The Development of a National Multicentre Maternal and Perinatal Clinical Trials Network
– a Feasibility Study (2014)

Dr Katie Groom 1,2,3
Professor Frank Bloomfield 2,3,4
Professor Lesley McCowan 1,2,3
Professor Caroline Crowther 3,4

Sue Copas (Project Co-ordinator) 1

1 Department of Obstetrics and Gynaecology, University of Auckland, 2 National Women’s Health, Auckland City Hospital, 3 Gravida, National Centre for Growth and Development, 4 Liggins Institute, University of Auckland.

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Background

Why clinical research networks?

Multicentre clinical trials in maternal and perinatal medicine are central to the translation of scientific research into clinical practice. They allow important, clinically relevant research questions to be answered effectively and in a timely way, leading to improved maternal and neonatal outcomes and life-long health for mothers and babies.

In New Zealand clinical trials in obstetrics, maternal fetal medicine (MFM) and neonatology are generally funded in response to investigator-initiated research proposals and rely on the traditional approach of coordinating-trial-specific personnel and resources along with a temporary consortium of research sites for each new study; an approach which can be slow and inefficient.[1] Despite this approach, New Zealand researchers in maternal, perinatal and neonatal healthcare have an excellent reputation in leading and contributing to internationally recognised multicentre clinical trials that have changed clinical practice. [2-6] Over time informal research collaborations have developed across New Zealand and Australia. In part this has been supported by the Interdisciplinary Maternal and Perinatal Australasian Clinical Trials (IMPACT) Network, a sub-committee of the Perinatal Society of Australia and New Zealand (PSANZ).

Collaborative research groups and clinical networks involved in multicentre trials are not new phenomena; they have been evolving internationally in a number of medical specialties for some time. However, the inherent inefficiencies of the traditional trial-specific approach have been highlighted recently, and the need for a more centralised, structured and sustainable long-term coordination of networks has been recognised.[7-11] As the National Institute of Neurological Disorders and Stroke (NINDS), among others, has learned, “One of the best ways to decrease the time and cost of clinical research is through well-coordinated networks”[1] With the growing emphasis on evidenced-based clinical practice, and pressures on health care expenditure creating a push for a more efficient use of increasingly scarce resources, has come the need to rethink existing research collaborations to forge more effective and sustainable alliances. [10-14] While informal networks enhance collaboration, and facilitate information sharing, most, like the IMPACT Network, have limited organisational capacity. They do not include all potential research units and recruiting centres or comprise all specialties within perinatal medicine, nor do they have any formal infrastructure to support clinical investigators.

Internationally, established clinical trials collaborations tend to follow three models of network organisation and governance (Appendix 1 provides an overview of the network models and some international examples).

1. Investigator-initiated clinical research. Investigators are supported by network infrastructure that facilitates collaborative relationships, trial management (coordination, data management, and statistical advice), information and knowledge sharing, and translation into practice.

2. Network-initiated clinical research. The network itself is set up to select, govern and support multicentre clinical trials research.

3. A mixed model approach that contains a range of both individual investigator-initiated/led, and network initiated/led clinical trials research.

Investigator-initiated clinical trials networks are the most common way of organising collaborations, and in many ways they are seen as the most effective. For example, a submission from a Clinical Trials Research Summit convened by the Medical Journal of Australia in 2012 contended:
The most effective way of conducting multiple clinical trials is by the establishment and maintenance of investigator-initiated clinical trials networks supported by experienced coordinating centres. This is because all of the work that is necessary to establish the infrastructure for a single trial — project coordination, sites with suitable potential participants, data management, and statistical advice — is available for future trials if this infrastructure is created and sustained as part of an ongoing collaborative network. Furthermore, these networks tend to be led by clinicians, and this has two important consequences. Firstly, the research questions that these networks answer are those that are most relevant to practising clinicians. Secondly, the results tend to be implemented into practice rapidly because a community of clinician-researchers has undertaken the research and is heavily invested in implementing evidence derived from their own trials.[15]

Successful, mature, clinical trials research networks, like the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) prove this contention, demonstrating the value of long-term investment in investigator-initiated clinical trials coordination, infrastructure and personnel development.

The ANZICS CTG, a sub-committee of the Australia and New Zealand Intensive Care Society, is now one of the world’s largest and most successful critical care investigator-initiated research networks.[16, 17] Established in 1994 with the aim that all Australasian intensive care units and their dedicated professionals would work together to conduct world-class clinical research, ANZICS CTG has created a network incorporating 73 Intensive Care Units, 2 methods centres and more than 600 clinicians and researchers. Strong partnerships with external research bodies, locally and internationally have attracted approximately $60m (AUD) in grant funding to-date, and this has enabled the network to endorse, coordinate and support over 30 clinical studies, including published landmark trials in major medical journals. [16] Future-focused, their strategy includes the education, training and development of emerging clinical researchers; and with the benefit of twenty years organisational learning ANZICS CTG has also provided advice to other specialties, thereby assisting the development of effective new research networks such as the Australasian Kidney Trials Network.[18]

The ongoing success of such networks proves the worth of sustainable infrastructure, research coordination and collaboration. Not only do these factors enhance completion of world-class clinical trials, they also promote a culture of research within clinical practice, improve translation of research into practice and significantly strengthen further funding opportunities.

Why a maternal and perinatal network in New Zealand?
New Zealand is a small country with a population of approximately 4.4 million and around 60,000 live births per annum.[19]) Most health services are provided within a regionally-based system of 20 District Health Boards (DHBs). Hospitals within five DHBs are able to provide level-three neonatal intensive care and three of these provide MFM services. However, the remaining 15 DHBs also provide obstetric and neonatal services for New Zealand women. Multicentre clinical research is currently predominantly led from the largest centre, University of Auckland at Auckland City Hospital. Other centres have participated in New Zealand’s contribution to international collaborations[20], and at present these hospitals including Middlemore, Waikato, Palmerston North, and Wellington in the North Island, and Christchurch and Dunedin in the South Island are making significant contributions as collaborating centres. All sites have the potential to lead trials in the future.

Unlike some other jurisdictions New Zealand is renowned for its collaborative scientific research culture.[21] This ethos provides a strong foundation on which to develop a national maternal and perinatal clinical trials network. While the country has a relatively small number of births per year, and a limited number of birthing
and neonatal units, there is a wealth of internationally recognised clinical researchers who have the experience and motivation to lead such a network.

Given the strength of investigator-initiated research in New Zealand, and growing calls for clinical trials research to be considered a core component of healthcare systems, [8, 10, 11] developing a cohesive maternal and perinatal network would allow clinical trials to be carried out in all maternity and neonatal units around the country. This would provide opportunities for smaller regional units to become involved in research, promote a research culture in all maternity and neonatal settings, and contribute to improved outcomes in mothers’ and babies’ health across the country. With a growing emphasis on promoting efficient and cost-effective healthcare, with more New Zealand-led studies planned or underway, and with multidisciplinary collaboration being key to the successful completion of research trials and their translation into enhanced clinical practice, it’s timely to consider improving infrastructure and coordination across the country in all areas of maternal and perinatal medicine.

A maternal and perinatal network for New Zealand and Australia?
A similar reconsideration is also occurring in Australia led by PSANZ. In 2013 a multidisciplinary working party was set up to address how PSANZ could enhance the conduct of clinical trials across both countries more effectively. The working party involved researchers and clinicians from both Australia and New Zealand including Professor Frank Bloomfield, Professor Caroline Crowther and Dr Katie Groom from the University of Auckland/Auckland City Hospital.

The terms of reference included:
- To profile Australia and New Zealand activity to-date in maternal and perinatal clinical trials.
- To review existing clinical trials networks in Australasia and internationally to identify strengths, translatable to the Australasian setting, potential synergies and any weaknesses.
- To make recommendations to the PSANZ Board on the framework, governance structure and potential sources of funding for a maternal perinatal clinical trials group.

The work from this New Zealand project significantly contributed to the considerations of the working party including the use of information from our review of existing clinical trials networks, the multidisciplinary national surveys and scoping of past and on-going multicentre clinical trials within New Zealand.

An important issue considered by the working party was that of the Australian Clinical Trials Alliance (ACTA). This new enterprise is gaining considerable momentum in Australia. Driven by the investigator-initiated trials sector the alliance aims to enhance the conduct and impact of clinical trials activity across the health spectrum in Australia. ACTA is a ‘network of networks’ that will act as a single coordinated peak body connecting clinical networks with governments, health care policy makers, funders and consumers with the aim of significantly improving the process of generating high-quality evidence to promote effective and cost-effective health care in Australia. In 2013 the IMPACT Network did not meet the criteria to become members of ACTA. However, as there are likely to be significant advantages for any clinical trial network in Australia to be included in the alliance the recommendations of the PSANZ multidisciplinary working party in early 2014 were made to ensure that PSANZ could endorse IMPACT as its clinical trials group and meet the ACTA clinical trial network full membership eligibility criteria. The working party recommendations were for a revitalisation of the IMPACT Network with an enhanced strategic framework, higher profile, increased organisational capacity and activity, development of a trial endorsement process and more formalised terms
of reference and governance. There is no such equivalent ‘network of networks’ in New Zealand and although ACTA does not extend to New Zealand, over 50% of these trial networks are bi-national ones and so ACTA may provide some benefit to New Zealand based multicentre clinical trial activity.

Establishing the feasibility study
In a parallel process with that of the IMPACT Network, the core group of research active clinicians noted above; Dr Katie Groom (obstetrics and MFM), Professor Caroline Crowther (obstetrics and MFM) and Professor Frank Bloomfield (neonatology) from the Department of Obstetrics and Gynaecology and Liggins Institute, University of Auckland and Auckland City Hospital saw the need to review current clinical trial practice and consider a more formal national network to enhance the conduct of high quality trials in New Zealand. They became Lead Investigators for the study.

In line with international examples they envisaged the scope of a proposed network may encompass:

- Infrastructure to support world-class clinical research in New Zealand. Led by a central coordinating centre (able to offer services such as study design advice, statistical support, central randomisation services and central database systems) with local co-ordinators at each centre.
- A national register of maternal and perinatal clinical trials to promote collaboration and recruitment with a central online presence where resources can be accessed and knowledge shared.
- Engagement with communities. Promoting research to women and their families, and involving consumers in network governance.
- Professional development and training to prepare, support and advance future clinical researchers in maternal and perinatal medicine.
- Promoting and monitoring the translation of research findings into clinical practice.
- Enhancing future funding opportunities for clinical research in maternal and perinatal medicine.
- Collaboration with Australian researchers to ensure parallel collaborative networks or a single network functioning across both countries.

A clinical trials network of this calibre requires substantial planning. The important first step was to establish and fund a feasibility study. Envisaged as a one year project, the feasibility study sought to ascertain whether it would be possible to achieve such a network across New Zealand, and how best this could be done. The data gathered would also provide a wealth of information to support network establishment. The proposed study encompassed the following design and methods:

1. Form a multidisciplinary New Zealand wide Advisory Group.
2. Identify all maternal and perinatal medicine related centres within New Zealand.
3. Engage with centres by questionnaire/survey and interview. Identify past and current involvement in clinical research, specific research interests, potential research capabilities and the barriers and enhancers for a clinical trials network.
4. Consult with successfully established clinical trials network groups.
5. Consult with stakeholders, official bodies, Colleges and funding bodies.
6. Collate and review the findings.
7. Lead a stakeholders/collaborators meeting to propose and establish a maternal and perinatal clinical trials network.
Two organisations saw merit in funding the feasibility study through competitive grant review processes; Gravida, the National Centre for Growth and Development [22] and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) through the Mercia Barnes Trust. In July 2013 a part-time project coordinator was appointed to manage the study.

The Feasibility Study

**Multidisciplinary New Zealand wide Advisory Group**

Key research active clinicians from the five main centres (specialising in obstetrics, neonatology, midwifery, neonatal nursing and allied women’s health) were invited to form the national multidisciplinary Advisory Group (Figure 1). Two consumers were invited to be part of the Advisory Group recognising the importance of service user contributions to the quality of health and medical research through their experiential expertise and broader community perspectives. [23-26] A Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) trainee was co-opted to the Advisory Group to provide a research opportunity and provide insight from a junior doctor/researcher perspective.

*Figure 1. The feasibility study National Advisory Group*

The National Advisory Group first met via teleconference in early September 2013. At this meeting the functions of the group were agreed and on-going correspondence was by group e-mail discussion and a one day face-to-face workshop.

*Identification of all maternal and perinatal medicine related centres within New Zealand*

All maternal and perinatal medicine related centres in New Zealand were identified, and information on DHB population demographics and maternity facilities collected and collated (Appendix 2).

*Engaging with clinicians in maternal and perinatal health*

Two surveys were designed for widespread distribution. The first was a general survey to be distributed amongst all maternal, perinatal and neonatal healthcare professionals around the country; the second, a
more detailed survey targeting research active practitioners in the field. These surveys were developed by the Lead Investigators with the Project Coordinator primarily responsible for the general survey and the RANZCOG trainee responsible for the research active survey.

The general survey was designed to investigate awareness of, and experience with, clinical trials research, and attitudes towards participating in future clinical trials research. It also sought to identify factors that help or hinder current or future involvement in research. The second survey, aimed at research active practitioners, was designed to gauge this particular cohort’s current research involvement and experience, assess their future research interests and potential, and gain a better understanding of the organisational processes that support them. It also sought to assess their attitudes towards developing a national clinical trials network, and the range of network infrastructure research active practitioners would support.

Both surveys were initially piloted by National Advisory Group members and a few minor amendments were made to questions and formats following their positive and constructive feedback (Appendix 3).

The 20-item general survey contained 17 binary and multiple-option forced-choice questions, and three open-ended questions, used to ensure both high discriminative value and to allow participants to elaborate on their responses.

The survey was organised into three sections.
- The first contained four demographic questions
- The second contained 13 questions directed at the individual level and asked about current and future involvement in clinical trials research. The open-ended questions in this section asked participants about their current and/or future research interests, and what barriers or enablers helped or hindered their individual involvement in clinical trials research
- The third section contained four questions directed at workplace level factors that help or hinder clinical trials research

The 25-item research active survey contained a mix of binary and multiple-option forced-choice questions, some of which allowed a limited text-based elaboration of responses.

The survey was organised around four substantive areas.
- The first contained nine demographic questions
- The second contained nine questions directed at participants’ research involvement, experience and interests,
- The third contained three questions about current funding and infrastructure
- The fourth section contained seven questions investigating individual and infrastructural factors that would be likely to increase research participation in the future.

The surveys were accessible via a Survey Monkey web link and distributed consecutively. The general survey was accessible from mid-October 2013 to early February 2014, and the research active survey went live in mid-December 2013 and closed in early February 2014. The intention was to distribute the surveys through professional networks, however this strategy proved challenging. Processes for access to the distribution lists of some of the professional colleges took more time than anticipated, and was not always successful.

Invitations to complete the general survey were distributed to all obstetricians and gynaecologists and neonatal nurses with the assistance of RANZCOG and the Neonatal Nurses College of Aotearoa (NNCA) respectively via their distribution lists. A targeted email invitation went to neonatologists using contacts from the Australia and New Zealand Neonatal Network (ANZNN) Directory. It was not possible to utilise the New Zealand College of Midwives (NZCOM) distribution list and so the survey was distributed to midwives via DHB contacts using a snowball technique. A follow-up reminder email was sent to all contacts in early November 2014.
A snowball technique was employed to distribute the research active survey. The web link was initially sent via a targeted email invitation to 189 clinicians and researchers deemed to be ‘research active’ by members of the National Advisory Group. They in turn were asked to forward the link on to colleagues they considered fitted the research active criterion. A follow-up reminder was sent to the initial contact group in early January 2014. It was expected there would be crossover participation with some clinicians responding to both surveys.

General Survey Results

Response rates
The target group for the general survey comprised clinicians working in maternal, perinatal and neonatal health across the country, with particular emphasis on the four major professions in this area; obstetricians, neonatologists, neonatal nurses and midwives. The distribution to, and response rates, from these groups were as follows:

- **Obstetricians**: The RANZCOG New Zealand Office sent the survey link via e-mail to 635 fellows, members and trainees on their mailing list (personal communication, Jane Cumming, Executive Officer, New Zealand Office, 15th October 2013). Responses were received from 89 individuals (14%).
- **Neonatologists**: The survey link was directly e-mailed to 34 neonatologists listed in the ANZNN Directory. Responses were received from 30 individuals (88%).
- **Neonatal Nurses**: The NNCA Office sent the survey link via e-mail to the NNCA distribution list of 533 members (personal communication Annie Marshall, Chairperson NNCA, 26th November 2013). Responses were received from 54 individuals (10%).
- **Midwives**: Following a formal submission process, NZCOM declined access to their database (13th December 2013). We subsequently utilised DHB midwifery contacts asking these initial contacts to distribute the survey link as widely as possible to their networks (a snowball technique). Responses were received from 120 individuals.

The response rate from obstetricians, neonatal nurses and midwives was low, in contrast to that from neonatologists which was excellent. These variable response rates may be indicative of a number of factors. The timing of the survey, over the Christmas/New Year period, may have affected up-take. The interest and/or priority placed on research within the clinical landscape may also have been a factor. Arguably this could explain the high uptake by neonatologists. The relatively small size of this professional grouping, and their location in tertiary units in main centres associated with universities in New Zealand, suggests there is greater recognition of the importance of research participation in this group and that it may be easier to be involved in research compared with other professional groups. The low response rates may also be symptomatic of the overwork/over-capacity experienced by many clinicians in maternal and perinatal health. However, despite the low and variable up-take, thematic analysis of barriers and enablers to research involvement did suggest saturation of themes was reached across the four major professions, indicating that at least in this regard; the inclusion of additional participants would be unlikely to generate any new factors.

Demographic of respondents
There were 339 responses from healthcare professionals involved in mothers’ and babies’ health across New Zealand (Table 1). Participants ranged in age from 21-60+ years and were located in 19 of the 20 DHBs in New Zealand, with the largest cohorts coming from the Waikato (n=45, 14%), Canterbury (n=43, 13%) and Auckland (n=39, 12%) DHB regions. The only area with no respondents was Wairarapa DHB. Those surveyed worked in tertiary Units (54% in hospitals providing <32 weeks neonatal intensive care units), secondary Units (35% in hospitals providing >32 weeks neonatal facilities), primary birthing units (7%), and in the community (14%) with some practising in more than one area.
Table 1. Self-identified profession (n=339 respondents)

<table>
<thead>
<tr>
<th>Profession</th>
<th>Number</th>
<th>% of total responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrician</td>
<td>89</td>
<td>26</td>
</tr>
<tr>
<td>Neonatologist</td>
<td>30</td>
<td>9</td>
</tr>
<tr>
<td>Midwife</td>
<td>120</td>
<td>35</td>
</tr>
<tr>
<td>Neonatal nurse</td>
<td>54</td>
<td>16</td>
</tr>
<tr>
<td>Other: Other</td>
<td>46</td>
<td>14</td>
</tr>
</tbody>
</table>

*Other: this category included paediatric nurses, physicians, lactation consultants, paediatricians, neonatology registrars, senior house officers, fertility specialists, GPs, gynaecologists, colposcopy specialists and dieticians.*

Prior involvement in clinical trials

The majority of participants (217/337 64%) had prior involvement in clinical trial research. Involvement rates varied across the four main professions surveyed; with all neonatologists (29/29, 100%), 68/88 (77%) obstetricians, 35/54 (65%) neonatal nurses and 51/119 (43%) midwives having prior involvement in research.

Involvement in prior research was in a range of capacities (Figure 2) and these prior research capacities and functions varied by profession. Principal and local investigators were predominantly neonatologists and/or obstetricians and these professional groups also figured highly in the largest categories; recruitment to the research, and explaining/discussing the research and providing information to participants and their families (Table 2).

Figure 2. Type of prior involvement in clinical research trials (n=203 respondents).

These results support the contention that attitudes towards research participation and the barriers experienced are inflected through different professional cultures [27]. For example a relatively small number of midwives and neonatal nurses categorised themselves in designated research roles such as research midwife/nurse, but with much larger representation in the categories concerned with research functions (recruitment, discussing the research with participants, administration and data collection). Midwives and nurses attitudes towards clinical research appear to continue to be influenced by their role expectations which are often limited to acting as contributors to and facilitators of other peoples’ studies. This remains a significant barrier to creating a participatory and collaborative clinical research culture where complementary knowledge and skills can be recognised and valued. [28-30] The lack of paid research roles available for nurses and midwives, and the lack of equity within them, was highlighted as a contributing factor to this issue in a comment made by a neonatal nurse within the general survey.
“Lack of funding to provide hours required to complete trials to an optimum level and make pay equitable with nursing wages. I was paid by the university rather than the DHB and they did not recognise my nursing thus was on a university general collective and not even covered by the nurses’ union. We were as a group (others within the DHB employed under the same conditions) trying to rectify this proactively meeting to bring about change.” (Neonatal nurse, in a tertiary unit).

**Table 2.** Type of prior involvement in clinical research trials by profession.

<table>
<thead>
<tr>
<th>Profession</th>
<th>Principal Investigator</th>
<th>Local Investigator</th>
<th>Research Midwife/Nurse</th>
<th>Recruitment to the research</th>
<th>Explaining discussing the research &amp; providing information to participants &amp; their families</th>
<th>Administration of the research treatment</th>
<th>Data collection and/or study follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrician (n=67)</td>
<td>17 (25)</td>
<td>20 (30)</td>
<td>0</td>
<td>43 (64)</td>
<td>47 (70)</td>
<td>12 (18)</td>
<td>18 (27)</td>
</tr>
<tr>
<td>Neonatologist (n=28)</td>
<td>15 (53)</td>
<td>22 (78)</td>
<td>0</td>
<td>20 (71)</td>
<td>22 (78)</td>
<td>11 (39)</td>
<td>16 (57)</td>
</tr>
<tr>
<td>Midwife (n=43)</td>
<td>1 (2)</td>
<td>4 (9)</td>
<td>7 (16)</td>
<td>26 (60)</td>
<td>30 (70)</td>
<td>14 (33)</td>
<td>15 (35)</td>
</tr>
<tr>
<td>Neonatal nurse (n=32)</td>
<td>2 (6)</td>
<td>0</td>
<td>4 (12)</td>
<td>7 (22)</td>
<td>16 (50)</td>
<td>17 (53)</td>
<td>14 (44)</td>
</tr>
</tbody>
</table>

Expressed as n (%)

Two questions were designed to understand more about the role clinical trials may play in professional development. Participants were asked if their past involvement in clinical trials research was toward a further qualification, 176/188 (94%) indicated it was not. Participants were also asked if they had ever considered a role in clinical trial research towards a further qualification, 185/320 (58%) indicated they had not, suggesting a significant proportion may have considered but not undertaken further postgraduate study. Text analysis of the reasons why participants chose not to undertake further qualifications revealed 8 themes, which were (in order of prevalence):

1. Time constraints  
2. Limited opportunity to undertake, and limited support  
3. Not interested and/or not relevant to current role  
4. Work-life stage and work/life balance factors  
5. Had not considered it  
6. Had qualifications and no need for further in current role  
7. Funding and financial constraints  
8. Could be interested in the future

A number of participants from outside the main centres indicated they were interested in clinical trial research roles but had not considered the option of combining this with undertaking further qualifications, for example:

“I had not thought about it as a possibility” (Midwife, in a secondary unit outside the main centres).

“Just never considered it, nor been around nurses who have done such work” (general nurse in paediatrics in a secondary unit outside the main centres).

A number also cited a lack of opportunity and/or lack of support as reasons for not considering clinical trial research roles as vehicles for further qualifications, for example:
“Little access to a team and no support” (obstetrician in a secondary unit outside the main centres).
“The opportunity has never arisen” (midwife in a secondary unit outside the main centres)
“Never seen research opportunity at the beginning phase where it would be appropriate to be involved” (midwife in a secondary unit in a main centre).

More than half of the respondents reported their current workplaces were already involved in clinical trials including mothers, babies or mothers and babies (155/288, 54%). However, 85/288 (29%) respondents reported that no clinical trials involving either mothers or babies were on-going in their workplace and 47/288 (16%) did not know if their workplace was involved in clinical trial research.

Future interest in involvement in clinical trials

The vast majority of participants (284/322, 88%) agreed more clinical trial research in maternal and perinatal health was needed, although 38/322 (12%) were unsure and one (1/322 <1%) did not agree that more clinical trial research was needed. Most participants (287/322, 89%) reported a willingness to be involved and in a spectrum of ways across the range of suggested activities (Figure 3).

**Figure 3.** Range of future involvement in clinical trials research (n=283 respondents)

The high numbers willing to be involved in clinical trials in the future was consistent across all the four major professions surveyed (Table 3) across all workplaces (tertiary, secondary, primary and community-based practice) and all DHB regions. More health professionals indicated a willingness to be involved in the future than indicated involvement in research in the past.

**Table 3.** Willingness to be involved in future clinical trials research by profession.

<table>
<thead>
<tr>
<th>Profession</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrician (n=86)</td>
<td>77 (90)</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Neonatologist (n=28)</td>
<td>27 (96)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Midwife (n=112)</td>
<td>97 (87)</td>
<td>8 (7)</td>
</tr>
<tr>
<td>Neonatal nurse (n=50)</td>
<td>46 (92)</td>
<td>3 (6)</td>
</tr>
</tbody>
</table>

Expressed as n (%). The remainder identified ‘non-applicable’ as their response.

The majority of respondents (203/294, 69%) agreed their workplaces would support involvement in a clinical trial, although 89 (30%) were unsure if this would be the case and two (0.7%) reported their workplaces would not support involvement.
Current and/or potential research interests
A question about current or potential research interests revealed a broad range of categories and interests. The most common research areas identified (with their frequencies) were; birth and delivery (n=15), obesity and diabetes (n=14), neonatal cardio-respiratory (n=13), preeclampsia/pregnancy induced hypertension/small for gestational age/fetal growth restriction (n=11), breastfeeding (n=8), preterm infant health (n=7), neonatal nutrition (n=6), models of antenatal care (n=6), neonatal allergy (n=4), stillbirth and other mortality (n=4), infection and sepsis (n=2), fetal effects of drug and alcohol (n=2) and quality improvement (n=2).

Barriers to involvement in clinical trials
A key part of the survey investigated participants’ opinions of factors that hindered involvement in clinical trials. A text-based question asked, “What are the barriers preventing you as an individual from being involved in clinical trials research?” At the organisational level, participants were asked to select from pre-designated categories, choosing as many barriers as applied. There was also an opportunity to comment on any other organisational barriers they encountered.

There was a high rate of response to this question including a surprisingly high number of free text comments. There were 297 text responses to individual barriers noted with many participants noting multiple obstacles to their involvement in clinical trials. Thematic analysis across the data set generated seven key themes (Table 4).

Table 4. Barriers to respondents’ involvement in clinical trials research.

<table>
<thead>
<tr>
<th>Key themes identified</th>
<th>Number of responses</th>
<th>% of total response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>135</td>
<td>45</td>
</tr>
<tr>
<td>Work/life stage, and work/life balance</td>
<td>50</td>
<td>17</td>
</tr>
<tr>
<td>Funding/financial constraints</td>
<td>44</td>
<td>15</td>
</tr>
<tr>
<td>Lack of opportunity to undertake research</td>
<td>39</td>
<td>13</td>
</tr>
<tr>
<td>Lack of support, understanding, and/or guidance to undertake research</td>
<td>36</td>
<td>12</td>
</tr>
<tr>
<td>Professional development factors</td>
<td>36</td>
<td>12</td>
</tr>
<tr>
<td>Specified research-related factors</td>
<td>20</td>
<td>7</td>
</tr>
</tbody>
</table>

Lack of time was considered the major barrier and this was noted across the four major professions surveyed. Indicative comments included;

“Time, clinical work always seems more urgent” (obstetrician)

“Constraints of work providing care to patients/daily clinical responsibilities. Research required my personal time after hours.” (obstetrician)

“One of the barriers is, and has been, needing to take time off from paid employment to undertake research.” (midwife)

“Time – busy clinical workloads make pursuing hypotheses to a research trial level challenging.” (neonatologist)

“Time and commitment can intrude on actual clinical duties during a nursing shift. Documentation can be lengthy.” (neonatal nurse)

The second most prevalent theme, ‘work/life stage and work/life balance’ denoted two distinct but related factors. Work/life stage referred to barriers inherent in the professional location and motivations of respondents at varying stages in their career trajectories (for example, those early in a professional career, and/or undertaking postgraduate training, as opposed to those nearer to retirement). Indicative comments included;

“Currently I am focussing on entering the training program but hope to be actively involved in research soon.” (obstetrician)
“I find the concept of research interesting and stimulating and wouldn’t mind being involved in it, but have no desire to gain a qualification at this stage in my life.” (neonatal nurse)
“I am coming towards the end of my career as a clinician and so I do not have the commitment.” (obstetrician)
“Temporary nature of my job” (senior house officer)
“Recent research about stillbirth I would have been interested in being involved with but too busy completing my DHSC.” (midwife)

In contrast, work/life balance issues referred to the time constraints involved in juggling work commitments with outside of work factors, with respondents generally citing home and family responsibilities as barriers to involvement in research. Indicative comments included;

“The increasing demands of work mean the balance of family life is compromised. My family always comes first. I am also unsure of the demands of what it will involve” (neonatal nurse)
“Have other responsibilities; work currently 54+ hours per week; have a family which need some parental investment.” (midwife)
“Currently I have two small children and am on ITP [Integrated Training Programme] (trainee obstetrician)
“Time involved and trying to make it all fit in with work and home life” (midwife)

The words “funding” and “financial support” were most commonly used by those who noted financial constraints as a barrier to research involvement. Again this issue was mentioned by all the major professions surveyed. Indicative comments included;

“Terrible state of funding in New Zealand (obstetrician)
“Financial support” (neonatologist)
“Being paid for the time involved.” (midwife)
“Lack of funding for postgraduate study.” (neonatal nurse)

Lack of opportunity to undertake research was more commonly mentioned by neonatal nurses and midwives. In this theme respondents typically referred to their geographical location and the size of the unit where they worked, to a lack of clinical trials happening, and to issues with access to participants. Indicative comments included;

“Location and size of the unit I work in.”(neonatal nurse – secondary unit outside main centres)
“Based away from academic or metropolitan centre.” (obstetrician, secondary unit outside main centres)
“No opportunity at all. All the hospitals I worked with don’t do research” (neonatal nurse, secondary unit outside main centres)
“Centre size.” (paediatrician, secondary unit outside the main centres)

While the survey question specifically asked for barriers ‘as an individual,’ respondents noting lack of support, understanding and/or guidance as a barrier to research tended to refer to workplace cultures and more systemic barriers. Indicative comments included;

“When I was working clinically I found that research trials were poorly publicised and supported within our department. The service side was quite busy at the registrar level, so consultant input and support would have been critical for research success.” (Registrar in obstetrics and gynaecology, currently working in research)
“Lack of a local peer group involved in similar interests” (neonatologist)
“Lack of management and organisation support, bureaucracy to get an idea heard and developed, knowing who to contact and how to get involved in research” (midwife – secondary unit outside main centres)
“Lack of enthusiasm from department managers/SMOs (obstetrician – tertiary unit)
The theme ‘professional development factors’ relatedly directly to individual perceptions and assessments of confidence and competence, and the professional development needed to undertake clinical trials research. Indicative comments included;

“Lack of training in skills needed for research” (neonatologist)
“Lack of familiarity with statistical methods” (obstetrician)
“Lack of training/education/experience” (neonatal nurse)
“Unsure what is required, how to start, or what would be relevant” (midwife)

Specific research-related barriers to undertaking clinical trials were noted by 20/297 (7%) who responded to this question. In this category difficulties with ethics processes and approvals (including locality approvals) were mentioned most often. Sample size (the small pool of participants/patients) and issues with statistical analysis were also noted, as was the need for greater administrative support. Indicative comments included;

“Ethics approval, lack of biostatistician. The fact ethics approval needs to be obtained in each individual DHB seems to me to be a major obstacle to allowing research to occur. (obstetrician, secondary unit outside main centres)
Often not aware of what research is going on. If not very knowledgeable about trials reluctant to recruit as feel unable to counsel families fully. (trainee obstetrician, tertiary unit)
“Amount of paperwork involved in locality approvals” (neonatologist, tertiary unit)
“Lack of a coordinated trials network to allow adequate numbers in trials to provide sufficient power to answer research question adequately.” (neonatologist, tertiary unit)

At the organisational level, when asked to select as many pre-designated categories as applied (Figure 4), participants’ choices reflected many of the concerns noted above, with lack of time and funding again figuring prominently.

**Figure 4.** Current workplace barriers to clinicians’ involvement in clinical trials (n=259)
Additional comments reiterated the difficulties involved in creating a research culture within the workplace.

“The lack of a local nursing research profile is a major deterrent. Two additional points are the need to include research consumers in all research interests and the need to inspire colleagues to recognise that evidence based practice is better practice.” (neonatal nurse)

“Working in a unit undergoing perpetual change in administration, policies and procedures.” (neonatal nurse)

“Clinical commitments spill into research time as we are under-resourced and that is not understood by management, plus research time allocated not adequate to set up trials I would like to do in the absence of other support systems in place.” (physician)

“Research seems to be seen as the exception rather than the rule in NZ hospitals throughout the country.” (obstetrician)

“We are constantly expected to do more for less.” (obstetrician)

Enablers of involvement in clinical trials

Two questions were designed to better understand what enables respondents’ involvement in clinical trials. At the individual level a text-based question asked. “What encourages you, and/or enhances your ability to be involved in clinical trials research?” At the organisational level, participants were asked to select from pre-designated categories, choosing as many enablers as applied. An opportunity to note any other workplace factors that assisted them to be involved in clinical trials research was also provided.

Again the uptake to this question was high, with 298 text responses. The bifurcated nature of the question meant responses fell into two broad categories; intrinsic (internal motivating factors that encourage people to undertake research) and extrinsic (external factors that support and enhance peoples’ ability to carry out research). Thematic analysis across the data set generated seven themes (Table 5).

Table 5. Enablers to respondents’ involvement in clinical trials research

<table>
<thead>
<tr>
<th>Key themes identified</th>
<th>Number of responses</th>
<th>% of total response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intrinsic Enablers: Internal motivating factors that encourage people to undertake research.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. To improve outcomes for mothers and babies (including being part of a process that builds a relevant evidence base to guide and improve clinical practice)</td>
<td>83</td>
<td>28</td>
</tr>
<tr>
<td>2. By interesting, important and relevant research questions</td>
<td>33</td>
<td>11</td>
</tr>
<tr>
<td>3. To experience new learning, acquire additional qualifications and/or further career</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td><strong>Extrinsic Enablers: External factors that support and enhance peoples’ ability to carry out research</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Management and organisational support (this included appropriate research culture and infrastructure)</td>
<td>47</td>
<td>16</td>
</tr>
<tr>
<td>5. Collaboration and collegial support</td>
<td>37</td>
<td>12</td>
</tr>
<tr>
<td>6. Dedicated time</td>
<td>35</td>
<td>11</td>
</tr>
<tr>
<td>7. Funding and financial support</td>
<td>25</td>
<td>8</td>
</tr>
</tbody>
</table>

The most enabling factor for research involvement was the respondent’s intrinsic motivation to undertake meaningful research that had the potential to improve practice and provide better outcomes for mothers and babies. Indicative comments included;

“I love research and putting together what is already known theoretically into ‘real world’ situations to improve and enhance women’s experiences in mothering their babies. This has such an important flow on to the remainder of our society.” (midwife, secondary unit, outside maincentres)
“Interest in burning issues in perinatal health e.g. stillbirth, prematurity, obesity. Potential benefits for population health when perinatal health is improved.” (midwife, secondary unit, outside main centres)

“Desire to find meaningful local data to support practice.” (obstetrician)

“The need to learn more with regard to reducing risk, morbidity and mortality among neonates, especially extreme preterm infants.” (neonatal nurse, tertiary unit)

Support from senior colleagues and managers to facilitate this internal drive, along with organisational cultures that recognise, value and resource research appropriately, were seen as the most important external factors to enhance research practice. Indicative comments included;

“Having good management, being in an innovative organisation, creativity is supported and long-term vision is part of strategy for health would be beneficial.” (midwife, secondary unit, outside main centres)

Support from the local DHB (obstetrician, secondary unit, outside main centres)

Support from experienced researchers, dedicated time for research, and value seen for research in DHB (neonatologist, tertiary unit)

“Clear, comprehensive research protocols. A randomisation process which is fast, and easy to use. Research with clear aims and tangible clinical benefits. Clinical trials with concepts that are easily understood by patients and concise easily understood patient information is available. Projects which are “well advertised” and well explained throughout the department so that many people (midwives/obstetricians/junior staff) are confident in identifying potential recruits or recruiting to the trial.” (obstetrician, tertiary unit)

“Senior support. Training in skills needed. Nationally coordinated approach and networking-including recognition of important contribution centres outside Auckland can have.” (neonatologist, tertiary unit)

These findings were reiterated and consolidated in the responses to workplace factors that would help involvement in clinical trials research (Figure 5).

Figure 5. Workplace factors that would support and enhance clinicians’ involvement in clinical trials (n=276)
One participant summed up what is possible when a range of pivotal individual and organisational enablers are present and embedded within practice.

“Our workplace is already heavily involved in clinical trials. We have supportive senior staff, dedicated research nurses and coordinators... there is a large pool of expertise and knowledge about how to undertake trials, and a large number of trials underway.” (neonatal nurse, tertiary unit)

### Research Active Survey Results

**Response rates**
The second survey was designed for those professionals identified as ‘research active’ in maternal, perinatal and neonatal health. Advisory Group members were asked to provide the initial contacts. On 16 December 2013 individual email invitations were sent to 189 professionals considered to meet the criteria, and they in turn were asked to forward the link on to colleagues they considered fitted the parameters required.

**Demographics**
There were 73 responses to this survey from a range of practitioners, 95% of who considered themselves to be currently, or previously, research active (Table 6).

**Table 6.** Respondents identified professions.

<table>
<thead>
<tr>
<th>Profession</th>
<th>Number of responses</th>
<th>% of total response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetrician</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>Obstetrician in training</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Neonatologist</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>Neonatologist in training</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Paediatrician</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Paediatrician in training</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Midwife</td>
<td>19</td>
<td>28</td>
</tr>
<tr>
<td>Neonatal Nurse</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Physician</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Epidemiologist</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Participants ranged in age from 31-60+ years, with the majority (32/73, 44%) in the 51-60+ years category. They were located in 12 of the 20 DHB regions in the country, most in the five main centre DHBs that contain tertiary level hospitals and universities. The majority (48/73, 65%) were based in the three Auckland region DHBs; Auckland (31), Counties Manukau (11) and Waitemata (six). Eight respondents were based in each of the Waikato, Canterbury and Southern DHB regions, and four in the Capital and Coast DHB region.

Primary appointments were in DHBs (42/71, 59%), and universities (28/71, 39%). More than half (45/71, 63%) had an official/paid appointment that included a research component. The majority (54/65, 83%) of those in clinical practice worked at a tertiary level hospital (providing <32 weeks neonatal intensive care facilities). All those in non-clinical practice worked at a university with a significant majority based at the county’s two main medical and health sciences training institutions; the University of Auckland (27/45 60%), and the University of Otago (12/45, 27%). Four worked at AUT University, one at Victoria University and one at Massey University.

**Past or current research involvement, experience and interests**
Most participants reported involvement in a range of research methodologies (Table 7) with experience in randomised controls trials the most prevalent. Preterm birth was the most studied research area, followed
by neonatal respiratory disorders, stillbirth/perinatal mortality, neonatal neurodevelopment and gestational diabetes.

**Table 7.** Research Active survey respondents’ involvement in research methodologies by profession

<table>
<thead>
<tr>
<th>Methodology/design</th>
<th>All respondents (n=71)</th>
<th>Obstetricians (n=15)</th>
<th>Neonatologists (n=15)</th>
<th>Midwives (n=19)</th>
<th>Neonatal Nurses (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic science/laboratory-based</td>
<td>19 (27)</td>
<td>7 (47)</td>
<td>5 (33)</td>
<td>0</td>
<td>1 (11)</td>
</tr>
<tr>
<td>Epidemiology/population-based</td>
<td>16 (22)</td>
<td>7 (47)</td>
<td>3 (20)</td>
<td>1 (5)</td>
<td>0</td>
</tr>
<tr>
<td>Randomised controlled trials</td>
<td>50 (70)</td>
<td>9 (60)</td>
<td>13 (87)</td>
<td>10 (53)</td>
<td>6 (67)</td>
</tr>
<tr>
<td>Observational studies</td>
<td>40 (56)</td>
<td>11 (73)</td>
<td>9 (60)</td>
<td>3 (16)</td>
<td>5 (55)</td>
</tr>
<tr>
<td>Qualitative research</td>
<td>20 (28)</td>
<td>2 (13)</td>
<td>2 (13)</td>
<td>7 (37)</td>
<td>4 (44)</td>
</tr>
<tr>
<td>Research synthesis</td>
<td>4 (6)</td>
<td>1 (6)</td>
<td>3 (20)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Research translation/implementation</td>
<td>16 (22)</td>
<td>6 (40)</td>
<td>4 (27)</td>
<td>1 (5)</td>
<td>1 (11)</td>
</tr>
<tr>
<td>Correlational research</td>
<td>2 (3)</td>
<td>0</td>
<td>0</td>
<td>1 (5)</td>
<td>1 (11)</td>
</tr>
<tr>
<td>Descriptive or survey/interviews</td>
<td>30 (42)</td>
<td>4 (27)</td>
<td>5 (33)</td>
<td>12 (63)</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>8 (11)</td>
<td>3 (33)</td>
<td>5 (33)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Expressed as n (%)*

Most participants had been involved in clinical trials research across a range of capacities. Recruitment/randomisation and the administration of the research intervention were the largest categories reported. The type of involvement varied across the four main professions surveyed, largely followed the pattern observed in the general survey results. Principal and local investigators were primarily obstetricians and/or neonatologists. These professionals also figured highly in the recruitment and administration categories noted above, with midwives and neonatal nurses also prominent.

Participants were asked to indicate which specific clinical trials (from a list of 30) they had personally contributed to. While the numbers were small, those who responded (n=47) noted international collaborations (generally Australian-led) most often. The top six trials participants were involved with were: The Australian Placental Transfusion Study (APTS) (n=18), Magnesium Sulphate at 30-34 weeks Gestational Age Neuroprotection Trial (MAGENTA) (n=15), International Neonatal Immunotherapy Study (INIS) (n=14), Lower vs higher oxygen saturation targets in neonates < 28 weeks gestation (BOOST NZ) (n=14), and Early planned delivery of women with PPROM close to term vs expectant management trial (PPROMPT) (n=11).

Given these results it is unsurprising that only a minority reported they did not work collaboratively with other researchers and/or research centres (10/64, 16%). The majority collaborated with researchers within their centre (40/62, 62%), nationally (29/62, 45%) and internationally (27/62, 42%).

Some respondents were involved in supervising others. 42% (30/71) undertook research supervision. This encompassed formally supervising students (from undergraduate to PhD); research staff; overseeing vocational training (for example RANZCOG, FRACP), and the informal supervision of others.

There was support for professional development, with a majority of participants indicating they would like to develop their research capabilities across a range of areas with reasonable consistency across the four main professions surveyed (Table 8).
### Table 8. Research capabilities participants would like to develop

<table>
<thead>
<tr>
<th>Research capabilities</th>
<th>All respondents (n=56)</th>
<th>Obstetricians (n=12)</th>
<th>Neonatologists (n=15)</th>
<th>Midwives (n=13)</th>
<th>Neonatal Nurses (n=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishing a research team</td>
<td>20 (36)</td>
<td>6 (50)</td>
<td>4 (26)</td>
<td>1 (7)</td>
<td>4 (66)</td>
</tr>
<tr>
<td>Development of study design &amp; methodology</td>
<td>25 (45)</td>
<td>8 (66)</td>
<td>6 (40)</td>
<td>5 (38)</td>
<td>0</td>
</tr>
<tr>
<td>Grant writing</td>
<td>18 (32)</td>
<td>5 (41)</td>
<td>4 (26)</td>
<td>2 (15)</td>
<td>2 (33)</td>
</tr>
<tr>
<td>Ethics development</td>
<td>14 (25)</td>
<td>4 (33)</td>
<td>3 (33)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
<tr>
<td>Research protocol development</td>
<td>21 (37)</td>
<td>5 (41)</td>
<td>1 (8)</td>
<td>2 (15)</td>
<td>2 (33)</td>
</tr>
<tr>
<td>Lead a randomised control trial</td>
<td>15 (27)</td>
<td>1 (8)</td>
<td>6 (40)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
<tr>
<td>Development of research schedules &amp; financial budgets</td>
<td>10 (18)</td>
<td>2 (16)</td>
<td>3 (20)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
<tr>
<td>Data management</td>
<td>16 (28)</td>
<td>2 (16)</td>
<td>6 (40)</td>
<td>3 (23)</td>
<td>1 (16)</td>
</tr>
<tr>
<td>Developing randomisation programs</td>
<td>7 (12)</td>
<td>2 (16)</td>
<td>2 (13)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
<tr>
<td>Participant recruitment</td>
<td>23 (41)</td>
<td>5 (41)</td>
<td>3 (20)</td>
<td>2 (15)</td>
<td>3 (50)</td>
</tr>
<tr>
<td>Clinical trial management</td>
<td>17 (30)</td>
<td>4 (33)</td>
<td>3 (20)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
<tr>
<td>Statistical analysis of results</td>
<td>22 (39)</td>
<td>6 (50)</td>
<td>3 (20)</td>
<td>5 (38)</td>
<td>0</td>
</tr>
<tr>
<td>Preparation and submission for publication</td>
<td>21 (37)</td>
<td>5 (41)</td>
<td>2 (15)</td>
<td>3 (23)</td>
<td>0</td>
</tr>
<tr>
<td>Supervision of research students</td>
<td>13 (23%)</td>
<td>4 (33)</td>
<td>2 (15)</td>
<td>1 (7)</td>
<td>0</td>
</tr>
</tbody>
</table>

Expressed as n (%)

### Awareness of current infrastructure and funding

Participants reported a range of funding sources for their current research (Figure 6), with the majority being supported by national funding agencies, such as the Health Research Council (HRC), or university funds, such as Faculty Research Development Funds. A small number of international funding agencies were mentioned (including the World Universities Network and the Gates Foundation), as were funders associated with international multicentre collaborations (such as the American National Institutes of Health (NIH), and National Institute of Child Health and Development (NICHD).

**Figure 6. Current funding sources for research (n=47)**

The four major professions were all represented in the unfunded category, with the majority of these noting their self-initiated research was done in their own time.

Research active practitioners were generally aware of how the salaries for research assistants, midwives and nurses in obstetric and neonatal practice were funded, with 31/61 (51%) attributing the source to specific project grants. University and DHB funds were noted by 12/61 (20%) and 8/61 (13%) of participants respectively, however 21/61 (34%) did not know how these research support roles were funded.
To gain a better understanding of research active practitioners’ awareness of, and access to research support and infrastructure for current maternal, perinatal, neonatal and/or paediatric clinical trials, we asked a sixteen-factor question with items clustering around three key areas; collaboration, resources and the funding of research assistance (Figure 7).

**Figure 7.** Awareness of, and access to, research support and infrastructure within each individual’s work place by the four main professions (n=41).

Within the main unit where you work do you have;

- **F1** - an established maternal, perinatal, neonatal and/or paediatric clinical trials centre
- **F2** - an established maternal, perinatal, neonatal and/or paediatric clinical trials group (i.e. group of individuals focused on more than one clinical trial)
- **F3** - a designated statistician available to advise on clinical trials in maternal, perinatal, neonatal and/or paediatric health
- **F4** - access to an electronic data collection system
- **F5** - access to advice and assistance with ethics applications
- **F6** - access to an electronic randomisation programme/service
- **F7** - access to data management support
- **F8** - access to laboratory services to support clinical trials
- **F9** - access to pharmacy services to support clinical trials
- **F10** - access to appropriate facilities for clinical trials follow up studies
- **F11** - Paid research assistants/midwives/nurses time in obstetric practice funded by a specific grant for a single clinical trial (part-time or full-time)
- **F12** - Paid research assistants/midwives/nurses time in obstetric practice funded by a specific grant to work across two or more clinical trials (part-time or full-time)
- **F13** - Paid research assistants/midwives/nurses time in obstetric practice funded by other means to work on several clinical trials
- **F14** - Paid research assistants/midwives/nurses in neonatal practice funded by a specific grant for a single clinical trial (part-time or full-time)
- **F15** - Paid research assistants/midwives/nurses in neonatal practice funded by a specific grant to work across two or more clinical trials (part-time or full-time)
- **F16** - Paid research assistants/midwives/nurses in neonatal practice funded by other means to work on several clinical trials
Of the four major professional groupings, neonatologists and research midwives, who were generally associated with established clinical trials groups and located in tertiary units within main centres had the greatest awareness of, and access to the range of support, infrastructure and resourcing specified. Most participants (51%) were aware that paid research assistants, midwives and neonatal nurses in obstetric and neonatal practice were usually funded via project research grants, from a specific funding body, although 34% did not know how these roles were funded.

**Factors likely to increase research participation in the future**
Research active practitioners demonstrated consistent and significant identification of a range of individual and organisational factors deemed likely to increase their participation in research (Figure 8). Likert scale assessment of attitudes showed particularly strong support for; allocated research time within an FTE, designated staff to assist with research, employer recognition for research on a par with clinical duties, being part of a bigger research group or team, assistance in applying for funding and clear, coordinated and well understood processes in the professional area of practice for recruiting people to participate in clinical research.

**Figure 8.** Support for individual and organisational factors likely to increase participation in research (n=61)

![Bar chart showing support for individual and organisational factors likely to increase participation in research (n=61)](chart.png)

I would increase my participation in research if;
F1 Allocated time within my FTE
F2 Designated staff to assist with research
F3 Ability to exchange a current commitments for research
F4 Employer gives research the same recognition as clinical duties
F5 More recognition of the importance of research and support for undertaking it from senior staff
F6 Be part of a bigger research group or team
F7 Better access to training in the skills needed for research
F8 Better promotion of funding opportunities
F9 Assistance in applying for funding
F10 Greater awareness of the potential benefits of clinical research in the geographical area where I work
F11 Greater awareness of the potential benefits of clinical research in the professional area where I work
F12 Clear, coordinated and well understood processes in the geographical area where I work for recruiting people to participate in clinical research
F13 Clear, coordinated and well understood processes in the professional area where I work for recruiting people to participate in clinical research
Support for a national clinical trials network in the future

63% (43/68) of those surveyed indicated they would like to be involved in more than one research project at a time and 72% (49/68) indicated a national clinical trials network would enhance their research practice (only 4 disagreed and the remainder were unsure). One respondent’s comment exemplifies the positive attitudes expressed towards the establishment of a national clinical trials network;

*I am very much a junior researcher but would greatly value participation in a clinical trials network to help develop my research career. I also highly value the concept of a national network to allow participation of all centres involved in perinatal clinical care and to allow collaboration that will strengthen the quality of research.*

Respondents noted they would be more likely to conduct or participate in maternal and perinatal research with the support and assistance of a clinical trials network that had a range of functions (Figure 9).

**Figure 9.** Functions of a clinical trials network that would increase likelihood of respondents conducting and participating in maternal and perinatal health research.

Survey comments

The rich data sets from the two surveys provided valuable understandings about the enablers of, and barriers to, current involvement in clinical trials research. The data also provided an indication of participants’ future research motivations and interests, along with their opinions on the type of support and infrastructure required to develop and sustain more effective research endeavours.

While one survey explicitly targeted a research active cohort, the high proportion of participants across both surveys with research experience or interest suggests that clinicians are interested in pursuing ways to improve research participation, collaboration and translation into practice across the whole of New Zealand. This point was further emphasised in the results from the follow-up provisions of the general survey. Of the 105 participants who indicated they would be willing to be contacted for a follow-up interview to discuss the feasibility of establishing a maternal and perinatal research network in New Zealand, 54 (51%) came from individuals working in secondary units and 50 (48%) of these were clinicians (from all four major professions) located outside the main centres. The fostering of this constituency is important because experience shows that the dedication and enthusiasm of research-focused clinicians is fundamental to setting up and maintaining successful network collaborations [14, 16, 18].
There are headwinds aplenty. Evidenced in our data were barriers to undertaking clinical trials research that have remained entrenched for decades. [28, 29, 31-35] In particular the perennial trinity; lack of time, lack of resources, and lack of institutional support (which includes poor institutional attitudes and infrastructure) were reported as barriers to research participation by all the professional groups we surveyed. While in any field, and in any setting, only a minority of health practitioners produce research [36], for the vital cohort that do, the importance of a supportive organisational culture cannot be overstated [29, 37, 38]. Unfortunately our survey findings confirm and reiterate a point made recently by another clinical discipline. In 2013 Morrish et al noted:

> The daily operational activities of the AKTN [Australasian Kidney Trials Network] provide a unique insight into the culture of health-care facilities across Australia and New Zealand. The barriers and hurdles encountered in conducting clinical trials at these facilities suggest a widespread perception that clinical research, and investigator-initiated clinical trials in particular, are a drain on hospital resources.[18]

However the tide is turning, as initiatives like the development of ACTA demonstrate. ACTA has significant inter-disciplinary momentum, Australian State and Federal government support, and as the single co-ordinating organisation for investigator-initiated clinical trial networks, a mandate to support and shape effective and cost-effective medicine in Australia into the future. Cognisant of this context, the Advisory Group convened a one-day workshop in early February 2014 to review both the survey data and the feasibility study progress to-date, and consider next steps in the development of a properly resourced and co-ordinated clinical trials network to address some of the shortcomings clinical researchers, and would-be clinical researchers, in maternal and perinatal health currently face in New Zealand.

**Advisory Group Workshop**
The meeting was held in Auckland on 12 February 2014. Advisory Group members met face-to-face for a one day workshop shaped around three key sessions (Appendix 4 for attendee list and meeting report).

The first session recapped the aims of the feasibility study and set the work in the context of international clinical trials networks, with particular emphasis on Australasian examples. Dr Colin McArthur, the current Chair of the ANZICS CTG, gave a presentation on the history and development of the ANZICS CTG. A lively question and answer session followed and Dr McArthur undertook to share the CTG’s Governance Model and Terms of Reference with the Advisory Group.

In the second session the preliminary results from the two surveys were presented and discussed.

The third session built on the information conveyed earlier and comprised a series of small inter-disciplinary group discussions addressing critical issues in the set-up of a New Zealand network. At the conclusion of the day, outcomes included;

- agreement for an investigator-initiated and led network model (research emphasis on multicentre clinical trials and other observational studies)
- an agreed set of network objectives
- consensus for the network to be under the umbrella of the Perinatal Society of New Zealand (PSNZ), linking to Australia via PSANZ

**Network development: in parallel and tandem with Australia.**
In April 2014 several members of the Advisory Group attended the annual PSANZ conference in Perth, Australia.1 At a pre-conference meeting of the IMPACT Network Dr Katie Groom presented the results to-date from the New Zealand feasibility work. This was very well received, particularly by the ACTA members present, Professor Steve Webb (Intensive Care Medicine) and Associate Professor Ross Haslam (Neonatal

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1 Advisory Group members who attended the PSANZ conference were: Professor Frank Bloomfield, Professor Caroline Crowther, Dr Katie Groom, Dr Jane Alsweiler, and Dr Deborah Harris, along with the Project Coordinator Dr Sue Copas.
who requested copies of the survey instruments with the intention of using these as the basis for similar engagement with their Australian research constituency. The PSANZ Clinical Trials Network Working Party\(^2\) also met in Perth and finalised its recommendations to the PSANZ Board of Directors. These recommendations, subsequently approved by the PSANZ Board in June 2014, seek to remodel and rebrand the IMPACT Network (Appendix 5). As part of this process the New Zealand general survey instrument has been adapted for distribution to clinicians involved in mothers’ and babies’ health in Australia. Once circulated and analysed this will complete a gathering of information across the two countries to inform future network development in both jurisdictions. With the work of the PSANZ Clinical Trials Network Working Party complete, a follow-up IMPACT Network Working Group was formed to progress and implement the ratified recommendations. Frank Bloomfield, Caroline Crowther and Katie Groom, the leads for the New Zealand feasibility study, are part of the IMPACT Working Group which agreed that any New Zealand developments should be compatible with Australia.

Cognisant of, and to some degree contingent on work in Australia, the New Zealand initiative cannot move to future engagement with funders and other bodies until a more solid proposal for what a network will encompass (including a co-ordinating centre) is developed. Of note, the recommendations to reinvigorate the IMPACT Network contain less infrastructure than that proposed for New Zealand. With progress occurring on both sides of the Tasman, the Advisory Group will meet via teleconference in the near future to consider next steps.

### Concluding remarks

This is the first study of its kind to investigate the feasibility of establishing a clinical trials network in mothers’ and babies’ health in New Zealand. We found significant challenges face this undertaking, along with substantial support for the endeavour. Internationally and across Australasia the development of new research networks has initially been achieved with very little financial outlay, relying instead on the valuable time, expertise and enthusiasm of founding members [14, 16, 18]. This is indeed the case with the feasibility work to-date. In the first instance the key to success will involve the local lead research active clinicians prioritising network development, and engaging further with research-interested clinicians in all major disciplines and units across New Zealand to enhance inclusivity and harness the enthusiasm evident in the surveyed cohort.

Engaging and energising the research, and the research-interested community, to establish a co-ordinated investigator-driven network and develop a culture of research across professional groupings and geographic locations will take time and effort. Nonetheless international examples have shown that much can be achieved in time frames as short as five years [14, 18]. The feasibility work to-date has provided a strong foundation on which to proceed. The objective of increasing collaborations and more effectively supporting maternal, perinatal and neonatal researchers with the ultimate aim of improving health outcomes for mothers and babies remains compelling.

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\(^2\) Members of the PSANZ Clinical Trials Network Working Party were: Frank Bloomfield (NZ, co-chair), William Tarnow-Mordi (Aust. co-chair), Vicky Flenady, Philippa Middleton, Caroline Crowther, Ross Haslam, Katie Groom, Sue Copas, Jonathan Morris, Carmel Collins, Melinda Cruz, Maria Makrides.
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Appendix 1:  

Clinical Trial Networks (CTNs) – Examples of Pre-Existing Models

While many established and developing networks continue to face challenges in finding the resources to maintain network organisation and governance, the following examples are proving the multi-layered worth of a joined-up approach. The networks profiled below are examples of three different models of clinical trials collaboration.

1. **Investigator-initiated** collaborative clinical research. (CTN acts in advisory and advocacy capacity to facilitate and support relationships information/knowledge sharing/translation into practice.) E.g. ANZICS CTG, GOnet, WOMBAT, IMPACT

2. **Clinical Trial network initiated**, supported and governed collaborative multicentre clinical research. E.g. MFMU

3. **Mixed Model Approach** (a range of both individual investigator initiated/led, and network initiated/led CT research). E.g. UKCRC, UKCTN

1. **Investigator-initiated networks**

**ANZICS CTG: Australia and New Zealand Intensive Care Society - Clinical Trials Group**

The ANZICS Clinical Trials Group (www.anzics.com.au/clinical-trials-group) formed in 1994 is a network of intensive care units (ICUs), clinicians and researchers who collaborate to conduct multicentre research aimed at improving outcomes for people who are admitted to an ICU. All of the research conducted by the CTG is investigator-initiated and funded through competitive grants or unrestricted funding from government or corporate sources.

- **Members:** 73 Adult and Paediatric Intensive Care Units across Australia and New Zealand.
- **People:** Over 600 clinicians and researchers currently subscribe to the CTG mailing list.
- **Funding:** Over $55 million in grant funding.
- **Patients:** To date the CTG has randomised over 28,000 patients into clinical trials and studied more than 16,000 patients in observational studies.
- **Publications:** 80 peer reviewed publications, including 7 papers in the New England Journal of Medicine.
- **Current Research:** 3 studies recently completed and pending publication. 18 studies recruiting or in follow-up. 4 major studies under review for funding. (As of October 2012)

**Strategic objectives** (as of March 2013)

To facilitate and promote investigator-initiated, collaborative clinical research in critical illness throughout Australia and New Zealand.

1. Provide sound leadership and transparent governance.
2. Strengthen and sustain the CTG network and capacity
3. Develop and support the pivotal role of Intensive Care Research Coordinators
4. Strengthen the profile of CTG locally and internationally

To foster and promote multidisciplinary and international research collaboration.

5. Identify and reduce barriers to multidisciplinary research.
6. Expand and deepen relationships with international trials groups
7. Enhance intensive care research capacity beyond Australian and New Zealand.

To develop high-quality programs addressing clinically relevant research questions

8. Develop a closer relationship with the ANZICS Centre for Outcome and Resource Evaluation.
9. Provide opportunities for collaborative research planning and development.
10. Ensure all CTG studies are conducted in accordance with the CTG Terms of Reference.
11. Foster the translation of CTG research into practice.

To advance the education and understanding of research methodology and critical analysis.

12. Actively support the professional development of clinician-researchers.
13. Maintain strong relationships with research methods centres.
14. Participate in the advancement of clinical research methods.

Structure: CTG comprises an Executive Committee which is a sub-committee of the ANZICS Board. In addition to a Chair, Vice-Chair, Secretary and Treasurer, this committee consists of a representative from each Australian state, New Zealand (nominated by the ANZICS Regional Committees) and a representative from the Paediatric Study Group. Other co-opted members include the Immediate Past Chair, the CTG Executive Officer, a representative of the Intensive Care Research Coordinators Interest Group (IRCIG), a representative from the ANZICS CORE Management Committee and research strategy leaders as required.

Network Administration of the CTG is supported by annual membership subscriptions received from Intensive Care Units across Australia and New Zealand. Currently CTG employs two staff who coordinate all CTG activities. These include:

- Three CTG Executive meetings per year
- Three critical care research meetings per year
- A closed mailing list. This provides a peer review forum for developing studies, facilitates communication between Investigators and ICUs and fosters a network of support and interaction for the large number of individuals contributing to intensive care research in Australia and New Zealand
- A newsletter, which is circulated via e-mail three times a year after each of the three CTG Executive meetings and corresponding scientific meeting. The main aim of the newsletter is to provide an update on presentations, particularly for those who were unable to attend the scientific meeting, and to better communicate, and explain, the decisions that the CTG Executive have made to provide on-going governance for the group.

A secondary aim of the newsletter is to highlight research that is related to Translation of Research into Practice. TRIPS research asks questions related to whether the results of our trials that report a difference in outcomes are being taken up in routine clinical practice and, if not, why not. Major funding bodies and policymakers are increasingly of the view that it is not enough to just conduct the trial but that the responsibility of researchers extends to optimising the uptake of evidence that deserves to change clinical practice.

**GONet: The Global Obstetrics Network Initiative, Global Alignment, Coordination, and Collaboration in Perinatal Research**

GONet formed 2010, is a recent and evolving collaboration. It was initiated (by representatives of multicentre trial groups in the USA, Canada, UK, The Netherlands, Hong Kong, Australia and New Zealand) to provide a forum for interaction and collaboration among international groups that perform clinical trials and observational studies in maternal fetal medicine and obstetrics.

**Aims and Objectives:** Members of GONet identified several aims. These include:

- To facilitate an interface of knowledge and collaboration through the development of a database of ongoing and planned studies.
- To define obstetrical trial/study terms/definitions and create a registry of definitions.
• To provide suggested tables/minimal data to be collected for different clinical problems for obstetric trials.
• To coordinate study protocols to facilitate and initiate prospective meta-analyses of studies and retrospective IPD meta-analysis.
• To identify opportunities to participate in and support current research.
• To identify novel research opportunities for the GONET group – develop pathways for protocols to be submitted/discussed at GONet.
• To determine if it is feasible to facilitate an international collaboration of funding bodies to support trials.
• To discuss areas of critical importance in obstetrics and identify trials/studies that need to be performed.
• To enhance international education and training in the design and performance of studies and clinical trials.

The expectation is that this collaboration will lead to better studies, the more efficient use of resources, and to minimise duplication.

Structure and Administration: In 2010 a charter and organisational structure was finalised by a small working group, and a board was formed with representation from groups in Europe, North America, Australia and Asia. A members’ website has been developed (www.globalobstetricsnetwork.org), including a database of ongoing/planned trials.

GONet is requesting funding support to provide infrastructure. The network plans to establish two international offices responsible for overseeing and managing technical and financial functions (each led by an experienced researcher in maternal health; and each to include a researcher with subject specific expertise, and an administrative post). One office will be in a developed country and the other in a developing country, to facilitate research collaboration worldwide.

WOMBAT: Women and Babies Health and Wellbeing: Action through Trials

The WOMBAT Collaboration promotes and supports high quality randomised clinical trials in the maternal and perinatal area in order to improve the health and wellbeing of women and their children. WOMBAT was supported through a 5 year Australian NHMRC Enabling Grant, awarded to a national, multidisciplinary, group of investigators to provide research infrastructure support and co-ordinated through the Australian Research Centre for Health of Women and babies (ARCH) based in Adelaide, Australia.

Aims and Objectives: WOMBAT aims to:

• Provide high level support to researchers undertaking multicentre trials in the perinatal area. This support spans assistance with formulating trial questions, to trial design, methods and conduct, through to dissemination of the results of the trial.
• Identify research areas and encourage appropriate clinical and methodological trials. Cochrane reviews and other sources will be systematically used to identify research gaps in perinatal evidence and WOMBAT will assist researchers to develop trial protocols to address these gaps.
• Provide education and training in trial design and conduct. WOMBAT offers workshops and other educational resources on the various aspects of trial design.

The WOMBAT Collaboration activities started in late 2005. One of its initiatives was to develop and track all the randomized trial activity within in Australia and later New Zealand. As at March 2013, 94 trials are currently recruiting or due to start recruitment (65 in pregnancy and childbirth and 29 in neonatology). Details of all maternal and perinatal trials in the WOMBAT cohort collected since 2003 (including recently completed ones) can be found on the WOMBAT Collaboration website (www.wombatcollaboration.net) and on the Australia and New Zealand Clinical Trials Registry. This trials registry is now maintained by PSANZ.
ANZCTR: Australia and New Zealand Clinical Trials Registry (www.anzctr.org.au)

ANZCTR established at the NHMRC Clinical Trials Centre, University of Sydney, with funding from the Australian National Health and Medical Research Council (NHMRC) and New Zealand Health Research Council. ANZCTR (a primary registry in the WHO Registry Network) is an online register of clinical trials being undertaken in Australia, New Zealand and elsewhere. The ANZCTR includes trials from the full spectrum of therapeutic areas of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies.

- Reproductive Health and Childbirth (“Condition Category”) had 484 Registered Trials as of end of July 2013. The registry records a trial’s:
  - objectives
  - main design features
  - sample size and recruitment status
  - treatments under investigation
  - outcomes being assessed
  - principal investigators
  - contact details for specific trial information

Interdisciplinary Maternal Perinatal Australasian Clinical Trials Network: IMPACT:

The IMPACT Network, a sub-committee of the Perinatal Society of Australia and New Zealand (PSANZ). IMPACT (www.psanz.com.au/special-interest/impact) which began in Sydney in 1994 and is dedicated to the improvement of maternal and perinatal health by the promotion of appropriately designed RCTs and the dissemination and application of their results.

Aims and Objectives:

- To identify key research issues in maternal and perinatal care.
- To promote the design, registration, completion, dissemination and application of appropriate RCTs in maternal perinatal care.
- To provide a forum for discussion, communication and collaboration between consumers and investigators in all disciplines, for planned or ongoing trials in maternal perinatal care.
- To provide information to the Perinatal Society of Australia and New Zealand (PSANZ) newsletter.
- To establish priorities for funding clinical trials in maternal perinatal health with funding agencies.
- To establish international links with the Pregnancy and Childbirth and Neonatal Collaborative Review Groups of the Cochrane Collaboration, the Perinatal Clinical Trials Service at The National Perinatal Epidemiology Unit in the UK, other clinical trials networks and organisations or bodies.
- To assist in bringing research evidence into clinical practice by promoting evidence-based care within the clinical colleges and other professional societies.
- To provide educational opportunities in critical appraisal and trial design.

Structure and Administration: An executive committee (elected for a term of two years), and made up of representatives from Consumers, Midwifery, Neonatology, Neonatal Nursing, Obstetrics, Scientists and others, is responsible for coordinating activities that promote the aims and objectives of the IMPACT Network.
2. Clinical Trials Network initiated

**MFMU: Maternal–Fetal Medicine Units Network**
**Created by the National Institute of Child Health and Human Development (NICHD) USA**

NICHD created MFMU ([https://mfmu.bsc.gwu.edu](https://mfmu.bsc.gwu.edu)) in 1986 to focus on clinical questions in maternal-fetal medicine and obstetrics, particularly with respect to the continuing problem of preterm birth. More than 45 randomised clinical trials, cohort studies and registries have been completed or are in progress at MFMU.

**Strategic Objectives**
The MFMU is designed to conduct perinatal studies to improve maternal, and fetal outcomes. Greatest emphasis and priority are given to randomised-controlled trials, followed by observational studies. The major aims of the Network are to:
- Reduce the rates of preterm birth, fetal growth abnormalities, neurologic sequelae of the newborn, and maternal complications of pregnancy.
- Evaluate maternal and fetal interventions for efficacy, safety and cost-effectiveness

Included in these aims are:
- Translational research
- The use of genetics
- The evaluation of new technologies in the promotion of maternal-child health and the prevention of disease

**Structure:** The Network consists of a variable number of major medical training institutions around the U.S.A which are supported under NIH Cooperative Clinical Research Award agreements. To be included in the Network, clinical centres undergo a competitive selection every five years. They are chosen to participate based on leadership, the number of inborn deliveries, experience in multicentre clinical research, state-of-the-art facilities and subspecialty support. Operating under cooperative agreements, the current network is comprised of fourteen university-based clinical centres (performing more than 160,000 deliveries per year) and an independent data coordinating centre.

**Administration:** MFMU is a well-established network of some 27 years standing. Its administration reflects its longevity and the organisational learning and development that has ensured over this timeframe.

The base budget for each University-based centre supports a principal investigator (a maternal-fetal medicine specialist), a research nurse coordinator, a research nurse, and a data entry person. Additional research nurses and technicians are hired as studies require and are supported by capitation, a reimbursement mechanism wherein the centres “earn” a specific amount of funds for each person enrolled in a research study.

A biostatistical coordinating centre (BCC), funded by a separate cooperative agreement, supports the Network in all phases of a research study. The centre is not simply a data management team but fully participates in the scientific and clinical research. The George Washington University Biostatistics Centre in Rockville, Maryland, has served in this capacity since 1986. The PI at the BCC collaborates with the clinical centre investigators and NICHD staff on biostatistical issues related to the design, development, and implementation of all research studies and in the analysis of the results. The PI is assisted by other biostatisticians who assume day-to-day responsibilities for specific protocols. A technical programming unit is responsible for the distributed data entry (DDE) system which includes developing software for each protocol, programming editing and reporting systems and supporting the hardware and software needs of the clinical centres. Research assistants are responsible for the quality of the study data and a research coordinator provides overall study organization.
The process of protocol development is guided by the Steering Committee which is composed of the Principal Investigator (PI) from each of the participating centres, the PI from the BCC, the NICHD Program Scientist and an ex-officio, non-voting member from NICHD. The Chair of the Steering Committee, a person independent of the participating institutions, is appointed by NICHD and votes only to break a tie.

An Advisory Board helps identify and prioritize topics for research and reviews protocols that are approved by the Steering Committee for scientific merit. The Data and Safety Monitoring Committee (DSMC) reviews final Network-approved protocols to ensure the safety of study subjects. The DSMC also examines interim data analyses and makes recommendations regarding the conduct of ongoing trials in terms of recruitment, patient safety, protocol adherence and data quality. At each interim review, the DSMC may advise stopping the trial, continuing the trial as originally designed, or continuing with a modification to the protocol. The NICHD staff sometimes seeks collaboration with other agencies, Institutes and industry to provide expertise and additional funding for protocols.

**Network initiated and developed clinical trials processes and protocols**

Unlike the ANZICS CTG profiled above (which provides support for investigator initiated research trials), MFMU is set up to select, undertake and support clinical research.

The way that the Network organizes itself in terms of proposing, selecting, and setting priorities for new studies has evolved over the years, as it has learned from its mistakes and built on its successes. While much of the quarterly Steering Committee meetings are spent reviewing and deliberating the status of ongoing studies, time is also allocated for considering new ideas for maternal-fetal research. At each meeting, several investigators may propose research concepts and, following extensive discussion, the concept either receives a vote of no interest or a vote to proceed to a “mini” protocol. The investigator will use input from the discussion to elaborate on the details in the mini protocol and will also include feasibility and budgetary estimates. The investigator presents this more developed protocol for Steering Committee approval at a following meeting. If the protocol receives a favourable response through secret ballots from the Steering Committee, the protocol is placed in the queue with other protocols that have received approval.

The NICHD program scientist determines when a new protocol should be implemented in the Network taking into consideration the timeline of ongoing studies, funding requirements and availability of resources. The Subcommittee is polled for their preference for which of the approved protocols being held in the queue should be selected. The Network’s Prioritization Committee takes the results of the poll and, after considering clinical importance, clinical practice, feasibility, cost, and resources, recommends the next protocol to be implemented by the Network.

Upon the decision to begin a new study, a protocol subcommittee is appointed and assumes responsibility for the final protocol under the leadership of the study’s investigator. Preparations for implementing the protocol begin, and include setting the protocol into the standard Network format, developing the final data collection forms and manual of procedures, and developing the software for data entry and monitoring. The clinical centres apply for Institution Review Board approvals, plan staffing, and organise screening and recruitment procedures. When all of the essential systems are in place, training is held for the research nurses and other staff who will perform the study. Staff must obtain certification through successful completion of quizzes, mock data acquisition and demonstration of specific technical skills required by individual protocols before the centre is allowed to begin the study.

The Network uses a distributed data entry system by which data collected from each patient are entered by centre staff into a dedicated computer and electronically transferred to the data centre on a weekly basis. The data are checked for accuracy several times, beginning when they are entered into the computer and
continuing after transfer to the data centre where they undergo more intensive data editing. Edit reports are sent weekly to each centre for clarification or correction with more extensive audit reports sent monthly.

After the final patient enters the study, the BCC begins to close-out the data and the protocol subcommittee begins work on the primary manuscript. Over the years, the Network has developed specific policies that define the prioritisation of analysis, assurance of timely presentation and manuscript preparations, authorship and coordination of secondary analyses.

3. Mixed Model Networks

**UKCRC: UK Clinical Research Collaboration**

The UKCRC (http://www.ukcrc.org/home) was established in 2004, following the Government’s recognition of the need for further investment in clinical research and the importance of a collaborative approach. It brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environment that facilitates and promotes high quality clinical research for the benefit of patients.

**Strategic Objectives:** The UKCRC represents a new way of working in which complex long-standing issues are tackled by key stakeholders working together. Strategic direction and oversight is provided by the UKCRC Board with broad stakeholder input into key issues. The Partnership is supported by a jointly funded, independent Secretariat and has a mixed model of working, where activities are:

- Led and administered by individual Partners on behalf of the Partnership
- Led by individual Partners and administered by the UKCRC Secretariat
- Led and administered by UKCRC Secretariat.

One of the key aims of the UKCRC is the UKCRN: **UK Clinical Research Network**

The UKCRN (comprises clinical research networks established in each of the four UK nations funded by the UK Health Departments. Together these national networks form the UK Clinical Research Network (UKCRN), strategic oversight for which is provided by the UKCRC

**Purpose and Aims:** Strategically the UKCRN is geared to one outcome: supporting the NHS to deliver quality research studies effectively and efficiently. The Network does this by providing the practical support the researchers need to carry out high quality clinical studies. This includes:

- Helping researchers to identify suitable NHS sites with the facilities and patient populations required by the study (“feasibility”).
- Providing a streamlined system for gaining the necessary permissions to carry out the research study in hospitals and healthcare practices.
- Recruiting patients into studies, and managing this process effectively, so that researchers can answer the research question within their required timeframe.
- Giving researchers advice on how to make their study “work” in the NHS environment, from a practical point of view.

**Structure:** The structure of the networks varies between each country, but all share the common goal of providing the infrastructure to support high quality clinical research studies for the benefit of patients. There is a commitment to ensure that the clinical research networks across the UK work together in an integrated
manner to share experiences develop joint initiatives and promote partnership and UK-wide working wherever possible.

Topic specific research networks have been established within this infrastructure with the Reproductive Health and Childbirth (REACH) Network supporting all clinic-based studies in obstetrics and gynecology (current studies >120).

Administration: The National Institute for Health Research, Clinical Research Network, Coordinating Centre (NIHR CRN CC), based in Leeds and London has been established to support clinical research and to facilitate the conduct of trials and other well-designed studies within the NHS. The Coordinating Centre delivers and manages the NIHR Clinical Research Network (NIHR CRN) in England and facilitates a range of activities across the UK, through agreed approaches between the various coordinating centres and clinical research network staff, working closely with the Health Departments in Northern Ireland, Scotland and Wales.

The NIHR CRN CC is building a complete picture of the clinical research taking place within the UKCRN across the UK. Details of studies which meet specific eligibility criteria are recorded in a database, known as the UKCRN Portfolio. This comprises the National Institute for Health Research (NIHR) Clinical Research Network Portfolio in England, and the corresponding portfolios of Northern Ireland, Scotland and Wales. The UKCRN Portfolio is a national data resource which will be used for research management and to support the performance management of the UK clinical research networks.
4. Other Networks

**Australian Clinical Trials Alliance (ACTA)**

This new initiative has been formed to improve the landscape for investigator-led clinical research in Australia. In May 2012 the *Medical Journal of Australia* hosted the MJA Clinical Trials Summit; subsequently a working group developed ACTA on the premise that an umbrella group to foster and sustain clinical trials networks would provide significant benefits. Namely:

- To advocate for the importance of clinical research in improving the healthcare of all Australians.
- Provide the infrastructure to maintain clinical research networks.
- Help foster and sustain new clinical trials sites.
- Leverage additional funding from government, community and commercial sources for worthwhile research projects.
- Assist in bringing groups in similar research fields together providing access to common resources and experienced staff.
- Enabling collaboration to develop standard operating procedures.
- Helping groups to obtain access to databases and web-based (e-health) functionality.
- Provide a central overview of the research proposals of research groups in the network.

ACTA has been established by those who have played key roles in successful clinical trials networks and registries in Australia. ACTA will not conduct clinical trials. It will act in an advisory, advocacy and support capacity around the funding, infrastructure and management of clinical research. Its vision is to streamline and simplify clinical trial processes, promote sustainable infrastructure and funding pathways; provide a forum to share ideas, promote common education and training opportunities; and achieve widespread appreciation and support by consumers, health practitioners and policy makers for the critical importance of clinical research to improve policy and practice.

**Administration:** In March 2014 ACTA was set up as a not-for-profit public company limited by guarantee. The 12 members of the interim executive have formed a Board of Directors for an establishment period of 1-2 years. This is a transitional arrangement that has been used successfully by similar representative organisations to bridge between needing to be a legal entity prior to the organisation being in a position to formalise its membership basis. During this time, ACTA will seek to build its membership, develop a strong and sustainable operating platform and, through its membership, develop and implement its definitive, membership-based organisational and governance model. During this time ACTA’s constitution will be revised following consultation with the sector in preparation for transition to a representative governance model at the end of its establishment period.

**Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) USA**

NICHD is the parent organisation which created the Maternal-Fetal Medicine Units (MFMU) detailed above. Established in 1962, its broad mission is to study the “complex process of human development from conception to old age.” Over fifty years on this undertaking continues. NICHD conducts and supports laboratory research, clinical trials, and epidemiological studies that explore health processes; examines the impact of disabilities, diseases, and variations on the lives of individuals; and sponsors training programs for scientists, health care providers, and researchers. The Institutes visioning document (2012) for the next ten years provides a great overview of the seven scientific areas for on-going research focus (developmental biology, developmental origins of health and disease, pregnancy and pregnancy outcomes, reproduction, behaviour and cognition, plasticity and rehabilitation, and population dynamics) including what scientists should be able to accomplish in these areas. The final section of this document — “The Conduct of Science” - argues strongly for a transdisciplinary and collaborative approach to all research, along with the necessary infrastructure, and training to facilitate this. As such this provides an excellent and wide-ranging rationale...
for the networked approach we are proposing on a more modest scale. See https://www.nichd.nih.gov/publications/pubs/Documents/NICHD_scientific_vision120412.pdf

**Vermont Oxford Network**

The Vermont Oxford Network (VON) is a non-profit voluntary collaboration of health care professionals dedicated to improving the quality and safety of medical care for new-born infants and their families. Established in 1988, the Network is today comprised of over 900 Neonatal Intensive Care Units around the world. www.vtoxford.org

**Aims and Objectives:** VON aims to provide a range of quality management tools, research and collaborative opportunities to assist neonatal intensive care units improve their quality of care. The heart of the network is the VON Database which maintains data on very low birth weight babies, as well as certain additional infants meeting eligibility requirements.

More than a simple data repository, VON serves as a neutral, independent party in analyzing data for its member centres. The Database is used to provide comprehensive, confidential reports to participating hospitals, which serve as the foundation for local quality improvement projects, internal audit, and peer review. The Database also provides information for use in outcomes research. All network members participate in the very-low-birth-weight (VLBW) database and have the option to participate in the expanded database for all neonatal intensive care unit (NICU) infants and the Registry for infants with neonatal encephalopathy.

**Structure and administration:** Basic membership is via an annual membership fee of US$4,200, and over 900 Neonatal Intensive Care Units around the world are members. Well established and resourced, the network is governed by a Board of Directors and employs staff across a range of divisions including:

- Administration and member services
- Information technology
- Quality improvement and education
- Research and trials
- Statistics
- Operations
### Appendix 2: Babies Born at DHB Maternity Facilities in 2011 (Data from NZ Maternity Clinical Indicators 2011)

<table>
<thead>
<tr>
<th>DHB Population</th>
<th>Tertiary</th>
<th>Caesarean sections</th>
<th>Babies born between 32 weeks and 36 weeks 6 days</th>
<th>Induction of labour among standard primiparae</th>
<th>Spontaneous vaginal birth among standard primiparae</th>
<th>All babies born in Tertiary Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northland 159,795</td>
<td>Whangarei</td>
<td>339</td>
<td>105</td>
<td>4 (1.8%) 218 (N)</td>
<td>147 (67%) 218 (N)</td>
<td>1704</td>
</tr>
<tr>
<td></td>
<td>Dargaville Hospital Kaitaia Hospital Hokianga</td>
<td></td>
<td>Induction of labour among standard primiparae</td>
<td>Spontaneous vaginal birth among standard primiparae</td>
<td>All babies born in Secondary Facility</td>
<td></td>
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<tr>
<td></td>
<td>North Shore</td>
<td>1094</td>
<td>198</td>
<td>52 (6.2%) 826 (N)</td>
<td>512 (62%) 826 (N)</td>
<td>3761</td>
</tr>
<tr>
<td></td>
<td>Waitakere</td>
<td>573</td>
<td>124</td>
<td>15 (2.6%) 567 (N)</td>
<td>428 (75%) 567 (N)</td>
<td>2904</td>
</tr>
<tr>
<td>Waitemata 562,970</td>
<td>National Women’s (Auckland City Hospital)</td>
<td>2443</td>
<td>552</td>
<td>62 (4.7%) 1299 (N)</td>
<td>846 (65%) 1299 (N)</td>
<td>7587</td>
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<tr>
<td></td>
<td>Birthcare Auckland</td>
<td></td>
<td></td>
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<tr>
<td>Auckland 449,400</td>
<td>Middlemore Hospital</td>
<td>1517</td>
<td>437</td>
<td>31 (3%) 1032 (N)</td>
<td>673 (65%) 1032 (N)</td>
<td>6945</td>
</tr>
<tr>
<td></td>
<td>Botany Downs Birthing Unit Papakura Obstetric Pukekohe Obstetric</td>
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<tr>
<td>Counties Manukau 516,050</td>
<td>Waikato Hospital</td>
<td>1044</td>
<td>345</td>
<td>25 (5.8%) 426 (N)</td>
<td>259 (60%) 426 (N)</td>
<td>3465</td>
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<tr>
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<td>Birthcare Huntly Matariki Pohlen Maternity Trust River Ridge East Birth Centre Rhoda Read Taumarunui Hospital Te Kuiti Hospital Thames Hospital Tokoroa Hospital</td>
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<tr>
<td>Waikato 373,220</td>
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<tr>
<td>DHB Population</td>
<td>Tertiary</td>
<td>Caesarean sections</td>
<td>Babies born between 32 weeks and 36 weeks 6 days</td>
<td>Induction of labour among standard primiparae</td>
<td>Spontaneous vaginal birth among standard primiparae</td>
<td>All babies born in Tertiary Facility</td>
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<td>Waikato (cont)</td>
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<tr>
<td>Bay of Plenty 214,910</td>
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<tr>
<td>Taranaki 110,258</td>
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<td>Lakes 103,170</td>
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<tr>
<td>Tairawhiti 46,753</td>
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<tr>
<td>Whanganui 62,630</td>
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<tr>
<td>Mid Central 170,200</td>
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<td>Hawkes Bay 156,490</td>
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<td>DHB Population</td>
<td>Tertiary</td>
<td>Caesarean sections</td>
<td>Babies born between 32 weeks and 36 weeks 6 days</td>
<td>Induction of labour among standard primiparae</td>
<td>Spontaneous vaginal birth among standard primiparae</td>
<td>All babies born in Tertiary Facility</td>
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<tr>
<td>Capital &amp; Coast 299,720 Wellington Hospital</td>
<td>1206</td>
<td>329</td>
<td>53 (9.2%)</td>
<td>336 (58%)</td>
<td>574 (N)</td>
<td>3584</td>
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<tr>
<td>Hutt Valley 145,215</td>
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<tr>
<td>Wairarapa 40,735</td>
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<tr>
<td>Nelson Marlborough 141,933</td>
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<td>West Coast 33,055</td>
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<tr>
<td>Canterbury 509,860</td>
<td>Christchurch Women’s</td>
<td>1745</td>
<td>391</td>
<td>37 (4.5%)</td>
<td>436 (53%)</td>
<td>808 (N)</td>
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<tr>
<td>DHB</td>
<td>Population</td>
<td>Queen Mary Hospital</td>
<td>Tertiary</td>
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<td>593</td>
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<td>297</td>
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<td>Caesarean sections</td>
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<td>Babies born between 32 weeks and 36 weeks 6 days</td>
<td>Induction of labour among standard primiparae</td>
<td>Spontaneous vaginal birth among standard primiparae</td>
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<td>8 (13%)</td>
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<td>27 (13%)</td>
<td>133 (13%)</td>
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<td>297 (N)</td>
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<td>205 (N)</td>
<td>205 (N)</td>
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<td>Induction of labour among standard primiparae</td>
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<td>Spontaneous vaginal birth among standard primiparae</td>
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<td>72 (69%)</td>
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<td>B babies born between 32 weeks and 36 weeks 6 days</td>
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<td>Spontaneous vaginal birth among standard primiparae</td>
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<td>All babies born in Secondary Facility</td>
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<td>13 (11%)</td>
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<td>All babies born in Primary facility</td>
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<td>119</td>
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<td>22</td>
<td>96</td>
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<td>1793</td>
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<tr>
<td></td>
<td>DHB Total babies born</td>
<td>554</td>
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</tbody>
</table>
Appendix 3: Surveys

Development of a National Maternal and Perinatal Trials Network – A Feasibility Study

General Survey

Thank you for taking the time to complete this short survey. The questions are part of a study examining the feasibility of establishing a maternal and perinatal clinical trials network to support researchers from all disciplines across New Zealand. Your input is important to increase our understanding about the general awareness of, and experience with, maternal and perinatal clinical trials research; including what might help or hinder your current and any future involvement. The information gathered will be used as part of a wider feasibility study which aims to ascertain whether it’s possible to achieve a clinical trials network across New Zealand, and how best this could be done.

The survey should take about 10 minutes to complete and your answers will be completely anonymous.

1. What is your profession?
   - Obstetrician
   - Neonatologist
   - Midwife
   - Neonatal Nurse
   - Physician
   - Other (please specify; including your area e.g. predominantly women’s health or neonatology)

2. Which category below includes your age?
   - 18-20
   - 21-29
   - 30-39
   - 40-49
   - 50 – 59
   - 60 or older

3. Where do you practice?
   - In the community
   - Primary/Birthing Unit
   - Secondary Unit (Hospital providing neonatal facilities >32 weeks)
   - Tertiary Unit (Hospital providing NICU facilities < 32 weeks)
   - Other (please specify)

4. In which DHB region do you work? Tick as many as apply
   - Northland
   - Waitemata
   - Auckland
   - Counties Manukau
   - Waikato
   - Bay of Plenty
   - Lakes
   - Tairawhiti
   - Taranaki
   - Whanganui
   - Mid Central
   - Hawkes Bay
   - Hutt Valley
   - Wairarapa
   - Capital & Coast
   - Nelson Marlborough
   - West Coast
5. In your practice have you ever been involved in a clinical research trial?
   - Yes
   - No

6. If yes, in what capacity? Tick as many as apply.
   - Principal Investigator
   - Local Investigator
   - Research Midwife/Nurse
   - Recruitment to the research
   - Explaining/discussing the research and providing information to participants and their families
   - Administration of research treatment
   - Data collection and/or study follow-up
   - Other (please specify)

7. If yes, was the clinical trials research role toward a further qualification?
   - Postgraduate Certificate/Diploma
   - Masters Degree
   - PhD
   - Other (please specify)

8. What are your current and/or potential research interests? Briefly state
   - Current research interests
   - Potential research interests

9. Do you think more clinical trials research is needed in maternal and perinatal health?
   - Yes
   - No
   - Unsure

10. In your practice would you be willing to be involved in a clinical trial in the future?
    - Yes
    - No
    - Not applicable

11. If yes, in what capacity would you be willing to act? Tick as many as apply
    - As a Principal Investigator
    - As a Local Investigator
    - As a paid Research Midwife/Nurse
    - In recruiting participants to the study
    - In discussions explaining the research and providing information to participants and their families
    - In data collection and/or study follow-up
    - Other (please specify)

12. Have you ever considered a role in clinical trials research for a further qualification?
    - Not applicable
    - Yes
    - No
    - Unsure
13. If yes, what qualification?
   □ Postgraduate Certificate/Diploma
   □ Masters Degree
   □ PhD
   □ Other (please specify)

14. If no, briefly state reasons.

15. What are the barriers preventing you as an individual from being involved in clinical trials research? (briefly state)

16. What encourages you, and/or enhances your ability to be involved in clinical trials research? (briefly state)

17. In your workplace(s) are there clinical trials currently taking place involving?
   □ Mothers
   □ Babies
   □ Both
   □ None of the above
   □ Don’t know
   □ Not applicable

18. Would your workplace(s) support involvement in a clinical trial?
   □ Yes
   □ No
   □ Unsure
   □ Not applicable

19. In your workplace(s), what would help your involvement in a clinical trial? Tick as many as apply
   □ A designated research coordinator within the workplace
   □ Assistance with ethics approval processes
   □ Supportive senior staff
   □ Designated time to undertake research
   □ Funding
   □ Involvement in research included in your job description
   □ Acknowledgement as a co-author in any resulting publications
   □ Other (please specify)

20. In your workplace(s), what current barriers are there to your involvement in a clinical trial? Tick as many as apply
   □ Lack of a designated research coordinator in the workplace
   □ No assistance with ethics approval processes
   □ Unsupportive senior staff
   □ No designated time to undertake research
   □ Lack of funding
   □ Lack of local expertise/knowledge about how to undertake clinical trials
   □ Lack of clear process in the workplace for obtaining the necessary approvals to undertake clinical trials
   □ Other factors that are barriers to research involvement (please specify)

21. All done – many thanks! If you are willing to be contacted for a follow-up interview to discuss in more detail the feasibility of establishing a New Zealand wide maternal and perinatal clinical trials network please note your name and contact details in the box below.
Thank you for taking time to complete this short survey. The questions are part of a study to examine the feasibility of establishing a maternal and perinatal clinical trials network to support researchers from all disciplines across New Zealand. You have been selected as 'research active' and regardless of how you define your research active status we would appreciate you completing the survey. The survey aims to gauge current research experience, capability and capacity as well as assess future research potential. Your input is critical to understanding whether a maternal and perinatal clinical trials network to support studies to improve outcomes for mothers and babies in New Zealand is achievable. The survey should take about 10 minutes to complete and all your answers will be completely anonymous.

1. You have been selected as ‘research active’ – would you consider yourself as such?
   - Yes – currently
   - Yes – in the past
   - No – not at all

2. What is your profession?
   - Obstetrician
   - Obstetrician in training
   - Neonatologist
   - Neonatologist in training
   - Paediatrician
   - Paediatrician in training
   - Midwife
   - Neonatal Nurse
   - Physician
   - Epidemiologist
   - Scientist
   - Other (please specify)

3. Which category below includes your age?
   - < 20 Years
   - 21 -30 years
   - 31- 40 years
   - 41- 50 years
   - 51 – 60 years
   - 60 plus years

4. Where is your primary appointment?
   - Private Practice
   - DHB
   - University
   - Other (please specify)

5. Do you have an official/paid appointment that includes research (part-time or full time)?
   - Yes
   - No

6. If yes, how would you describe your appointment?
   - Senior Lecturer/ Associate Professor/ Professor
   - Lecturer
   - Research Fellow
   - PhD Student
   - Research Midwife
   - Research Nurse
   - Research Assistant
   - Other (please specify)
7. If you are in clinical practice, where do you practice? Tick as many as apply
- In the community
- Primary Birthing Unit
- Secondary Unit (Hospital providing neonatal facilities >32 weeks)
- Tertiary Unit (Hospital providing <32 weeks NICU facilities)
- Other [please specify]

8. If you are in non-clinical practice, where do you practice? Tick as many as apply
- University
- Private Research Institute
- Other (please specify)

9. In which region (as defined by DHB regions) do you work? Tick as many as apply
- Northland
- Waitemata
- Auckland
- Counties Manakau
- Waikato
- Bay of Plenty
- Lakes
- Tairawhiti
- Taranaki
- Whanganui
- Mid-Central
- Hawkes Bay
- Hutt Valley
- Wairarapa
- Capital & Coast
- Nelson Marlborough
- West Coast
- Canterbury
- South Canterbury
- Southern
- Overseas
- Not applicable

10. If you are based in a university, which university?
- University of Otago
- University of Canterbury
- Lincoln University
- Victoria University of Wellington
- Massey University
- Waikato University
- AUT University
- University of Auckland
- If overseas (please specify)

11. Describe the research methodologies/designs you are, or have been involved with? Tick as many as apply
- Basic science/laboratory based
- Epidemiology/population based
- Randomised controlled trials
- Observational/cohort studies
- Qualitative research
- Research synthesis
- Research translation/implementation
- Correlational research
- Descriptive or survey/ interviews
- Meta-analysis
- Other [please specify]

12. Describe the main research fields you are, or have been involved with? Tick as many as apply
- Pre-term birth
- Stillbirth/ Perinatal mortality
- Intrauterine fetal growth restriction (IUGR)
- Preeclampsia/ Hypertensive disorders of pregnancy
- Gestational Diabetes Mellitus
- Nutrition in pregnancy
- Obesity in pregnancy
- Pain
- Management of labour
- Fertility
- Fetal medicine
- Genetics/ prenatal diagnosis
- Multiple pregnancy
- Pre-conceptional care
- Antenatal care & assessment
- Medical disorders in pregnancy
- Infections in pregnancy
- Bleeding in pregnancy
- Postnatal depression
- Neonatal neurodevelopment
- Neonatal nutrition
- Neonatal metabolic disorders
- Neonatal respiratory disorders
- Neonatal infection
- Paediatric neonatal endocrinology
- Resuscitation
- Cerebral Palsy
- Childhood development
- Gynaecology
- Maori and Pacific Health
- Global Health
- Health delivery/consumer experience
- Substance use
- Palliative care
- Mental health
- Medical ethics
- Other (please specify)

13. How is your current research funded? Tick as many as apply
- International funds [please specify – free text field]
- National funds (for example, HRC, Cure Kids) [please specify – free text field]
- University Funds [please specify – free text field]
- Charitable Funds [please specify – free text field]
- DHB Funding [please specify – free text field]
- Private Practice Funding [please specify – free text field]
- Unfunded
- Other (please specify)

14. For Clinical Trials Research how would you describe your level of involvement? Tick as many as apply
- Director of Research Institute
- Head of Department
- Programme Director
- Lead Investigator/Principal Investigator
- Local Principal Investigator
- Research Fellow
- Research Midwife
- Research Nurse
- Research Assistant
- Scientist/Laboratory analysis
- Data management/statistical support
- Scientific writing
Clinician actively involved in administration of research intervention
Clinician actively involved in recruitment/randomisation
Clinician actively involved in RCT follow-up/data collection
Other (please specify)

15. Please indicate which of these clinical trials you personally have contributed to? (for example, by recruiting a patient, data collection etc.) Tick as many as apply
- MiG
- MiG TOFU
- ASTEROID
- MAGENTA
- Acto RDS
- Acto MgSo4
- PPROMT
- HINT
- FLoRa
- EPPI
- Sugar Babies
- pre-hPOD
- hPOD
- PROGRESS
- STRIDER
- PROVIDE
- APTS
- BOOST NZ
- TIP Trial
- CAP Trial
- LessMAS
- Optimist
- INIS
- ICE
- PROPREMS
- Post Dates Pregnancy Trial
- MCA Doppler Trial
- Term PPROM
- Term Breech Trial
- Timing of Twin Birth Trial
- Other [please specify]

16. Do you supervise others in their research?
- Yes
- No

17. If yes, who do you supervise? Tick as many as apply
- PhD students
- Masters students
- Undergraduate students
- Summer studentships
- Vocational training (for example RANZCOG, FRACP)
- Research staff
- Informal supervision (of any of the above)
- Other (please specify)

18. Do you collaborate with other researchers and/or research centres? Tick as many as apply
- No not at all
Researchers within my centre
Nationally
Internationally

19. What research capabilities would you personally like to develop? Tick as many as apply
- Establishing a research team
- Development of study design & methodology
- Grant writing
- Ethics development
- Research protocol development
- Lead a randomised control trial
- Development of research schedules & financial budgets
- Data management
- Developing randomisation programs
- Participant recruitment
- Clinical trial management
- Statistical analysis of results
- Preparation & submission for publication
- Supervision of research students
- Other (please specify)

20. Within the main unit where you work (e.g. hospital or university department) do you have an established maternal, perinatal, neonatal and/or paediatric clinical trials centre
- Yes
- No
- Don’t know

Within the main unit where you work (e.g. hospital or university department) do you have an established maternal, perinatal, neonatal and/or paediatric clinical trials group (i.e. a group of individuals focused on more than one clinical trial)
- Yes
- No
- Don’t know

Within the main unit where you work (e.g. hospital or university department) do you have a designated statistician available to advise on clinical trials in maternal, perinatal, neonatal and/or paediatric health
- Yes
- No
- Don’t know

Within the main unit where you work (e.g. hospital or university department) do you have access to an electronic data collection system
- Yes
- No
- Don’t know

Within the main unit where you work (e.g. hospital or university department) do you have access to advice and assistance with ethics applications
- Yes
- No
- Don’t know

Within the main unit where you work (e.g. hospital or university department) do you have access to an electronic randomisation program / service
- Yes
- No
- Don’t know

Access to data management support
- Yes
- No
- Don’t know

Access to laboratory services to support clinical trials
- Yes
- No
- Don’t know

Access to pharmacy services to support clinical trials
- Yes
- No
- Don’t know

Access to appropriate facilities for clinical trials follow up studies
- Yes
- No
- Don’t know

Paid research assistants/midwives/nurses time in obstetric practice funded by a specific grant for a single clinical trial (part-time or full-time)
- Yes
- No
- Don’t know
Paid research assistants/midwives/nurses time in obstetric practice funded by a specific grant to work across two or more clinical trials (part-time or full-time)  
☐ Yes ☐ No ☐ Don’t know

Paid research assistants/midwives/nurses time in obstetric practice funded by other means to work on several clinical trials  
☐ Yes ☐ No ☐ Don’t know

Paid research assistants/midwives/nurses in neonatal practice funded by a specific grant for a single clinical trial (part-time or full-time)  
☐ Yes ☐ No ☐ Don’t know

Paid research assistants/midwives/nurses in neonatal practice funded by a specific grant to work across two or more clinical trials (part-time or full-time)  
☐ Yes ☐ No ☐ Don’t know

Paid research assistants/midwives/nurses in neonatal practice funded by other means to work on several clinical trials  
☐ Yes ☐ No ☐ Don’t know

21. How are paid research assistants midwives/nurses in obstetric and neonatal practice predominantly funded?  
☐ DHB funds  
☐ University funds  
☐ Specific project grants (specify funding body)  
☐ Don’t know  
☐ Other sources

22. I would increase my participation in research...Each item to be answered on a Likert scale

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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</thead>
<tbody>
<tr>
<td>☐ if I was given allocated time within my FTE</td>
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<td>☐ if I had designated staff to assist</td>
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<tr>
<td>☐ if I could exchange one of my current commitments for research</td>
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<td>☐ if my employer gave research the same recognition as my clinical duties</td>
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<tr>
<td>☐ if there were more recognition of the importance of research and support for undertaking it from senior staff</td>
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<tr>
<td>☐ if I could be part of a bigger research group/team</td>
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<td>☐ if there were better access to training in the skills needed for research</td>
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<td>☐ if there were better promotion of funding opportunities</td>
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<td>☐ if there were assistance in applying for funding</td>
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<tr>
<td>☐ if there were greater awareness of the potential benefits of clinical research in the geographical area where I work</td>
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<td>☐ if there were greater awareness of the potential benefits of clinical research in the professional area where I work</td>
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<tr>
<td>☐ if there were clear, coordinated and well understood processes in the geographical area where I work for recruiting people to participate in clinical research</td>
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<tr>
<td>☐ if there were clear, coordinated and well understood processes in the professional area where I work for recruiting people to participate in clinical research</td>
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</table>

23. I would be keen to be involved in more than one research project at a time.  
☐ Yes  
☐ No

24. I would be more likely to conduct, or participate in maternal and perinatal research if there was a national clinical trials network to: Each item to be answered on a Likert scale

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Coordinate and manage clinical research trials</td>
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<tr>
<td>☐ Provide guidance with ethics processes</td>
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<tr>
<td>☐ Assist with research methods and statistical analysis</td>
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</table>
Consult about research ideas
Assist with funding applications and grant writing
Contact for troubleshooting
Assist with networking and research collaboration
Other functions that a network may provide (please specify)

25. A national clinical trials network would enhance my research
   - Agree
   - Disagree
   - Unsure
   - Additional comments [Text Box]

All done - Many thanks! If you are willing to be contacted for a follow-up interview to discuss setting up a national maternal and perinatal clinical trials network in more detail, please note your name and contact details in the box below.
Appendix 4: Advisory Group Workshop 12 February 2014

In attendance: Katie Groom, Caroline Crowther, Frank Bloomfield, Pip Shirley, Robin Cronin, Jane Alsweiler, Lesley McCowan, Sue Copas, Kelly Thompson, Colin McArthur, Bill Tunnicliffe, Mike Meyer, Graham, Parry, Deb Harris, Max Berry, Di Leishman, Jo Gullam, Roland Broadbent.

Apologies: Barbara Cormack, Phil Weston, John Tait, Ruth Hughes, Rosemary Reid, Marama Davidson

Schedule

<table>
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<tr>
<th>Morning</th>
<th>Presenter/Facilitator</th>
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<tbody>
<tr>
<td>1.</td>
<td>Welcome and introductions</td>
</tr>
<tr>
<td>2.</td>
<td>Aims and objectives of the feasibility study</td>
</tr>
<tr>
<td>3.</td>
<td>Overview of International Clinical Trials Networks</td>
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<td>4.</td>
<td>ANZICS CTG Network overview and Q&amp;A</td>
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<td>5.</td>
<td>PSANZ Working Group Initiative and ACTA</td>
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<td>6.</td>
<td>WOMBAT and IMPACT networks</td>
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<td>Afternoon</td>
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<td>7.</td>
<td>General survey: presentation of results</td>
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<td>8.</td>
<td>Research active survey: presentation of results</td>
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<td>Breakout group discussion and feedback (1)</td>
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<td>9.</td>
<td>Key questions: (2x2 interdisciplinary groups)</td>
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<td>How could a network help overcome barriers?</td>
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<td>How could a network harness or facilitate enablers?</td>
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<td>Breakout group discussion and feedback (2)</td>
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<td>Key questions: (2x2 interdisciplinary groups)</td>
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<td>What would the most effective relationship with DHB and University Research Offices look like, feel like and work like?</td>
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<td>Why and how should we engage with funding bodies, Colleges, Consumer Groups, Government Agencies? Which ones are important?</td>
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<tr>
<td></td>
<td>Breakout group discussion and feedback (3)</td>
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<td>Key questions: (2x2 interdisciplinary groups)</td>
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<td>10.</td>
<td>What are the objectives of the network?</td>
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<td>What does it look like (model/infrastructure)?</td>
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<td>How would it be coordinated?</td>
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<td>How should it be funded?</td>
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<td>Summary of the day and scoping the way forward</td>
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<td>11.</td>
<td>What network model are we aiming for?</td>
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<td>How will we achieve it?</td>
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Workshop Item 4: The ANZICS Clinical Trials Group – 20 years in the making (Colin McArthur)

Colin presented an overview of the establishment and development of the ANZICS CTG

Key points

- The network began in 1994 with individual enthusiastic practitioners getting together to undertake observational studies initially. These could be completed on relatively low budgets and allowed a collaborative network to become established. This led to track record of successful completion and publication of work. First publication occurred 1996.

- Intervventional studies followed, initially unfunded, with Principal Investigators doing much of the work. It was, “done on the smell of an oily rag but meant we started to get noticed and create a track record of success that funders could see.” The first interventional study recruited in 1998-99 and was published in the Lancet in 2000.

- Growth; both of the network and the numbers of studies followed, e.g. SAFE Study published in the New England Journal of Medicine (NEJM) 2004, Randomised controlled trial (RCT) comparison of two usual therapies within the scope of normal practice, n=6993. Triggered by meta-analysis. “By using two accepted treatments for comparison were able to obtain ethics approval not requiring prospective consent, and consent for data collection only after therapy given - this resulted in a withdrawal of only two percent and so it was very easy to achieve study size numbers in a short time-frame.”

- Growth and expansion followed, including collaboration with non-intensive care groups, e.g. Australasian Maternity Outcomes Surveillance System (AMOSS), Emergency Medicine and Infectious Disease medicine, studies outside Australia and New Zealand, (Canadian ICU network), studies with industry collaboration (ensuring academic independence and data ownership was preserved), and links with other international studies (where ANZICS CTG was not the lead group)

- This has led to the development of a key group of 15-20 Principal Investigators (PIs) with successful grant and publication track records. Resulting in >25 000 recruited into randomised studies, >16 000 enrolled in observational studies. There is a strong commitment to include younger investigators in authorship and grants to enable them to develop a track record and ensure continuity of the network.

- Infrastructure is membership model based at Unit level (unlike the Canadian model which is based on individual membership). ANZICS CTG has 73 member ICUs, 65 adult/mixed, 8 PICUs including 13 NZ units.

- The $2,500 annual subscription comes mostly out of hospital operations funding, and this is at saturation in Australia and New Zealand.

- There is a Secretariat based in Melbourne and funded by membership fees.

- Currently ANZICS CTG has 27 endorsed studies active, along with 2 supported studies (international collaborations).

- The network charges endorsed studies for base infrastructure.

- Funding to date: Competitive ANZ grants – Projects $42.9M, infrastructure $3.8M
  Competitive international grants - $8.3M
  Unrestricted industry grants - $5M

- HRC has been willing to fund on-going Australian studies for New Zealand centres to be involved.

- Separate grants for infrastructure (there are better pathways in Australia; this is a problem in New Zealand however). “Having 2 countries and 2 funders is good, but a bi-national model would be better.”

- Colin described 3 secret ingredients to the network
  1. **Science:** The network holds twice yearly meetings including project review sessions. One meeting in Noosa and a second in a major city. Projects are presented by investigators at varying stages of development. Debate, discussion and reflection are offered, and there is a time interval for amendments and representation. There is a rigorous formal project endorsement process to assess science and feasibility. Both science and practicality must be right: there are three independent peer reviews of each project proposal, (a research coordinator is included as one of the reviewers to ensure the practicality of the study). The typical development cycle to reach definitive Phase lll study is 2-4 years.

Programmes of research include: **Observational studies** - clinical practice, incidence, point prevalence (the network undertakes an annual 1-day point prevalence study... who’s in your ICU? This gathers common core data, demographics, baseline diagnosis, severity of illness etc. and can
include a few additional questions submitted by individual investigators or research groups) This is done voluntarily (workload vs funding issues) for central database analysis of common core data.

**Pilot trials** - Is randomisation feasible? Separation between groups? Case Report Forms (CRFs) suitable? etc. “I would really encourage pilot trials, they are very helpful, and we learned the hard way the benefit of this.”

**Phase IIA** – is it biologically active on surrogate?

**Phase IIB** – is it clinically active on surrogate?

**Phase III** – Does it influence a patient centred end-point? Should it be in clinical practice?

**Translation into practice.**

2. **Organisation:** Network Governance is by the CTG Executive Committee. The role of the committee is to:
   - set and maintain standards and policy
   - facilitate researchers getting together (it does not run trials)
   - maintain the CTG ‘brand’ (valid science, ethics, trial progress, publication standards)
   - run meetings and disseminates proposals
   - endorse projects and manuscripts, with transparent and explicit process including the resolution of disagreement

Colin is willing to share the Terms of Reference

The Executive Committee is a sub-committee of the Intensive Care Society; regional representatives are elected onto it by state groups via a competitive process. There are four office bearers (usually past regional representatives). Most office bearers cycle through the positions but have a limited duration of service.

The network has two Methods Centres; the George Institute (University of Sydney) and ANZIC Research Centre (Monash University, Melbourne). It is crucial to have well run centres to manage data and projects. These are located within existing university departments and utilise university infrastructure. Funding for Methods Centres is achieved by payment for service from each individual study’s budget (projects can elect to use other research centres for these services but generally use the Methods Centres). ANZICS now has sufficient overlapping funding from endorsed studies to achieve consistency of staffing in the Methods Centres (approximately 6 staff at The George Institute, and 10 at ANZICS Monash). The network does however need more funding for broader infrastructure.

Self-formed Study Management Committees at the sites actively run each individual project (supported by the Methods Centres). Each management committee is responsible for design, protocol development, funding, and study management.

Sites do the work - including patient recruitment and data collection. Site Research Coordinators are essential. In approximately 50% of sites there is some hospital operational funding to support this (however <50% of DHBs in New Zealand contribute funds). Often sites can be financially supported by commercial studies to cover research co-ordinator costs. Sites also undertake training and professional development.

3. **Passion:** There is an organised culture of collaborative research characterised by enthusiasm, fun, collegiality, pragmatism, hard work, and a non-hierarchical culture of questioning, where cooperation is the norm, and the group takes precedence over the individual. Group authorship is common.
PSANZ and a perinatal clinical trials network (Frank Bloomfield)
Frank provided an overview of the work of a PSANZ (Perinatal Society of Australia and New Zealand) Clinical Trials Working Group, set up to investigate a strategic approach to enhancing perinatal research.

Key points

- The working group is multidisciplinary with representatives from Australia and New Zealand. Chaired by Frank, it convened in mid-2013. Its brief is to profile the activity in both countries of trials involving mothers’ and babies health, and to report back to the PSANZ Board on recommendations for the establishment of a clinical trials network in this area.
- Profiling found there are over 200 maternal and perinatal randomised trials currently active in Australia and New Zealand (218 multicentre trials and/or >100 participants)
- A third of those currently recruiting, or about to start recruiting, are funded by the Health Research Council (HRC) New Zealand, The National Health and Medical Research Council (NH&MRC) Australia, and the Australian Research Council (ARC).
- Approximately 13,000 mothers or babies per annum are recruited into clinical trials in Australia and New Zealand, and 3-4% of all births across both countries are represented in randomised controlled trials (RCTs).
- New Zealand activity is a major contributor to the working party, especially the work of this feasibility study, and there is a proposal to extend this work around Australia.
- Any PSANZ initiative will be for Australia and New Zealand. Therefore:
  - There is opportunity for PSANZ to provide (limited) support for a clinical trials network.
  - There is opportunity for this project and this group to influence direction significantly.
  - There is a need to consider how a New Zealand network would link with Australian activity.

Frank also provided a brief overview of the Australian Clinical Trials Alliance (ACTA). This new initiative involves Australia’s national and state-based clinical trials networks, clinical trial coordinating centres and clinical quality registries across all of the major disciplines and disease groups connecting with one another and with key health policymakers and opinions leaders. ACTA’s seeks to:

- Increase the impact of investigator-led clinical trials by providing an advisory and advocacy role.
- Provide an opportunity for the investigator-led clinical trials community to have direct input into the development of the Australian Clinical Trials Alliance, its strategic goals and priorities for supporting the sector.

ACTA has widespread support from the Australian clinical trials community, representation from the Australia and New Zealand Neonatal Network (ANZNN) (Ross Haslam), and although keen to support similar initiatives in New Zealand, will not extend ACTA to include New Zealand. ACTA has a foothold with government and funding agencies (including a significant relationship with NH&MRC – providing $60 000 support for an ACTA clinical trials summit).

IMPACT and WOMBAT (Caroline Crowther)
Caroline provided an overview of two Australasian examples of collaborations: IMPACT (Interdisciplinary Maternal Perinatal Australasian Trials Network) and the now completed WOMBAT (Women and Babies Wellbeing Action Through Trials) project.
Key Points

- IMPACT is a subcommittee of the PSANZ dedicated to the improvement of maternal and perinatal health by the promotion of well-designed randomised controlled trials and the dissemination and application of their results.
- Membership of IMPACT is free and open to all members of PSANZ which funds the initiative.
- IMPACT is overseen by a committee selected from within the network membership made up of a representative from each of the PSANZ disciplines (consumers, midwifery, neonatology, neonatal nursing, obstetrics, scientists and other).
- Elected for a term of three years the committee is responsible for coordinating activities that fulfil the aims and objectives of the network, which are:
  - to identify key research issues in maternal and perinatal health
  - to promote the design, registration, completion, dissemination and application of appropriate RCTs in maternal perinatal care
  - to provide a forum for discussion, communication and collaboration between investigators in all disciplines, for planned or ongoing trials in maternal perinatal care
  - to establish priorities for funding clinical trials in maternal perinatal health with funding agencies
  - to establish international links with the Pregnancy and Childbirth and Neonatal Collaborative Review Groups, other clinical trials networks and organisations or bodies
  - to assist in bringing research evidence into clinical practice by promoting evidence-based care within the clinical colleges and other professional societies
  - to provide educational opportunities in critical appraisal and trial design
  - to provide information to PSANZ via newsletter
- Caroline suggested that it was perhaps time for a refresh of the IMPACT network (“new era, new knowledge, and new funding arrangements”), and it may transform into a new PSANZ initiative pending the outcomes of the working group Frank profiled above.

- WOMBAT was designed to promote and support high quality maternal and perinatal randomised clinical trials in Australia, including providing high-level operational support for the design, initiation, recruitment, completion, publication and dissemination of results. In 2005, following the review of 78 papers reporting barriers to clinicians and patients’ involvement in clinical trials, 10 investigators received funding for five years to identify solutions, and WOMBAT was born. A national collaboration with regional bases in Adelaide, Brisbane, Melbourne, Perth and Sydney, WOMBAT sought to counter the common barriers of time, information and knowledge constraints by providing national and state coordinators to act as networkers and trial consultants, liaising with experts and providing assistance if required. The WOMBAT collaboration also ran workshops and short study programmes, including web-based training materials to cover the essential components that underpin high quality clinical trials. Another significant component of its work was the compilation of a yearly trials booklet (and web resource) that provided details of all maternal and perinatal trials in the WOMBAT cohort (which included details of multicentre trials across Australia and more recently New Zealand).
- Funded for five years the project that is now in a legacy space with much to be learned from its contributions to knowledge and practice.
Afternoon breakout sessions: questions and feedback

Workshop Item 9: Breakout group discussion (1) How could a network help overcome barriers? How could a network harness or facilitate enablers?

- A network could help to make research core business, part of our daily life.
- Time barriers could be overcome by:
  - Inclusion of research in job descriptions and evaluations
  - Integration of research into clinical work (an increased profile for research culture with all perceived to be involved)
  - More paid research employment
  - Research Coordinators within each centre (the network empowers, encourages, facilitates)
  - Integrated professional development: Support/advice from senior colleagues. Authorship, particularly for junior investigators. Official recognition of involvement towards standards review etc.
  - The provision of multidisciplinary education, information packs, resources and networking for coordinators.
- The network could:
  - Provide a national body to simplify the research process (including high level overarching processes to streamline local consultation; Maori involvement and facilitation)
  - Provide a national overview of what research is occurring. Provide a log of projects in the field around the country; provide a log of researchers... who is out there and what are they doing. Become a central knowledge resource. Breakdown barriers between professional groups by sharing knowledge.
- Profile/visibility for the network would be an enabler. A multimedia, social media presence (Facebook page) also for consumers to access and interact with.
- Online (web presence). A forum for Q&As. A safe place to ask the “whatever” and “noddy” questions.
- Endorsement by a credible research network (a ‘gold standard brand’) could take the burden of assessment away from DHBs.
- Provide quality and cost savings attractive to DHBs
- Great potential to promote relevant high quality research training via a quorum of people/expertise across the country (DHBs are currently not meeting research training obligations; talking to DHBs about where the money for this goes and what it is used for). Education and training supporting the smaller regions. DHB obligations for training doctors could be met by the network
- Buy-in from key people in the Universities and DHBs will be crucial. Clinical Directors in O&G could be useful. What other networks are out there that could assist? Identify and engage.

Workshop Item 10: Breakout group discussion (2) What would the most effective relationship with DHB and University Research Offices look like, feel like and work like?

- DHBs and Universities research offices... What is their role? What is their purpose? To facilitate research. (DHB goals are quality and safety; University goals are outputs and publications). Currently drowning in process. For example, Otago University interfaces with 3 DHBs with 3 different processes.
- Huge efficiencies to a joint service, DHBs and Universities co-located (live together/talk together/work together).
- Huge potential for efficiencies by collaborating to create combined and streamlined processes to facilitate research. Would feel collaborative, supportive and friendly.
- Important to facilitate appropriate levels of remuneration for people of appropriate skill. Pay equity
How are why should we engage with funding bodies, Colleges, Consumer Groups, Government Agencies? And which ones are important?

- Groups identified as important to engage with

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<thead>
<tr>
<th>Colleges</th>
<th>Consumer Groups</th>
<th>Government Agencies</th>
<th>Funding Bodies</th>
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<tbody>
<tr>
<td>Royal Australia and New Zealand College of Obstetricians &amp; Gynaecologists (RANZCOG)</td>
<td>Neonatal Trust</td>
<td>Health Quality &amp; Safety Commission</td>
<td>Health Research Council</td>
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<tr>
<td>New Zealand Nurses Organisation (NZNO)</td>
<td>Parents Centres</td>
<td>Ministry of Social Development</td>
<td>Cure Kids</td>
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<td>New Zealand College of Midwives (NZCOM)</td>
<td>The Parenting Place</td>
<td>Ministry of Health</td>
<td>Auckland Medical Research Foundation (AMRF)</td>
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<tr>
<td>Neonatal College</td>
<td>Child Birth Educators</td>
<td>National Maternity Monitoring Group</td>
<td>Nurture</td>
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<td>Cerebral Palsy Society</td>
<td>Perinatal &amp; Mortality Review Committee</td>
<td>Gravida: National Centre for Growth &amp; Development</td>
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<td>Stillbirth and Neonatal Death Society (SANDS)</td>
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<td>The Liggins Institute</td>
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<td>Speech Language Therapists</td>
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<td>Mercia Barnes Trust</td>
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<td>Well Child/Tamariki Ora</td>
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Workshop Item 11: Breakout group discussion (3) What are the objectives of the network?

- To be a high calibre entity and brand that can endorse high quality investigator led research. Quality measures to be included in the network.
- To have government, Colleges and allied health professionals, and consumer endorsement.
- To have a clear and robust governance structure with representation from all sectors of the workforce and geographic locations.
- To provide a central online presence where resources can be accessed and knowledge shared. Member only and public sections to a website.
- To provide regular forums/workshops for researchers and support staff to discuss their work, access professional development and provides training in research eventually.
- To be a virtual lobby group to present consensus views to Universities, DHBs and government agencies.
- To include and engage with the lay community. Promoting research to women and families, and involving consumers in maternal and perinatal research network.
- To raise the profile of the network and research in the area.

What does it look like? (Model/infrastructure/name/logo)

- Investigator initiated and led. RCTs and other multicentre observational studies.
- Under the umbrella of PSANZ and ultimately link to Australia via PSANZ. Aims and infrastructure linked with both New Zealand and Australian compatibility.
- Need to determine the type of organisation (legal entity/structure).
- Bi-annual meetings (similar to ANZICS).
How would it be coordinated?

- Executive committee (meets quarterly) multidisciplinary and geographically representative. Include people in leadership roles who are not in Auckland.
- Consumer involvement at all levels very important.
- Coordinating centre for infrastructure: a physical site where administration and methods centres are co-located. A DHB or tertiary centre... suggestion is to utilise Auckland Academic Health Alliance (AAHA: UoA and ADHB), Department of O&G and Liggins Institute.

How should it be funded?

- Individual fees
- DHB annual fee (tiered?) FTE allocation for Trial Coordinator roles. Will need to establish what DHBs are buying. Leverage could be:
  - Commitment to research
  - Research training
  - Quality and safety
  - Improved outcomes
  - Reduce inequalities across New Zealand
- National DHB (DHB NZ) funding.
- Network generates income: fees for trial services (with goal to be self-sustaining).
- Ministry of Health (MoH), Ministry of Social Development (MSD), Quality and Safety Commission.
- Philanthropy: Sponsorship and Naming Rights (e.g. Cure Kids).
- Universities – FTE allocations, Methods Centres?
- PSANZ

Workshop Item 12: Summary and actions

1. Engagement with consumers and philanthropic funding. Liaison with Cure Kids, Starship Foundation, Liggins Institute etc.
2. Engagement with other bodies.
3. Strategic Plan (write protocol and strategic plan: how we plan to get there).
4. Scoping of current resources (How do we get runs on the board fast? Studies being undertaken now?)
5. Governance document/Terms of Reference.

At the workshop it was suggested Advisory group members form working groups to progress these actions. However, the development of a strategic plan is a necessary foundation. And so, feedback from the workshop, together with the research findings to-date will inform this important next step in the feasibility process.
Appendix 5:

Recommendations of the PSANZ Clinical Trials network Working Party to the PSANZ Board of Directors (accepted at the PSANZ BOD meeting 3 June 2014)

i. That IMPACT draft updated Terms of Reference and Governance Documents to regulate its activities.

ii. That IMPACT modifies its name to reflect its activities to external stakeholders. A suggestion of: “IMPACT for Mothers’ and Babies’ Health. The Clinical Trials Group of the Perinatal Society of Australia and New Zealand.”

iii. That IMPACT considers how to raise its profile.

iv. That PSANZ, through IMPACT, become a member of ACTA.

v. That IMPACT should hold 2-3 meetings a year in different locations with increased emphasis on reviewing / critiquing planned trials and on capacity building.

vi. That IMPACT consider how to engage more widely with potential constituencies.

vii. That all PSANZ members whose clinical trials have been supported by input from IMPACT acknowledge IMPACT in the publications arising from those trials.

viii. That IMPACT develop a strategic plan leading on to an action plan to achieve the above.

ix. That the BOD provide financial support to undertake a survey of clinical trials activities, including enhancers and barriers, based firmly on the completed survey in New Zealand.

x. That the BOD undertake to promote IMPACT more widely, e.g.
   a. Regular IMPACT updates in the newsletter
   b. Consider re-launch of IMPACT at PSANZ 2015 Congress
   c. That the IMPACT session within PSANZ be reinstated (e.g. a half-day session)
   d. PSANZ endorses IMPACT as its Clinical Trials Group