



Australian Government



COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy

Version 6

15 September 2021

What has changed?

- *The newly registered Spikevax COVID-19 vaccine (Moderna) has been included in this advice.*
- *If Pfizer or Moderna are not available, AstraZeneca can be considered if the benefits to the individual outweigh the potential risks*

The Department of Health will publish updated versions of this guide as more information and new vaccines become available.

Please note:

- *Spikevax COVID-19 vaccine (Moderna) will be referred throughout this guide as Moderna*
- *Comirnaty COVID-19 vaccine (Pfizer) will referred throughout this guide as Pfizer*
- *Vaxzevria COVID-19 vaccine/COVID-19 Vaccine AstraZeneca (AstraZeneca) will referred throughout this guide as AstraZeneca*

This decision guide contains information about Pfizer and Moderna, the COVID-19 vaccines recommended if you are pregnant, breastfeeding or planning pregnancy. This guide will be updated as new information becomes available.

Key points

- If you are pregnant you are a priority for COVID-19 vaccination and should be routinely offered Pfizer or Moderna at any stage of pregnancy.
- If you are trying to become pregnant, you do not need to delay vaccination or avoid becoming pregnant after vaccination.
- Real-world evidence has shown that Pfizer and Moderna are safe if you are pregnant and breastfeeding.
- AstraZeneca can be considered if you are pregnant, breastfeeding or planning pregnancy, if you cannot access Pfizer or Moderna, and if the benefits of vaccination outweigh the risks for you.
- If you are pregnant, you have a higher risk of severe illness from COVID-19.
- Your baby may also have a higher risk of being born prematurely.
- COVID-19 vaccination may provide indirect protection to babies by transferring antibodies through the placenta (during pregnancy) or through breastmilk (during breastfeeding).

What are the current recommendations for COVID-19 vaccination in pregnancy?

If you are pregnant you are in a priority group for COVID-19 vaccination. You should be routinely offered Pfizer or Moderna at any stage of pregnancy. Research has shown that those who are pregnant have a higher risk of severe illness from COVID-19 and their babies have a higher risk of being born prematurely. Vaccination is the best way to reduce these risks.

If you are pregnant, you are recommended to complete the routine schedule of Pfizer or Moderna to ensure adequate protection.

- For Pfizer, this is two doses, 3-6 weeks apart.
- For Moderna, this is two doses, 4-6 weeks apart.

The recommended interval between COVID-19 vaccine and any other vaccine given during pregnancy is seven days. In special circumstances this interval can be shortened (including same day administration), such as after a tetanus prone wound or during an outbreak of influenza or COVID-19.

Vaccine preference recommendations

Pfizer and Moderna are the preferred COVID-19 vaccines for people under 60 years in Australia, and if you are pregnant, breastfeeding or planning pregnancy. This is for two reasons:

- Research has shown that Pfizer and Moderna are safe in pregnancy and during breastfeeding. This research has not yet been carried out for AstraZeneca.
- AstraZeneca is associated with a rare risk of a clotting condition called thrombosis with thrombocytopenia syndrome (TTS), which appears to be more common in people under 60 years of age.

If Pfizer or Moderna are not available, AstraZeneca can be considered if the benefits of vaccination outweigh the risks for an individual. For example, in outbreak settings. There are no theoretical safety concerns associated with AstraZeneca specific to pregnancy, breastfeeding or planning pregnancy.

Pfizer and Moderna are registered for use in people aged 12 and older. AstraZeneca is registered for use in people aged 18 and older. All three vaccines work by delivering the genetic code for an important part of the COVID-19 virus called the spike protein. After vaccination your body reads the genetic code and makes copies of the spike protein. This trains your immune system to recognise and fight against the COVID-19 virus.

Recommendations if you are pregnant and have already received a dose of AstraZeneca

If you are pregnant and have already received a first dose of AstraZeneca, you can receive Pfizer, Moderna or AstraZeneca for your second dose, although Pfizer or Moderna are preferred.

While generally it is recommended that the same vaccine brand is used for both doses, Pfizer or Moderna is preferred in pregnancy because there is more information regarding safety of Pfizer and Moderna in pregnancy compared with AstraZeneca.

You and your provider may wish to consider the following factors:

- There is a growing body of evidence supporting the safety of mRNA COVID-19 vaccines (Pfizer or Moderna) in pregnancy
- There are still very limited data on the safety of viral vector vaccines (such as AstraZeneca) in pregnancy
- There is comparatively less data on the safety and efficacy of mixed vaccine schedules than completing the series with the same vaccine.

Why have the recommendations for COVID vaccination during pregnancy changed?

Pregnant women were not included in the first clinical trials for COVID-19 vaccines, so at the time of initial guidance there was limited evidence confirming the safety of COVID-19 vaccines during pregnancy. The initial advice from immunisation expert groups was therefore cautious, and COVID-19 vaccines were not routinely recommended in pregnancy.

Over time, 'real-world' evidence from other countries has accumulated and reports show that the mRNA COVID-19 vaccines Pfizer and Moderna are safe to use in pregnancy. Emerging research also demonstrates there is a similar immune response to mRNA vaccines in pregnancy compared to those who are not pregnant. Therefore, it is likely there is similar protection from the vaccines against COVID-19 during pregnancy. Results from the vaccine program in Israel have suggested that Pfizer is effective in preventing COVID-19 in pregnancy.¹ Furthermore, research shows that the antibodies produced by vaccination cross the placenta and may provide some protection to newborn babies.

What are the risks of COVID-19 in pregnancy?

Women who contract COVID-19 whilst pregnant have a higher risk of certain complications compared to non-pregnant women of the same age who contract COVID-19, including:

- An increased risk (about 5 times higher) of needing admission to hospital.²
- An increased risk (about 2-3 times higher) of needing admission to an intensive care unit.^{3,4}
- An increased risk (about 3 times higher) of needing invasive ventilation (breathing life support).^{3,4}

COVID-19 during pregnancy also increases the risk of complications for the newborn, including:

- A slightly increased risk (about 1.5 times higher) of being born prematurely (before 37 weeks of pregnancy).³

- An increased risk (about 3 times higher) of needing admission to a hospital newborn care unit.³

Some who are pregnant are more likely to have severe illness from COVID-19 compared to those who are pregnant *without* these conditions. The conditions are:

- Being older than 35 years
- Being overweight or obese (body mass index above 30 kg/m²)
- Having pre-existing (pre-pregnancy) high blood pressure
- Having pre-existing (pre-pregnancy) diabetes (type 1 or type 2)

Are mRNA COVID-19 vaccines (Pfizer and Moderna) safe in pregnancy?

Yes, mRNA vaccines have been shown to be safe in pregnancy based on accumulated real-world evidence from other countries. A US study of over 35,000 women who were pregnant and had an mRNA COVID-19 vaccine showed that the side effects following vaccination were very similar in those who were pregnant when compared to those who were not.⁵ Those who were pregnant appeared slightly more likely to report pain at the injection site, but were less likely to report generalised symptoms such as fever or tiredness. Fever of 38°C or above was reported in fewer than 1% of those who were pregnant who had Pfizer or Moderna after the first dose, fewer than 5% after the second dose of Pfizer, and 11.8% after the second dose of Moderna. The findings from this large study are supported by other smaller studies.⁶⁻⁸

This study also reported the outcomes for 827 completed pregnancies. They did not identify any safety concerns for those who received an mRNA COVID-19 vaccine in pregnancy. Complications such as premature delivery, stillbirth, small for gestational age infants and congenital anomalies occurred at a similar rate to what is seen in the general population.⁵

A number of smaller studies have shown that receiving an mRNA vaccine during pregnancy does not increase the risk of pregnancy complications for those who are pregnant or their babies.^{6,7,9,10}

Animal studies of Pfizer and Moderna have not shown any negative effects on fertility or pregnancy.^{11,12}

Overall the data on COVID-19 vaccines in pregnancy are still limited, but growing. A clinical trial of Pfizer is underway in the US, and further real-world evidence is being gathered.¹³

There are still very limited data on the safety of viral vector vaccines (such as AstraZeneca) in pregnancy.

What are the possible harms from vaccination with Pfizer or Moderna during pregnancy?

1. You may experience side effects after vaccination. Common side effects reported after Pfizer and Moderna in the clinical trials in people aged 18-55 (Pfizer) or 18-65 (Moderna) include:
 - pain at the injection site (in about 84% after Pfizer and 90% after Moderna). Those who are pregnant appear more likely to report injection site pain compared to those who are not.⁵
 - tiredness (in about 62% and 68%)
 - headache (in about 52% and 63%)
 - muscle pain (in about 37% and 62%)
 - chills (in about 35% and 49%)
 - joint pain (in about 22% and 46%)
 - fever (in about 16% and 17%)
 - diarrhoea (in about 10% and 21%)

Fever is considered undesirable in early pregnancy, but most people who have COVID-19 vaccination will not have a fever. As Paracetamol is safe in pregnancy, you can take it to reduce the following symptoms if you experience them:

- fever
- pain at the injection site
- headache
- muscle pain
- joint pain
- chills

2. COVID-19 vaccination may cause rare side effects in those who are pregnant or their babies that we do not yet know about:

- Real-world evidence is available from a study of over 35,000 women who were pregnant and who had an mRNA COVID-19 vaccine.⁵ This study did not find any side effects specific to those who were pregnant or their babies. However, it is still possible that there are very rare side effects that have not been detected in this study.

Are there any benefits for my baby from having a COVID-19 vaccine during pregnancy?

COVID-19 in pregnancy may present a higher risk of stillbirth or premature (early) delivery.³ Babies are also more likely to show distress during delivery, or to need treatment in a newborn intensive care unit. COVID-19 vaccination during pregnancy may reduce the risk of premature delivery of the baby, if it prevents infection in the mother.

Several studies have shown that the antibodies induced by COVID-19 vaccine can cross the placenta, particularly in those vaccinated early in pregnancy, and who received both doses prior to delivery.^{6,7,10,14,15} These antibodies may provide your baby with some protection against COVID-19 for the first few months of life. However, there have not yet been any studies to confirm such protection.

When is the best time to have a COVID-19 vaccine if I am pregnant?

Currently we do not know if there is an optimal time to have a COVID-19 vaccine during pregnancy, either for the benefit of the mother or to protect her baby. Therefore, you are recommended to have a COVID-19 vaccine as soon as you are offered one. COVID-19 vaccines can be given at any stage of pregnancy.

Can I just have one dose during pregnancy, and delay the second dose?

Having only one dose will provide partial protection against COVID-19, and we do not yet know how long this protection will last. Having the second dose is important to gain optimal protection against COVID-19. Two doses of a COVID-19 vaccine provides good protection against COVID-19, including against the Delta strain. A single dose is not as effective at preventing infection but does reduce the risk of severe illness. Now that there is good data on the safety of mRNA vaccines in pregnancy, it is recommended to have two doses of Pfizer 3-6 weeks apart or Moderna 4-6 weeks apart.

If you choose to delay the second dose, you will not need to repeat the first dose.

Can Pfizer or Moderna be given at the same time as influenza or whooping cough vaccines?

It is not routinely recommended to co-administer COVID-19 vaccine with other vaccines. The minimum recommended interval between COVID-19 vaccine and any other vaccine is seven days. However, this interval can be shortened (including same day administration) in special circumstances, such as a tetanus prone wound or outbreak of influenza or COVID-19.

What are the recommendations if you are breastfeeding?

Pfizer and Moderna are the preferred vaccines for people under 60 years of age, which includes those who are breastfeeding. You do not need to stop breastfeeding before or after vaccination.

If you are breastfeeding can you have AstraZeneca?

If Pfizer or Moderna is not available, you can consider having AstraZeneca after talking to your healthcare provider about the benefits and potential rare risks. AstraZeneca has not been formally studied in those who are breastfeeding, however there are no theoretical safety concerns for its use while breastfeeding. It is not a live vaccine and cannot cause COVID-19 in your infant.

Are Pfizer and Moderna safe if you are breastfeeding?

Yes, these vaccines are considered safe for those breastfeeding and their babies. While there is limited research on the safety of COVID-19 vaccines in those who are breastfeeding, there are no theoretical safety concerns. Several small studies have shown that those breastfeeding have similar side effects after having an mRNA COVID-19 vaccine compared to the general population.^{6,7,16}

The mRNA in Pfizer and Moderna is rapidly broken down in the body and we do not think that it passes into breastmilk. This has been confirmed by one small study.¹⁷ Even if it did, it would be quickly destroyed in the baby's gut and is therefore extremely unlikely to have any effect on your baby.

Are there any benefits for my baby from having COVID-19 vaccine while breastfeeding?

Several small studies have shown that the antibodies induced by COVID-19 vaccines pass into breastmilk.^{6,7,16,18} This may provide your baby with some protection against COVID-19, however there have not yet been any studies to confirm such protection.

What are the recommendations if you are planning pregnancy?

If you are planning pregnancy you are recommended to receive Pfizer or Moderna. You do not need to avoid becoming pregnant before or after vaccination. Getting vaccinated before conceiving means you are likely to have protection against COVID-19 throughout your pregnancy. Vaccination does not affect fertility. You are not required to have a pregnancy test before getting vaccinated. If Pfizer or Moderna is not available, you can consider having AstraZeneca if the benefits outweigh the potential risks for you.

For more information

For more information about COVID-19 and COVID-19 vaccines, refer to:

- [Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women](#)
- [Information on COVID-19 Pfizer \(Pfizer\) vaccine](#)
- [Information on COVID-19 Moderna \(Moderna\) vaccine](#)
- [Preparing for COVID-19 vaccination](#)
- [After your Pfizer \(Pfizer\) vaccine](#)
- [After your COVID-19 Moderna \(Moderna vaccine\)](#)

References

1. Goldshtein I, Nevo D, Steinberg DM, et al. Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. *JAMA*. Published online July 12, 2021. doi:10.1001/jama.2021.11035
2. Magnus MC, Oakley L, Gjessing HK, et al. Pregnancy and risk of COVID-19. *medRxiv*. Published online March 26, 2021:2021.03.22.21254090. doi:10.1101/2021.03.22.21254090
3. Allotey J, Stallings E, Bonet M, 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. doi:10.1136/bmj.m3320
4. Zambrano LD. 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. doi:10.15585/mmwr.mm6944e3
5. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*. Published online April 21, 2021. doi:10.1056/nejmoa2104983
6. Gray KJ, Bordt EA, Atyeo C, et al. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol*. Published online March 2021:S0002937821001873. doi:10.1016/j.ajog.2021.03.023
7. Collier AY, McMahan K, Yu J, et al. Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. *JAMA*. 2021;325(23):2370. doi:10.1001/jama.2021.7563
8. Kadali RAK, Janagama R, Peruru SR, et al. Adverse effects of COVID-19 messenger RNA vaccines among pregnant women: a cross-sectional study on healthcare workers with detailed self-reported symptoms. *Am J Obstet Gynecol*. Published online June 10, 2021. doi:10.1016/j.ajog.2021.06.007
9. Shanes ED, Otero S, Mithal LB, Mupanomunda CA, Miller ES, Goldstein JA. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Pregnancy: Measures of Immunity and Placental Histopathology. *Obstet Gynecol*. 2021;138(2):281-283. doi:10.1097/AOG.0000000000004457
10. Beharier O, Mayo RP, Raz T, et al. Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine. *J Clin Invest*. 2021;131(13). doi:10.1172/JCI150319
11. Bowman CJ, Bouressam M, Champion SN, et al. Lack of effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, a mRNA-based COVID-19 vaccine. *Reprod Toxicol Elmsford N*. 2021;103:28-35. doi:10.1016/j.reprotox.2021.05.007
12. United States Food and Drug Administration. Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum. Accessed August 10, 2021. <https://www.fda.gov/media/144673/download>
13. National Library of Medicine (US). Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older - Identifier NCT04754594. ClinicalTrials.gov [Internet]. Bethesda (MD). Accessed on 10 August 2021

14. Prabhu M, Murphy EA, Sukhu AC, et al. Antibody Response to Coronavirus Disease 2019 (COVID-19) Messenger RNA Vaccination in Pregnant Women and Transplacental Passage Into Cord Blood. *Obstet Gynecol.* 2021;138(2):278-280. doi:10.1097/AOG.0000000000004438
15. Mithal LB, Otero S, Shanes ED, Goldstein JA, Miller ES. Cord blood antibodies following maternal coronavirus disease 2019 vaccination during pregnancy. *Am J Obstet Gynecol.* 2021;225(2):192-194. doi:10.1016/j.ajog.2021.03.035
16. Perl SH, Uzan-Yulzari A, Klainer H, et al. SARS-CoV-2–Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women. *Jama.* Published online 2021.
17. Golan Y, Prah M, Cassidy A, et al. Evaluation of Messenger RNA From COVID-19 BTN162b2 and mRNA-1273 Vaccines in Human Milk. *JAMA Pediatr.* Published online July 6, 2021:e211929. doi:10.1001/jamapediatrics.2021.1929
18. Kelly JC, Carter EB, Raghuraman N, et al. Anti–severe acute respiratory syndrome coronavirus 2 antibodies induced in breast milk after Pfizer-BioNTech/BNT162b2 vaccination. *Am J Obstet Gynecol.* 2021;225(1):101-103. doi:10.1016/j.ajog.2021.03.031