The Immunisation Advisory Centre | COVID-19 EDUCATION

VERSION 5

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.

Vaccination against COVID-19 is recommended for pregnant people* at any stage of pregnancy.
Vaccination is highly recommended during pregnancy, especially for those with underlying health conditions or high-risk pregnancies. The mRNA COVID-19 vaccine, Comirnaty™ (Pfizer/BioNTech, 30µg with purple cap) is available to anyone from 12 years of age. Two primary doses are given, ideally at least six weeks apart (minimum 21 days apart). For those aged 18 years or over, a booster dose can be given from three months after the primary course, and if aged 16 to 17 years from six months after the primary course. Further doses (ie, second boosters) are not required at this stage for healthy people, including in pregnancy.

Millions of people have been given this vaccine while pregnant, and large-scale, international 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 also offers 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.

COVID-19 vaccination recommendations in pregnancy

Age group	Primary course[1]	Booster	Second booster
Age 12–15 years	Two doses, given at least 21 days apart; ideally 6-8 weeks apart	Not currently recommended	Not currently recommended
Age 16–17 years	Two doses, given at least 21 days apart; ideally 6-8 weeks apart	Given ≥6 months after dose 2	Not routinely required in pregnancy, unless underlying medical conditions increase risk from COVID-19
Age 18+	Two doses, given at least 21 days apart; ideally 6-8 weeks apart[2]	Given ≥3 months after dose 2	

[1] – if not vaccinated prior to conception
[2] – consider shorter spacing if at high risk of exposure, increased risk from severe COVID-19 complications, or prior to urgent travel overseas.

Pregnant people aged 16 years or over can receive a booster dose of Comirnaty at any stage of pregnancy (see table). Although the use of a booster dose in pregnancy is limited to date, as with the primary course, initial data shows it is safe and effective. A second booster dose is not currently required for healthy pregnant people. Pregnant people are encouraged to discuss timing of booster dose with their health professional, taking into consideration their individual health status and risks from COVID-19.

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

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) such as masks, as needed. It is also advisable for all household and healthcare contacts of pregnant people, new parents and their infants to be up to date with their vaccinations against COVID-19, as age-appropriate from the age of 5 years.

Comirnaty is the preferred vaccine for use during pregnancy. Where available, the use of the recombinant adjuvanted COVID-19 vaccine, Nuvaxovid in pregnant people needs to be based on an assessment of whether the benefits of vaccination with this vaccine outweighs the potential risks.

COVID-19 disease in New Zealand

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

COVID-19 disease and pregnancy

Pregnant people are at greater 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.

From early in the pandemic, it was shown that although the risk of catching COVID-19 is not increased, severe COVID-19 in pregnancy increases the risk of adverse outcomes.[6] Pregnant women with a COVID-19 diagnosis were over three times more likely to have severe disease and require hospitalisation, and five times more likely to require intensive care unit admission than non-pregnant women.[2, 7-10] 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.[9, 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.[11] During the Delta wave in mid-2021, infection among unvaccinated pregnant people was associated with more severe maternal outcomes and preterm birth than for the earlier variants.[12] This variant further increased the risk for severe disease and critical care admission by more than three times.[13] Although seemingly milder, the severity of infection with Omicron in pregnancy is similar to the pre-Delta period.[12] Unvaccinated pregnant people continued to be at increased risk of moderate or severe illness and of requiring oxygen support with Omicron infection compared with those who were vaccinated.[14]

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

A 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. The risks of medically-indicated preterm birth and preeclampsia were twice as high in mothers with COVID-19.[7]

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.[15] COVID-19 in those with underlying health conditions poses a significantly higher risk of preterm labour, preeclampsia and eclampsia than in those without underlying conditions.[16]

COVID-19 increases the risk of preterm birth, Caesarean delivery and neonatal intensive care admission.
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.[10] 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, 17] As reported by the New Zealand Ministry of Health, in 2018, 7.5% of babies were born preterm (before 37 weeks);[18] 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.[19] The risk for preterm birth due to COVID-19 is higher among mothers with underlying health conditions such as hypertension, diabetes or obesity.[20]

The risk of transmitting SARS-CoV-2 infection from the mother to her newborn appears to be small, is often asymptomatic and rarely severe, but COVID-19 severity is higher in newborn infants than for older infants.[21, 22] One study in Italy found around half of the neonates infected with SARS-CoV-2 were likely to have been infected by close contacts.[1]

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 up by specialist cells 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 specific 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,[23] and will not cause genetic changes in those vaccinated or in the baby. The remainder of the vaccine components are also rapidly cleared from the body within a few days after vaccination, as with 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 to produce 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 and produces high levels of antibodies, which decline gradually after dose two.

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 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.[24, 25] 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.[26] 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.[27] 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.[28]

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.[29, 30]

A booster dose in pregnancy was found to be safe and not associated with adverse birth outcomes. This small study did report an increased risk for postpartum haemorrhage in the group of 294 triple vaccinated women, however, this group was older and had more smokers than the group of 3,368 unvaccinated women.[31]

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. Vaccination at any stage of pregnancy is recommended to protect the mother and baby.

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.[32, 33] The risk of COVID-19 infection was approximately five times less for those vaccinated in pregnancy than for unvaccinated pregnant women.[34] From December 2020 to October 2021 in Scotland, 77% of SARS-CoV-2 infections, 91% of COVID-19-associated hospital admissions and 98% of COVID-19-associated critical care admissions in pregnancy were unvaccinated pregnant women.[35]

A critical care report from the UK from May 2021 to February 2022 showed COVID-19 vaccination was highly protective against severe COVID-19 in pregnancy and postpartum: fewer than five pregnant women who had received at least two doses or a booster dose required critical care compared with 294 unvaccinated women.[36]

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.[37, 38]

Furthermore, passive transfer of protective antibodies from the mother to baby occurs through the placenta.[39, 40] Vaccination in the second or early third trimester has been suggested to be optimal for COVID-19 protective antibody transfer.[41, 42] When the second dose was given in the second trimester, the neonatal IgG antibody titres were shown to be 2.6 times higher than the maternal titre at delivery.[43] Maternal vaccination with two doses of mRNA vaccine was shown to be protective in infants younger than 6 months against hospitalisation with COVID-19 during July 2021 and March 2022 in the US.[44] A third dose given in the third trimester of pregnancy to those who were vaccinated early in pregnancy or pre-conception improves maternal and neonatal antibody levels to protect against Omicron infection.[42, 45, 46]

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.[47] There is emerging evidence that vaccination in pregnancy or while breastfeeding provides temporary antibody protection to the baby through the cord blood and breastmilk.[47-49]

What are the likely responses to vaccination?

After hundreds of millions of doses of Comirnaty® given worldwide, the potential reactions to the vaccine have remained 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.[50, 51] Booster doses induce similar responses to the second dose. Data from v-Safe found no differences in local and systemic responses between pregnant and non-pregnant women.[26]

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. 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).[52] 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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