

COVID-19 vaccination, pregnancy and lactation

For health professional use

COVID-19 Comirnaty™ (Pfizer/BioNTech) vaccination and pregnancy

It is recommended that pregnant women/people are routinely offered the COVID-19 vaccine (Comirnaty) at any stage of pregnancy.

This recommendation aligns with those in many other countries, including the U.K., the U.S., Australia and Israel. Internationally, many people have been given this vaccine while pregnant and large-scale surveillance data indicate that there are no safety concerns with administering this COVID-19 vaccine at any stage of pregnancy. Vaccinating during pregnancy may also offer temporary protection for newborns across the placenta and in breast milk via passive immunity through the transfer of antibody.

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.

Routine pregnancy testing before COVID-19 vaccination is not recommended and for those who are planning pregnancy, it is not necessary to delay pregnancy after receiving a COVID vaccine.

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.

COVID-19 disease and pregnancy

Risks from COVID-19 for the mother

Like influenza, healthy pregnant women/people who are infected with the SARS-CoV-2 virus have an increased risk of severe COVID-19 disease compared with non-pregnant women/people.¹

COVID-19 infection when pregnant or soon after pregnancy substantially increases the risk of severe disease. When compared with non-pregnant people, COVID-19 in pregnancy increases the risk of admission to an intensive care unit by up to four times. Twice as many pregnant women/people with symptomatic COVID-19 die than those with COVID-19 who are not pregnant.^{1,2} 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.²

The increased risk of severe COVID-19 disease is likely to be related to some of the physiologic changes during pregnancy.¹ The mother's immune system is temporarily suppressed to prevent her immune system from harming her growing baby, which is genetically different to her. This can make her more susceptible to bacterial and viral infection.³⁻⁶ As the baby grows, the mother's lung function decreases, her body needs more oxygen, the volume of blood being pumped around her body increases and her heart works harder.³

Risks from maternal COVID-19 for the baby

Babies born to mothers with COVID-19 are more likely to be born pre-term (up to seven times) and more likely to require neonatal intensive care (up to five times) when compared with babies born to mothers without the disease.² The babies of women hospitalised with COVID-19 are more likely to be born by caesarean section and delivered preterm out of concern for the maternal health.⁷

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SARS-CoV-2 infection in pregnancy does not appear to affect fetal growth or the rates of neonatal death and stillbirth.⁷ The risk of SARS-CoV-2 infection from the mother during birth (vertical transmission) to her newborn appears to be small and is often asymptomatic and rarely severe, although the risk of severe disease in newborns is higher than seen for older infants.^{8,9}

COVID-19 disease in New Zealand

As of June 2021, New Zealand has minimal community transmission of COVID-19. Management at the border to prevent new cases of COVID-19 entering our community, rapid identification of unexpected community cases and comprehensive contact tracing have ensured little community spread of the disease.¹⁰ However, recent outbreaks in Australia and other countries that had previously controlled the virus have highlighted the need for ongoing vigilance.

Priority COVID-19 vaccination populations

After a successful vaccine rollout in groups at high risk of exposure to COVID-19 cases, such as those working at the border, health care professionals and their household contacts, the focus is now on vaccinating groups (group 3) who would be at high risk if they were infected with COVID-19.¹⁰ Group 3 includes those who are pregnant.

How the COVID-19 vaccine works

The Comirnaty COVID-19 vaccine is a messenger ribonucleic acid (mRNA) vaccine. It is not a live vaccine. After injection, the mRNA is taken into the cell cytoplasm where it delivers the instructions to make a protein that resembles part of the SARS-COV-2 virus (the spike protein). RNA is an unstable molecule which breaks down quickly after this process takes place. The mRNA from the vaccine is unable to enter the cell nucleus, it cannot integrate with DNA,¹¹ and will not cause genetic changes in the mother or the baby. The protein produced activates the immune response against COVID-19 in the same way as antigens in conventional vaccines.

COVID-19 vaccine safety in 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, from large-scale surveillance, data does not indicate any safety concerns.

Although pregnant women were not formally included in the initial clinical trials, the potential importance of immunising pregnant women 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.^{12,13}

To date, large-scale surveillance data have found no increased risk of problems in pregnancy after vaccination with mRNA COVID-19 vaccines compared to the unvaccinated pregnant population.¹³ The quantity of safety data in people who are pregnant continues to increase. At the end of May 2021, 121,244 people reported to the 'V-Safe after vaccination health checker' in the U.S. that they were pregnant when they received a COVID-19 vaccine (either Pfizer/BioNTech or Moderna mRNA vaccine) and over 5,000 of these people are being followed up throughout their pregnancy until their infant is around 3 months of age.¹² Published data from the first two months COVID-19 immunisation programme in the U.S. (to 16 February 2021) found no safety concerns among those vaccinated in pregnancy.¹⁵

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COVID-19 vaccination and breastfeeding

Breastfeeding women/people can receive a COVID-19 vaccine. There are no safety concerns associated with having this COVID-19 vaccine while breastfeeding 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.^{16,17}

What are the likely vaccine responses?

During Pfizer/BioNTech's phase 3 clinical trial for Comirnaty™, the most common vaccine responses reported by adults aged 16–55 years were a 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.¹⁸ These findings are also seen in real-world surveillance data (such as those reported to CARM in New Zealand¹⁹), after hundreds of millions of doses given worldwide. Data from v-Safe found no differences in local and systemic responses between pregnant and non-pregnant women.¹⁵

Prior to receiving their vaccination, we recommend that pregnant women discuss the best ways to relieve possible post-vaccination discomfort and fever with their health professional. Paracetamol is considered safe during pregnancy to reduce headache or fever. Non-steroidal anti-inflammatories (NSAIDs) including ibuprofen and diclofenac should not be taken during pregnancy.

Anaphylaxis following vaccination is very rare. For most vaccines, up to three cases of anaphylaxis could occur for every million doses administered.¹⁹ Initial surveillance data from the U.S. COVID-19 vaccination programme suggested that anaphylaxis could occur at up to five times per one million doses of the Comirnaty™ (Pfizer/BioNTech) vaccine.²⁰ For this reason, all COVID-19 vaccine recipients are currently being asked to remain under observation for at least 20 minutes after receiving their vaccine. 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?

Women/people who are pregnant or who are planning a pregnancy can make an informed decision to receive Comirnaty™ (Pfizer/BioNTech) mRNA COVID-19 vaccine at any stage. Women planning pregnancy can receive mRNA COVID-19 vaccines.

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

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References

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