

## Evidence check

2 July 2021

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

## COVID-19 and maternity and newborn communities of practice

### Evidence check question

- Q1. What is the best practice management of a COVID-19 positive neonate?
- Q2. What is the current evidence for vaccinating breastfeeding and pregnant women and women who are on oral contraceptive pill?
- Q3. What are the current recommendations for infection control measures for group sessions in an indoor setting?

### In brief

#### Vertical transmission

- There is no clear evidence of vertical transmission of SARS-CoV-2.(1-4) In COVID-19 positive neonates born to infected individuals, it is challenging to determine if the transmission occurred in utero, intrapartum or postpartum due to lack of standardised international definition and classification system for timing; diagnostic testing limitations, such as lack of timely collection of appropriate specimens; and method specificity and sensitivity.(3)
- A population-based cohort study from the United Kingdom estimated the neonatal incidence of SARS-CoV-2 infection to be 5-6 (95% confidence interval 4·3-7·1) per 10,000 live births.(5) In an overview of systematic reviews of outcomes of COVID-19 positive mothers, the neonatal polymerase chain reaction positivity rates range between 1.6% and 10%.(6) There were reports of neonates with serum antibody positivity yet negative polymerase chain reaction (PCR) positivity.(6) There is no clear evidence of SARS-CoV-2 transmission to neonates via breastmilk.(7)
- Around 20% of neonates with SARS-CoV-2 infection are asymptomatic and further 40%-50% have mild symptoms.(5, 7, 8) Reported symptoms include rhinorrhoea, cough, lethargy, vomiting, diarrhoea, apnea, fever, tachycardia, tachypnea, leucocytosis, thrombocytopenia, hypoxemia, hypotension, raised C-reactive protein, elevated lactate and radiographic findings of ground-glass opacities.(4, 5, 8, 9) Early onset of neonatal COVID-19 infection (between two and seven days after birth) is likely, however, the majority of symptomatic infections are late-onset (after 7 days of birth).(5, 7, 10)

## Q1. What is the best practice management of a COVID-19 positive neonate?

### Prevention of transmission for those with suspected or confirmed COVID-19

Peer-reviewed literature and international consensus guidance recommend the following.

- Obstetrician and neonatologist joint debriefing and preparation for neonatal resuscitation before delivery.(11)
- Neonatal clinicians attend deliveries based on hospital policies and risk indication.(7, 12)
- Personal protective equipment for healthcare providers and masks for individuals in labour (7, 11)
- Use of precautionary measures to minimise the risk of infection during aerosol-generating procedures.(13) Such procedures include T-piece and mask ventilation, bag-mask ventilation, intubation, suctioning, high-flow oxygen therapy at more than 2L/min, continuous positive airway pressure, and mechanical ventilation.(7)
- The World Health Organization does not recommend separating infants from mothers suspected or confirmed to have COVID-19 after birth.(14) The USA Centers for Disease Control and Prevention recommends not isolating infants born to suspected or confirmed COVID-19 mothers in neonatal intensive care units, unless the neonate's clinical condition warrants neonatal intensive care unit admission.(4) It recommends having a discussion between the mother and healthcare provider to decide whether a neonate should remain in mother's room, taking into consideration mother's preferences, benefits of room-in, and certain criteria concerning the COVID-19 symptoms of the mother.(4)
- In the event of transportation of neonates born to COVID-19 positive individuals to a neonatal intensive care unit, use a predetermined path in a closed incubator.(7, 13, 15)
- If the mother's clinical condition allows, both the World Health Organization and the Centers for Disease Control and Prevention recommend encouraging breastfeeding.(16, 17)
- The Australian Breastfeeding Association states that the mother and baby can be supported to remain together while breastfeeding.(18)
- Use of surgical masks, washing hands and breasts prior to breastfeeding (7, 11, 16, 18) and placing the neonate's crib, cot or incubator 1.8m away from the mother are recommended.(7, 11, 16-18) The use of masks for neonates is not recommended due to risk of suffocation.(16)
- Alternative to direct breastfeeding from the mother, expressed milk can be fed by healthy healthcare workers or caregiver.(7, 16-18)
- The World Health Organization recommends encouraging early and uninterrupted skin-to-skin contact after delivery given the low risk of transmission.(14)

### Management COVID-19 positive neonates

- Currently, there are no clinical trials evaluating treatment for neonates with COVID-19 and very limited data on the safety and efficacy of drug therapy.(19) The *Coronavirus Disease 2019 (COVID-19) Treatment Guidelines* by the National Institutes of Health recommends that mild and moderate COVID-19 should be managed with supportive care alone and drug therapy should be considered based on the assessment of illness severity, age, and other risk factors.(19)
- Supportive care and management

- Appropriate respiratory support, such as continuous positive airway pressure or supplemental oxygen, in case of respiratory distress. (7)
- Although the risk of aerosol generation by respiratory support of neonates may be low, personal protective equipment and precautionary measures to limit the transmission is recommended.(15, 20)
- Fluid resuscitation.(7)
- Temperature control.(7)
- Antiviral medications
  - Remdesivir is approved by Food and Drug Administration *Emergency Use Authorization* for the treatment of paediatric patients weighing at least 3.5kg.(21) Children were not included in clinical trials of remdesivir and therefore no data is available for its pharmacokinetics, efficacy, or toxicity in children.(19)
    - Several case report studies described treating neonates, including premature infants, with remdesivir and observed clinical improvement and no adverse effects.(5, 22-25)
- In cases of COVID-19-associated multisystem inflammatory, immunomodulatory therapy, using intravenous immunoglobulins or monoclonal can be considered.(15)

## Q2. What is current evidence for vaccinating breastfeeding and pregnant women and women who are on oral contraceptive pill?

### Efficacy

- Pregnant and lactating individuals were not included in initial vaccine clinical trials.(26)
- For mRNA vaccines, a similar immune response in vaccinated pregnant and lactating women compared to vaccinated non-pregnant women was reported.(27)

### Safety

- No obvious safety signals in pregnancy or neonatal outcomes, especially in women vaccinated during the third trimester.(28)
- In a study comparing the immunity and placental histopathology outcomes of vaccinated and non-vaccinated pregnant women, women with vaccination had higher rates of vaginal delivery, robust antibody response, and no increased incidence of decidual arteriopathy, foetal vascular malperfusion, low-grade chronic villitis, or chronic histiocytic intervillitis.(29)
- Latest update (17 May 2021) from the *Drug and Lactation Database* by the US National Library of Medicine include the following key points.(30)
  - Some mild infant effects were reported after mRNA vaccination in breastfeeding mothers, however direct attribution to the vaccines is not established.
  - Mothers who received mRNA vaccines had higher milk SARS CoV-2 antibody levels than those who were infected.
  - Shared decision approach to vaccination decisions in breastfeeding mothers are encouraged.

### Newborn protection

- SARS-CoV-2 immunoglobulin G antibodies were detected in cord blood in a newborn after maternal vaccination (mRNA vaccines).(31-34)
- Maternal antibody production 5 days to 15 days after dose 1, transplacental transfer of immunity to neonate 16 days after dose 1 of mRNA vaccines were reported.(32, 35)

### Recommendations

- Most national and international professional bodies recommend that pregnant and breastfeeding women are offered the vaccine with an informed and/or shared decision-making approach. According to the World Health Organization, pregnant women may receive the vaccine if the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks.(36-38)

### Oral contraceptive pill and COVID-19 vaccines

- No relevant peer-reviewed or grey literature was retrieved.

### Q3. What are the current recommendations for infection control measures for group sessions in an indoor setting?

#### Clinical Excellence Commission, NSW (39)

- Outlines the principles of hierarchy of controls and safe working for acute and non-acute healthcare settings.
- From most effective to least effective, the risk avoidance or mitigation strategies include:
  - elimination: social isolation
  - substitution: not applicable
  - engineering controls: ventilation, physical barriers
  - administrative controls: work from home, stagger schedules and hand hygiene
  - personal protective equipment: masks, respirators and gloves; should be used in accordance with clinical circumstances and risk assessment; a risk assessment to be performed on the use of personal protective equipment according to current epidemiological data, local prevalence and clinical features that might indicate elevated COVID-19 risk.
- Multiple mitigation strategies can be used at the same time.
- *NSW Risk Matrix* has been developed to provide guidance to NSW health facilities on the various levels (low, moderate and high) of COVID-19 transmission risk.

### Infection control and prevention strategies in acute settings and in shared spaces

Apart from physical distancing in the waiting rooms and during physical examinations and procedures, additional precautions are required in shared spaces such as meeting rooms.

Where possible:

- maintain physical distancing
- use virtual meetings
- consider having a person perform random checks on the activities in shared spaces.

Ensure:

- signage is displayed at the entrance to advise on the number of people allowed
- personal protective equipment is removed before entering the shared spaces
- hand hygiene is performed when entering or leaving the shared space
- crowding is avoided and breaks are scheduled in advance with flexibility
- when physical distancing is not possible, surgical masks are used and disposed of correctly and safely
- detergent products are made available for cleaning surfaces
- products that cannot be cleaned, such as magazines or clutter, are removed and signs or notices are laminated for wiping down with detergents
- stationary or belongings are not shared and personal belongings are not left in the shared spaces when leaving
- food or beverages are not consumed in acute settings
- ongoing enhanced cleaning and person is designated to ensure cleaning and documentation.

#### **Infection control and prevention strategies in non-acute settings and in shared spaces**

- COVID-19 risk screening prior to entering the facility should be undertaken in accordance with the recommendations as outlined in *Response and Escalation Framework (NSW Risk Matrix)*.
- A risk assessment should be undertaken, and a risk management plan developed for community group meetings and sessions in different venues. Guidance on COVID-19 infection prevention and control risk assessment for group community sessions and meetings and templates for risk assessment and action plans are available. The guiding principles include the following.
  - Use telehealth when viable.
  - Under the current *Public Health Gathering and Movement Order*,<sup>(40)</sup> health facilities are exempt from the four-square metre rule.
  - Healthcare workers to model COVID-19 safe behaviours and implement physical distancing when possible.
  - Use physical distancing markings on the floor if required.

#### **Australian Government, Department of Health (41)**

- Outlines the use of the hierarchy of control to manage the risk of transmission in healthcare, residential care and quarantine settings.
- From the highest level of health and safety protection and reliability to the lowest, the control measures include:
  - eliminate risks
  - substitute the hazard with a safer alternative
  - isolate the hazard from people
  - reduce the risks through engineering controls
  - reduce exposure to the hazard using administrative controls

- use personal protective equipment (with situational risk assessment)
- Engineering and administrative control measures can be directed at shared facilities such as meeting rooms, along with the use of personal protective equipment.
- Physical distancing strategies that are specific to shared spaces include using floor markings, spaced seatings and maximum room occupancy notices.

## Limitations

This evidence check for Q1 does not cover the management aspects of diagnostic testing, discharge planning and re-admission of neonates who are suspected, probable or confirmed to have COVID-19 infection. Only limited key organisation statements and recommendations were reviewed for Q2 and only infection prevention and control guidelines from NSW Clinical Excellence Commission and Australian Department of Health was reviewed for Q3.

## Background

Pregnant individuals were associated with an increased risk of adverse outcomes such as respiratory failure needing intensive care and stillbirth if infected with COVID-19.(42-46) The risk of transmission of COVID-19 from infected mother to the neonate is low (between 1.6% and 10%), however, the route and timing of the transmission are often unclear.(3, 6)

## Methods (Appendix 1)

- Peer-reviewed articles were identified through PubMed, Google and Google Scholar. The search terms used are outlined in Appendix 1.
- A grey literature search was conducted using Google and Google Scholar.

## Results

### Evidence for vaccinating breastfeeding and pregnant women and women who are on oral contraceptive pill

Key organisation recommendations and statements have been summarised below and ordered by priority for NSW.

#### Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Australian Technical Advisory Group on Immunisation (47)

- Recommend that pregnant women are routinely offered Pfizer mRNA vaccine (Cominarty) at any stage of pregnancy.
- Pregnant women are encouraged to discuss the decision in relation to the timing of vaccination with their health professional.
- Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination.

#### National Centre for Immunisation Research and Surveillance, Australia (48)

- Comirnaty (Pfizer) vaccine is now routinely recommended for pregnant women.

- Comirnaty continues to be recommended for breastfeeding women and women planning pregnancy.
- If Comirnaty is not available, COVID-19 Vaccine AstraZeneca can be given to pregnant women if the benefits of vaccination outweigh the risks for the individual.
- Women who are breastfeeding don't need to stop breastfeeding after vaccination.
- Women who are planning pregnancy don't need to avoid becoming pregnant after vaccination.

**Australian Breastfeeding Association, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Baby Friendly New Zealand (49)**

- Breastfeeding women do not need to stop breastfeeding to receive the vaccine.
- It is important for breastfeeding women to discuss vaccination with health professionals.

**World Health Organization (36-38)**

- Limited data on safety in pregnancy.
- Pregnant women may receive the vaccine if the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks.
- Pregnant women at high risk of exposure or who have comorbidities, which add to their risk of severe disease, may be vaccinated in consultation with a healthcare provider.

**American College of Obstetricians and Gynecologists (50)**

- Pregnant and lactating women should be offered access to COVID-19 vaccines
- Individuals to be provided with information about efficacy, safety and uncertainties about the vaccines.
- A consultation with a clinician may be helpful, but not required.
- Vaccination may occur in any authorised setting similar to that of non-pregnant individuals.
- Pregnancy testing prior to vaccination not required.

**Centre for Disease Control and Prevention (US) (46)**

- Pregnant individuals with COVID-19 are at increased risk of severe illness.
- Limited data on the safety of vaccines in pregnant individuals.
- COVID-19 vaccines unlikely to cause risk to pregnant individuals or foetus.
- Pregnant and lactating individuals are eligible for and can receive a COVID-19 vaccine.
- Side effects of vaccines among pregnant individuals are expected to be similar to that of non-pregnant individuals.
- No recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.

**Academy of Breastfeeding Medicine (51)**

- Lactating individuals were excluded from vaccine trials.
- An informed and shared decision-making approach to decision making is recommended.
- Individuals who received COVID-19 vaccines are not recommended to cease breastfeeding.

- It is unlikely that the vaccine lipid enters the bloodstream or breast tissue, or intact nanoparticle or mRNA transfer into milk.
- Antibodies and T-cells triggered by the vaccine may transfer into milk.

#### **Royal College of Obstetricians and Gynaecologists (UK) (52)**

- Pregnant individuals should be offered COVID-19 vaccines at the same time as the rest of the population.
- Pregnant individuals can receive the COVID-19 vaccine even if they have not consulted a health professional.
- There is no evidence of COVID-19 vaccines affecting fertility and individuals do not need to avoid pregnancy after vaccination.
- There is no need to stop breastfeeding to be vaccinated.

#### **European Board and College Obstetrics and Gynaecology (53)**

- Pregnant women need to be considered a high-risk population for serious COVID-19 infection.
- Breastfeeding women are believed to have a similar risk of serious infection as non-pregnant women.
- The possibility of vaccination should be offered to all pregnant women, after being adequately informed of the benefits and risks.
- All health authorities and governments are urged to make vaccination available to all pregnant women wishing to take them.

#### **International Federation of Fertility Societies and European Society of Human Reproduction and Embryology (54)**

- Women who plan to conceive but are not yet pregnant can either:
  - defer pregnancy until steps to effectively mitigate the risk of the pandemic have been undertaken (i.e. substantially reduced virus transmission or availability of vaccines and ready access to prenatal care), or
  - proceed with efforts at conception, continue with mitigation measures and seek a COVID-19 vaccination as soon as possible.
- Women who are currently pregnant can either:
  - continue all established mitigation strategies and defer COVID-19 vaccination until after pregnancy, or
  - seek a COVID-19 vaccine as soon as possible and continue established mitigation strategies including social distancing, mask-wearing, and hand washing.

#### **Italian scientific societies (55)**

- Breastfeeding individuals are not recommended to be systematically invited to cease breastfeeding to be vaccinated.
- The decision to vaccinate should be based on mutual agreement between breastfeeding individuals and health professionals.



- The risk to infants being breastfed by vaccinated individuals is extremely low based on biological plausibility.

## Appendix

### PubMed search terms

#### Q1.

("infant, newborn"[MeSH Terms] OR "infant"[Title/Abstract] OR "newborn"[Title/Abstract] OR "newborn infant"[Title/Abstract] OR "neonatal"[Title/Abstract] OR "neonate"[Title/Abstract] OR "neonates"[Title/Abstract] OR "neonatality"[Title/Abstract] OR "neonatalis"[Title/Abstract] OR "neonate's"[Title/Abstract]) AND ("2019-nCoV"[Title/Abstract] OR "ncov\*"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "covid19"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[Title/Abstract] OR "sars-cov-2"[Title/Abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept]) AND 2019/12/01:3000/12/31[Date - Publication] AND "LitCTREATMENT"[Filter] AND (systematicreview[Filter])

49 hits on 26 May 2021.

#### Q3.

##### Search 1

("pregnant women"[MeSH Terms] OR "pregnan\*"[Title/Abstract]) AND ("2019-nCoV"[Title/Abstract] OR "ncov\*"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "covid19"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[Title/Abstract] OR "sars-cov-2"[Title/Abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept]) AND ("vaccin\*"[Title/Abstract] OR "immuniz\*"[Title/Abstract] OR "vaccination"[MeSH Terms]) AND 2019/12/01:3000/12/31[Date - Publication]

204 hits on 26 May 2021.

##### Search 2

("lactat\*"[Title/Abstract] OR "lactation"[MeSH Terms] OR "breast feeding"[MeSH Terms] OR ("breast"[Title/Abstract] AND "feeding"[Title/Abstract]) OR "breast feeding"[Title/Abstract] OR "breastfeeding"[Title/Abstract]) AND ("2019-nCoV"[Title/Abstract] OR "ncov\*"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "covid19"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[Title/Abstract] OR "sars-cov-2"[Title/Abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept]) AND ("vaccin\*"[Title/Abstract] OR "immuniz\*"[Title/Abstract] OR "vaccination"[MeSH Terms]) AND 2019/12/01:3000/12/31[Date - Publication]

73 hits on 26 May 2021.

##### Search 3

("contraceptives, oral, combined"[MeSH Terms] OR ("contraceptive\*"[Title/Abstract] AND "oral"[Title/Abstract]) OR ("birth control"[Title/Abstract] AND "pill\*"[Title/Abstract]) OR ("contraceptive\*"[Title/Abstract] AND "pill\*"[Title/Abstract])) AND ("2019-nCoV"[Title/Abstract] OR "ncov\*"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "covid19"[Title/Abstract] OR "covid-19"[Title/Abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[Title/Abstract] OR "sars-cov-

2"[Title/Abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept]) AND ("vaccin\*" [Title/Abstract] OR "immuniz\*" [Title/Abstract] OR "vaccination"[MeSH Terms])

3 hits on 26 May 2021.

**Inclusion and exclusion criteria**

Inclusion	Exclusion
<ul style="list-style-type: none"> <li>Population: neonates, pregnant women, lactating women, women on oral contraceptive pill</li> <li>Intervention: management of neonates suspected, probable or confirmed to have COVID-19; vaccination of COVID-19</li> <li>Study design: review studies, consensus statements, key organisation statements</li> </ul>	<ul style="list-style-type: none"> <li>Management of pregnant mothers without the mention of management of neonates</li> <li>Not in English</li> <li>Not related to COVID-19</li> </ul>

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**Evidence checks are archived a year after the date of publication**

SHPN: (ACI) 210643 | ISBN: 978-1-76081-856-2 | TRIM: ACI/D21/695-24 | Edition 1