Immunisation Advisory Centre

VERSION 9

# COVID-19 disease and COVID-19 vaccination in pregnancy and when breastfeeding

**Vaccination against COVID-19 is recommended for pregnant people* at any stage of pregnancy. It is highly recommended for those with underlying health conditions or high-risk pregnancies.**

The mRNA COVID-19 vaccine, Comirnaty 30mcg JN.1, is available to anyone from aged 12 years as a single-dose primary course, and a second dose is available to anyone aged 16 years over.

An additional dose of Comirnaty 30mcg JN.1 is available to individuals with underlying health conditions aged from 12 years, including when pregnant, and to anyone aged 30 years or over. This additional dose is given at least six months after any prior COVID-19 vaccinations or confirmed COVID-19 infection, following any number of previous COVID-19 vaccinations.

Millions of people have received the original and variant-specific Comirnaty vaccines while pregnant. Large-scale, international surveillance data indicate that there are no safety concerns when administering Comirnaty at any stage during pregnancy. As well as protecting the mother, vaccinating during pregnancy also offers temporary protection for infants via passive transfer of antibody across the placenta and in breastmilk.

Anyone with questions or concerns about receiving these vaccines in pregnancy is advised to discuss these with their health professional. Everyone has a right to make an informed decision about receiving the vaccine. This factsheet is intended to help support health professionals with these discussions.

## Use in pregnancy

- If unvaccinated at the time of pregnancy, an individual can have single primary dose of Comirnaty 30mcg JN.1, and an additional dose six months later.
- If previously vaccinated, an individual can have an additional dose if it has been six months or more since their previous COVID-19 vaccine or confirmed COVID-19 infection.
- An additional dose is particularly recommended for anyone aged from 30 years, or those pregnant at any age with underlying medical conditions, considered a high-risk pregnancy, or who meet other eligibility criteria. (For further details, see COVID-19 chapter of the *Immunisation Handbook 2024*, Section 5.5.3 and Table 5.6).
- Comirnaty 30mcg JN.1 can be given at the same time as other vaccines given in pregnancy, including influenza and Boostrix (Tdap).

Pregnant people are encouraged to discuss timing of additional doses with their health professional, taking into consideration their individual health status and risks from COVID-19. Routine pregnancy testing before COVID-19 vaccination is not required, and for those who are planning pregnancy, it is not necessary to delay pregnancy after receiving a COVID-19 vaccine.

Currently, data on the use of Comirnaty 30mcg JN.1 is limited. However, based on experience with the previous Comirnaty formulations and other mRNA COVID-19 vaccines, there is no theoretical reason to suggest any increased risk with the JN.1 formulation. The only difference between these vaccines is related to each variant-specific spike protein mRNA sequence. Safety profiles of the previous formulations demonstrated that they are safe and effective for use in pregnancy.

COVID-19 vaccination does not replace the use of simple measures to reduce the risk of infection, such as physical distancing, handwashing and use of personal protective equipment (PPE) such as masks. It is also advisable for all household contacts from the age of 5 years and healthcare contacts of pregnant people, new parents and their infants to be up-to-date with their COVID-19 vaccinations, as age-appropriate.

** IMAC acknowledges that not everyone who becomes pregnant identifies as being a woman.*

## COVID-19 in New Zealand

COVID-19 remains widespread in New Zealand, with ongoing community transmission of the SARS-CoV-2 virus. Infection waves are tending to peak during the summer and winter months. While vaccine coverage was high in 2022, the evolving nature of the SARS-CoV-2 means that individuals at highest risk, including when pregnant, may require additional vaccine doses to maintain protection.

## COVID-19 infection when pregnant or post-partum

Pregnant women with COVID-19 face a higher risk of hospitalisation and intensive care unit (ICU) admission than non-pregnant people of the same age. As with the general population, the risk from COVID-19 is elevated for those with underlying medical conditions, especially those affecting the immune, respiratory or cardiovascular systems. Pregnancy-related health changes further amplify those risks. Even healthy pregnant women infected with the SARS-CoV-2 virus are at a higher risk of developing severe COVID-19 than non-pregnant women due to physiological changes occurring during pregnancy[1], including:

- During pregnancy, the mother's immune system is temporarily suppressed to prevent it from harming the developing baby, which makes her more susceptible to infections.
- Changes in blood composition increase the risk for clots (thrombosis).
- As the baby grows, the mother's lung capacity decreases and her blood volume increases, leading to higher oxygen demand causing the heart to work harder.[2, 3]
- Consequently, COVID-19 infection during pregnancy or shortly after substantially increases the risk of severe illness, blood clots and respiratory difficulties.
- Pregnancy-related risk are heightened for those aged over 35 years and for those who have a chronic condition such as obesity, high blood pressure, thrombosis risk factors or pre-existing diabetes.[4, 5]

Early in the pandemic, with highly virulent variants and low levels of immunity, the risk of severe COVID-19 during pregnancy was extremely high. Generally, the severity of SARS-CoV-2 in pregnancy has decreased with changes in the virus and improved immunity through vaccination and prior virus exposure. Despite this, SARS-CoV-2 infection during pregnancy, labour or post-partum are still associated with a need for respiratory support, maternal ICU admission and preterm birth.[6, 7] Unvaccinated pregnant individuals with COVID-19 remain at greater risk of adverse outcomes than those without COVID-19.[8] Vaccination in pregnancy remains a key defence against COVID-19 in pregnant individuals.[1]

Shortness of breath (dyspnoea) and fever as symptoms of COVID-19 infection have been strongly associated with severe illness in pregnancy.[9] An early multinational cohort study found that fever and shortness of breath for any duration in women with COVID- 19 infection was associated with two-and-a-half times increased risk for severe maternal complications and five times increased risk for neonatal clinical complications.[10] Reassuringly, COVID-19 infection in early pregnancy in non-hospitalised women was not associated with miscarriage or fetal damage.[11]

## COVID-19 disease increases risk of complications in pregnancy, such as preeclampsia and hypertension

Throughout the pandemic, the risk for medically indicated preterm birth and preeclampsia have been twice as high in unvaccinated mothers with COVID-19 than those without COVID-19. Although the rates have reduced with Omicron infections, the risk is considerably increased for those with severe COVID-19.[8] Furthermore, COVID-19 infection significantly increases the risk of preeclampsia and eclampsia, predominantly in pregnant individuals with underlying health conditions.[8]

## COVID-19 disease increases the risk of preterm birth and neonatal intensive care admission

A systematic review assessing neonatal outcomes in mothers with confirmed COVID-19 infection during pregnancy demonstrated that COVID-19 was significantly associated with lower birth weights, high risk of fetal distress, respiratory distress, premature death, preterm birth and lower APGAR scores.[12] But these outcomes where not directly attributed to the severity of the maternal COVID-19 infection.

Early in the pandemic, mainly out of concern for maternal health, babies of women hospitalised with COVID-19 were likely to be born preterm by Caesarean section.[13, 14] The risk for preterm birth continues to be higher for infants of mothers with COVID-19 than those without, particularly for mothers with underlying health conditions such as hypertension, diabetes or obesity.[8]

The risk of vertical (transplacental or intravaginal) transmission of SARS-CoV-2 infection from the mother to her newborn appears to be very small (less than 2% of cases).[15, 16] Infection in neonates is often asymptomatic and rarely severe, but COVID-19 severity is higher in newborns than for older infants.[15, 17]

### How the Comirnaty mRNA COVID-19 vaccine works

Vaccination stimulates the production of antibodies that can block the COVID-19 virus (SARS-CoV-2) from entering our cells, while also activating specialised T cells to identify and destroy any infected cells. However, as antibody levels gradually decline after each dose and the virus evolves to better evade the immune system, additional vaccine doses are necessary to restore high levels of protective antibodies. By using variant-specific versions of Comirnaty, these booster doses enhance immunity and target the most prevalent strains of the SARS-CoV-2 virus. This increased protection is especially crucial for individuals at high risk of severe COVID-19.

Comirnaty is not a live vaccine and contains no part of the SARS-CoV-2 virus. Instead, it contains a modified messenger ribonucleic acid (mRNA) sequence that instructs our cells to produce copies of a viral protein. This protein is a replica of the spike protein used by the virus to infect our airways. It specifically triggers an immune response against COVID-19, like traditional vaccine antigens. The amount of this protein produced after vaccination is much lower than the amount produced during infection when the virus spreads throughout the body. While mRNA is a type of nucleic acid, it is unable to enter the cell nucleus or integrate with DNA.[18] Therefore, it cannot cause genetic changes in either the vaccinated person or in their baby. The components of the vaccine and replica spike proteins break down very quickly after vaccination, most within a few days.

The differences between the variant-specific vaccine formulations and the original Comirnaty vaccines are confined to mRNA spike protein sequences. One 0.3mL dose of Comirnaty 30mcg JN.1 contains 30 micrograms of bretovameran (the mRNA expressing the spike protein of Omicron JN.1) embedded in lipid nanoparticles to protect the fragile mRNA until it enters the cell.

### COVID-19 vaccine safety in pregnancy

There are no safety concerns around giving Comirnaty to pregnant people or those planning pregnancy. This vaccine is considered safe to use in pregnancy, based on two premises: firstly, that there is no known physiological mechanism by which the vaccine is likely to cause problems with pregnancy, and secondly, accumulating large-scale surveillance data do not indicate any safety concerns.

Even though pregnant women were not formally included in the original clinical trials, the importance of immunising pregnant people against COVID-19 is acknowledged internationally. There is very good evidence that COVID-19 vaccination in pregnancy is protective and not associated with an increased risk for adverse maternal, perinatal or neonatal outcomes.[19-21] When given in pregnancy, vaccination does not affect the neurodevelopmental outcomes of infants at ages 12 months and 18 months.[22]

Although there are no data available yet for the use of the Comirnaty 30mcg JN.1 formulation in pregnancy, the data are reassuring predominantly following the use of the original Comirnaty. No plausible theoretical reasons exist to suggest any increased risk in pregnancy since the differences between these vaccine formulations are confined to mRNA spike protein sequences. Generally, the rate of adverse events after successive doses of Comirnaty are similar to earlier doses, in pregnant and non-pregnant individuals.[23]

## Effectiveness of COVID-19 vaccination when given in pregnancy

Vaccination at any stage of pregnancy is recommended to protect the mother and baby. COVID-19 vaccination is highly protective against severe disease, hospitalisation and death, in pregnancy and for the general population.[8] An additional dose of Comirnaty given in pregnancy is highly effective against severe maternal COVID-19 symptoms, hospital and ICU admission, and death.[8, 24]

Furthermore, protective antibodies transfer across the placenta from the mother to baby. When the second dose was given in the second trimester, the cord blood anti-SARS-CoV-2 IgG antibody levels at birth were shown to be 2.6 times higher than in the mother's blood.[25] Passive immunity has also been shown against Omicron infection, when a booster dose is given in pregnancy, lasting for the infant's first few months of life.[26, 27]

## COVID-19 vaccination and breastfeeding

People can receive a COVID-19 vaccine when lactating. No safety concerns have been associated with having this COVID-19 vaccine while breastfeeding for the parent or for the infant. Vaccination in pregnancy or while breastfeeding provides temporary antibody protection to the baby through the cord blood and breastmilk.[28, 29]

## What are the likely responses to vaccination?

Following the administration of billions of doses of Comirnaty worldwide, the potential reactions to the vaccine have remained consistent with those seen during the initial clinical trials. These include mild to moderate pain at the injection site, fatigue, headache, muscle aches, nausea and fever of 38–39°C. These reactions were more likely after the second dose.[30, 31] Additional doses given from six months after the previous dose induce similar or milder responses to the second dose.[23] Data from v-Safe in the US found no differences in local and systemic responses between pregnant and non-pregnant women.[30]

Before vaccination, we recommend pregnant individuals to discuss the best ways to relieve possible discomfort and fever with their health professional. Non-steroidal anti-inflammatory drugs, including ibuprofen and diclofenac, should not be taken during pregnancy. If feeling unwell after vaccination, it is important to rest, drink plenty of fluids and avoid vigorous activities, and to seek medical advice if symptoms worsen or last longer than three days.

Rare but increased incidences of myocarditis and pericarditis have been observed around one to five days after vaccination with Comirnaty. Myocarditis occurs mainly in young males aged 12 to under 30 years (1-13 cases per 100,000 doses), and pericarditis in a range of age groups (four cases per 100,000 doses). This potential risk has been reduced with wider spacing between doses.

Anaphylaxis following vaccination is very rare (around five cases per million doses).[32] Waiting for at least 15 minutes after vaccination ensures immediate adverse reactions are identified and promptly treated. All vaccinators in NZ have training and equipment to manage anaphylaxis should it occur.

## Who should not receive a COVID-19 vaccine?

- A COVID-19 vaccine is contraindicated (should not be given) for anyone who has had **anaphylaxis to an ingredient in the vaccine or a previous dose** of the same vaccine.
- People who develop myocarditis or pericarditis attributed to a COVID-19 vaccination are advised to defer further doses. Seek clinical advice from IMAC before giving further doses.
- Administration of Comirnaty should be postponed in individuals suffering an acute severe febrile illness (fever over 38°C) or who are systemically unwell. However, the presence of a minor infection is not a reason to delay immunisation.

## CALL 0800 IMMUNE (0800 466 863) for clinical advice