



The Hong Kong College of Obstetricians and Gynaecologists advice on COVID-19 vaccination in pregnant and lactating women (interim; updated on 6th May 2022)

Data shows that vaccines are effective in protecting people from serious illness from COVID-19. Pregnant women are at a higher risk of developing severe adverse outcomes following SARS-CoV-2 infection, when compared with the non-pregnant population. COVID-19 also increases the risk of preterm birth by 2-fold and the extended perinatal mortality by about 50%.

Women who are planning to conceive, are pregnant, or are breastfeeding should be vaccinated with COVID-19 vaccine as the rest of the population, unless contraindicated due to underlying medical reasons.

Our consensus has been further strengthened by a recent review of studies conducted by the European Medicines Agency, involving around 65,000 pregnancies at different stages. The review has not identified any sign of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects in the fetuses following mRNA COVID-19 vaccination. Studies have also shown that the COVID-19 vaccines are as effective at reducing the risk of hospitalization and deaths in pregnant women as they are in the non-pregnant population. The most common side effects of the vaccines in pregnant women also match those in the overall vaccinated population. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

In addition, based on Scottish population-level data on COVID-19 vaccination in pregnancy, partially vaccinated and fully vaccinated pregnant women have a significant reduction in risk of acquiring SARS-CoV-2 infection (unvaccinated 77.4% vs partially vaccinated 11.5% vs fully vaccinated 11.1%), SARS-CoV-2 associated hospitalization (unvaccinated 19.5% vs partially vaccinated 8.3% vs fully vaccinated 5.1%) and SARS-CoV-2 associated critical care admission (unvaccinated 2.7% vs partially vaccinated 0.2% vs fully vaccinated 0.2%). Additional benefits relate to the reduction of preterm birth rate (unvaccinated 16.6% vs vaccinated 8.2%) and extended perinatal mortality rate (unvaccinated 22.6 per 1,000 births vs vaccinated 4.3 per 1,000 births). Pregnant and lactating women should be encouraged to have at least one dose of the COVID-19 vaccine.

Recent studies of COVID-19 vaccination during pregnancy also suggested benefits for the infants. Transplacental transfer of SARS-CoV-2-specific antibodies was documented following maternal vaccination in pregnancy. Between 96-98% of cord blood and all breast milk samples were positive for SARS-CoV-2 specific antibodies. In one longitudinal study, 57% of the infants still had the antibodies at 6 months of age. Recent data from 20 pediatric hospitals in the US demonstrated that completion of a two-dose mRNA COVID-19 vaccination series during pregnancy was associated with reduced risk for COVID-19-associated hospitalization among infants aged <6 months (vaccine effectiveness 61%, 95% CI 31% to 78%). Hence, maternal vaccination during pregnancy might help protect the newborn.

The choice of vaccine

Currently, there are two kinds of vaccines available in Hong Kong, namely Comirnaty (BioNTech) and CoronaVac (Sinovac). Comirnaty (BioNTech) is an mRNA vaccine, while CoronaVac (Sinovac) is an inactivated SARS-CoV-2 vaccine. The mRNA vaccine has been widely used worldwide. Hence, published data in pregnant and lactating women in the medical literature are largely based on the mRNA vaccine. There is limited safety data in pregnancy published for CoronaVac (Sinovac). 'Pregnancy and lactation' was previously listed as contraindications for CoronaVac (Sinovac). However, in principle, inactivated whole virus vaccines are considered safe in pregnancy. The World Health Organization has endorsed its use in pregnant and lactating women in their interim recommendations on 5th January 2022. In February 2022, the CoronaVac (Sinovac) company removed 'Pregnancy and lactation' from its 'Contraindications' list. CoronaVac (Sinovac) use in pregnant and lactating women is now authorised by the Hong Kong Government. While the efficacy and safety data of CoronaVac (Sinovac) will likely accumulate following its use, Comirnaty (BioNTech) remains as the preferred choice of vaccine for pregnant and lactating women by the HKCOG, based on the available published data.

Booster dose

Currently, the Royal College of Obstetricians and Gynaecologists (RCOG) in the United Kingdom and the Department of Health in Hong Kong all recommend that pregnant and lactating women receive a booster dose of COVID-19 vaccine 3 months after the second dose of their initial COVID-19 vaccine series.

Such recommendations are based on evidence that neutralizing antibodies against SARS-CoV-2 wane over time after the primary two-dose series. Further, the effectiveness of the COVID-19 vaccines in preventing disease and reducing viral loads of breakthrough infections has decreased, concomitantly with the rise of the Delta variant of SARS-CoV-2. Evidence on mRNA-based COVID-19 vaccines in non-pregnant individuals has demonstrated that a booster dose increases the antibody titers and restores neutralization. The booster dose has also been shown to effectively reduce the risks of symptomatic infection and severe complications including mortality. Booster vaccine efficacy is

consistent irrespective of age, sex, race, ethnicity, and comorbid conditions. The booster doses have adverse events similar to those seen in previous studies with no safety signal identified. These include injection site reactions, fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain and joint pain.

The committee acknowledges that there is so far limited evidence on the efficacy and safety of the booster dose of COVID-19 vaccine in pregnant and lactating women. However, given the established efficacy and safety profile of the primary two-dose series, the efficacy and safety data of the booster dose is therefore expected to be comparable to that observed in non-pregnant women of similar age. We therefore support the recommendation of the Centre of Health Protection, Department of Health on the use of booster dose in pregnant and lactating women.

Pregnant women may wish to discuss the risks and benefits of vaccination with their clinician, including the latest evidence on its safety and which vaccines they should receive. The HKCOG COVID-19 Vaccination Committee will continue to closely monitor the evidence on COVID-19 vaccination in pregnancy and will update its advice as required.

FAQ

1. Q: Do I need to take a pregnancy test before receiving the vaccine?
A: There is no need to take a pregnancy test before receiving the vaccine. However, if you wish to avoid being pregnant while receiving the full course of vaccination then you should consider appropriate contraception. If you are unsure whether you are pregnant, you may wish to wait for your period before receiving the first dose of the vaccine.
2. Q: I am trying to become pregnant, can I be vaccinated?
A: You are recommended to complete the course of vaccination (2 doses received) before you become pregnant. This will reduce your risk of contracting the virus during pregnancy and therefore severe COVID-19-associated complications such as preterm birth.
3. Q: What do I do if I become pregnant after receiving one dose of the vaccine?
A: You should have the second dose after the recommended interval as scheduled. Similarly, we also recommend you to have the booster dose as scheduled during the pregnancy.
4. Q: Does COVID-19 vaccine affects fertility?
A: There is no evidence to suggest that COVID-19 vaccines will affect fertility.
5. Q: After completing the course of vaccination, do I need to wait for a few months before becoming pregnant?
A: No, there is no need to wait to try to become pregnant.
6. Q: I am pregnant, should I be vaccinated against SARS-CoV-2?
A: Yes, you are advised to be vaccinated against SARS-CoV-2 at the same time as the rest of the population.
7. Q: Which vaccine is recommended for pregnant women?
A: Both mRNA vaccine (Comirnaty/BioNTech) and inactivated SARS-CoV-2 vaccine (CoronaVac /Sinovac) are available for use. So far the published data on efficacy and safety for pregnant and lactating women in the medical literature are from the mRNA vaccine but not the inactivated vaccine. Hence, mRNA vaccine is preferred by the HKCOG.
8. Q: Do I need extra medical care if I get vaccinated during pregnancy?
A: You will be given one day sick leave or attendance for the day you receive the vaccine. If you feel unwell following vaccination, you are advised to seek medical attention.
9. Q: Do I need to tell the vaccination center or the attending nurse/ doctor that I am pregnant before the vaccination?
A: Yes.

10. Q: When should I get vaccinated during pregnancy?
A: You are advised to be vaccinated at the earliest opportunity. As COVID-19 infection in pregnancy is more likely to be associated with severe symptoms and adverse outcome in the later part of pregnancy, vaccination during the first or second trimester is advisable. However, if you are already in your third trimester, you can still be vaccinated to minimise your risk of severe COVID-19.
11. Q: Does COVID-19 vaccine increase the risk of miscarriage?
A: There is no evidence to suggest that COVID-19 vaccine increases the risk of miscarriage. If you are concerned about the baby's development during the first 12 weeks of pregnancy, you may wish to be vaccinated after 12 weeks' gestation.
12. Q: What are the side effects from the vaccine?
A: Non-pregnant specific side effects from the vaccine are common, such as injection site reactions, headache, muscle pain, fever, chills, fatigue and joint pain. You are advised to seek medical attention if you feel unwell following vaccination in order to rule out other causes of your symptoms.
13. Q: Do I need to stop breastfeeding in order to be vaccinated?
A: There is no need to stop breastfeeding while being vaccinated.
14. Q: Are there any contraindications with maternal Pertussis vaccination or flu vaccination?
A: COVID-19 vaccines can be administered at the same time as other vaccines, including the Pertussis (DTaP) and flu vaccination.
15. Q: Can I receive a booster dose of the COVID-19 vaccine if I am pregnant?
A: If you have completed your initial COVID-19 vaccine series (either mRNA or inactivated vaccine) and did not have any serious side effects, you should get a booster dose of vaccine at the recommended interval.

References

European Medicines Agency. COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy. <https://www.ema.europa.eu/en/news/covid-19-latest-safety-data-provide-reassurance-about-use-mrna-vaccines-during-pregnancy>.

Accessed 19 January 2022.

Kachikis A, Englund JA, Singleton M, Covelli I, Drake AL, Eckert LO. Short-term Reactions Among Pregnant and Lactating Individuals in the First Wave of the COVID-19 Vaccine Rollout. *JAMA Network Open*. 2021;4(8):e2121310.

Zauche LH, Wallace B, Smoots AN, et al. Receipt of mRNA Covid-19 vaccines and risk of spontaneous abortion. *N Engl J Med* 2021;385:1533-1535.

Magnus MC, Gjessing HK, Eide HN, Wilcox AJ, Fell DB, Håberg SE. Covid-19 Vaccination during Pregnancy and First-Trimester Miscarriage. *N Engl J Med*. 2021 Nov 18;385(21):2008-2010.

Kharbanda EO, Haapala J, DeSilva M, et al. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. *JAMA*. 2021 Oct 26;326(16):1629-1631.

Wainstock T, Yoles I, Sergienko R, Sheiner E. Prenatal maternal COVID-19 vaccination and pregnancy outcomes. *Vaccine*. 2021;39(41):6037-6040.

Bookstein Peretz S, Regev N, Novick L, et al. Short-term outcome of pregnant women vaccinated with BNT162b2 mRNA COVID-19 vaccine. *Ultrasound Obstet Gynecol*. 2021 Sep;58(3):450-456.

Rottenstreich M, Sela HY, Rotem R, Kadish E, Wiener-Well Y, Grisaru-Granovsky S. Covid-19 vaccination during the third trimester of pregnancy: rate of vaccination and maternal and neonatal outcomes, a multicentre retrospective cohort study. *BJOG*. 2022 Jan;129(2):248-255.

Blakeway H, Prasad S, Kalafat E, et al. COVID-19 vaccination during pregnancy: coverage and safety. *Am J Obstet Gynecol*. 2021 Aug 10:S0002-9378(21)00873-5. UK Health Security Agency. COVID-19 vaccine surveillance report. Week 47. 25 November 2021.

Theiler RN, Wick M, Mehta R, Weaver AL, Virk A, Swift M. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. *Am J Obstet Gynecol MFM*. 2021;3(6):100467.

Trostle ME, Limaye MA, Avtushka V, Lighter JL, Penfield CA, Roman AS. COVID-19 vaccination in pregnancy: early experience from a single institution. *Am J Obstet Gynecol MFM*. 2021;3(6):100464.

Shimabukuro TT, Kim SY, Myers TR, et al. CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*. 2021 Jun 17;384(24):2273-2282.

Lipkind HS, Vazquez-Benitez G, DeSilva M, et al. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth - Eight Integrated Health Care Organizations, United States, December 15, 2020-July 22, 2021. *MMWR Morb Mortal Wkly Rep*. 2022 Jan 7;71(1):26-30.

ACIP Presentation Slides: Sept 22-23, 2021 Meeting. COVID-19 vaccine safety in pregnancy: Updates from the v-safe COVID-19 vaccine. Sept 22, 2021.

Stock SJ, Carruthers J, Calvert C, Denny C, Donaghy J, Goulding A, Hopcroft LEM, Hopkins L, McLaughlin T, Pan J, Shi T, Taylor B, Agrawal U, Auyeung B, Katikireddi SV, McCowan C, Murray J, Simpson CR, Robertson C, Vasileiou E, Sheikh A, Wood R. SARS-CoV-2 infection and COVID-19 vaccination rates in pregnant women in Scotland. *Nat Med* 2022 Jan 13. doi: 10.1038/s41591-021-01666-2. Online ahead of print.

Arbel R, Hammerman A, Sergienko R, Friger M, Peretz A, Netzer D, Yaron S. BNT162b2 Vaccine Booster and Mortality Due to Covid-19. *New England Journal of Medicine* 2021 Vol. 385 Issue 26 Pages 2413-2420. DOI: 10.1056/NEJMoa2115624 <https://www.nejm.org/doi/full/10.1056/NEJMoa2115624>

Barda N, Dagan N, Cohen C, Hernán MA, Lipsitch M, Kohane IS, Reis BY, Balicer RD. Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study. *The Lancet* 2021 Vol. 398 Issue 10316 Pages 2093-2100 DOI: 10.1016/S0140-6736(21)02249-2 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02249-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02249-2/fulltext)

Bar-On YM, Goldberg Y, Mandel M, Bodenheimer O, Freedman L, Kalkstein N, Mizrahi B, Alroy-Preis S, Ash N, Milo R, Huppert A. Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel. *New England Journal of Medicine* 2021 Vol. 385 Issue 15 Pages 1393-1400 Accession Number: 34525275 DOI:10.1056/NEJMoa2114255 <https://www.nejm.org/doi/full/10.1056/NEJMoa2114255>

Bar-On YM, Goldberg Y, Mandel M, Bodenheimer O, Freedman L, Alroy-Preis S, Ash N, Huppert A, Milo R. Protection against Covid-19 by BNT162b2 Booster across Age Groups. *New England Journal of Medicine* 2021 Vol. 385 Issue 26 Pages 2421-2430 DOI: 10.1056/NEJMoa2115926 <https://www.nejm.org/doi/full/10.1056/NEJMoa2115926>

Choi A, Koch M, Wu K, Chu L, Ma L, Hill A, Nunna N, Huang W, Oestreicher J, Colpitts T, Bennett H, Legault H, Paila Y, Nestorova B, Ding B, Montefiori D, Pajon R, Miller JM, Leav B, Carfi A, McPhee R, Edwards DK. Safety and immunogenicity of SARS-CoV-2 variant mRNA vaccine boosters in healthy adults: an interim analysis. *Nature Medicine* 2021 Vol. 27 Issue 11 Pages 2025-2031 DOI: 10.1038/s41591-021-01527-y <https://www.nature.com/articles/s41591-021-01527-y>

Falsey AR, Frenck RW, Walsh EE, Kitchin N, Absalon J, Gurtman A, Lockhart S, Bailey R, Swanson KA, Xu X, Koury K, Kalina W, Cooper D, Zou J, Xie X, Xia H, Türeci O, Lagkadinou E, Tompkins KR, Shi PY, Jansen KU, Şahin U, Dormitzer PR, Gruber WC. SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3. *New England Journal of Medicine* 2021 Vol. 385 Issue 17 Pages 1627-1629 DOI: 10.1056/NEJMc2113468 <https://www.nejm.org/doi/full/10.1056/NEJMc2113468>

Levine-Tiefenbrun M, Yelin I, Alapi H, Katz R, Herzal E, Kuint J, Chodick G, Gazit S, Patalon T, Kishony R. Viral loads of Delta-variant SARS-CoV-2 breakthrough infections after vaccination and booster with BNT162b2. *Nat Med* 2021 Vol. 27 Issue 12 Pages 2108-2110 Accession Number: 34728830 DOI: 10.1038/s41591-021-01575-4 <https://www.nature.com/articles/s41591-021-01575-4>

Perez JL. Efficacy & Safety of BNT162b2 booster - C4591031 2 month interim analysis.
Corporate Authors(s) : Pfizer Ltd.
Conference Author(s) : United States. Advisory Committee on Immunization Practices. Meeting (2021 November 19 : Atlanta, GA)
Published Date : November 19, 2021
Series : ACIP meeting COVID-19 Vaccines
URL : <https://stacks.cdc.gov/view/cdc/111885>
<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf>
<https://clinicaltrials.gov/ct2/show/NCT04955626>

World Health Organisation. The Sinovac-CoronaVac Covid-19 vaccine- what you need to know. <https://www.who.int/news-room/feature-stories/detail/the-sinovac-covid-19-vaccine-what-you-need-to-know>

Nir O, Schwartz A, Toussia-Cohen S, et al. Maternal-neonatal transfer of SARS-CoV-2 immunoglobulin G antibodies among parturient women treated with BNT162b2 messenger RNA vaccine during pregnancy. *Am J Obstet Gynecol MFM* 2022;4:100492. PMID:34547533 <https://doi.org/10.1016/j.ajogmf.2021.100492>

Shook LL, Atyeo CG, Yonker LM, Fasano A, Gray KJ, Alter G, Edlow AG. Durability of Anti-Spike Antibodies in Infants after Maternal Covid-19 Vaccination or Natural Infection. *JAMA* 2022 Feb 7:e221206. doi: 10.1001/jama.2022.1206

Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19–Associated Hospitalization in Infants Aged <6 Months — 17 States, July 2021–January 2022
[https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e3.htm?s_cid=mm7107e3_x#:~:text=What%20is%20added%20by%20this,%3D%2031%25%20to%2078%25\).](https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e3.htm?s_cid=mm7107e3_x#:~:text=What%20is%20added%20by%20this,%3D%2031%25%20to%2078%25).)