Australian Government

COVID-19 VACCINATION

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

Version 7.2

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What has changed?

- *Booster dose information has been updated to include use of Spikevax (Moderna) and note the booster interval had been changed from 6 to 4 months.*

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

This decision guide contains information about Pfizer and Moderna vaccines. These COVID-19 vaccines are recommended if you are pregnant, breastfeeding or planning pregnancy.

Key points

- If you are pregnant you are recommended to have Pfizer or Moderna at any stage of pregnancy.
- 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)
- 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.
- If you are 18 years or older and had your initial two doses of COVID-19 vaccine (called the primary course) at least four months ago, you can have a booster dose. This may improve your protection against the newly emerged Omicron variant.
- Pfizer and Moderna are the preferred brands for booster doses for all people, including pregnant women, regardless of the brand used initially.
- People aged 12-17 years with severe immunocompromise are recommended to receive a 3rd primary dose of COVID-19 vaccine. A 4th doses is not recommended at this time, and ATAGI continue to review and may update this advice.
- People aged 18 years and over with severe immunocompromise who have received 3 doses of a COVID-19 vaccine are recommended to receive a booster dose (I.e. 4th dose) at 4 months, in line with the timing for the general population.

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 pregnant women 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 primary course 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.

People aged 12-17 years with severe immunocompromise are recommended to receive a 3rd primary dose of COVID-19 vaccine, however further (i.e. 4th) doses are not recommended for this age group at this time. More information is available here: 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.

People aged 18 years and over with severe immunocompromise who have received 3 doses of a COVID-19 vaccine are recommended to receive a booster dose (i.e. 4th dose) at 4 months, in line with the timing for the general population.

Pfizer and Moderna are the preferred brands for booster doses for all people, including in pregnancy, regardless of the brand used initially.

Booster doses have been shown to be safe and effective in non-pregnant adults but have not yet been studied in those who are pregnant. Speak to your health professional about the benefits of a booster dose and if it is right for you.

More information about boosters is available here: www.health.gov.au/resources/publications/atagi-recommendations-on-the-use-of-a-booster-dose-of-covid-19-vaccine.

Why have the recommendations for COVID-19 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.

Vaccine preference recommendations

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

- Research has shown that Pfizer and Moderna are safe in pregnancy and during breastfeeding. This research has not yet been carried out for AstraZeneca.
- Both Pfizer and Moderna have a very rare risk of heart inflammation (myocarditis or pericarditis). In some countries, myocarditis and pericarditis have been reported more commonly after Moderna than after Pfizer. Most people who have had these conditions after their vaccine have recovered fully. The benefits of vaccination outweigh this very rare risk and vaccination with either Pfizer or Moderna is still recommended for pregnant women.
- 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, such as in outbreak settings. There are no known safety concerns associated with AstraZeneca that are specific to pregnancy, breastfeeding or planning pregnancy.

Pfizer and Moderna are registered for use in people aged 12 years and older. AstraZeneca is registered for use in people aged 18 years 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 have Pfizer, Moderna or AstraZeneca for your second dose, although Pfizer or Moderna are preferred.

While it is generally recommended that the same vaccine brand is used for both doses, Pfizer or Moderna are 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.

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

Yes, accumulated real-world evidence from other countries has shown that mRNA vaccines 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. [5] 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.[6–8]

This study also reported the outcomes for 827 completed pregnancies. No safety concerns were identified 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 as that of 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 is still limited data available on the safety of viral vector vaccines (such as AstraZeneca) in pregnancy.

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.

What are the possible harms if I get vaccinated 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 with 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. There is the possibility that 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 if I have 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.

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 reliable data on the safety of mRNA vaccines in pregnancy, it is recommended that you 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 other vaccines?

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

COVID-19 vaccines can also be co-administered with other vaccines if required. But there is limited data on using COVID-19 vaccines at the same time as other vaccines.

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 recommendations if I am breastfeeding?

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

Are Pfizer and Moderna safe if I am breastfeeding?

Yes, these vaccines are considered safe for those breastfeeding and their babies. 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 this.

What are the recommendations if I am 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 are not available, you can consider having AstraZeneca if the benefits outweigh the potential risks for you.

If I am breastfeeding can I have AstraZeneca?

If Pfizer or Moderna are not available, you can consider having AstraZeneca after talking to your healthcare provider about the benefits and potential rare risks. It is not a live vaccine and cannot give your baby COVID-19.

More information

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

- Joint RANZCOG and ATAGI statement:

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

- Information about the Pfizer vaccine:

  www.health.gov.au/resources/publications/covid-19-vaccination-information-on-comirnaty-pfizer-covid-19-vaccine

- Information about the Moderna vaccine:

  www.health.gov.au/resources/publications/covid-19-vaccination-information-on-spikevax-moderna-covid-19-vaccine

- Preparing for COVID-19 vaccination:

  www.health.gov.au/resources/publications/covid-19-vaccination-preparing-for-covid-19-vaccination

- After your Pfizer vaccine:

  www.health.gov.au/resources/publications/covid-19-vaccination-after-your-comirnaty-pfizer-vaccine

- After your Moderna vaccine:

  www.health.gov.au/resources/publications/covid-19-vaccination-after-your-spikevax-moderna-vaccine

- Information about boosters:

  www.health.gov.au/resources/publications/atagi-recommendations-on-the-use-of-a-booster-dose-of-covid-19-vaccine

  https://www.health.gov.au/news/australian-technical-advisory-group-on-immunisation-atagi-recommendations-on-the-use-of-spikevax-moderna-as-a-covid-19-booster-vaccine

- 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

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