

COVID-19 in Pregnancy New Zealand Registry

Investigator Group

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Associate Professor Nicola Austin, neonatal paediatrician, Canterbury District Health Board. Paediatric Society of New Zealand (President)

Dr Kasey Tawhara, obstetrician and gynaecologist, Lakes District Health Board. Te Kāhui Oranga ō Nuku Royal Australian and New Zealand College of Obstetricians and Gynaecologists (New Zealand Office) He Hono Wāhine (member). Ngāti Raukawa, Ngāti Porou

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Ms Laura Mackay, clinical research coordinator, University of Auckland

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Dr Colin McArthur, intensive care physician, Auckland District Health Board. Short Period Incidence Study of Severe Acute Respiratory Infection (SPRINT-SARI) Lead Investigator (New Zealand)

Dr Claire McLintock, obstetric physician, Auckland District Health Board, Australasian Maternity Outcomes Surveillance Survey (investigator)

Dr Sally Roberts, infectious disease physician, Auckland District Health Board

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Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the cause of the pandemic coronavirus disease 2019 (COVID-19). Only small numbers of births have been reported among women infected with SARS-CoV-2 during pregnancy and, to date, these are almost exclusively reports of births to women infected in the third trimester of pregnancy who were severely unwell including approximately 50% of cases complicated by pneumonia. Within these small case series and reports a disproportionate number of babies were born before 37 weeks and by caesarean section.¹ Previous influenza epidemics including severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and influenza A virus subtype H1N1 (H1N1) were all associated with severe illness and mortality in pregnant women.

As yet, no reliable data are available for rates of SARS-CoV-2 infection in pregnant populations or on pregnancy outcomes for women, or neonatal outcomes for their infants, affected by COVID-19 in pregnancy whether unwell and requiring hospital admission or for those who remain well and are managed within the community.

Risk of *in utero* or vertical transmission is currently unknown.² Inconclusive evidence from China based on IgG/IgM data only in three babies suggests vertical transmission may occur. Previous data on nine babies with RT-PCR (also from China) suggested no *in utero* transmission.³ The risk of horizontal transmission from mother to newborn baby after birth is also unknown. New Zealand is taking a pragmatic approach to newborn care after maternal SARS-CoV-2 infection, encouraging breastfeeding and joint self-isolation of mother and baby with physical distancing and mask and hand hygiene for contact. This is different from some other countries where babies have been isolated from their mothers. The safety of each approach is yet to be determined.

Establishing the COVID-19 in Pregnancy New Zealand Registry will allow us to provide New Zealand specific data on how common COVID-19 in pregnancy is; what are the risks of severe illness for pregnant women; if there is any effect on unborn babies, such as pregnancy loss or congenital anomaly if they are infected early in pregnancy, or fetal growth restriction, or preterm birth if infected later in pregnancy; and what are the risks for the newborn from *in utero* infection or infection at or soon after birth.

Relevant Studies on COVID-19 Infection in New Zealand

The Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trial Group has commenced collection of COVID-19 data via an international collaboration called the Short Period Incidence Study of Severe Acute Respiratory Infection⁴ (SPRINT-SARI) Study. SPRINT-SARI began in 2016 to establish research preparedness for future pandemics. SPRINT-SARI will collect data in eight (and possibly a further three) hospitals in New Zealand. Only two of these hospitals are planning to collect data on all hospital admissions with COVID-19, with most only collecting data on intensive care unit (ICU) admissions. No collection of data from community managed cases is currently planned. SPRINT-SARI data includes a limited amount of data on pregnancy, including gestation at diagnosis/time of admission to hospital, stage of pregnancy (antepartum or postpartum) at diagnosis of infection, pregnancy outcome (live or still birth), date of birth, viral testing and results of viral testing of babies of mothers with COVID-19, along with comprehensive clinical information on ICU admission. Dr Colin McArthur, the New Zealand lead on SPRINT-SARI,

¹ Cochrane review of cases reported 26/3/2020; <https://cgf.cochrane.org/news/covid-19-coronavirus-disease-fertility-and-pregnancy>

² Kimberlin DW, Stagno S. JAMA. Published online March 26, 2020. doi:10.1001/jama.2020.4868

³ Chen H, Guo J, Wang C, et al. Clinical characteristics and intrauterine vertical transmission potential of COVID-19 infection in nine pregnant women: a retrospective review of medical records. Lancet. 2020;395(10226):809-815. doi:10.1016/S0140-6736(20)30360-3

⁴ <https://www.anzics.com.au/current-active-endorsed-research/sprint-sari/>

has agreed in principal to share data on pregnant women in New Zealand who are included in the SPRINT-SARI study.

We are also aware of other potential COVID-19 studies and data collection systems in pregnancy that are being considered.

The Australasian Maternity Outcomes Surveillance System (AMOSS) was established in 2009 to provide a surveillance system for selected severe maternal morbidities. Case identification is performed prospectively with retrospective data collection to allow incidence reporting and case-control studies. AMOSS is planning to collect data on COVID-19 in pregnancy in some Australian states (confirmed in New South Wales) and this study could include New Zealand. They are in the early stages of developing their response, which will follow their usual process, co-opting local coordinators of the New Zealand Perinatal and Maternal Mortality Review Committee (PMMRC) in each district health board to collect data. This will provide data retrospectively and so will not be able to provide contemporaneous information on the developing pandemic of infection in New Zealand. Dr Claire McLintock, a Chief Investigator of the AMOSS group, and Dr John Tait, Chairperson of the PMMRC, support a New Zealand specific approach to collection of data about COVID-19 in pregnancy.

Clinicians and researchers from Melbourne, Australia, are also planning to collect pregnancy data on COVID-19 in Victoria. They have approached maternal fetal medicine subspecialists in other states in Australia and New Zealand to contribute state and country data. It is likely that these researchers will work with AMOSS to create a single COVID-19 in pregnancy reporting/data collection system for Australian states.

While joining an Australian system may be feasible there are several advantages to New Zealand having its own registry. These include:

- New Zealand specific methodology to ensure all cases are identified;
- Opportunity to safeguard use of New Zealand data;
- Prioritise equity and Māori;
- Ensure control of data for early reporting and ongoing review to assist in the national COVID-19 pandemic response;
- Data can be interpreted in the context of New Zealand's unique maternity healthcare system and New Zealand's policies and approach to combat the COVID-19 pandemic.

Any New Zealand specific dataset can be created to be compatible with other international datasets such as those planned, e.g., in Australia, and those already established, e.g., in the United Kingdom via the United Kingdom Obstetric Surveillance System (UKOSS), which commenced data collection on 1st March 2020 but will only include COVID-19 in pregnancy cases where hospital admission occurred. Ensuring compatibility will allow for a global perspective on COVID-19 in pregnancy as well as comparisons between countries.

We are also aware of other potential COVID-19 studies and data collection systems for neonates and children and other relevant specialist groups that are being considered.

The Australian and New Zealand Neonatal Network (ANZNN) was established in 1994 as a collaboration of all neonatal intensive care and special care units across New Zealand and Australia. Within New Zealand all secondary and tertiary units providing newborn special care contribute data. All units provide a core dataset of outcomes to a clinical quality registry to enable benchmarking and collaborative audit, as well as to facilitate research. ANZNN are currently planning to extend their dataset to include all admissions to neonatal units of newborns of COVID-19 positive mothers and/or COVID-19 positive newborns. They do not plan to collect data on newborns of COVID-19 positive mothers and/or COVID-19 positive newborns who are cared for on postnatal wards, in primary birthing units or in the community. It is likely that ANZNN will collaborate with the International Network for Evaluation of Outcomes (iNeo) of Neonates which will include data from a number of national neonatal networks. Dr Malcolm Battin is the

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Chairperson the New Zealand Newborn Network and a New Zealand representative in ANZNN. We will work with all New Zealand units to ensure data collection is complimentary and not repetitive.

The Pediatric Emergency Research Network (PERN), led by Professor Stuart Dalziel, plan to collect data related to emergency department presentations with SARS-CoV-2 infection in over 50 emergency departments globally, including data from New Zealand. Further Professor Dalziel, together with colleagues from the New Zealand Paediatric Surveillance Unit will collect data on all paediatric admissions to hospital with COVID-19 in New Zealand. This University of Otago group, led by Dr Mavis Duncanson, was established as a national surveillance unit for acute flaccid paralysis but also aims to facilitate national surveillance of other uncommon childhood conditions in New Zealand. It is also possible that an infectious disease-led observational study may be considered but further detail is currently unavailable.

No other groups are currently planning a New Zealand COVID-19 in pregnancy specific study and no other group is planning to include all newborn infants exposed to and/or infected by COVID-19 during fetal and/or early newborn life. We plan to continue to collaborate with all groups in New Zealand working in this space to ensure that data collection is as effective and efficient as possible, and that where possible safe and effective data linkage occurs to reduce duplication of effort.

Study Aims

To create a registry of all cases of COVID-19 in pregnancy and the newborn period in New Zealand to answer these, and other, research questions:

- 1 What is the incidence of SARS-CoV-2 infection/COVID-19 in pregnancy in New Zealand; and are there differences in incidence of SARS-CoV-2 infection/COVID-19 in pregnancy for Māori and non-Māori? Including contemporaneous reporting of cases to support local maternity and neonatal care responses.
- 2 What is the natural history of SARS-CoV-2 infection/COVID-19 in pregnancy in New Zealand, including outcomes for mothers and babies, from infection in early (<20 weeks) and later (>=20 weeks) pregnancy? Are there differences in outcomes for mothers and babies for Māori and non-Māori, and if so why? What is the risk of infection in babies by vertical transmission and horizontal transmission in the first six weeks of life?
- 3 How do rates of SARS-CoV-2 infection/COVID-19 in pregnancy and its effect on adverse outcomes (such as maternal death, adult respiratory distress syndrome (ARDS), maternal ICU admission, and requirement for ventilation, miscarriage, fetal anomaly, preterm birth, fetal growth restriction, stillbirth and perinatal death) vary by country where onset of widespread infection occurred early or late, with different approaches to containment, and with different models of maternity care?
4. The impact of COVID-19 vaccination on the incidence and severity of SARS-CoV-2 infection/COVID-19 in pregnancy in New Zealand. (Addition October 2021).

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Study Design

This is a prospective registry study of all cases of probable or confirmed COVID-19, and SARS-CoV-2 infection, occurring in pregnancy and up to six weeks postpartum in New Zealand, including outcomes for mother and baby.

Study Population

The registry will aim to include all maternal cases of probable or confirmed COVID-19, and SARS-CoV-2 infection, that are diagnosed in pregnancy or within six weeks of birth in New Zealand, including the outcome of the babies of these women.

We will aim to include all cases from the date of first confirmed case in New Zealand (28th February 2020).

Inclusion Criteria (case definition)

- All women with confirmed or probable COVID-19⁵ or laboratory confirmed SARS-CoV-2 infection during pregnancy and up to six weeks postpartum.
- All newborns born to mothers with COVID-19 or laboratory confirmed SARS-CoV-2 infection during pregnancy and up to six weeks postpartum regardless of SARS-CoV-2 status.

Cases managed in hospital and in the community will be included.

Infection in pregnancy at all gestations will be included (confirmed pregnancy by urine or blood hCG test and/or ultrasound).

Study Procedures

To enable the establishment and effective use of this registry the study investigator group includes representatives from the wider maternity community including consumers. To optimise engagement with Māori, we are working in partnership with members of Te Kāhui Oranga ō Nuku He Hono Wāhine (Māori women's health subcommittee of the New Zealand office of Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). To identify women with SARS-CoV-2 infection both in the community and from hospitals it will be important to have support from general practice, midwifery lead maternity carers (LMCs), obstetric LMCs and hospital clinicians. To this end, we have taken advice from, and enlisted as co-investigators, representatives from the New Zealand College of Midwives (NZCOM), the Royal New Zealand College of General Practitioners (RNZCGP) and RANZCOG.

Study promotion: The Registry will be promoted to healthcare providers by email via the appropriate Colleges (NZCOM, RNZCGP and RANZCOG).

We will also generate public awareness through a dedicated webpage on the Liggins Institute website and via social media. To maximise understanding and interest for Māori we will provide

⁵ As at 31/03/2020 defined as

- Probable: A case that meets both clinical and epidemiological criteria where other known aetiologies that fully explain the clinical presentation have been excluded, and either has laboratory suggestive evidence or for whom testing for SARS-CoV-2 is inconclusive.
- Confirmed: A case that has laboratory definitive evidence of SARS-CoV-2 infection.

Māori specific messages and ask that they be distributed via Te Rōpū Whakakaupapa Urutā and Tumu Whakarae (the National DHB Māori General Managers Group) for dissemination to DHB Māori Directorates.

Case identification and notification: We will use several methods to maximise the opportunity to include all eligible cases including via DHB clinical leads/nominated contacts, colleges, Lead maternity carers (LMCs) and consumers.

A REDCap database hosted by the Liggins Institute Clinical Data Research Hub (CDRH) was planned from the outset to record notification of cases and for later data collection. The provider quote was greater than \$30,000 to host and maintain this database. There were not enough cases to justify this cost and an initial funding application for the Registry was unsuccessful. The management team subsequently explored commencing notification and data collection via hardcopy forms, rather than through a REDCap database (as documented in Protocol V4, 21Aug2020). After consultation and consideration of data privacy, hard copy forms were not utilised and a series of REDCap databases were established through the University of Auckland FMHS REDCap. All data has been collected via the electronic REDCap databases. Case notification is via a REDCap survey, and the permalink to access this is present on the registry website, information sheet for health professionals, and has been distributed to DHB contacts and the colleges.

1 Primary care (general practice, midwifery, obstetric) and hospital clinicians will be asked to notify cases of confirmed or probable COVID-19 or laboratory confirmed SARS-CoV-2 infection in pregnancy via the notification link: <https://redcap.fmhs.auckland.ac.nz/surveys/?s=M9DKWNAYYH>. We will work with health professional colleges (NZCOM, RNZCGP and RANZCOG) and DHBs (via named representatives) to advertise and promote the Registry and to develop regular reminder systems.

2. The Registry webpage www.liggins.auckland.ac.nz/covid19 will provide opportunity for women to self-report SARS-CoV-2 or COVID-19 diagnosis. Contact details of their healthcare provider (LMC, GP or DHB) will be requested and the research team will make direct contact with their healthcare provider to commence the notification process.

3. We will work with other systems that are expected to collect data on COVID-19 cases that may include or relate to pregnancy, to cross-reference our registry notifications, including:

- district health board (DHB) records;
- the Ministry of Health public health surveillance system (which includes a flag for pregnancy);
- regional public health services such as ARPHS; and
- ANZNN and the New Zealand Paediatric Surveillance Unit (NZPSU) reporting systems;

to ensure ascertainment of cases is as complete as possible.

We will strive to ensure the notification of cases is straight-forward and is as time-limited as possible, with the option to include minimum mandatory fields only. We anticipate multiple notifications per case are likely to occur and will develop the system to accommodate this.

Consent: We applied to the Health and Disability Ethics Committees for a waiver of consent on the following grounds:

1. Notification of cases by healthcare workers is not considered research
2. The research component of this proposal is observational research of only de-identified routinely collected data.

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3. All data will be de-identified beyond the notification set, which will only be used for the purpose of requesting missing and prospective data, and merging data from various sources. No identifiable data will be included in the dataset for analysis, and no individual data will be reported. The re-identification key will be carefully protected in a separate secure database at the University of Auckland.

4. Collection of consent will be burdensome for individual cases, healthcare providers and researchers. Notifications will be requested from a large group of providers, and from cases where contact (including of time, and with paper and electronic devices) is advised to be strictly limited to essential requirements only in order to reduce transmission of infection. Specifically, caregivers are currently advised not to handle or store 'infected' hard copy materials and should not share a device to gain electronic consent, and so in practical terms consent could only be provided verbally.

5. COVID-19 is a serious and potentially fatal infection that is causing a pandemic of unprecedented scale and cost to human health, not seen since the influenza pandemic of the early 20th century. Accurate national epidemiological data are urgently needed to plan the national response to this (and future SARS infections), in order to prevent massive loss of life.

6. Data collection systems and studies of this type are in existence in New Zealand in the areas of maternal and newborn health including ethics approval for use of routinely collected data without participant consent for use of de-identified data (AMOSS, ANZNN and NZPSU).

The use of waiver of consent was declined by the Northern B Health and Disability Ethics Committee and subsequently a request for use of opt-out consent has been made and approved.

The information sheet for mothers who are included in the Registry (Appendix 1) provides brief information on the purpose of the Registry, the data that will be collected and ways it will be used. It is clear that women will not be required to take any additional actions as a consequence of their data being included. It includes information on how to request to opt-out- of inclusion in the registry as well as contact details for the research team to request a copy of individual data and published results. This information sheet will be made available to all healthcare providers for distribution to all women who met the eligibility criteria at the time of notification to the Registry. It will also be accessible from the Registry webpage.

Dataset: The investigators have reviewed the data collection reporting forms from the Melbourne COVID-19 in pregnancy and the UKOSS surveillance datasets to inform the data collection instruments in this registry so that the findings from studies using this registry can be compared internationally. Addition October 2021: addition of COVID-19 vaccination status including dates and type given.

Data collection: Web based REDCap databases managed by Laura Mackay and Rebecca Hay, Liggins Institute, and hosted by The University of Auckland, will be used for notification of cases and data collection (Figure 1).

Case notification. The notification dataset will include identifiable personal details of women and their babies, only available to the researchers for the purpose of later extraction of routine data (from the LMC, clinical notes, or routine datasets) and to exclude duplicate notifications. This dataset will also hold details of the notifying clinician and the LMC (if known at that time). The research team will negotiate with each DHB via the New Zealand Midwifery Leaders Forum to identify an appropriate nominee from each DHB who may be, for example, the PMMRC local co-ordinator (as per current mechanism for maternal morbidity data collection for AMOSS) or the local Maternity Quality and Safety Programme (MQSP) Co-ordinator.

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Case notification will include a limited number of data items. The notifying clinician will be asked to provide identifying data for the woman and baby/babies (if applicable), and the woman's estimated date of delivery (EDD).

De-identified Registry Database

1. Notification – Registry Data. The LMC, notifying clinician or nominated DHB delegate will be sent a secure electronic REDCap survey link to provide data relating to the diagnosis of COVID-19, the woman's medical history and pregnancy risk factors. Notifiers will be asked to provide as much information as possible and data collection will be supported by the research team if required. The email request will include contact details for the research team if assistance is required.

2. Pregnancy Outcome Data. The LMC, notifying clinician, or the nominated DHB delegate will be contacted via email after the expected time of birth (EDD). They will receive a secure electronic survey link for reporting of the remaining data related to the pregnancy and birth. All data items are routinely included in standard maternity clinical records/datasets. The email request will include contact details for the research team if assistance is required.

3. Six Week Postpartum Data. A further email with a secure electronic survey link will be sent to the LMC, notifying clinician or nominated DHB delegate six weeks post birth/pregnancy completion. The email request will again include contact details for the research team if assistance is required.

Non-responders to email requests for data collection will be contacted by follow up email or a telephone call from the research team 1-2 weeks after the initial request.

Data relating to babies admitted to a neonatal special or intensive care unit will be extracted by the research team, or with assistance from the neonatal units, using the recently developed ANZNN COVID-19 data form to avoid duplication of data collection and additional burden on neonatal clinicians.

Data for women admitted to Intensive care will be extracted by the researchers or requested from the SPRINT-SARI (ANZICS) team.

If outcome data cannot be found via GP, LMC, or hospital sources, a request will be made for data from the Ministry of Health national maternity (MAT) or hospital discharge (NMDS) datasets for women notified as having COVID-19 in pregnancy.

Only routinely available data will be included in the Registry. No extra tests outside of routine care will be requested for this study.

Sample Size

At this time it is difficult to estimate the impact of COVID-19 in New Zealand. There are approximately 60,000 births per year in New Zealand. If SARS-CoV-2 infected 10% of the population and this included women of reproductive age, this might include 6,000 women. If 1% of people were infected, this would include 600 women.

Confidentiality and Data Security

Data will be managed by the Liggins Institute, University of Auckland. Oversight of data security and access will be managed by the Registry Data Governance Group (Appendix 2).

Individual privacy will be protected by the use of three separate REDCap databases which will be stored on a secure password protected server at the University of Auckland. Identifiable personal information of women and their babies will be collected in order to facilitate follow-up data collection through to six weeks postpartum, and to exclude duplicate notifications.

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After removal of duplications, each case will be assigned a unique registry number and an identification dataset will be created consisting of maternal name, NHI, date of birth, registry number and caregiver contact details. Cleaned de-identified notification data will be transferred to a third registry database identifiable only by the unique registry number. The electronic follow-up surveys will be sent by email to LMC, notifying clinician or nominated DHB delegate via the identification dataset and will include a secure one-time link to the outcome form in the de-identified registry database. All transmitted data will be encrypted. This system will enable collection of fully de-identified outcome data and for the correct merge of later data with the correct case in the de-identified registry database.

Participant privacy and the re-identification processes will be closely controlled. Access to notification, identification and de-identified registry data base will be limited to select members of the research team, including the Registry Data Governance Group and research staff appointed by the Data Governance Group.

Extracted data files will be fully de-identified. Study presentations and publications will contain only summary data and individual participant data will not be reported. The research team will be responsible for data access. Identifiable data will not be released to any third party for any purposes, including for the purpose of future research.

At the completion of the study, all electronic registry data will be permanently digitally archived and accessible only to the lead investigators. Any remaining hard copy records will be stored in a locked cabinet in a secure office and will be accessible only to the lead investigators and research staff appointed by the Data Governance Group. Records will be retained for a minimum of 10 years after the age of majority. If a data sharing option is mandated by the publisher, only de-identified data will be released and its use will be strictly controlled by a data sharing agreement overseen by the Data Governance Group.

Data Analysis

The frequency of data review will be dependent on case numbers. Data will be used to inform the approach to COVID-19 among pregnant women in New Zealand and to inform women. These data will be shared with the investigators, Colleges (RACGP, NZCOM, RANZCOG) and the Ministry of Health.

During and at the end of the study, to be determined by the birth of all babies of women with COVID-19 in pregnancy and after such time that COVID-19 is significantly reduced in New Zealand, data will be compiled for peer reviewed publication.

An equity analysis will be undertaken if possible, contingent on numbers of cases among groups by age, ethnicity, and socioeconomic advantage, to determine whether there are differences in severity of disease and outcome.

A detailed statistical analysis plan will be developed.

Responsiveness to Māori

It is, as yet, unclear if there may be any difference in rates of COVID-19 in pregnancy or its effect on pregnancy outcome, for Māori and non-Māori. Assessment of this is one of the objectives of this study.

Issues of special importance to Māori for this study include waiver of consent for inclusion and use of data, data security, and data governance. The team of study investigators includes representatives of Te Kāhui Oranga ō Nuku He Hono Wāhine (Māori women's health subcommittee of the New Zealand office of RANZCOG) and Māori clinicians (midwives and obstetricians), Māori health researchers and wāhine Māori (consumers).

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Governance

The team of Registry investigators has been selected with consideration of key stakeholders including consumers, Māori health representatives, clinicians, researchers and collaborator groups. We have consulted with:

- The Ministry of Health
- He Hono Wāhine, a subcommittee of Te Kāhui Oranga ō Nuku (the New Zealand Committee) of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- Te Kāhui Oranga ō Nuku (the New Zealand Committee) of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- New Zealand College of Midwives
- Royal New Zealand College of General Practitioners
- New Zealand Perinatal and Maternal Mortality Review Committee
- New Zealand National Maternity Monitoring Group
- Paediatric Society of New Zealand
- New Zealand Newborn Network
- Australian and New Zealand Neonatal Network
- New Zealand Paediatric Surveillance Unit
- Australian and New Zealand Intensive Care Society
- Perinatal Society of New Zealand
- New Zealand Midwifery Leaders Forum
- New Zealand Clinical Directors Forum

The Registry Data Governance Group has been established to provide oversight of data security and to consider applications for data access (Appendix 2).

Consumer Representation: Consumer input is vital in the design of the Registry, to inform decision making on request for use and sharing of data, to assist with raising public awareness of the Registry and to inform plans for dissemination of findings. Consumers have been included in the investigator team.

Ethics and Locality Approval

Ethics approval will be obtained from the Health and Disability Ethics Committee prior to commencement of any data collection.

The study will be conducted in line with the Principles of the Declaration of Helsinki (1996), with the International Conference on Harmonisation and Good Clinical Practice guidelines, and in compliance with the Protocol.

Locality approval will be sought from the Liggins Institute at The University of Auckland.

Publication and Dissemination of Findings

We will develop a publication and dissemination plan which will include regular reporting and later study reports and peer reviewed publications. We will ensure all reports are available publicly via the Registry webpage and other avenues and shared with Te Rōpū Whakakaupapa

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Urutā (the National Māori Pandemic Group) and Tumu Whakarae (the National DHB Māori General Managers Group) for dissemination to DHB Māori Directorates.

Funding

We will seek funding to support the ongoing costs of maintaining the Registry and subsequent data cleaning, linkage and analysis. Seed funding is available to support this project through cluster funding from the Hugo Charitable Trust that supports research activities for Associate Professor Katie Groom.

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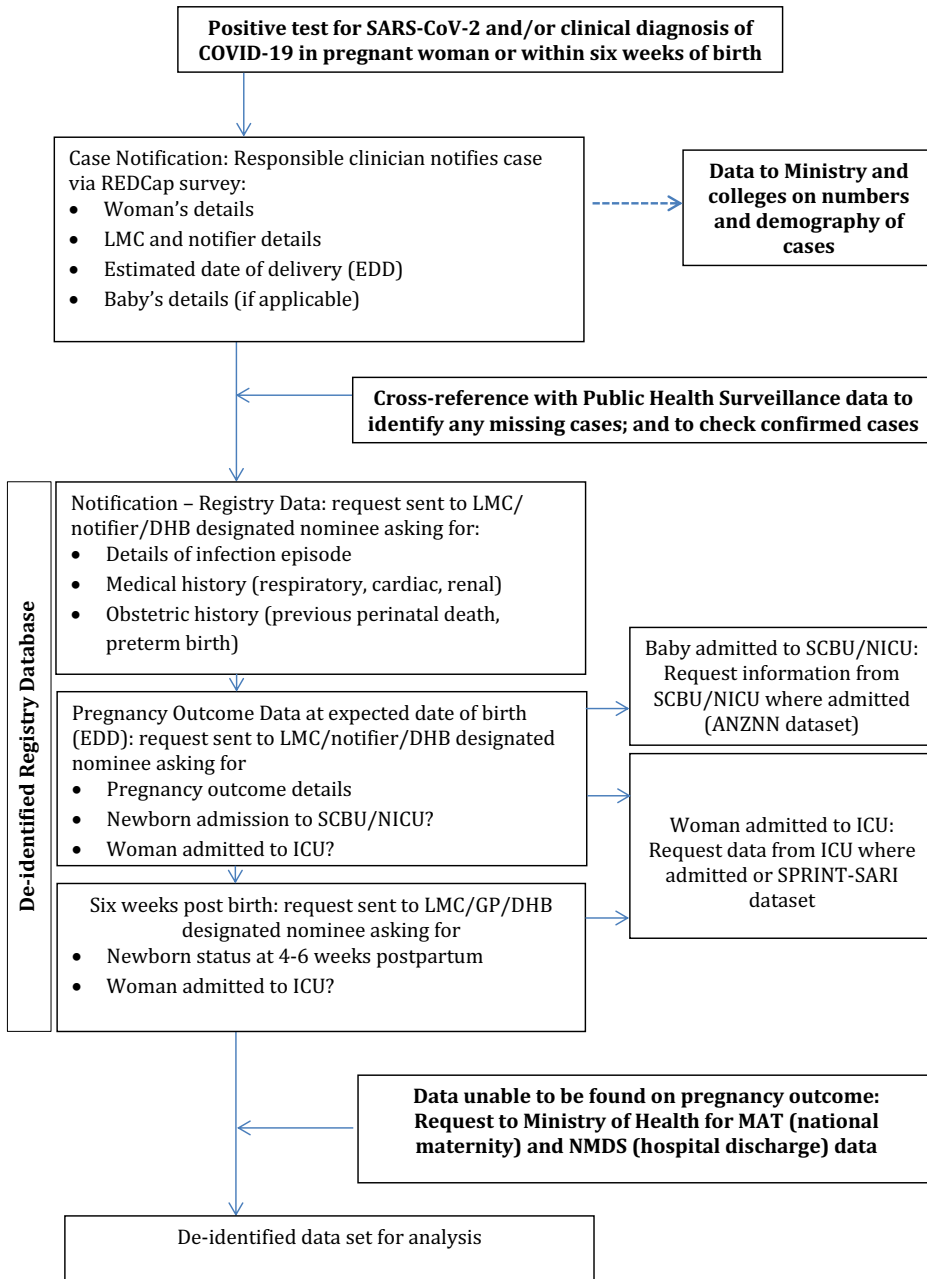


Figure 1: Flow of information COVID-19 in Pregnancy New Zealand Registry

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APPENDIX 1: The COVID-19 in Pregnancy New Zealand Registry INFORMATION SHEET

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APPENDIX 2: The COVID-19 in Pregnancy New Zealand Registry DATA GOVERNANCE CHARTER

Deleted: 21Oct2021