

COVID-19 vaccination, pregnancy and lactation

For health professional use

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

Women who are pregnant and at risk of exposure to SARS-CoV-2 virus can receive a COVID-19 vaccine at any stage of pregnancy. For those at low risk of exposure, it is recommended to delay vaccination until after birth.

Routine pregnancy testing before COVID-19 vaccination is not recommended and those who trying to become pregnant do not need to avoid pregnancy after receiving a COVID vaccine. It is recommended that a pregnant woman, her whānau and her healthcare professional discuss the risks associated with COVID-19 disease for pregnant women and the growing baby and consider the available safety data of COVID-19 vaccination during pregnancy.

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 vaccination and breastfeeding

Breastfeeding women can receive a COVID-19 vaccine. There are no safety concerns for a breast-feeding woman or her infant associated with having this COVID-19 vaccine.

COVID-19 disease and pregnancy

Risk from COVID-19 for the mother

Like influenza, 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

Healthy pregnant women with COVID-19 are up to four times more likely to be admitted to an intensive care unit (ICU) and need ventilation support than women who are not pregnant.^{1,2} Pregnant women from age of 35 years and those who have a chronic condition, such as obesity, high blood pressure or pre-existing diabetes, are 2–5 times more likely to need ICU care and ventilation.²

The increased risk of severe COVID-19 disease is likely to be related to some of the physiologic changes during pregnancy.¹ During pregnancy, 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 getting infections, especially with viruses.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

Risk from maternal COVID-19 for the baby

Babies born to mothers with COVID-19 disease were up to seven times more likely to be born pre-term and up to five times more likely to require neonatal intensive care when compared with babies born to women 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

COVID-19 vaccination, pregnancy and lactation

For health professional use

SARS-CoV-2 infection in pregnancy does not appear to affect fetal growth or the rates of early neonatal death and stillbirth.⁷ The risk of SARS-CoV-2 infection from the mother during birth (vertical transmission) to her new born appears to be small and is often asymptomatic and rarely severe.^{8,9}

COVID-19 disease in New Zealand

As of March 2021, New Zealand has minimal community transmission of COVID-19. Management at the border to prevent new cases of COVID-19 disease entering our community, rapid identification of unexpected community cases and comprehensive contact tracing have ensured little community spread of the disease.¹⁰

The risk of exposure to SARS-CoV-2 infected people is highest in those working around people who have recently arrived from overseas, such as staff working at the border, at or with managed isolation facilities, at the ports, and staff at the hospitals who caring for people with severe COVID-19 disease. Household contacts of these workers have the next highest risk of SARS-CoV-2 exposure.

Priority COVID-19 vaccination populations

While there is minimal community spread, immunisation to protect against COVID-19 is initially focused on the people with an occupational risk of being exposed to those potentially infected with SARS-CoV-2, those working at the border, managed isolation facilities and the ports and their households, followed by staff at major hospitals near managed isolation facilities.¹¹

Those with an occupational risk of exposure to COVID-19 cases and their households are likely to include women who are pregnant or planning pregnancy, and women who are breastfeeding.

COVID-19 vaccine safety in pregnancy

The Pfizer-BioNTech COVID-19 vaccine is a mRNA vaccine. It is not a live vaccine. After injection, the mRNA delivers a genetic message to manufacture proteins inside the target cells in the person who received the vaccine and then breaks down. The mRNA from the vaccine does not enter the nucleus of any cells and does not integrate with DNA,¹² which means the vaccine cannot cause genetic changes in the mother or her baby. It is considered highly unlikely this vaccine would cause problems in pregnancy; however pregnant women were not formally included in the initial clinical trials.

Safety data on the use of the mRNA COVID-19 vaccine (Comirnaty, Pfizer-BioNTech) in women who are pregnant is currently limited. During the phase 3 clinical trials of the Pfizer-BioNTech COVID-19 vaccine, some pregnant women were inadvertently vaccinated. A total of 23 pregnancies were reported (12 received the vaccine, 11 received the placebo). After around 2 months after the start of the COVID-19 immunisation programme in the U.S (as of 16 February 2021), the 'V-Safe after vaccination health checker' had received 16,039 reports from women who were pregnant when they received the Pfizer-BioNTech vaccine and a further 14,455 who had received a different mRNA COVID-19 vaccine.¹³ No safety concerns have been identified among vaccinated pregnant women.

The potential importance of immunising pregnant women against COVID-19 is known, and several studies are underway to improve the evidence around safe use of COVID-19 vaccines in pregnancy. For example, in February 2021, Pfizer and BioNTech began a clinical trial to formally evaluate mRNA COVID-19 vaccine

COVID-19 vaccination, pregnancy and lactation

For health professional use

safety, tolerability and immunogenicity in women who are pregnant.¹⁴ In the U.S, a V-safe pregnancy register was established to monitor participants for pregnancy and infant outcomes; no safety concerns have been raised to date. Furthermore, COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER) study is also underway.¹³

What are the likely vaccine responses?

During the Pfizer-BioNTech COVID-19 vaccine phase 3 clinical trials, the most common vaccine responses reported by adults aged 16–55 years were a fever of 38°–39°C, fatigue and headache, more likely after the second vaccination, and/or mild to moderate pain at the injection site.¹⁵ Data from V-Safe found no differences in local and systemic responses between pregnant and non-pregnant women.¹³

Prior to receiving their vaccination, we recommend that pregnant women discuss, with their doctor or midwife, the best ways to relieve possible post-vaccination discomfort.

Anaphylaxis following vaccination is very rare. For most vaccines, up to three cases of anaphylaxis could occur for every million doses administered.¹⁶ Initial surveillance data from the U.S. COVID-19 vaccination programme suggest that anaphylaxis could occur at a slightly higher rate for the Comirnaty™ (Pfizer-BioNTech) vaccine, at up to five times per one million doses administered.¹⁷

For this reason, all COVID-19 vaccine recipients are currently being asked to remain under observation for 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 for anyone who has had **anaphylaxis to an ingredient in the vaccine or a previous dose** of the vaccine.

Who can receive a COVID-19 vaccine?

For women who are pregnant and at high risk of exposure to SARS-CoV-2 can be offered mRNA COVID vaccine (Comirnaty) with informed consent. For those at low risk of exposure, it is recommended to delay vaccination until after birth.

Women planning pregnancy can receive a COVID-19 vaccine.

- Pregnancy testing is not recommended prior to vaccination.
- It is not necessary to delay pregnancy after receipt of a COVID-19 vaccination.

The presence of a minor infection is not a reason to delay vaccination. For anyone who is acutely unwell, fever >38°C or acute systemic illness, vaccination should be deferred until they are no longer acutely unwell.

COVID-19 vaccination, pregnancy and lactation

For health professional use

References

1. Zambrano L, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, et al. Update: Characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(44):1641-7.
2. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. *BMJ.* 2020;370:m3320.
3. Branch DW. Physiologic adaptations of pregnancy. *Am J Reprod Immunol.* 1992;28(3-4):120-2.
4. Jamieson D, Theiler R, Rasmussen S. Emerging infections and pregnancy. *Emerg Infect Dis.* 2006;12(11):1638-43.
5. Robinson DP, Klein SL. Pregnancy and pregnancy-associated hormones alter immune responses and disease pathogenesis. *Horm Behav.* 2012;62(3):263-71.
6. Kay AW, Fukuyama J, Aziz N, Dekker CL, Mackey S, Swan GE, et al. Enhanced natural killer-cell and T-cell responses to influenza A virus during pregnancy. *Proc Natl Acad Sci U S A.* 2014;111(40):14506-11.
7. Mullins E, Hudak ML, Banerjee J, Getzlaff T, Townson J, Barnette K, et al. Pregnancy and neonatal outcomes of COVID-19: co-reporting of common outcomes from PAN-COVID and AAP SONPM registries. *Ultrasound Obstet Gynecol.* 2021.
8. Walker KF, O'Donoghue K, Grace N, Dorling J, Comeau JL, Li W, et al. Maternal transmission of SARS-COV-2 to the neonate, and possible routes for such transmission: a systematic review and critical analysis. *BJOG.* 2020;127(11):1324-36.
9. Liguoro I, Pilotto C, Bonanni M, Ferrari ME, Pusiol A, Nocerino A, et al. SARS-COV-2 infection in children and newborns: a systematic review. *European Journal of Pediatrics.* 2020;179(7):1029-46.
10. Ministry of Health. Aotearoa/New Zealand's COVID-19 elimination strategy: An overview [Internet]. 2020 [cited 2021 February 11]. Available from: https://www.health.govt.nz/system/files/documents/pages/aotearoa-new_zealands_covid-19_elimination_strategy- an_overview17may.pdf
11. Ministry of Health. COVID-19 Vaccine and Immunisation Programme update [Internet]. 2021 [cited 2021 February 11]. Available from: https://www.health.govt.nz/system/files/documents/pages/update_3_feb090321.pdf
12. Knezevic I, Liu MA, Peden K, Zhou T, Kang H-N. Development of mRNA vaccines: Scientific and regulatory issues. *Vaccines.* 2021;9(2):81.
13. Shimbabukuro T, CDC-COVID-19 Vaccine Task Force. COVID-19 vaccine safety update. March 2021. [cited 5 March 2021]. Available from: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf>
14. Pfizer. Pfizer and BioNTech commence global clinical trial to evaluate COVID-19 vaccine in pregnant women [Internet]. New York: Pfizer; 2021 [updated 2021 February 18; cited 2021 February 25]. Available from: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-commence-global-clinical-trial-evaluate>
15. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med.* 2020;383(27):2603-15.
16. McNeil MM, DeStefano F. Vaccine-associated hypersensitivity. *J Allergy Clin Immunol.* 2018;141(2):463-72.
17. Shimabukuro TT, Cole M, Su JR. Reports of anaphylaxis after receipt of mRNA COVID-19 vaccines in the US—December 14, 2020–January 18, 2021. *JAMA.* 2021.