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

The ON TRACK Network

Trial Development Workshop 2020 Report

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Aim of ON TRACK Network Trial Development Workshops

The ON TRACK Network Strategic Plan (2016-2020) contains three key pillars or objectives and their associated key performance indicators. To support pillar two 'to facilitate the design, conduct & integration of multicentre clinical trials nationwide' we set a goal to plan and facilitate a trial development workshop at least every two years. To date we have been successful in organising a workshop annually, with the 2020 workshop being the fourth we have hosted.

The aim of the Trial Development Workshop is to support the development of promising clinical trial concepts and ideas to a stage where they are ready for success in competitive funding applications. Concepts accepted for development during the workshops are for investigator-led collaborative clinical trials, which are likely to recruit across multiple New Zealand sites.

Previous workshops

Workshops have taken place annually since 2017 and have been very successful with several concepts evolving into funded clinical trials or active research in preparation for future clinical trials.

- Intravenous iron versus blood transfusion for moderate-severe postpartum anaemia (2019). The Concept Lead Investigator has been awarded a HRC Clinical Research Training Fellowship to undertake a PhD and complete feasibility and preliminary studies with the intention of conducting a future multicentre randomised controlled trial.
- Maternal posture for fetal malposition in labour to improve labour and birth outcomes for mothers and babies (2018). The Concept Lead Investigator is now undertaking a series of studies within a PhD investigating the feasibility of a randomised controlled trial.
- The OBLIGE Trial (2017) is a multicentre trial comparing the use of outpatient balloon versus inpatient prostaglandin for induction of labour. The trial includes 11 sites across New Zealand and is funded by the Health Research Council of New Zealand (HRC), the Auckland Academic Health Alliance and multiple smaller local grants.
- The LATTE Trial (2017) to assess the effect of caffeine on neurodevelopment in late preterm babies has been developed and is now undertaking a preliminary dosage trial funded by the HRC. Recruitment at two hospitals commenced in February 2019. This is likely to lead to a larger national multi-centre trial which will be further developed at a future workshop.
- The C*STEROID Trial (2017) to explore the effect of antenatal corticosteroids prior to planned caesarean section delivery from 35^{+0} weeks gestation on neonatal health. The C*STEROID Feasibility study, funded by Cure Kids, Lottery Health, and the Hugo Charitable Trust, is currently recruiting across three New Zealand sites. A full project grant has been submitted to the HRC for a national, multi-centre trial expected to open in June this year.

- The PINTO study (2017) to assess whether early intervention for women with pre-diabetes in pregnancy may improve pregnancy outcome 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 mothers and babies across New Zealand.

The 2020 ON TRACK Network Trial Development Workshop

Introduction

The fourth ON TRACK Network Trial Development Workshop took place at Auckland City Hospital Thursday 20th and Friday 21st February 2020. It focused on four clinical trial concepts:

- Peer review of Induction of Labour booking requests to improve adherence to a national guideline: a stepped wedge randomised trial (Michelle Wise).
- RAPID: Rapid Antibiotic Prophylaxis Informed Decision-making (Rebecca Hay).
- Neonatal Glucose Optimisation (NeoGluco) study – diazoxide ± continuous glucose monitoring for severe/recurrent neonatal hypoglycaemia (Chris McKinlay).
- Calcium (+/- Vitamin D) oral prophylaxis for prevention of preeclampsia in a healthy, primiparous cohort in a NZ region identified at risk for environmental lead exposure (Rachel Taylor).

Workshop promotion

The workshop was promoted via ON TRACK Network newsletters; the Network website; Twitter; Facebook; flyers distributed via email; and by direct verbal and email communications.

The Paediatric Society of New Zealand invited Associate Professor Katie Groom (National Executive Committee Chairperson) and Gillian Vernon (Network Manager) to give a presentation on the Network and the value of the workshops at their annual scientific meeting, providing opportunity for wider engagement and discussion.

Promotion timeline:

- September 2019 newsletter – save the date and call for concept submissions

- October 2019 newsletter – front page advertising of the workshop and call for submissions
- November 2019 newsletter – Registration open
- November 2019 - Presentation at Pediatric Society New Zealand ASM
- December 2019 newsletter – Promotion of free registration with details of concepts to be developed
- January 2020 and February 2020 – Registration reminders via email and Twitter

How the 2020 workshop operated

The 2020 workshop process began with a national call for submissions of concepts with a pro-forma available to download from our website (Appendix 1) and a submission deadline 25th October 2019. Submissions were reviewed and selected by members of the ON TRACK Network National Executive Committee.

A programme was devised for the workshop (Appendix 2).

Facilitators & Faculty

Individuals who submitted selected concepts (nominated Concept Lead Investigators), were paired with, and supported by a Facilitator identified as an expert in the field with content knowledge and senior clinical trials experience. Facilitators were identified and invited to attend once concepts had been selected.

- Adrienne Gordon, Clinical Professor/Specialist Neonatologist, University of Sydney, facilitated Peer review of Induction of Labour booking requests.
- Joanne Said, A/Professor, Head of Maternal Fetal Medicine, University of Melbourne, facilitated Rapid Antibiotic Prophylaxis Informed Decision-making
- Lex Doyle, Professor Neonatal Paediatrics, the Women's Victoria, facilitated Neonatal Glucose Optimisation (NeoGluco) study.
- Amanda Henry, Senior Lecturer, UNSW Sydney, facilitated Calcium (+/- Vitamin D) oral prophylaxis for prevention of preeclampsia

Additional faculty experts in health economics, consumer opinion, clinical trial design, funding, and Māori health and research were also invited.

- Frances Benge, CEO Cure Kids
- Greg Gamble, Biostatistician, University of Auckland
- Thomas Lumley, Professor Biostatistics, University of Auckland

- Helen Wihongi, Director Māori Health Research, Waitemata DHB
- Jenny Warren, Consumer Representative, ON TRACK Network
- Jessica Steele, Consumer Representative, ON TRACK Network
- Louise Locock, Professor Health Services Research, University of Aberdeen
- Lynn Sadler, Epidemiologist, Auckland DHB
- Richard Edlin, Head of Health Systems Group, University of Auckland

Registrations and attendance

Registration for the workshop was free and open to all. Using the ON TRACK Network's Forum for Women & Whānau we actively encouraged consumers to register. Concept Lead Investigators were advised to register their investigator teams and to encourage potential collaborators to attend. The four trial concepts selected for the workshop were advertised to encourage attendance by interested clinicians and researchers. Online registration opened in November 2019. We received 62 registrations and 52 of those attended the workshop.

Introductory presentations

ON TRACK Network & Trial Development Workshop (Katie Groom).

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.

Cure Kids, Child Health Research, Mission Led or Research Led? (Frances Benge).

The CEO of Cure Kids, Frances Benge, presented the organisation's commitment to funding clinical research to improve the health of New Zealand children. The talk highlighted the significant investment made over recent years across various fields of health by Cure Kids, including preterm birth and prevention of stillbirth.

Māori responsiveness, Māori advantage (Helen Wihongi)

The Director of Māori Health Research at Waitemata and Auckland District Health Boards presented on Māori health disparities and the drivers and changing practice to address them.

Clinical Data Research Hub (Chris McKinlay)

An overview of the Clinical Data Research Hub was provided including the support and resources available.

Presentations are available on the ON TRACK Network website (http://ontrack.perinatalsociety.org.nz/meetings-and-resources/past-meetings/).

Once introductory talks were complete, each Concept Lead Investigator gave a 'concept pitch' which allowed workshop participants to select which of the four groups to attend during the parallel work sessions. Participants were able to move across concept groups depending on their own interests.

Facilitators and Concept Lead Investigators guided discussions within each of the small groups. Expert faculty members linked in with all concept group discussions throughout the duration of the workshop.

At the end of day one, Concept Lead Investigators submitted a 2-3 page summary of progress using an extended submission pro-forma (Appendix 3). These were reviewed overnight by the mock funding panel reviewers who provided critique in a whole audience session on the morning of day two.

Following the mock funding panel and further parallel group work discussion, next steps for each group were discussed in a whole audience session. This also included discussion of ways in which the Network may support further development of each trial concept and collectively support trial activities.

Network suggested actions

- Facilitating introductions to experts
    - Help to build collaborator teams
    - Help to identify potential supervisors / mentors for research
- Enable research teams to access the Forum for Women & Whānau to facilitate discussion groups and identify consumer collaborators
- Facilitate provision of peer review of proposed projects
- Support Māori responsiveness with Māori representation on the Network's National Executive Committee; promotion of research methodology workshops; supporting pipeline of Māori and Pasifika researchers.
- Facilitate introductions to participating sites via Site Network Leaders – circulating opinion / practitioner surveys and requests for letters of support
- Advertise and signpost the Clinical Data Research Hub

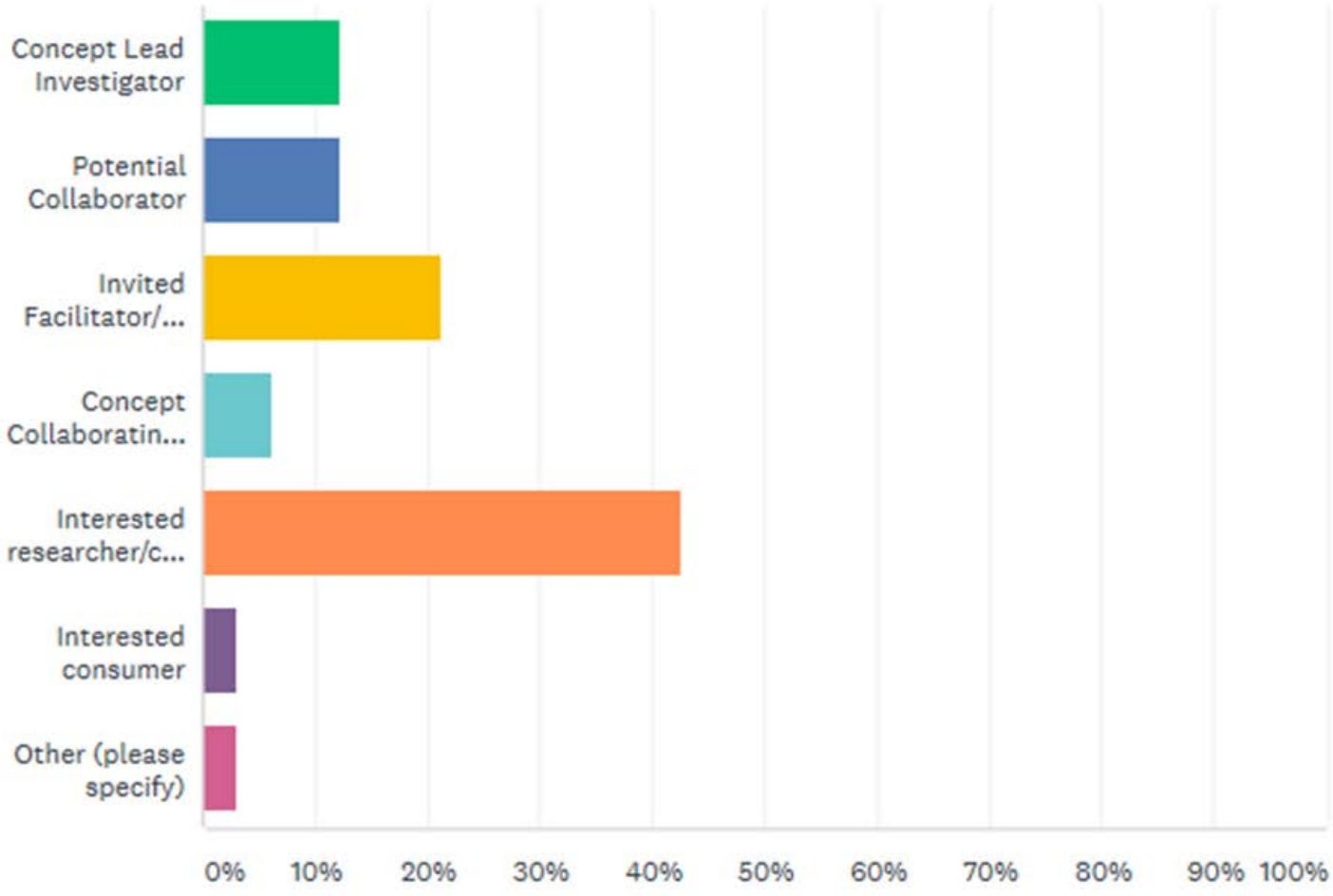
The above suggestions will be discussed at the ON TRACK Network National Executive Committee concerning feasibility, prioritisation and to devise respective actions.

Workshop evaluation

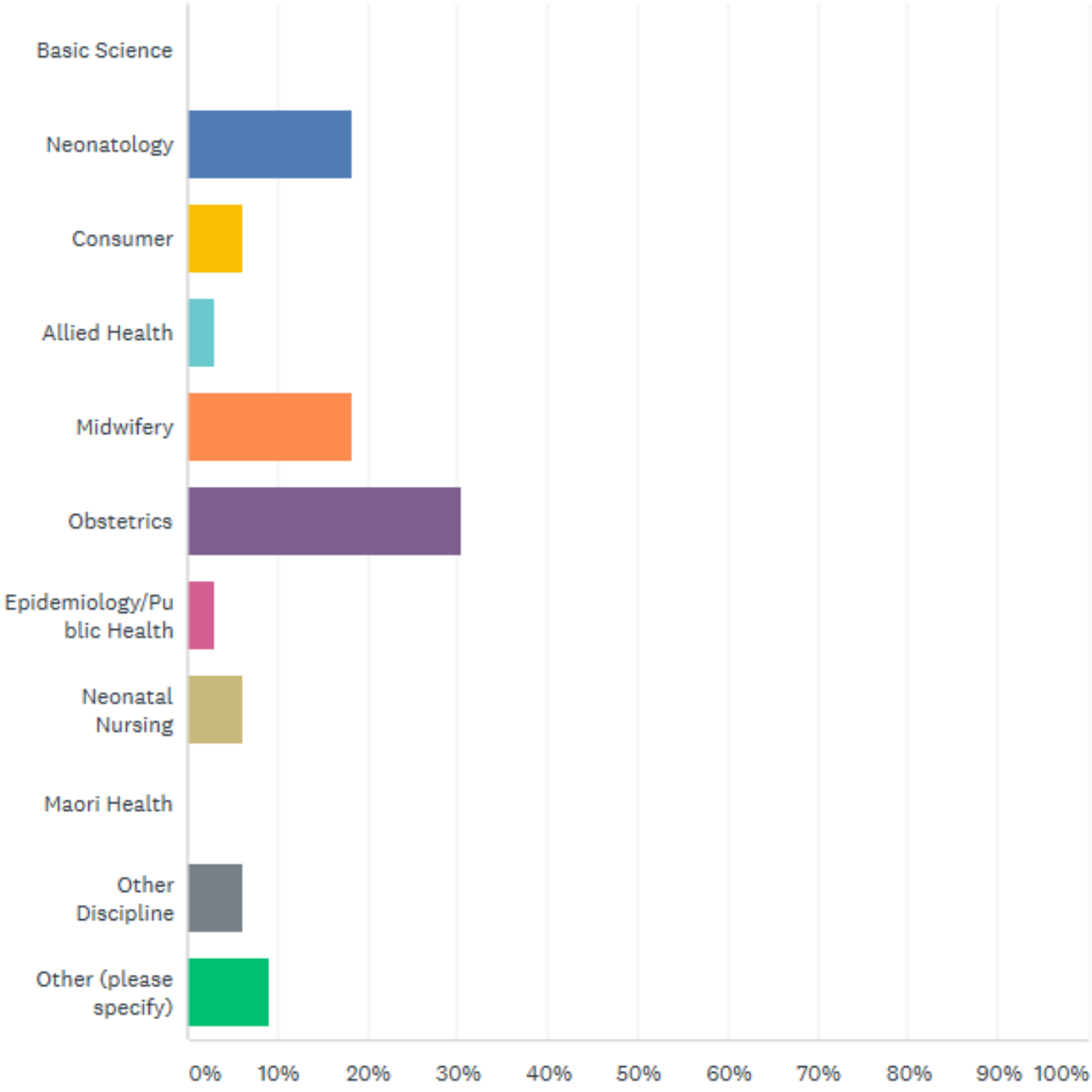
Thirty-three individuals responded to an evaluation survey which was distributed electronically at the end of the meeting. Using an evaluation online tool resulted

in an increased response rate; 63% of attendees providing feedback in 2020 compared to 26% in 2019.

Purpose for attending the workshop:



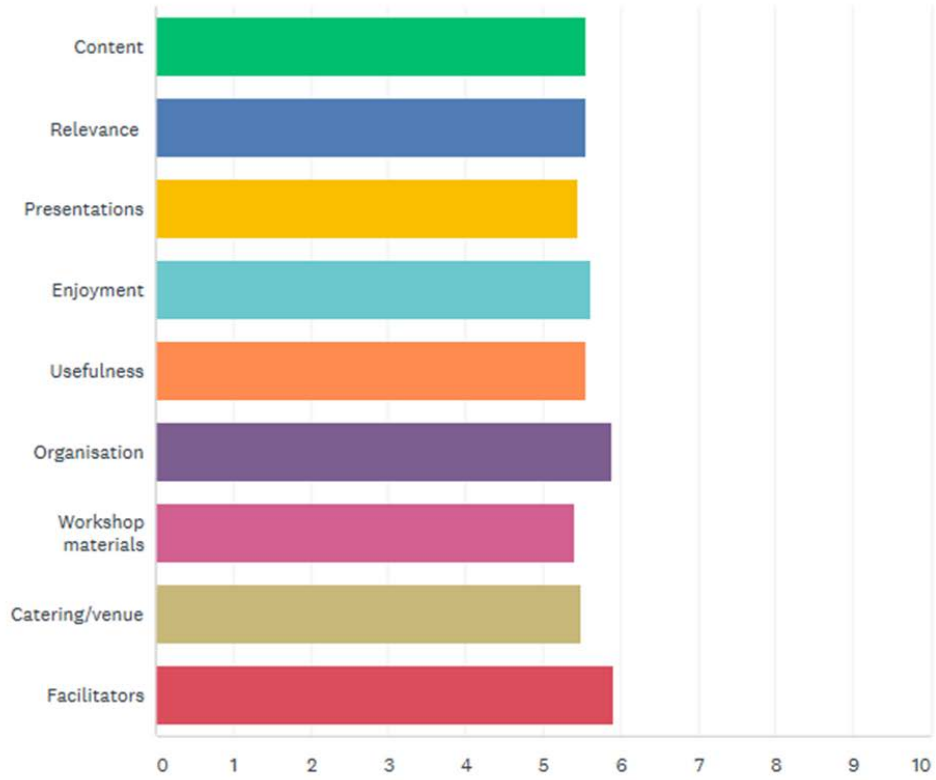
Which discipline do you primarily align with?



Participants were asked to rate workshop items on a scale of 1 (very poor) to 6 (excellent). A summary of ratings from the 33 participants who completed the online evaluation survey is presented below.

How would you rate this workshop on a scale of 1 (very poor) to 6 (excellent)?

Answered: 33 Skipped: 0



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 sharing and encouragement of ideas and expertise
Collegial discussions, very inclusive
Hearing from the panel
The work done in break out groups was the most informative and enjoyable part
Having all the experts in one place
The genuine interest from most participants in the consumer voice
Hearing feedback from the panel
The supportive nature of the individuals providing critique on our protocol
Networking
Positive and interested people giving their expertise
The collaborative nature, friendly feedback sessions and solid discussions
Incredible opportunity to seek feedback for potential research ideas, projects and opportunities. The entire experience was invaluable on every level, I cannot express my gratitude enough!!
Range of trial/research topics presented and opportunity to network
How collaborative attendees were
Multidisciplinary and inclusive
Opportunities for interaction with people with different expertise. Structured approach with a focus on development of a grant application. Very well organised
Contributing to the discussions and learning that I do not have to have all the answers - it's OK to share and try out

What did you like most about the workshop?
Venue much better. Good talks. Great facilitator
Supportive, positive, but helpfully critical
The comments and suggestions by facilitator
Meeting other researchers
Panel feedback on proposals
The workshop was welcoming, collaborative, relevant, interesting, informative, and fun.
Links with other researchers, sharing ideas
Friendly collaborative atmosphere. Excellent organisation. Interesting speakers and sessions
Opportunity to hear research ideas
It was very interesting seeing the development and transformation of the clinical trial concepts. The discussion between the facilitators and people who attended the workshop, and learning the opinions and perspectives of people from different professional backgrounds was really informative -- I learnt a lot about the logistics of developing a clinical trial and some of the considerations that go into that.
Collaborative constructive approach
The panel discussion. As a young researcher I found it incredibly informative and useful
Varied formats, interesting subject matter, hearing from experts
Critique of quality research
Excellent choice of venue - rooms for breakout sessions in close proximity. Comfortable facilities.

What did you like least?

Room was very squashed

It is always a little challenging as a non-clinician or researcher to get your head around everything

Last session on developing On Track Network - still important but not so exciting a topic to finish

Quite pressured. Almost needed more time

Concept I was working on was very early and concept lead had no "team" to assist with expertise / development

It would be great to get more diverse representation e.g. students and researchers from Maori, pacific, migrant backgrounds

Some ideas were quite poorly organised and executed, even by the end of the conference and feedback

Not at Liggins, which is the host. Some concepts were not trials and were unlikely to ever be trials

Room could have been a little larger for the size of our group

Do you have any recommendations for future workshops?

Keep the CEC venue- much better

Larger rooms

Continue to grow on the concept you have developed. I think the facilitated workshop with the morning feedback session was invaluable

Some outside space for break times

Limit concepts to multi centre RCT/cohort study proposals and increase number of such proposals reviewed

Would like to know more about Māori research methods

Would be great to see physician colleagues in relevant disciplines there also. Plus travel/accommodation scholarships for out-of-town attendees focused on Maori, students, early-career

Ensure that the concepts are submitted with an identified team of people and not just an individual.

More awareness amongst the students will increase more participation

Prep for concept pitch was detailed but it would have been also good to have the template for the 3-pager in advance with suggestion to start on it even just bullet

Do you have any recommendations for future workshops?
points prior to day 1 as half hour wasn't enough to put I together. Also instructions on prep for revised presentation On day 2 to be given on day 1 Try to encourage more Māori and Pacifica researchers to attend? advertise through HRC Maori and Pacific networks in addition to ON TRACK More whole-group discussions would be useful Some initial review/consultation with the panel, even before the beginning of the workshop. Alternatively, building in a session where a grant application is critiqued by the panel and presented to the group (this would help all thinking of applying). Try to keep the focus on potential trials

Report conclusions

The 2020 workshop was well attended with representation across disciplines. Although, there was representation by consumers and a Māori heath advisor, discussions during and after the workshop have highlighted the need to engage more participants from these groups.

Overall the feedback received was very encouraging with all aspects of the workshop being rated consistently as ‘very good’ or ‘excellent’.

This report will be presented to the ON TRACK Network oversight committees, the National Executive Committee and the Strategic Research Initiative Fund Steering Group, to ensure we continue to host these workshops for optimal benefit to researchers and clinicians and ultimately the health and wellbeing of mothers and babies across New Zealand.

Appendix 1: Call for proposals

ON TRACK Network Trial Development Workshop 20-21st February 2020

Call for Trial Proposals

Submission deadline by **Friday 25th October 2019**

Translating a research idea into a successful clinical trial proposal can be a daunting task. This two-day workshop, supported by the ON TRACK Network, will help you bring your research idea to reality.

We are ***calling for submissions of trial proposals in maternal, perinatal and neonatal health*** to be included in this Trial Development Workshop.

Proposals can be at early concept stage through to those that are starting to be developed and need further input and additional collaborators. This will be an interactive workshop rather than a lecture-based meeting on clinical trial design.

Benefits of bringing your trial proposal to the workshop:

- Expert advice on trial design - expert facilitators, along with leading trialists and statisticians
- Input from a multidisciplinary group of researchers and members of the OTN Consumer Forum
- Opportunity to build collaboration and discuss multi-centre recruitment within the Network
- Find the competitive edge for your protocol and grant application

Trial proposal submissions: These should be made on the attached single page pro-forma and submitted to ontracknetwork@auckland.ac.nz by Friday 25th October 2019. Proposals will be selected for development at the workshop and will be confirmed by mid November 2019. Concept lead investigators will be required to attend the full workshop and be actively involved in presentation of their concept. We encourage as many named collaborating investigators as possible to also attend the workshop.

WORKSHOP DETAILS

Location: Continuing Education Centre, Level 5, Auckland City Hospital

Date: Thursday 20th – Friday 21st February 2020

Registration: https://uoaevents.eventsair.com/on-track-2020/on-track

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The ON TRACK Network established in 2016 is a National Maternal Perinatal Clinical Trials Network aimed at improving the health of mothers and babies in New Zealand. The ON TRACK Network aims to assist all health professionals within hospitals in New Zealand to engage in research by identifying key research priority questions, offering opportunities for pregnant women and their babies to participate in multi-centre randomised trials and facilitating the dissemination and timely implementation of new research knowledge.

Title:
Identified collaborators:
Background:
Rationale:
Aim(s):
Hypothesis:
Objectives:
Population and setting:
Intervention:
Study design:
Outcomes and measures:
Consumer/parent consultation:
Māori responsiveness (planned consultation, potential benefit):

Appendix 2: Programme

ON TRACK Network Trial Development Workshop

20th and 21st February 2020

Clinical Education Centre, Level 5, Auckland City Hospital

Day 1: Build your trial proposals

Start	End	Speaker/Chair	Session
CEC Main Foyer			
10:00	10:30		Registration and Morning Tea
Auditorium		***Chair: Katie Groom***	
10:30	10:50	Katie Groom	Welcome to the ON TRACK Network & Trial Development Workshop
10:50	11:05	Frances Benge	Cure Kids, Child Health Research, Mission Led or Research Led?
11:05	11:20	Helen Wihongi	Maori health gain in clinical research practice
11:20	11:25	Chris McKinlay	Clinical Data Research Hub
11:25	11:30	Katie Groom	Introduction to teams
11:30	11:40	Michelle Wise	***Concept pitch 1****: Peer review of Induction of Labour booking requests to improve adherence to a national guideline: a stepped wedge randomised trial (Facilitator: Adrienne Gordon)*
11:40	11:50	Rebecca Hay	***Concept pitch 2****: RAPID: Rapid Antibiotic Prophylaxis Informed Decision-making (Facilitator: Jo Said)*
11:50	12:00	Chris McKinlay	***Concept pitch 3****: (Facilitator: Lex Doyle)*
12:00	12:10	Rachel Taylor	***Concept pitch 4:*** *Calcium (+/- Vitamin D) Oral Prophylaxis for Prevention of Preeclampsia in a Healthy, Primiparous Cohort in a NZ Region Identified At-Risk for Environmental Lead Exposure (Facilitator: Amanda Henry)*
12:10	12:45		Lunch (CEC Main Foyer)

		Parallel sessions	
12:45	14:45	Group work	Focus on: background and rationale; aims and objectives; design and methods

Concept 1		Concept 2	Concept 3	Concept 4
14:45	15:00		Afternoon tea (CEC Main Foyer)	
		Parallel sessions		
15:00	17:00	Group work	Focus on: design and methods (cont.); research impact; Māori responsiveness; team capability *Finalise submission for mock review panel and submit to ontracknetwork@auckland.ac.nz by 5:30 pm*	
Concept 1		Concept 2	Concept 3	Concept 4

Dinner at 7pm for those who have confirmed they would like to attend (Blue Elephant, Parnell)

Day 2: Develop and extend your trial proposals

Start	End	Speaker/Chair	Session
Auditorium			
8:30	8:35	Katie Groom	Introduction to mock review panel
8:35	10:35	Lex Doyle, Lynn Sadler, Greg Gamble, Helen Wihongi, Jenny Warren, Caroline Crowther	Mock Review Panel feedback & group discussion *30 minutes allocated to each concept (5 minute summary with 25 minutes for review and discussion)*
10:35	10:50		Morning Tea (CEC Main Foyer)
			Parallel sessions
10:50	12:50	Group work	Revise project and establish next steps

Concept 1	Concept 2	Concept 3	Concept 4

12:50	13:20	Lunch (CEC Main Foyer)
Auditorium		
13:20	15:00	Final presentations and group discussion of next steps
15:00	15:15	Katie Groom	Closing comments and feedback

Appendix 3: Trial summary proforma

1. Title:
2. Identified collaborators:
3. Rationale for Research: *Provide the research rationale and a statement of purpose or research aims.*
4. Research Design and Methods: *Provide sufficient details for technical assessment of scientific protocol, feasibility and validity of data.*

5. **Research Impact**: *Include the anticipated outcomes of the research. What will be the significance and contribution of the new knowledge to the concepts, methods or evidence-base that drive the research field? How could the research impact upon clinical practice, community health, health policy and/or the provision of health services? Does the research have potential for economic gain? Comment on knowledge transfer.*

6. **Responsiveness to Maori:** *Comment on consultation, and the quality and extent of Maori involvement in the research*

7. **Team Capability**