



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

The ON TRACK Network Trial Development Workshop 2021 Report



2021 Workshop supported by the University of Auckland Strategic Research Initiative Fund, Perinatal Society of New Zealand and the Paediatric Society of New Zealand. The Hugo Charitable Trust supported Māori consumers, clinicians and researchers attendance.

Contents

Background and aims of the workshops	3
The 2021 ON TRACK Network Trial Development Workshop.....	4
How the 2021 workshop operated	4
Workshop promotion	5
Faculty members.....	5
Registrations and attendance	6
Introductory presentations.....	7
Network suggested actions.....	8
Workshop evaluation.....	9
Report conclusions.....	15

Background and aims of the ON TRACK Network Trial Development Workshops

The ON TRACK Network hosts an annual Trial Development Workshop to support the Network's mission to capacity-build and integrate high-quality clinical trials into clinical practice across New Zealand. The workshops aim to help maternal and perinatal health researchers develop their clinical trial ideas to a level ready for competitive grant funding. The workshops do this by providing clinical trials research education, resources, collaboration and networking.

Trial Development Workshops have an established track record that leads to grant submissions with several concepts evolving into funded clinical trials or active research in preparation for future clinical trials. Examples include:

- Peer review of induction of labour requests to improve adherence to a national guideline: a stepped wedge randomised trial (2020). This trial has been submitted to the Health Research Council of New Zealand (HRC) for funding.
- 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 12 sites across New Zealand and is funded by the 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 completed a preliminary dosage trial funded by the HRC. Analysis of the dosage trial is underway and is likely to lead to a larger national multi-centre trial which will be developed at a future workshop.
- The C*STEROID Trial (2017) will 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, completed recruitment across three New Zealand sites in March 2020. A HRC project grant now supports the roll out of a national, multi-centre trial with five sites already recruiting.
- 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.

The 2021 ON TRACK Network Trial Development Workshop

The fifth ON TRACK Network Trial Development Workshop took place at Auckland City Hospital 25th and 26th February 2021. It focused on three clinical trial concepts:

- Treatment of **pre-diabetes in pregnancy** (Concept Lead Investigator: Charlotte Oyston).
- **Dressing selection for caesarean section**: a non-blinded randomised controlled trial (Concept Lead Investigator: Simon Scheck).
- The **fetal pillow to reduce maternal and neonatal morbidity** at caesarean delivery (Concept Lead Investigators: Lynn Sadler & Meghan Hill).

In addition to the three trial concepts, **Māori models of pregnancy care** was included as a topic for discussion having been identified as a priority area for research by the recent ON TRACK Network Research Prioritisation Project. The workshop provided the opportunity to host a hui to begin a conversation with Māori clinicians and researchers on how this and other areas of Māori mothers and babies health could be considered in clinical trials research.

How the 2021 workshop operated

Planning for the 2021 workshop followed our standard process which began with promotion of the workshop (see below) and a national call for concept submissions. Submissions of concepts were made using a pro-forma available to download from our website (deadline 30th October 2020). Concepts were then reviewed and selected by members of the ON TRACK Network National Executive Committee.

In parallel to the national call, outcomes of the ON TRACK Network Research Prioritisation Project were reviewed to identify additional key priority concepts that could be considered at the workshop.

Preparation included contingency planning in case COVID-19 restrictions were in place at the time of the workshop. At level 1 and 2 restrictions the workshop was planned to proceed as an in-person meeting and physical attendance, which supports networking, was strongly encouraged. At level 3 or 4 restrictions the workshop could be switched to a full on-line platform or hybrid format using Zoom videoconferencing. This resource also enabled the participation of Australian experts as Facilitators given international travel restrictions.

Once the concepts for inclusion were confirmed the workshop programme was devised, uploaded to the ON TRACK Network website and used in promotional material. Faculty members were considered and invited (see below). Requests for sponsorship and funding applications were made. We were successful in securing

sponsorship from the Perinatal Society of New Zealand (PSNZ) and the Paediatric Society of New Zealand (\$1,500 from each).

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.

Promotion timeline:

- September 2020 newsletter – save the date and call for concept submissions
- October 2020 newsletter – front page advertising of the workshop and call for submissions
- November 2020 newsletter – Registration open
- December 2020 newsletter – Promotion of free registration with feedback from previous workshops.
- January 2021 and February 2021 – Registration reminders via email (including flyers with details of concepts), Facebook and Twitter.

On the basis of feedback received from last year's workshop, communications targeted medical students (via the Group Services Coordinator, Faculty of Medical & Health Sciences Administration) as well as health professionals and researchers in District Health Boards and University Departments, and members of the Forum for Women & Whānau.

Faculty members

For each concept selected we identified Facilitators identified as experts in the field with content knowledge and/or senior clinical trials experience.

- Treatment of pre-diabetes in pregnancy - Rinki Murphy, A/Professor & endocrinologist, University of Auckland.
- Dressing selection for caesarean section - Michelle Wise, Senior Lecturer, University of Auckland, and consultant obstetrician and gynaecologist, Auckland City Hospital and Rosalie Grivell, A/Professor and Maternal Fetal Medicine Subspecialist, Flinders University, Adelaide (via Zoom).
- Fetal pillow to reduce maternal and neonatal morbidity at caesarean delivery - Billie Bradford, Senior Lecturer (Midwifery), Victoria University, Wellington and Amanda Henry, A/Professor and consultant obstetrician and gynaecologist, University NSW, Sydney (via Zoom).

Additional faculty experts in health economics, consumer opinion, clinical trial design, funding, and Māori health and research were also invited. Some faculty members* also took part in the Mock Review Panel.

- Arier Lee*, Biostatistician, University of Auckland
- Greg Gamble, Biostatistician, University of Auckland
- Thomas Lumley, Professor Biostatistics, University of Auckland
- Helen Wihongi*, Director Māori Health Research, Waitemata DHB
- Felicity Ware, Hauora Maori Lecturer, Massey University
- Jenny Warren*, Consumer Representative, ON TRACK Network
- Jessica Steele, Consumer Representative, ON TRACK Network
- Chris McKinlay, Senior Lecturer Neonatology, University of Auckland
- Deborah Schlichting, Research Fellow Health Economics, University of Auckland
- Tara Satyanand, Director of Research & Innovation, Cure Kids
- Caroline Crowther*, Professor Perinatal Health, University of Auckland
- Dame Jane Harding*, Professor Neonatology, University of Auckland
- Lesley McCowan*, Professor Obstetrics and Gynaecology, 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 trial concepts selected for the workshop were advertised to encourage attendance by interested clinicians and researchers. Online registration opened in November 2020. We received 90 registrations and 60 of those attended the workshop in person, 8 indicated that they planned to participate by Zoom. The number of Zoom participants varied by session.

Pōwhiri

The workshop was opened with a pōwhiri delivered by Whae Lilla Te Tai from Waitemata District Health Board. All workshop participants contributed with the following:

He Honore

He hōnore, he korōria,

E Toru Puawai

E toru puawai o taku putiputi
Āroha, tūmananko me te whakapono

Maungārongo ki te whenua
Whakaaro pai e,
Ki ngā tāngata katoa,
Ake ake, ake ake, Amine,
Te Atua, te piringa, Toku oranga
Toku oranga

Te tino puawai ko te āroha
Hei whakawhanaunga i a tātou e

Unuhia i te rito o te harakeke
Kei hea ra ia te kōmako e
Māu e ui mai he aha te mea pai
Māku e ki atu he tangata

Introductory presentations

The ON TRACK Network

A/Professor Katie Groom presented the background to the ON TRACK Network, its strategic pillars, its structure and key activities. She provided an overview of the workshop and an introduction to faculty members.

How can clinical trials support pae ora?

Dr Felicity Ware, Māori Advisor on the ON TRACK Network National Executive Committee, gave a presentation considering equity and how Māori engagement in clinical trials may support health and wellbeing of iwi, hāpu, whānau, and Māori communities.

What makes a good study protocol?

Dr Chris McKinlay presented an introduction to the SPIRIT guideline, components of a successful clinical trial, and practical considerations in setting up and running clinical trials.

Compared to whom? Issues in designing your randomisation

Professor Thomas Lumley considered and explained the rationale for various models of randomisation for clinical trials including individual, cluster, and stepped wedge designs.

Concept pitches, parallel group work & Mock Panel Review

After the introductory presentations, each Concept Lead Investigator gave a 10 minute 'concept pitch' outlining the idea for their clinical trial and it's development to date. For the concept relating to Māori models of pregnancy care, Associate Professor Katie Groom provided information relating to how this concept was selected, this included provisional results of the ON TRACK Network Research Prioritisation Project and some background to the Carosika Project, Taonga Tuku Iho (national preterm birth project). She noted that this idea was not developed into a trial concept but the focus for the group would be to start a conversation and support further engagement with Māori clinicians and researchers.

Presentation of the concept pitches also enabled workshop participants who were not already part of any concept teams to select which group they would like to join during the parallel small group work sessions. Participants were also able to

circulate around concept groups if they wished to gain broader understanding of the clinical trial development process.

Parallel small group work then took place led by Concept Lead Investigators and guided by Facilitators. Expert faculty members contributed to concept group discussions. Each group was assigned a biostatistician who was able to support the same group throughout the duration of the workshop, other faculty members moved between groups.

At the end of day one, Concept Lead Investigators submitted a 2-3 page summary of progress using an extended submission pro-forma. These were reviewed overnight by the Mock Review Panel reviewers. At the start of day two, each Concept Lead Investigator provided a brief progress summary to the whole group followed by Mock Review Panel critique and limited audience discussion.

Following the Mock Review Panel further parallel small group work discussion extended the trial concept using the feedback given. At the end of the workshop 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

- To help identify key people to contact as first point of care providers who can disseminate trial information.
- To facilitate engagement with experts as required, e.g. health economist.
- To support engagement with the Forum for Women & Whānau.
- To continue to support meaningful engagement with Māori.

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

Karakia

The workshop was closed with a karakia led by Whae Lilla Te Tai

Te Āroha
Te āroha,
Te whakapono
Me te rangimarie,
Tātou tatou e

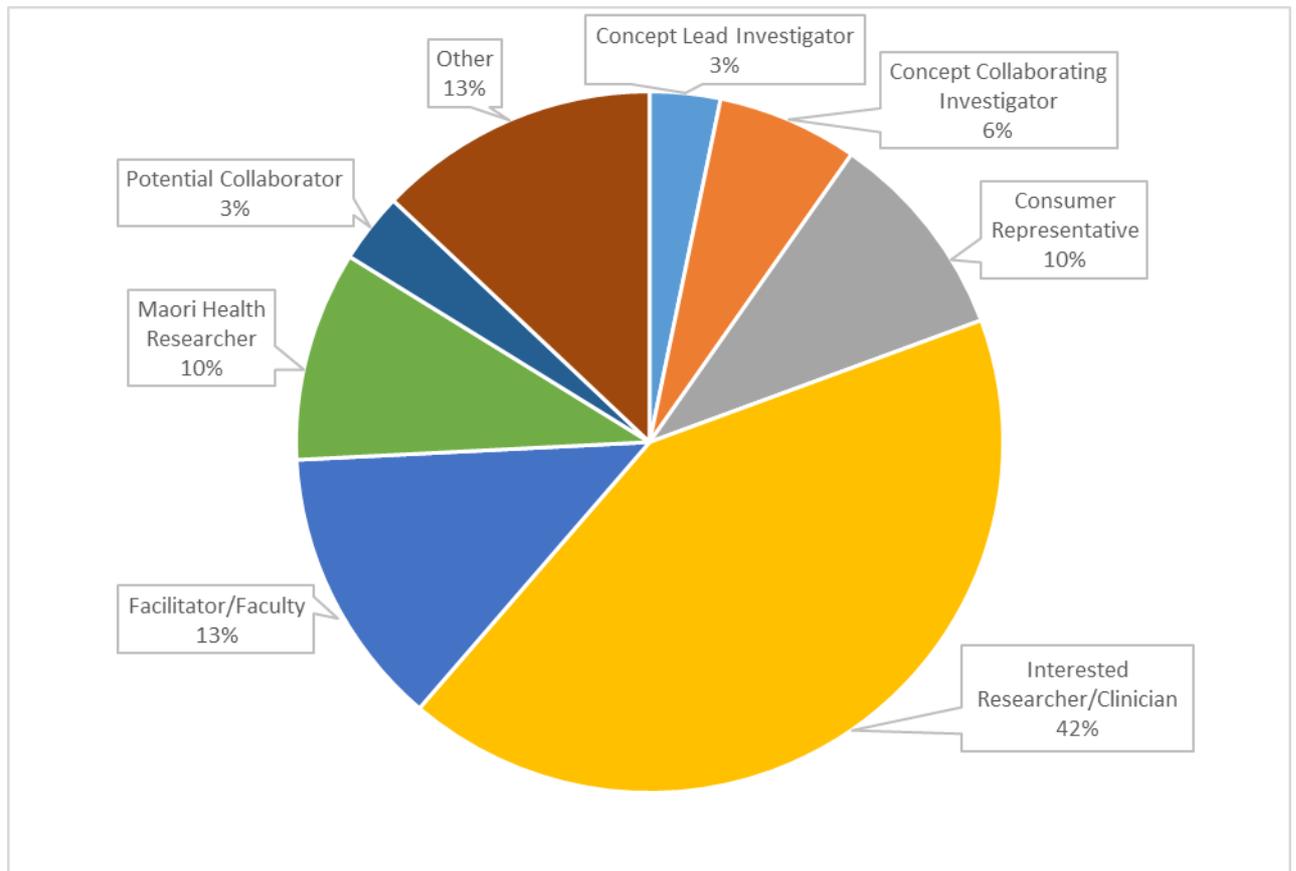
Te āroha,
Te whakapono
Me te rangimarie,
Tātou tātou e

Workshop evaluation

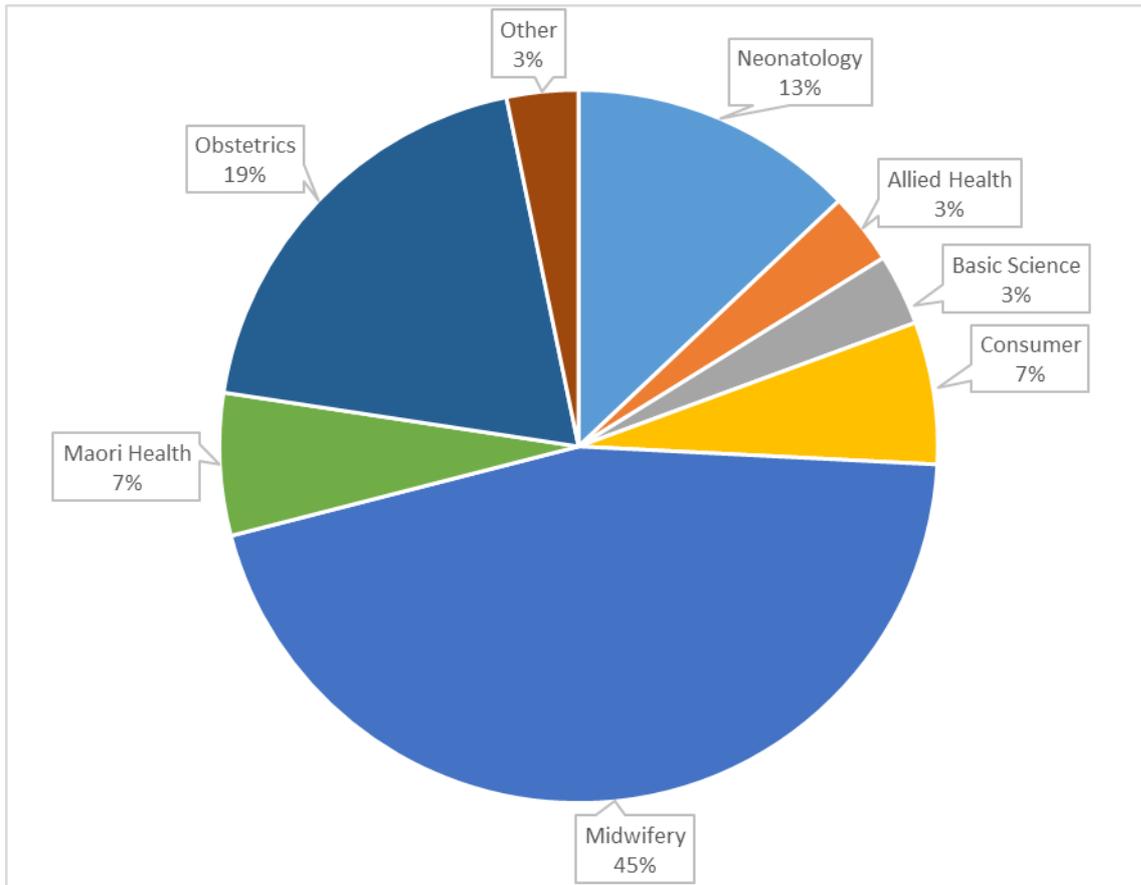
Thirty-one out of sixty eight (31/68) individuals who participated in the workshop responded to an evaluation survey which was made available in hard copy during the last session of the workshop and distributed electronically shortly before the close of the workshop.

Participants who completed the survey were as follows:

Purpose for attending the workshop:



Which discipline do you primarily align with?

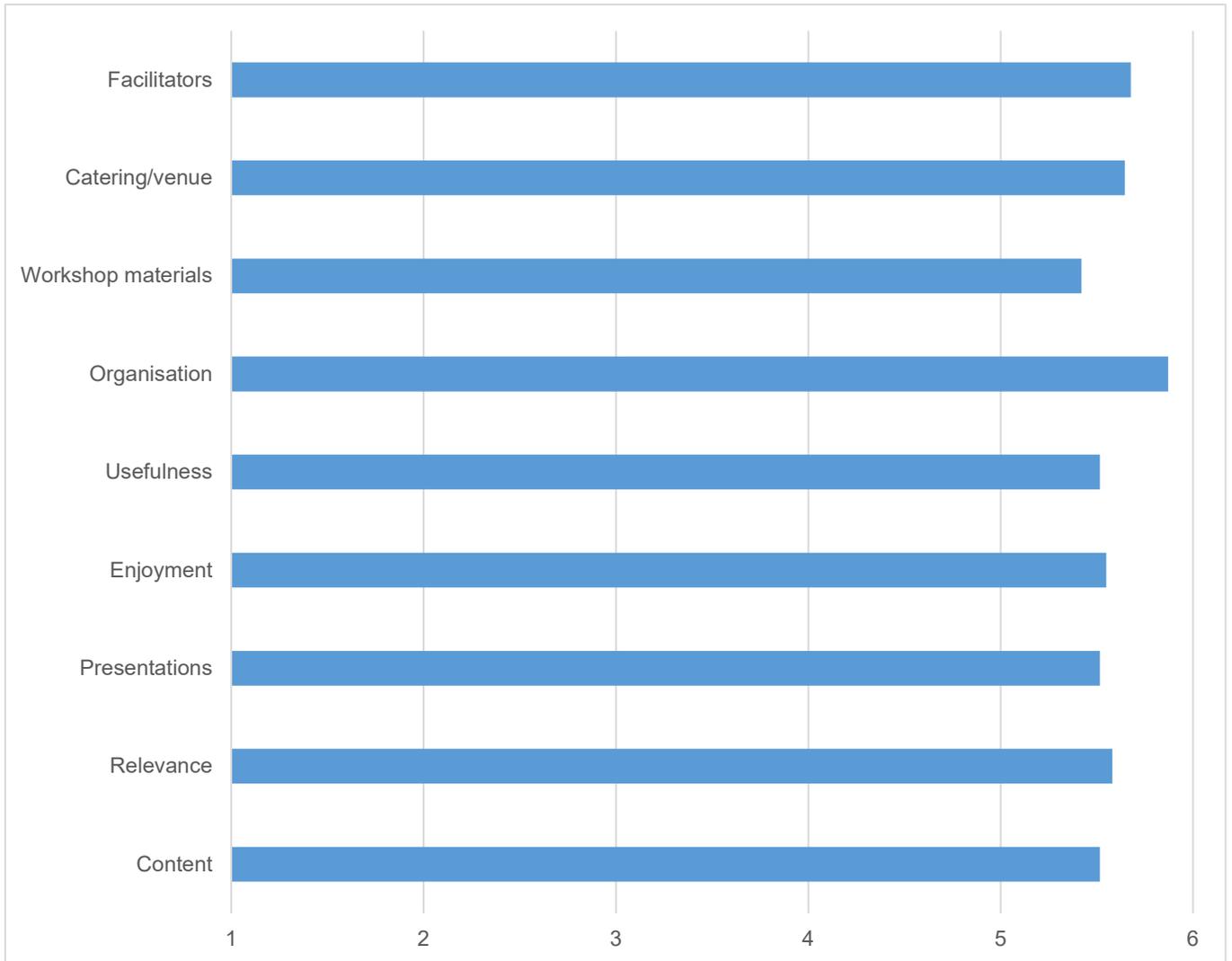


Twenty seven out of twenty-eight (27/28) people who answered the question **'Would you attend a similar workshop in the future?'** responded 'yes', with seven of those indicating they would like to attend in the future as a Concept Lead Investigator.

Twenty-four people responded to the question **'What registration fee would you be prepared to pay to attend a future workshop?'** Their responses were:



Participants were asked to rate workshop items on a scale of 1 (very poor) to 6 (excellent). A summary of ratings from the 31 participants who completed the evaluation is presented below.



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. Responses are presented below.

What did you like most about the workshop?

Hearing about what goes into developing a viable research project

Hearing about what clinical trials may be set up, listening to a wide range of expertise

Team panel discussion

Feedback on proposal

Meeting of such fabulous minds and keeping the research networks open

I am currently a medical student and so I found the whole event quite interesting because everything was new to me. I really enjoyed the social aspects of the event, being given the time to talk to older clinicians about their roles and pathway through research. Everyone was very friendly and passionate about research which definitely rubbed off on me, great community of people

Learning about how proposal for research grants are prepared

Opportunity for multi-disciplinary discussions and lots of viewpoints

Supportive positive encouraging environment. Huge number of attendees is inspiring that the Network is flourishing

So useful to have everyone one together, and get expert opinion

Debating trial design

The experts in the room

Collective thinking, problem solving and panel reviews

The ongoing journey to increase Māori participation

Networking

Learning what can be improved for what is currently in place for specific care. Care that will better benefit Māori and PI communities/whanau

Being part of the complex process of nutting out or workshopping research concepts and networking

Networking. Concept groups

Learning opportunity

What did you like most about the workshop?

Opportunities to interact and engage with a wide range of professionals, consumers and researchers

Everything

Opportunity to network with other Māori

Collaborative, facilitative environment

Concept leads. Break up discussion

Multidisciplinary

Small group sessions

Discussion between people

I enjoyed the conversations with so many different specialties & feeling like I had meaningful contribution

Learning from feedback panel e.g. for grant application. Learning from group discussions about clinical concerns & consumer & clinician views towards important outcomes and research questions

What did you like least?

I did not realise this would be the focus. I thought the workshop was focusing on development of a Māori Health Care model

Zoom issues

It would be great to get a bit more feedback from the working groups on other proposals. Perhaps the facilitator or a scribe could keep a record of the positive/negative feedback (whether it was incorporated or not) and present it to the group?

The cost of parking - NOT the fault of the workshop however

I would have liked access to the materials, for example of the second day when the proposals were updated I would have liked an e copy so I could have followed along each a bit more, and written down notes. A lot of the discussion was very clinician specific which I thought was great, but I would have liked a copy of material so I could have had a framework by which to refer to

Not being informed that the one topic I had really come for was intended for our Māori colleagues and not really anyone else

Missed having the expert Australians in the room (and too cold)

Break-out sessions were a little meandery at times

Too cold

Me personally, not having a medical background or education within any health sectors - so having little knowledge myself, is the least liked for me

Not enough G.F food. No GF morning tea. Very little GF food at lunchtime

Do you have any recommendations for future workshops?

Kindly send the slides presented in the workshop especially of the eminent speakers. It will provide a firm background for the researchers

I would really like an update on where the presentations from the prior few years have ended up

Perhaps start earlier on the first day and then give the presenters more time to rework their revised concepts for the next day

I don't think from a student perspective I would change it. I appreciated just observing experts at work, learning via observation. Great effort on conference would definitely come back, love to see where these projects even up in a year's time, would definitely recommend to other medical students

Be really clear in the intentions and what audience you are aiming for each topic

Slightly longer group time day two

Bit more preparation for the powhiri

Really experienced facilitators

Try to get DHB leaders/ managers involved

Question 10 is hard to answer. I usually charge overhead costs - so a two day hui with 2 lunches and 4 morning teas and cost of the venue x 100-200 people- \$200 is probably not enough

Longer initial presentations of concepts. Circulate plan of studies with workshop documents

Mock Review Panel - it would be good to give consumer & Māori researchers' equal opportunity to speak first. Not always clinical triallists

There needs to be a midwife researcher on the panel

Consider having midwifery (clinician) and Pacifica member included on panel. Would be happy to get my own lunch, saves costs for catering

Keep doing them

It would be great if the slides can be emailed

More breakout sessions

Report conclusions

The 2021 workshop was well attended, and the mixed format worked well. However, having the vast majority of participants in physical attendance was conducive to meaningful discussions with many participants commenting on the importance of networking over breaks and lunches.

There was good representation across disciplines but we need to continue efforts to engage more consumers. This will continue to be facilitated by the Forum for Women & Whānau.

With Māori models of pregnancy care being on the programme for this year's workshop and a concerted effort to identify and directly invite participants with an interest in, or working in this area, there were more Māori representatives, health practitioners and researchers in attendance than at previous workshops. However, Māori representation at the workshop was primarily for discussion of Māori models of pregnancy care and we need to continue efforts to engage more Māori representatives for future workshops.

Overall the feedback received was very encouraging with all aspects of the workshop being rated consistently as 'very good' or 'excellent'. There was also a strong indication that people would attend future workshops and would be willing to pay a fee to attend. We intend to look into this for future workshops to ensure they remain sustainable, perhaps encouraging those with CME to contribute towards costs.

This report will be presented to the ON TRACK Network oversight committees, the National Executive Committee and the Strategic Research Initiative Fund Steering Group. A copy will also be sent to the sponsors of this year's workshop, the Perinatal Society of New Zealand (PSNZ) and the Paediatric Society of New Zealand.