

COVID-19 and COVID-19 vaccination in pregnancy

For health professionals. A consumer version of information is available on the IMAC COVID-19 Education website.

Pregnant people* are recommended to have the COVID-19 vaccine, Comirnaty, at any stage of pregnancy.

Vaccination is highly recommended during pregnancy, especially for those with underlying health conditions or high-risk pregnancies. Vaccination with the mRNA COVID-19 vaccine, Comirnaty™ (Pfizer/BioNTech, 30µg with purple cap) is available to anyone from 12 years of age. Two doses are given at least 21 days apart. For those aged 18 years or over, a booster dose can be given from three months after the primary course.

Internationally, millions of people have been given this vaccine while pregnant and large-scale surveillance data (see below) indicate that there are no safety concerns with administering this COVID-19 vaccine in any stage of pregnancy. Vaccinating during pregnancy may also offer temporary protection for newborns via passive transfer of antibody across the placenta and in breastmilk.

Anyone with questions or concerns about receiving this vaccine 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 designed to help support health professionals with these discussions.

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.

Pregnant people aged 18 years or over can receive a booster dose of Comirnaty at any stage of pregnancy from three months after completion of the primary course. Although the use of a booster dose in pregnancy is limited to date, as with the primary course, it is expected to be safe and effective. If the full primary course has been given in pregnancy, a booster can be given before or after birth at least three months after completion of their primary course. Pregnant women are encouraged to discuss timing of a booster dose with their health professional, taking into consideration their individual health status and risks from COVID-19.

COVID-19 vaccination does not replace the need for simple measures that reduce the risk of disease transmission such as physical distancing, handwashing and use of appropriate personal protective equipment (PPE), as needed. It is also advisable for all household and health care contacts of pregnant people, new parents and their infants be fully vaccinated against COVID-19, as age appropriate, from the age of 5 years.

Where available, the use of the adenovirus vector COVID-19 Vaccine AstraZeneca in pregnant people needs to be based on an assessment of whether the benefits of vaccination with this vaccine outweigh the potential risks. Comirnaty is the preferred vaccine for use during pregnancy.

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

COVID-19 disease in New Zealand

Community transmission of COVID-19 is increasing in New Zealand, especially due to the highly infectious Omicron variant. We have achieved high vaccination coverage in those aged over 12 years, but further vaccine uptake, especially in pregnancy, and booster doses are needed to protect our communities, and those particularly at highest risk from COVID-19.

COVID-19 disease and pregnancy

Pregnant people are at a much higher risk from COVID-19 hospitalisation and intensive care unit admission than non-pregnant people of the same age.

Due to changes that take place during pregnancy, healthy pregnant women who are infected with the SARS-CoV-2 virus have an increased risk of severe COVID-19 disease compared with non-pregnant women.^{1, 2} The mother's immune system is temporarily suppressed to prevent it from harming the growing baby but this makes her more susceptible to infection.³ In addition, as the baby grows, the mother's lung capacity decreases and her blood volume increases, increasing the oxygen demand and requiring the heart to work harder.^{4, 5} As a result, COVID-19 infection when pregnant or soon after pregnancy substantially increases the risk of severe disease and breathing difficulties.

Although the risk of catching COVID-19 is not increased, pregnant women with a COVID-19 diagnosis are over three times more likely to have severe disease and require hospital admission, and five times more likely to require intensive care unit admission than non-pregnant women.^{6, 7} The risks in pregnancy increase from the age of 35 years and for those who have a chronic condition, such as obesity, high blood pressure or pre-existing diabetes.^{8, 9} During 2020 in the UK, one in ten women admitted to hospital with COVID-19 symptoms require critical care,⁹ and twice as many pregnant women with symptomatic COVID-19 died than those with COVID-19 who were not pregnant.^{2, 8} The Delta variant in 2021 further increased the risk for severe disease and critical care admission by more than three times.¹⁰

According to data collected by the UK Obstetric Surveillance System, the proportion of pregnant women hospitalised with moderate or severe COVID-19 increased significantly as new variants of SARS-CoV-2 virus emerged (from 24%, to 36% and 45% with wildtype, Alpha and Delta variants, respectively). Those with Delta COVID-19 were at the highest risk of being hospitalised with pneumonia. This study reported that 11 pregnant women with COVID-19 died compared with one in the comparator group of women without COVID-19 and no fully vaccinated pregnant women were admitted to hospital for COVID-19.¹¹ The risk from the Omicron variant in pregnancy is not yet known.

COVID-19 increased the risk of complications in pregnancy, such as preeclampsia, hypertension and poor fetal growth.

A multinational cohort study found that women with COVID-19 infection who experienced fever and shortness of breath for any duration was associated with two and a half times increased risk for severe maternal complications and five times increased risk in neonatal clinical complications. The risks of medically indicated preterm birth and preeclampsia were twice as high in mothers with COVID-19.⁶

COVID-19 infection early in pregnancy is not associated with increased risk for pregnancy loss,¹ but an increase in adverse pregnancy outcomes (gestational diabetes and hypertension, preeclampsia and poor fetal growth) has been observed during the COVID-19 pandemic in the US.¹² COVID-19 in women with underlying health conditions significantly increases the risk of preterm labour, preeclampsia and eclampsia than those without underlying conditions.¹³

COVID-19 increases the risk of preterm birth, caesarean section and baby admission to neonatal intensive care.

Babies are up to seven times more likely to be born preterm to mothers with COVID-19 and up to five times more likely to require neonatal intensive care when compared with babies born to mothers without the disease.⁸ Out of concern for the maternal health, the babies of women hospitalised with COVID-19 are more likely to be born by caesarean section and delivered early.^{9, 14} As reported by the Ministry of Health, in 2018, 7.5% of babies were born preterm (before 37 weeks),¹⁵ in comparison, about 50% of the babies born to mothers with COVID-19 are being

delivered early. Regardless of severity of illness, those who had COVID-19 in the first and second trimester are at increased risk for preterm birth and stillbirth.¹⁶ The risk for preterm birth is higher among those mothers with underlying health conditions such as hypertension, diabetes or obesity.¹⁷

The risk of transmitting SARS-CoV-2 infection from the mother to her newborn appears to be small, is often asymptomatic and rarely severe, although the risk of severe disease in newborns is higher than for older infants.^{18, 19} Emerging evidence suggests that Omicron is more serious in infants than previous variants.²⁰ One study in Italy found around half of the neonates infected with SARS-CoV-2 were likely to have been infected by family members or health care workers.¹ Note: to date in New Zealand, no women or their babies have been infected with COVID-19 by health workers.

How the Comirnaty mRNA COVID-19 vaccine works

Comirnaty COVID-19 vaccine contains messenger ribonucleic acid (mRNA) inside a lipid bubble which is delivered to muscle cells in the arm. It is not a live vaccine and contains no part of the SARS-CoV-2 virus. The mRNA and its protective bubble are so fragile that the vaccine needs to be stored at very cold temperatures to stop it from degrading too quickly.

After injection, the mRNA is taken into specialist cell where it delivers the instructions to make replicas of the spike protein that the SARS-CoV-2 virus uses to infect our airways. The cell uses this protein to specifically activate the immune response against COVID-19 virus, just like the more conventional vaccine antigens. The quantity of this protein produced after vaccination is much lower than the amount produced by a COVID-19 infection when virus spreads throughout the body. Furthermore, as soon as it is produced, it is dismantled inside these specialist cells and the pieces are used to activate the immune response.

The mRNA breaks down very quickly after this process takes place. It is unable to enter the cell nucleus, cannot integrate with DNA,²¹ and will not cause genetic changes in those vaccinated or the baby. The remainder of the vaccine components are also rapidly cleared from the body within a few days after vaccination, as for other vaccines. The vaccine components are unable to cross the placenta. The vaccine simply gives the body the recipe to make replicas of the virus protein, which in turn activate the immune response.

Vaccination primes the immune system with antibodies ready to block the COVID-19 virus from infecting our cells and specialist T cells can recognise and kill any cells that do become infected. The second dose of the vaccine reinforces this immune response to produce higher levels of more effective and longer lasting protection. The booster dose enhances this immunity.

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, large-scale surveillance data do not indicate any safety concerns.

Even though pregnant people were not formally included in the original clinical trials, the potential importance of immunising pregnant people against COVID-19 is now known, and several clinical studies are underway to improve the evidence around safe use of COVID-19 vaccines in pregnancy.^{22, 23}

To date, large-scale surveillance data have found no differences in pregnancy outcomes after vaccination with mRNA COVID-19 vaccines compared with the unvaccinated pregnant population.²⁴ The quantity of safety data in pregnancy continues to increase worldwide and no safety issues have arisen.

In the US, surveillance data (v-Safe) showed the rate of miscarriage was consistent with the expected rate and did not increase following receipt of mRNA COVID-19 vaccines preconception and prior to 20 weeks' gestation.²⁵ A larger Vaccine Safety Datalink study, involving over 100,000 pregnancies and 20,139 vaccinations, found that women who

had experienced a miscarriage were not more likely to have been vaccinated within 28 days than those who had ongoing pregnancies.²⁶

When women who were vaccinated in pregnancy were compared with unvaccinated pregnant women, studies in the UK and Israel found no significant differences in any perinatal outcomes, including: stillbirth, fetal abnormalities postpartum haemorrhage, caesarean delivery, small for gestational age, maternal HDU or ICU admission, or preterm birth.^{27, 28}

Effectiveness of COVID-19 vaccination when given in pregnancy

COVID-19 vaccination in pregnancy is highly protective against COVID-19 infection, severe disease, hospitalisation and death.

Increasing international evidence has shown that the effectiveness of Comirnaty when given in pregnancy is similar to that seen in the general population and that two doses are highly protective against symptomatic infection and hospitalisation.^{29, 30} The risk of COVID-19 infection was approximately five times less for those vaccinated in pregnancy than unvaccinated pregnant women.³¹ From December 2020 to October 2021 in Scotland, 77% of SARS-CoV-2 infections, 91% of COVID-19-associated hospital admission and 98% of COVID-19-associated critical care admissions in pregnancy were unvaccinated pregnant women.³²

This effectiveness is supported by the antibody response, vaccination was shown to induce a significantly higher protective antibody response than the natural viral infection.²⁸ There was no difference in antibody levels following vaccination between pregnant, lactating and non-pregnant women.^{33, 34}

Furthermore, there is mounting evidence of passive transfer of protective antibodies against COVID-19 from the mother to baby through the placenta.^{35, 36} Vaccination in the second or early third trimester has been suggested to be optimal for protective antibody transfer.³⁷ Vaccination at any stage of pregnancy is recommended to protect the mother and baby.

COVID-19 vaccination and breastfeeding

People can receive a COVID-19 vaccine when lactating. There are no safety concerns associated with having this COVID-19 vaccine while breastfeeding for the parent or for the infant.

There is emerging evidence that vaccination in pregnancy or while breastfeeding provides temporary antibody protection to the baby through the cord blood and breastmilk.^{38, 39}

What are the likely responses to vaccination?

After hundreds of millions of doses of Comirnaty[®] given worldwide, the potential reactions to the vaccine have stayed consistent with those seen during the initial clinical trials. These include fatigue, headache, muscle aches, nausea, fever of 38-39°C and mild to moderate pain at the injection site. These reactions are more likely after the second dose vaccination.^{40, 41} Data from v-Safe found no differences in local and systemic responses between pregnant and non-pregnant women.²⁴

Prior to receiving their vaccination, we recommend that pregnant people discuss the best ways to relieve possible post-vaccination discomfort and fever with their health professional. Paracetamol is considered safe during pregnancy to reduce pain and discomfort. Non-steroidal anti-inflammatory drugs, including ibuprofen and diclofenac, should not be taken during pregnancy.

Anaphylaxis following vaccination is very rare (around five cases per million doses).⁴² All COVID-19 vaccine recipients are asked to remain under observation for at least 15 minutes after receiving their vaccine to ensure immediate adverse reactions are identified and promptly treated. All vaccinators in New Zealand 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.

Who can receive a COVID-19 vaccine?

People who are pregnant or who are planning a pregnancy can make an informed decision to receive Comirnaty at any stage. People planning pregnancy can receive Comirnaty at any time.

For anyone who is acutely unwell, fever >38°C or has acute systemic illness, vaccination should be deferred until they are no longer acutely unwell.

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