Australian Government

COVID-19 VACCINATION

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

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**What has changed:**

- Updated links added to access information in the Australian Immunisation Handbook.
- Updated evidence that a dose of COVID-19 vaccine during pregnancy may reduce the risk of severe disease in young infants in the first few months of life.

To find out more about the available COVID-19 vaccines and who should be vaccinated, refer to the Australian Immunisation Handbook.

## Key points and recommendations

- Vaccine recommendations for pregnant women are the same as the general population, which can be found in the Australian Immunisation Handbook.
- If you are pregnant and due a COVID-19 vaccine, you are recommended to have a dose at any stage of pregnancy.
- If you are pregnant and unvaccinated:
    - You have a higher risk of severe illness from COVID-19 than pregnant women who are vaccinated.
    - Your baby may also have a higher risk of being born prematurely, particularly if you get severe disease.
    - Your baby will also be at higher risk of catching COVID-19 from you or other people in the first few months of life.
- COVID-19 vaccines can be given to people who are breastfeeding.
- Real-world evidence has shown that the mRNA Pfizer and Moderna original vaccines are safe if you are pregnant and/or breastfeeding. The evidence for the use of newer variant vaccines in pregnancy is limited, but there are no additional concerns regarding their safety compared with the original vaccines. There are currently less data available on the use of Novavax vaccine in pregnancy.
- COVID-19 vaccination during pregnancy may provide temporary protection to babies by transferring antibodies through the placenta. The additional antibodies against the Omicron variant after an Omicron-based vaccine may provide additional protection compared to original formulations. A dose during pregnancy may reduce the risk of severe COVID-19 in young infants in the first few months of life.
- If you are trying to become pregnant, you do not need to delay vaccination or avoid becoming pregnant after vaccination.
- It is recommended that you have two doses of COVID-19 vaccine (called the primary course). The interval between these doses is 8 weeks but can be shorter (3 or 4 weeks depending on brand) in immunocompromised or high-risk people, or in an outbreak.
- Recommendations for doses if you are pregnant are the same as for non-pregnant people of the same age. For more information on dose recommendations, refer to the Australian Immunisation Handbook.
- If you have previously had a primary course and one further dose of COVID-19 vaccine, you should discuss with your healthcare provider whether any further doses are required during your pregnancy. Pregnancy is not currently considered a risk factor for severe illness if you have already completed a primary course and one further dose, and if you do not have any medical risk conditions.
- COVID-19 vaccine doses can be given at any stage of pregnancy.
- People with severe immunocompromise are recommended to receive a 3rd primary dose of COVID-19 vaccine 8 weeks after their second dose. Recommendations for a 3rd primary dose in people with severe immunocompromise are the same for pregnant and non-pregnant women (see COVID-19 vaccine doses and administration for more information).

## What are the benefits of COVID-19 vaccination in pregnancy?

Vaccination with primary and recommended booster doses is the best way to reduce the higher risk of severe COVID-19 in unvaccinated pregnant women.

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 effective and very safe to use in pregnancy.

Results from the vaccine program in multiple countries have suggested that Pfizer and Moderna are effective in preventing SARS-CoV-2 infection[1,2,3], as well as severe outcomes from infection during pregnancy.[1,4,5] Two primary doses and one further dose are required for good protection against the Omicron variant.

Pregnant women who receive a further dose have been shown to have lower rates of severe disease compared to pregnant women who have only received 2 primary doses.[6,7] During the Omicron period, a 2 dose primary course of vaccine reduced the risk of severe complications from COVID-19 by 48% while 3 doses (primary course and further dose) reduced the risk by 76% compared to an unvaccinated pregnant woman.[8]

Pregnancy itself is not currently considered a risk factor for severe illness in women who have already received 3 doses of COVID-19 vaccine and who do not have other medical risk factors for severe illness. The risk of severe disease during the Omicron SARS-CoV-2 variant period is reduced substantially and rare in pregnant women who have received 3 doses of COVID-19 vaccine.[9,10]

A COVID-19 vaccine dose during pregnancy may reduce the risk of severe illness in young infants in the first few months of life.[11-13] Women who have previously been vaccinated or had prior infection will also pass some protective antibodies to their baby during their pregnancy.

The risk of severe illness from COVID-19 is low in Australian infants, therefore COVID-19 doses are not routinely recommended in each pregnancy but can be given if eligible for another dose according to latest recommendations.

## What are the risks of COVID-19 in pregnancy?

Studies conducted prior to the emergence of the Omicron strain of SARS-CoV-2 showed that unvaccinated 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[14]
- an increased risk (about 2-3 times higher) of needing admission to an intensive care unit[15,16]
- an increased risk (about 3 times higher) of needing invasive ventilation (breathing life support).[15,16]
- COVID-19 during pregnancy in an unvaccinated woman 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)[2]
- an increased risk (about 3 times higher) of needing admission to a hospital newborn care unit.[15]

The risk of severe disease decreases with the number of vaccine doses you have received. Studies have demonstrated that pregnant women who have received 3 doses of vaccine have low rates of severe COVID-19 with the Omicron strain.[9,14]

Some unvaccinated pregnant women who have certain conditions are more likely to have severe illness from COVID-19 compared to those who are pregnant without these conditions, including:

- being older than 35 years
- being obese (body mass index above 30 kg/m$^2$)
- having pre-existing (pre-pregnancy) high blood pressure
- having pre-existing (pre-pregnancy) diabetes (type 1 or type 2).

## Are COVID-19 vaccines safe in pregnancy?

Yes, accumulated real-world evidence from other countries has shown that mRNA vaccines (Pfizer and Moderna) are safe in pregnancy. 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.[17] Pregnant women 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.[18-20]

Receiving mRNA COVID-19 vaccines during early pregnancy does not increase the risk of miscarriage.[21-23] Many studies, including some large population-based studies, have also demonstrated that women who receive mRNA COVID-19 vaccination during pregnancy do not have an increased risk of complications such as premature delivery, stillbirth, small for gestational age infants and congenital anomalies compared to unvaccinated women.[2,24-28]

Animal and human studies of Pfizer and Moderna have not shown any negative effects on fertility or pregnancy (see What are the recommendations if I am planning pregnancy?).[4,5]

First booster doses have been shown to be safe in pregnancy and reduce severe disease in pregnant women.[6,25-29] Given that 2 primary doses and 1st booster doses, particularly of the mRNA vaccines, have been shown to be safe, no safety concerns are anticipated with a 2nd booster dose. No concerns have arisen in small numbers of women who have received a 2nd booster (4th dose).[9] Additionally, adverse events in the general population after a 2nd booster dose have been similar to the 3rd dose.[30]

There are limited data available currently on the safety of the Omicron-based vaccines in pregnancy, although no additional concerns exist compared to the original mRNA vaccines. In non-pregnant adults, bivalent vaccines had very similar side effects to the original vaccines.

There is limited data available currently on the safety of Novavax in pregnancy.

As with any vaccine, you may experience mild and temporary side effects after vaccination. Pregnant women have been found to have similar side effects to non-pregnant women following vaccination.[18,20] More information on common side effects following vaccination is available in the Australian Immunisation Handbook.

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

It is safe to have a COVID-19 vaccine at any time during pregnancy, to protect yourself and your baby. Therefore, you are recommended to have a COVID-19 vaccine as soon as you are offered one.

## Are there any benefits for my baby if I have a COVID-19 vaccine during pregnancy?

Getting COVID-19 during pregnancy may present a higher risk of stillbirth or premature (early) delivery[15] 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 vaccines can cross the placenta, particularly in those vaccinated early in pregnancy, and who received both doses prior to delivery.[18,19,31-33] Antibodies may remain present in infants for multiple months after delivery[34] These antibodies may provide your baby with some protection against COVID-19 for the first few months of life. A study showed that vaccine effectiveness against COVID-19 hospitalisation in infants during the first 6 months of life from maternal vaccination in pregnancy was estimated at 80% during the Delta period, 38% during the Omicron period, and 52% overall.[35] A Norwegian study found similar protection for infants against COVID-19 hospitalisation in the first 4 months after birth from mothers who received a 2nd or 3rd dose of a COVID-19 vaccine during pregnancy.[36]

## Can COVID-19 vaccines be given at the same time as influenza or other vaccines?

Yes. Evidence demonstrates that co-administering (i.e. given at the same time) a COVID-19 vaccine and an influenza vaccine is safe and produces good immune responses to both vaccines.

COVID-19 vaccines can also be co-administered with other vaccines, such as the pertussis vaccine, if required.

It is important to balance the need for co-administration of vaccines with delivering vaccines on separate visits, as there is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. It can also make it harder to attribute potential adverse events to specific vaccines.

## What are the vaccine recommendations if I am breastfeeding?

COVID-19 vaccines are considered safe for those breastfeeding and for their babies. Several small studies of the original mRNA vaccines have shown that those breastfeeding have similar side effects after having an mRNA COVID-19 vaccine compared to the general population.[18,19,37]

The mRNA in the Pfizer and Moderna vaccines is rapidly broken down in the body and is not thought to pass into breastmilk. This has been confirmed by one small study.[38] Even if it did, it would be quickly destroyed in the baby's gut and is therefore extremely unlikely to have any effect on breastfed babies.

## 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.[6-9,18,19,39,40] This may provide your baby with some protection against COVID-19, however there have not yet been any studies to confirm this.

## What are the recommendations if I am planning pregnancy?

If you are planning pregnancy you are recommended to complete a COVID-19 vaccine primary course. 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 in men or women.[40-44] You are not required to have a pregnancy test before getting vaccinated.

## More information

For more information about COVID-19 vaccines, including further doses, refer to:

- Australian Immunisation Handbook: https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/covid-19
- Information about third primary doses for people with severe immunocompromise:

  www.health.gov.au/resources/publications/atagi-recommendations-on-the-use-of-a-third-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised
- Joint RANZCOG and ATAGI statement:

  www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women

## Further reading


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