

Questions and Answers for pregnant or breastfeeding women and their doctors about COVID- 19 vaccination (information specific to the Pfizer/BioNTech vaccine Comirnaty®)

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Prepared by:



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ROYAL COLLEGE OF
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OF IRELAND**

**National Immunisation
Advisory Committee**

(NIAC)

Endorsed by:



**National
Women & Infants
Health Programme**

Questions and Answers for pregnant or breastfeeding women and their doctors about COVID- 19 vaccination

This information has been compiled by the Institute of Obstetricians and Gynaecologists in conjunction with the National Immunisation Advisory Committee at the Royal College of Physicians of Ireland and endorsed by the HSE National Women and Infants Health Programme.

The information contained within this document refers specifically to the Comirnaty® vaccine which is manufactured by Pfizer/BioNTech. If and when other vaccines are approved, we will update this document to include information and guidance on these additional vaccines.

Q. What are the risks to a pregnant woman from COVID-19 infection?

A. Pregnant women are at a similar risk to non-pregnant women of contracting COVID-19. Most pregnant women who are infected with COVID-19 will only experience mild to moderate symptoms and the risk of passing COVID-19 onto the baby is low. However, pregnant women with symptomatic COVID-19 may be more likely to be admitted to hospital, to need care in an ICU, and to die when compared with non-pregnant women. There may be an increased rate of preterm birth and stillbirth among pregnant patients with COVID-19, whether or not they have symptoms. The published literature relates mainly to UK and US experience. We have seen a higher rate of hospitalisation and high dependency care in Ireland but thankfully no maternal death from COVID in 2020.

Q. What is the COVID-19 vaccine?

A. The COVID-19 vaccine has been demonstrated to be very effective in clinical trials. The vaccine is called Comirnaty® and it is manufactured by Pfizer/-BioNTech. It is an mRNA vaccine that does not contain the live virus. mRNA vaccine stimulates the body to produce some of the viral proteins. The body then produces antibodies against the virus. These antibodies block the virus from entering the cells and can prevent disease. You cannot get COVID-19 from the vaccine.

Q. Are pregnant women able to get the COVID-19 vaccine?

A. Yes. Pregnant women are not excluded from getting the COVID-19 vaccine. Neither the European Medicines Agency (EMA) nor the Food and Drugs Administration (FDA) list pregnancy as a contraindication. A pregnancy test prior to vaccination is not required. The risk from mRNA vaccines is thought to be very low due to the rapid breakdown of mRNA in the body.

Q. What is the advice for pregnant women in Ireland?

A. The National Immunisation Advisory Committee, a group of independent experts in Ireland, recommends that pregnant women who are at high risk of severe COVID-19 and pregnant healthcare workers should talk to their obstetrics care provider about having the COVID-19 vaccine. They should discuss their risk of getting COVID-19 in light of their particular circumstances. Based on this they can consider getting the vaccine balancing the small unknown risks related to the vaccine against the serious risks associated with COVID-19.

Q. What are the benefits of getting the COVID-19 vaccine?

A. COVID-19 vaccines reduce the risk of developing COVID-19 and may reduce the spread of infection. For pregnant women, this will reduce the chance of becoming severely unwell. It may also reduce the chance of pregnancy complications, such as preterm birth, which are associated with severe COVID-19 illness.

Q. What is the advice for pregnant women in other countries?

A. The advice is the same as in the UK and the US, pregnant women are offered COVID-19 vaccination if they are a healthcare worker, or if they are clinically extremely vulnerable. Women in this group include:

- Solid organ transplant recipients
- Those with severe respiratory conditions including cystic fibrosis and severe asthma
- Those with homozygous sickle cell disease
- Those receiving immunosuppression therapies sufficient to significantly increase risk of infection
- Those receiving dialysis or with chronic kidney disease (stage 5)
- Those with significant congenital or acquired heart disease

Other risk factors, which may have a greater impact when combined include ethnicity, those with diabetes, obesity or those who are older.

Pregnant women are advised to discuss their circumstances with their obstetrics care provider.

Q. Is there a specific time in pregnancy to get the COVID-19 vaccine?

A. The Immunisation Guidelines for Ireland recommend two doses of the Comirnaty[®] vaccine at least 21 days apart. For pregnant women the first dose should be at or after 14 weeks (usually the pregnancy and dates have been confirmed) and the second dose ideally by 33 completed weeks. If the second dose is not given by 33 completed weeks, it should be delayed until after delivery. This will avoid confusion that may arise if a fever develops following the second dose.

Q. What are the potential side effects?

A. Common side effects include fatigue, headache, sore arm, fever and muscle or joint pains. These symptoms are more common after the second dose. Fever after vaccines usually starts within 24 hours after vaccination, is generally mild (39°C) and usually resolves within 2 days without treatment. Fever after vaccination can be managed with paracetamol. Do not take ibuprofen if pregnant. Remember if you are unwell after getting a vaccine, it could be for some other reason - don't assume it's the vaccine and seek medical advice if needed.

Q. Are there risks to the fetus from vaccinating the mother?

A. There is limited data on the safety of COVID-19 vaccines in pregnancy and breastfeeding. The COVID-19 vaccines are not expected to have any effect on the fetus. These are not live vaccines, so cannot infect either mother or fetus. The mRNA is rapidly broken down in the body. It cannot become part of your or your baby's DNA.

Q. When will we have more evidence about safety of COVID-19 vaccines in pregnancy?

A. Pregnant women were not intentionally recruited to the initial trials. Trials of the COVID-19 vaccine are now taking place in pregnant women, and results are expected in the next few months. Also, many pregnant and breastfeeding women have chosen to get the vaccine in other countries, so we will have a lot more information over the coming months.

Q. Can other vaccines, such as pertussis (whooping cough), be given at the same time as a COVID-19 vaccine?

A. There should be an interval of 14 days between COVID-19 vaccine and another vaccine, until more information is available.

Q. Can I breastfeed if I got the vaccine while I was pregnant?

A. Yes. If you were vaccinated while pregnant, antibodies against COVID-19 disease may pass into the breastmilk and give some protection to your baby.

Q. Can I get the vaccine if I am breastfeeding, and if so can I continue to breastfeed?

A. Yes. There is little data on breastfeeding but no theoretical risk from these vaccines. If remnants get into breastmilk they get digested in the baby's stomach.

Q. Do I need to leave any interval before getting pregnant?

A. You do not need to leave any interval after having the COVID-19 vaccine and becoming pregnant. If you become pregnant following the first dose, you should wait until 14 weeks or after to get the second dose.

Q. Does COVID-19 vaccine have any impact on fertility?

A. There is no evidence the vaccine affects fertility. COVID-19 mRNA vaccines cannot become part of your or your baby's DNA.

Q. Do I need to leave any interval before starting fertility treatment such as IVF?

A. You do not need to leave any interval after having the COVID-19 vaccine and starting to try to conceive or to have fertility treatment such as IVF. However, you may wish to defer it until you have completed the full course, in view of the risk of side effects such as fever in the 48 hours following the vaccine, especially the second dose.

Where to find more information on:

COVID-19

<https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/>

COVID-19 vaccines

HSE

<https://www2.hse.ie/screening-and-vaccinations/covid-19-vaccine/>

National Immunisation Office

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>