





These questions and answers (Q&As) are based on the most recent interim recommendations from the WHO Strategic Advisory Group of Experts on Immunization (SAGE) for COVID-19 vaccines that have been approved by WHO under Emergency Use Listing (EUL)^a as of 15 February 2022:

- Pfizer–BioNTech BNT162b2
- Moderna mRNA-1273
- AstraZeneca AZD1222 Vaxzevria[™], SII COVISHIELD[™] ChAdOx1-S [recombinant]
- Janssen Ad26.COV2.S
- Sinopharm BIBP
- Sinovac–CoronaVac
- Bharat Biotech BBV152 COVAXIN[®]
- Novavax NVX-Co2373

The Q&As are intended to provide answers to health providers and the public on COVID-19 vaccination during pregnancy. Q&As related to COVID-19 vaccines and breastfeeding can be found at the following link: FREQUENTLY ASKED QUESTIONS: COVID-19 vaccines and breastfeeding based on WHO interim recommendations.

This document uses the term 'pregnant women'. Although the majority of people who are or can get pregnant are cisgender women, who were born and identify as female, these Q&As are also relevant to the experiences of transgender men and other gender diverse people who may have the capacity to become pregnant.

1. Can pregnant women receive COVID-19 vaccines?

Yes. Pregnant women can receive COVID-19 vaccines. COVID-19 vaccines offer strong protection against severe illness from COVID-19. If not already vaccinated, **pregnant women should have access to WHO EUL-approved vaccines**, because COVID-19 during pregnancy puts them at higher risk of becoming severely ill and of giving birth to preterm babies. Increasing evidence on the safety and effectiveness of COVID-19 vaccination during pregnancy suggests that **the benefits of vaccination during pregnancy outweigh potential risks** whenever there is ongoing or anticipated community transmission of the virus. COVID-19 vaccination before or during pregnancy is especially important in settings with moderate to high community transmission^b or for women at higher individual risk of exposure or severe illness.

WHO SAGE interim recommendations	Pfizer– BioNTech BNT162b2	Moderna mRNA-1273	AstraZeneca AZD1222	Janssen Ad26. COV2.S	Sinopharm BIBP	Sinovac– CoronaVac	Bharat Biotech BBV152	Novavax NVX-Co2373
Can pregnant women receive the vaccine?	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	×

*Because of the limited experience with the MatrixMTM adjuvant of the Novavax NVX-Co2373 vaccine in pregnancy, the benefit-risk assessment for this vaccine includes considering whether any other WHO EUL COVID-19 vaccine with a more established safety record in pregnancy is locally available.

^a https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines.

^b World Health Organization. 2021. Considerations for implementing and adjusting public health and social measures in the context of COVID-19: interim guidance, 14 June 2021. https://apps.who.int/iris/handle/10665/341811.

2. How does COVID-19 affect pregnant women and their babies?

Numerous studies indicate that pregnant women with COVID-19 are more likely to develop severe illness compared with nonpregnant women (1, 2). This means that pregnant women with COVID-19 are more likely to require hospitalization, intensive care and invasive ventilation to help with breathing. In addition, compared with pregnant women without COVID-19, pregnant women with COVID-19 have an increased risk of preterm birth and of having babies that need neonatal intensive care. They might also have an increased risk of stillbirth and maternal death (1–3).

Although the greater risk for adverse outcomes from COVID-19 applies to all pregnant women, for some women the risk may be even higher. Pregnant women who are older (aged 35 years and above), are overweight (body mass index >30), or have a health condition such as diabetes or hypertension may be at even higher risk of serious outcomes from COVID-19.

3. Are COVID-19 vaccines during pregnancy effective?

COVID-19 vaccines have been found to be highly effective in preventing severe illness, hospitalization and death from COVID-19. Based on experience with other vaccines used during pregnancy, all of the WHO EUL-approved COVID-19 vaccines are expected to work as well in pregnant women as in nonpregnant people. Initial vaccine effectiveness studies in countries that have already vaccinated large numbers of pregnant women, primarily with mRNA vaccines, have shown high effectiveness in pregnant women, similar to effectiveness in nonpregnant people (4).

In addition, studies have shown that pregnant women who get COVID-19 vaccines develop antibodies that are present in babies' umbilical cord blood (5). This suggests that babies may receive protective benefits from the vaccine, in addition to the benefits for pregnant women.

4. What is known about the safety of COVID-19 vaccines during pregnancy?

Although pregnant women were not included in the initial clinical trials of COVID-19 vaccines, evidence on the safety of COVID-19 vaccination during pregnancy has been expanding. Three types of evidence support the safety of COVID-19 vaccines during pregnancy:

Monitoring of pregnant women who have received the vaccine

In several countries where COVID-19 vaccines are being given during pregnancy in large numbers, pregnant women are being monitored and evaluated for any safety issues. No pregnancy-specific safety concerns have been identified. For example:

- In the United States (US), as of February 2022 over 198,000 pregnant women have been monitored after receiving COVID-19 vaccines. Most of these women received mRNA vaccines (Pfizer–BioNTech BNT162b2 and Moderna mRNA-1273). Published studies from this monitoring system and other US vaccine safety-related databases have not found any adverse pregnancy-related outcomes associated with vaccination:
 - Overall maternal, pregnancy and birth outcomes (for example, preterm birth, stillbirth) in vaccinated women are similar to reported background rates among all pregnant women (6); and
 - Women vaccinated in early pregnancy have the same risk of miscarriage as women who were not vaccinated in early pregnancy (7, 8).
- In the United Kingdom (UK), over 100,000 pregnant women have received COVID-19 vaccines as of February 2022. The majority received mRNA vaccines, but approximately 10% received AstraZeneca AZD1222. An analysis of national data found similar rates of maternal and birth outcomes in vaccinated and unvaccinated pregnant women (9).^c

^c Thrombosis with thrombocytopenia syndrome (TTS) has been identified as a rare adverse event following immunization (AEFI) with the adenovirus-vectored vaccines AstraZeneca AZD1222 and Janssen Ad26.COV2.S. However, to date, current evidence does not suggest that pregnant women are at any greater risk of TTS than nonpregnant women. https://media.tghn.org/medialibrary/2021/09/COVAX_FAQ_on_TTS_15Sep2021.pdf

- In Brazil, as of February 2022 over 1 million women have been vaccinated during pregnancy. The majority received Pfizer–BioNTech BNT162b2, but over 296,000 received the inactivated vaccine Sinovac– CoronaVac, and over 60,000 received AstraZeneca AZD1222 (10). To date, no pregnancy-specific safety concerns have been identified.^c
- In India, over 120,000 pregnant women have received Bharat Biotech BBV152 as of October 2021, and only minor adverse events have been reported. However, detailed data on birth and neonatal outcomes have not yet been collected (*11*).

Animal studies

Specialized animal studies, known as developmental and reproductive toxicology (DART) studies, have been conducted for all the COVID-19 vaccines that have WHO interim recommendations. These studies did not show any harmful effects of vaccination in pregnant animals and their babies.

How the vaccines work

None of the COVID-19 vaccines contain the live virus that causes COVID-19. This means that the vaccines cannot cause infection in either pregnant women or their babies. In addition, for several COVID-19 vaccines, the vaccine components or platforms have been used safely in other vaccines given during pregnancy (12). For example:

- The viral vectors in the AstraZeneca AZD1222 and Janssen Ad26.COV2.S vaccines have been used in vaccines given to pregnant women in HIV and Ebola vaccine trials and in Ebola vaccine deployment programmes, and no significant safety concerns have been observed.
- The Sinopharm BIBP and Sinovac–CoronaVac vaccines are inactivated vaccines using an adjuvant that is routinely used in many other vaccines (for example, hepatitis B and tetanus vaccines) with a documented favourable safety profile in pregnant women.

Clinical trials in pregnant women are now underway or planned for several COVID-19 vaccines, and monitoring of women who received vaccines during pregnancy, and their babies, is ongoing.

5. Can women who are trying to become pregnant receive COVID-19 vaccines?

Yes. Getting vaccinated beforehand is an important way for women to protect themselves and their babies from COVID-19 during pregnancy. People who are trying to conceive can receive COVID-19 vaccines. A growing body of evidence has not identified any adverse effects of COVID-19 vaccines on fertility or the ability to become pregnant. In clinical trials of COVID-19 vaccines, and in a large prospective study of couples trying to conceive, rates of becoming pregnant were the same for those receiving COVID-19 vaccines and those not receiving the vaccines (13,14).

WHO does not recommend delaying pregnancy or terminating pregnancy because of COVID-19 vaccination, and no pregnancy testing is needed prior to vaccination.

Thrombosis with thrombocytopenia syndrome (TTS) has been identified as a rare adverse event following immunization (AEFI) with the adenovirusvectored vaccines AstraZeneca AZD1222 and Janssen Ad26.COV2.S. However, to date, current evidence does not suggest that pregnant women are at any greater risk of TTS than nonpregnant women. https://media.tghn.org/medialibrary/2021/09/COVAX_FAQ_on_TTS_15Sep2021.pdf

6. What do pregnant women and those planning to become pregnant need to know about COVID-19 vaccination?

Given the substantial risks from COVID-19 during pregnancy, it is critical to ensure pregnant women, and those planning to become pregnant, have access to WHO EUL-approved COVID-19 vaccines as soon as available. This will help protect their health and that of their babies. If pregnant women are not already vaccinated, current evidence suggests that the benefits of COVID-19 vaccination during pregnancy outweigh any potential risks whenever there is ongoing or anticipated community transmission of the virus.^d

Pregnant women and those planning to become pregnant should be informed about the risks of COVID-19 during pregnancy, the benefits of vaccination, the available safety data and factors that may make vaccination particularly important:

- **COVID-19 can have severe consequences in pregnancy:** Evidence indicates that pregnant women with COVID-19 are at increased risk of severe illness, of giving birth to preterm babies, and potentially of other adverse pregnancy outcomes such as stillbirth.
- **COVID-19 vaccines are highly effective:** COVID-19 vaccines provide strong protection against severe illness and deaths from COVID-19. Pregnant women are likely to receive the same level of protection from the vaccines as nonpregnant people.
- Safety data in pregnancy are increasing and are reassuring: Evidence on the safety of COVID-19 vaccines during pregnancy has been growing. To date, animal studies, monitoring of pregnant women who have received the vaccines, and experience using vaccines with similar components have not identified any pregnancy-specific safety concerns.
- Some factors make COVID-19 vaccination before or during pregnancy particularly important: The risk of COVID-19 increases in settings with more transmission of the virus. Even in areas with low transmission, certain individuals may still be at high risk of exposure, such as healthcare workers. Pregnant women who are 35 years of age or older, are overweight, or have an underlying health condition may be at even higher risk of serious outcomes if they acquire COVID-19.



Updates

This guidance will be periodically updated as new evidence on COVID-19 vaccines and pregnancy emerges, additional vaccines are approved and new questions arise. Questions and Answers: COVID-19 vaccines and pregnancy | 15 February 2022

^d Because of the limited experience with the MatrixMTM adjuvant of Novavax NVX-Co2373 in pregnancy, WHO recommends the use of NVX-CoV2373 vaccine in pregnant women if the benefits of vaccination to the pregnant woman outweigh the potential risks, for example, if there is elevated community transmission of infection and no other WHO EUL COVID-19 vaccine with a more established safety record in pregnancy is locally available.

- 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 [3 September 2020] ; updated 10 March 2021.
- 2. Wei SQ, Bilodeau-Bertrand M, Liu S, et al. The impact of COVID-19 on pregnancy outcomes: a systematic review and metaanalysis. CMAJ. 2021;193(16):E540–E48. doi:10.1503/cmaj.202604 [21 March 2021].
- Villar J, Ariff S, Gunier RB, et al. Maternal and neonatal morbidity and mortality among pregnant women with and without COVID-19 infection: The INTERCOVID multinational cohort study. JAMA Pediatr. 2021;175(8):817–26. doi:10.1001/ jamapediatrics.2021.1050 [23 April 2021].
- 4. Dagan N, Barda N, Biron-Shental T, et al. Effectiveness of the BNT162b2 mRNA COVID-19 vaccine in pregnancy. Nat Med. 2021;27(10):1693–95. doi:10.1038/s41591–021–01490–8 [OnlineFirst: 9 September 2021].
- 5. Fu W, Sivajohan B, McClymont E, et al. Systematic review of the safety, immunogenicity, and effectiveness of COVID-19 vaccines in pregnant and lactating individuals and their infants. Int J Gynaecol Obstet. 2021. doi:10.1002/ijgo.14008 [5 November 2021].
- Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. N Engl J Med. 2021;384(24):2273–82. doi: 10.1056/NEJMoa2104983 [22 April 2021].
- 7. Kharbanda EO, Haapala J, DeSilva M, et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA. 2021;326(16):1629–31. doi:10.1001/jama.2021.15494 [9 September 2021].
- 8. Zauche LH, Wallace B, Smoots AN, et al. Receipt of mRNA Covid-19 vaccines and risk of spontaneous abortion. N Engl J Med. 2021;385(16):1533–35. doi:10.1056/NEJMc2113891 [9 September 2021].
- COVID-19 vaccine surveillance report week 6. London: UK Health Security Agency; 2022 (https://assets.publishing.service. gov.uk/government/uploads/system/uploads/attachment_data/file/1054071/vaccine-surveillance-report-week-6.pdf, 10 February 2022).
- 10. Observatório Obstétrico Brasileiro COVID-19 Vacinação; 2022 (https://observatorioobstetrico.shinyapps.io/vacinacaocovid19/), accessed 11 February 2022.
- 11. Interim recommendations for use of the Bharat Biotech BBV152 COVAXIN® vaccine against COVID-19. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-bbv152covaxin, 3 November 2021).
- 12. Ciapponi A, Bardach A, Mazzoni A, et al. Safety of components and platforms of COVID-19 vaccines considered for use in pregnancy: A rapid review. Vaccine. 2021;39(40):5891-908. doi:10.1101/2021.06.03.21258283 [6 June 2021].
- 13. Hillson K, Clemens SC, Madhi SA, et al. Fertility rates and birth outcomes after ChAdOx1 nCoV-19 (AZD1222) vaccination. Lancet. 2021;398(10312):1683-4. doi: 10.1016/S0140-6736(21)02282-0 [21 October 2021].
- 14. Wesselink AK, Hatch EE, Rothman KJ, et al. A prospective cohort study of COVID-19 vaccination, SARS-CoV-2 infection, and fertility. Am J Epidemiol. 2022. doi: 10.1093/aje/kwac011 [22 January 2022].