

# The Hong Kong College of Obstetricians and Gynaecologists advice on COVID-19 vaccination in pregnant and lactating women (interim; updated on 21<sup>st</sup> February 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%.

Pregnant women should be offered the COVID-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group.

Women who are planning pregnancy, are in the immediate postpartum, or are breastfeeding should also be vaccinated with COVID-19 vaccine, 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 data from 20 pediatric hospitals in the US demonstrated that completion of a twodose 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 American College of Obstetricians and Gynecologists (ACOG) in the United States and the Department of Health in Hong Kong recommend that pregnant and lactating women receive a booster dose of mRNA COVID-19 vaccine at least 6 months following the completion of their initial COVID-19 vaccine series. The Royal College of Obstetricians and Gynaecologists (RCOG) in the United Kingdom recommends that such booster dose can be given 3 months after the second dose in pregnant and lactating women.

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 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.

- 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.
- 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 (3 weeks) 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.
- 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, based on age and clinical risk group.
- 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.
- 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.
- Q: Do I need to tell the vaccination center or the attending nurse/ doctor that I am pregnant before the vaccination? A: Yes.

## FAQ

- Q: When should I get vaccinated during pregnancy?
  A: You are advised to be vaccinated at the earliest opportunity. As symptomatic COVID-19 is associated with an increased risk of preterm birth, 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?A: COVID-19 vaccines are recommended not to be administered within 14 days of receipt of another vaccine. So DTaP vaccination should be deferred for 14 days after the administration of COVID-19 vaccines.
- 15. Q: Can I receive a booster dose of the COVID-19 vaccine if I am pregnant?A: If you completed your initial COVID-19 vaccine series (either mRNA or inactivated vaccine) about 6 months ago and did not have any serious side effects, you can get a booster dose of vaccine.

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Published Date : November 19, 2021

Series : ACIP meeting COVID-19 Vaccines

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