZ IMPACT Network (Virtual) Meeting & Symposium 6 Nov 2020 -https://www.psanz.com.au/

Nga Maia National Hui/AGM 2020 - *postponed until next year* - https://www.ngamaia.co.nz/

Society for Maternal Fetal Medicine **41st Annual Pregnancy Meeting 2021 -** Las Vegas - 25-30 Jan 2021 - https://www.smfm.org/

PSANZ Annual Congress (2020 postponement) Sydney - 10-13 Feb 2021 (format to be confirmed) - https://www.psanz.com.au/

RANZCOG 2021 ASM Hobart 14-17 Feb 2021 - https://ranzcogasm.com.au/

ON TRACK Network Trial Development Workshop - Auckland - 25 - 26 Feb 2021 - https://ontrack.perinatalsociety.org.nz/

RANZCOG 2020 NZ Annual Scientific Meeting (2020 postponement) Wellington - 21 - 22 Jun 2021 - https://www.nzasm.org.nz/

New Zealand College of Midwives 16th Biennial National Conference - Christchurch - 2-4 Sept 2021 - https://www.midwife.org.nz

PSNZ 72nd Annual Scientific Meeting 2021 - Rotorua - 2-5 Nov 2021 - https://www.paediatrics.org.nz/