



ON TRACK Network

Trial Development Workshop 2019 Report

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Aims of ON TRACK Network Trial Development Workshops

The ON TRACK Network mission is to engage with, and energise research, in the maternal and perinatal health community to optimise health for pregnant women and their babies in New Zealand. The ON TRACK Network will *champion* the identification of priority research questions, *capacity-build* to allow the integration of high-quality, sustainable clinical trials into routine clinical practice, and *facilitate* the dissemination and implementation of research findings into clinical practice in all regions across New Zealand.

To deliver this mission, the ON TRACK Network’s current strategic plan contains objectives and associated key performance indicators, including a Trial Development Workshop to be held at least every two years. The operational aim of the workshops is to develop promising clinical trial concepts for collaborative

multi-centre, investigator-led clinical trials to a level suitable for highly competitive grant funding.

The workshops also help us to achieve aims and performance expectations of the ON TRACK Network by ensuring that:

- consumers are represented and have input into research concepts being developed for implementation across New Zealand
- at least two research concepts are progressed into funding applications / study protocols every 2 years
- detailed reports of clinical trials are maintained in terms of their progress through the trial development process
- research leads and their teams continue to be supported with developing research protocols, and that the ON TRACK Network facilitates wider uptake of those research protocols throughout New Zealand
- researchers are supported with competence in Māori responsiveness (for our 2019 workshop it was particularly timely to discuss Māori responsiveness with the anticipated changes to the HRC assessment criteria expected in 2020).

How the workshops run

The workshop process begins with a national call for submissions of clinical trial concepts. Individuals are invited to submit a proposed clinical trial idea using a pro-forma. Submissions are formally reviewed and selected by the ON TRACK National Executive Committee.

Each individual whose concept is selected (Concept Lead Investigator), is paired with, and supported by an invited facilitator who is an expert in the field with content knowledge and senior clinical trials experience.

Faculty experts are identified and invited. They may provide relevant introductory talks and/or provide expertise across the concepts, for example: biostatistics, health economics, consumer opinion, clinical trial design, funding, and Māori health/research.

Registration for the workshop is open to all. In particular, investigator teams are all encouraged to attend with invites to potential collaborators. Once concepts have been selected these are advertised to encourage attendance by interested clinicians and emerging researchers.

The programme is developed to include:

- introductory talks; delivery of concepts (presented as 'pitches')
- parallel sessions for group work
- trial proposal submissions

- mock funding panel
- further group work on feedback received
- a final summary session including next actions.

Whilst listening to the 'pitches', independent workshop participants select which clinical trial concept to attend during the group sessions that run in parallel throughout the meeting. Participants can select to attend more than one concept group depending on their own interests.

Nominated Facilitators and Concept Lead Investigators guide discussion within each small group. Expert faculty members rotate across all concept group discussions throughout the duration of the workshop.

At the end of day one, Concept Lead Investigators submit a 2-3 page summary of progress using an extended submission proforma. These are reviewed overnight by mock funding panel reviewers who provide critique on the morning of day two.

Each workshop closes with a summary of actions for Concept Lead Investigators, together with discussion of how the ON TRACK Network can provide ongoing support to each concept.

Past workshops

Previous workshops have been very successful with several concepts evolving into funded and active trials. Examples of success from our 2017 workshop are:

- The OBLIGE Trial. A New Zealand-wide trial comparing the use of outpatient balloon versus inpatient prostaglandin for induction of labour (funded by the Health Research Council (HRC) and Auckland Academic Health Alliance). This trial is currently actively recruiting.
- The LATTE Trial assessing the effect of caffeine on neurodevelopment in late preterm babies. Dosage trial funded by the HRC. Recruitment commenced in February 2019. This is likely to be developed into a larger national multi-centre trial.
- The C*STEROID Trial to explore the effect of antenatal corticosteroids prior to planned caesarean section delivery from 35⁺⁰ weeks gestation on respiratory morbidity and glycaemic control. The C*STEROID Feasibility study is funded by Cure Kids, Lottery Health, and the Hugo Charitable Trust. It will commence recruitment at two sites within the next 2-3 months. A full project grant has been submitted to the HRC for a national multi-centre trial.
- The PINTO study to assess whether early intervention for women with pre-diabetes in pregnancy can improve outcomes has been developed into an observational study to gain additional data to support a future randomised trial.

These are very tangible examples of how valuable ON TRACK Network Trial Development Workshops are for developing and delivering important high quality clinical trials for women and babies across New Zealand.

With aims, operational delivery, and previous workshop examples in mind, this report provides the reader with an overview of the third ON TRACK Network Clinical Trials Development Workshop - 2019.

2019 ON TRACK Network Trial Development Workshop

Introduction

The third ON TRACK Trial Development Workshop took place at the Liggins Institute, University of Auckland Thursday 21st and Friday 22nd February 2019. This two-day workshop followed workshops held in 2017 and 2018, and focused on three clinical trial concepts selected by the ON TRACK National Executive Committee. Additional faculty members included biostatisticians, a health economist, two Māori health researchers and advisors, three consumer representatives, a Health Research Council (HRC) representative, and clinical trials teams.

Workshop promotion

The workshop was promoted via ON TRACK Network newsletters and our website; by flyers distributed via email and placed in clinical areas; and by direct verbal and email communications.

Promotion timeline:

- September 2018 newsletter – opening date for call for submissions for research ideas with a 'save the date' reminder
- October 2018 newsletter – front page advertising of the workshop and open of call for submissions by 16th November 2018
- November 2018 newsletter – Registration opening with details of three concepts included
- January 2019 and February 2019 – Registration reminders

Workshop specific flyers were distributed in hard copy and via email at the end of January 2019.

Registrations and attendance

Online registration opened in November 2018; we received 54 registrations and 49 of those attended the workshop.

Professional Group		Region		Discipline	
Consumer Representative	3	Auckland DHB	26	Allied Health/Other	18
Doctor	11	Australia	2	Midwifery	8
Maori Health Representative	3	Canterbury DHB	3	Neonatal Nursing	7
Midwife	6	Counties Manukau DHB	3	Neonatology	12
Nurse	7	Midcentral DHB	1	Obstetrics	9
Other	11	New Zealand Other	14		
Professor	8	Waitemata DHB	5		
Researcher	2				
Trial Coordinator	3				
Total	54		54		54

Workshop presentations

The workshop opened with introductory presentations:

1. 'ON TRACK Network overview, workshop overview, and developing a clinical trial' (Katie Groom).

The importance of clinical trials and the value of clinical trials networks was introduced. Background to the ON TRACK Network was provided, together with its strategic pillars, its structure and oversight. Workshop participants were also given a practical overview of how the workshop would run.

2. HRC Pathway to impact – considerations in your trial's development & grant submission (Lucy Pomeroy).

An introduction to the current New Zealand Health Research Strategy was presented. It covered the importance the HRC places on measureable and meaningful health impact of excellent research, and the HRC pathway to impact model.

3. Māori responsiveness – what does this really mean? How to respond throughout your trial's development & progress (Bev Lawton & Wendy Dallas-Katoa)

Colleagues from 'He Hono Wahine', introduced this subcommittee of RANZCOG, for the promotion of culturally acceptable and ethical research in Māori women's health. The presentation highlighted the concepts of partnership, participation, and protection, as well as the Te Ara Tika HRC Guidelines, and the importance of their implementation in clinical trial design.

4. Health Economics – why do you need to consider this now? (Richard Edlin)

This presentation highlighted some hurdles to clinical trials, explaining how with a focus on safety, efficacy, and quality, economic evaluation and impact can sometimes be overlooked during clinical trial design. Practical considerations for health economic evaluation (and more) were presented for trialists to consider during the trial design stage.

5. Central Coordinating Research Hub (Chris McKinlay)

The aims of the Maternal & Perinatal Central Coordinating Research Hub were presented with an overview of how the Hub works, and support and resources available for supporting trialists.

Presentations can be accessed via the ON TRACK Network website using the following link: <http://ontrack.perinatalsociety.org.nz/meetings-and-resources/past-meetings/>

Research concepts

Three concepts were submitted and selected for the workshop:

1. Sarah Harris: Communication and relationship focussed intervention to improve developmental and infant mental health outcomes at 2 years in children born very preterm (Facilitator: Trecia Wouldes)
2. Esther Calje: Blood transfusion versus intravenous iron for the treatment of severe postpartum anaemia (Facilitator: Jonathan Morris)
3. Annette Murphy: Preventing cold stress in the newborn while facilitating delayed cord clamping in emergency and elective caesarean section (Facilitator: Jennifer Dawson)

All Concept Lead Investigators provided a 10 minute 'concept pitch' on day one of the workshop.

The framework for each presentation was:

- Background and Rationale
- Aims and Objectives
- Design and Methodology
- Research Impact

- Maori Responsiveness
- Team Capability

Concept recommendations and suggested actions

Following group work discussion and the mock funding panel, suggestions for next steps for each of the clinical trial concepts were discussed amongst all workshop participants.

The question was also asked, "What can the ON TRACK Network do to help progress these concepts into actively recruiting clinical trials?"

Suggested actions/next steps are summarised below.

A communication and relationship focused intervention	Blood transfusion versus intravenous iron	Preventing cold stress in the newborn while facilitating delayed cord clamping
<p>LENA device: Ensure Te Reo compatibility</p> <p>Investigate distance range of recording (to offer reassurances of recordings being limited to consented cot-side)</p> <p>Gain more experience with the device</p> <p>Consider a pilot</p>	<p>Distinguish and investigate tools to use</p> <p>Identify a Fatigue Tool (a validated tool for use in pregnancy/postpartum)</p>	<p>Conduct a pilot/feasibility study (operational considerations, e.g. temperature control of warming cabinets and operating theatres)</p>
<p>Māori acceptability</p> <p>Ensure representation and expertise in team capability</p>	<p>Conduct an audit of current practice</p>	<p>Conduct a 12 month audit at Waitemata and Christchurch sites</p>
<p>How to deal with non-English speakers</p> <p>Enhancing equity, but mindful of translation capability of the software?</p>	<p>Conduct a consumer survey - willingness to participate?</p> <p>Conduct a practitioner survey - willingness to participate?</p> <p>Conduct a unit survey</p> <p>Current practice? Prescribing? Variation?</p> <p>Engage an Economist to evaluate local prescribing practice</p>	<p>Engage biomedical engineering team – how to calibrate /control variances in temperature of wraps</p>

A communication and relationship focused intervention	Blood transfusion versus intravenous iron	Preventing cold stress in the newborn while facilitating delayed cord clamping
Site legal advice How to deal with findings that may raise safeguarding concerns? Dealing with privacy issues?	Explore funding opportunities	Visit guidelines for DCC - ensure consistency across sites – re-writing/updating?
Prepare protocol documents Refine the primary outcome definition		Engage wider consultation – willingness to participate, consent process, Māori involvement
Further explore funding options		Consider a step wedge RCT for national implementation
What can the ON TRACK Network do for each concept?		
Provide a review of the trial design	Promote & distribute surveys Facilitate investigator supervision	Supervision for developing RCT
What can the ON TRACK Network do for clinical trials development and engagement across New Zealand generally?		
<p>Have discussions with sites to gain consensus on embedding clinical trials</p> <p>Consider facilitation of early circulation of concepts thereby sensitising sites to new research ideas</p> <p>Implement ON TRACK Network presence/profile on local hospital/university research committees</p> <p>Conduct site visits</p> <p>Provide mentorship</p> <p>Build multi-centre study groups</p>		

Workshop feedback

Thirteen workshop evaluations were returned at the end of the workshop. Participants were asked to rate workshop items on a scale of 1 (very poor) to 6 (excellent). A summary of ratings is presented below (the lowest rating given to any item was average).

Item	Average (3)	Good (4)	Very good (5)	Excellent (6)
Content	2	3	8	
Relevance		5	8	
Presentations	1	6	6	
Enjoyment		7	6	
Usefulness		8	5	
Organisation		3	10	
Workshop materials	2	1	6	4
Catering/Venue		1	5	7
Facilitators		1	2	10
Total rating	2	6	45	64

Participants were also asked to comment on what they liked most about the workshop, what they liked the least, and whether they had any recommendations for future workshops. This feedback is presented below.

What did you like most about the workshop?

"The expertise of the ON TRACK staff at the round the table break out discussions"

"Expertise in the room. Such a positive, supportive environment"

"Eye opening for non-researchers. Positive support for those presenting projects"

"Day 1 presentations"

"The set up and flow of events was excellent. Made the flow and order of research much easier to understand"

"Small group exercise of deconstructing study and rebuilding it"

"Looking at the wider picture for trials"

"Experience and knowledge of panel"

"Informality, supportive; good set-up talks"

"I enjoyed the interaction with the novice researchers. Hoping that I could help them to take their project forward. It was also helpful to hear about the studies I wasn't facilitating and how the other facilitators work shopped with their groups"

"Involvement of consumers; a non-threatening audience / setting created"

"Collegiality – good discussions"

"High standard of expertise"

What did you like least?

"No identified experienced collaborator for one of the concept leads"

"The Māori input – no facilitator available to come to our concept break out session"

"Slightly repetitive"

Do you have any recommendations for future workshops?

Advise lead investigators to bring own laptops

Advise lead investigators to ensure they have access to their email for communications from ON TRACK network staff throughout the workshop concerning any workshop tasks

Encourage lead investigators to bring along a dedicated support person (from their own site) to assist with the process

Report on previous ON TRACK studies would be of interest

Add health economics facilitator to roam around the break-out sessions

Consider replacing review panel with more group discussions

Report conclusions

The 2019 workshop was well attended with representation across disciplines and geography. Importantly, there was representation by consumers and Māori health researchers and advisors.

Feedback received was very encouraging with most workshop items being rated consistently as 'very good' or 'excellent', however we acknowledge the feedback we received was only representative of 26% of those who participated.

This report will now be presented to the ON TRACK Network oversight committees for further input and guidance on how we can continue to deliver these workshops for optimal benefit to investigators, and ultimately the health and wellbeing of women and babies across New Zealand.