

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

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

There is a lot of evidence regarding the potentially serious effects of COVID-19 on pregnant women and the safety of COVID-19 vaccines in pregnancy and during breastfeeding. This Q&A document has been updated to reflect current evidence and recommendations in Ireland.

What are the risks to pregnant women from COVID-19 infection?

Pregnant women (including adolescents) with COVID-19 are at significantly higher risk of severe illness compared with non-pregnant women. This is especially true for women in the third trimester.

Pregnant women who get COVID-19 are more likely to be admitted to hospital, to need care in an intensive care unit (ICU), and to die from COVID-19 than non-pregnant women. During the COVID-19 pandemic, there was a significant increase in the number of pregnant women admitted to hospital and the ICU with COVID-19. In Ireland, between March 2020 and August 2021, of the pregnant women admitted to ICU with severe COVID-19 none had been vaccinated.

If a woman is admitted to ICU, her baby may be affected by the medications she requires in ICU. There is evidence to suggest that babies born to mothers who were infected with COVID-19 are more likely to be admitted to the neonatal unit after birth.

Pregnant women with COVID-19 infection are at higher risk of stillbirth than those who are not infected with COVID-19.

While COVID-19 does not appear to cross the placenta or directly infect the infant in the womb, COVID-19 infection in the mother may result in preterm delivery due to deterioration in the mother's health or to concerns about the baby's wellbeing.

COVID-19 vaccines offer considerable protection from hospitalisation and severe COVID-19 infection.

Are some pregnant women at higher risk of becoming seriously ill from COVID-19?

Women in the third trimester (28 weeks or more) are more likely to become seriously ill if they get COVID-19 than those in early pregnancy.

Pregnant women from Black, Asian and ethnic minority backgrounds are more likely than other pregnant women to be admitted to hospital with COVID-19.

Serious COVID-19 illness is more likely to occur in pregnant women who:

- are aged 35 years and older
- are obese (have a BMI of 30 or more)
- have an additional problem, such as high blood pressure or diabetes

However, pregnancy alone is a risk factor for severe COVID-19. In other words, healthy pregnant women with none of the above risk factors have a significantly increased risk of severe COVID-19.

What is placentitis?

Placentitis is an inflammation of the afterbirth (the placenta). This is a rare condition that has caused fetal distress and stillbirth in a number of women who had COVID-19. It occurs within 7- 21 days of the infection. It has affected women in the second half of pregnancy. We are not sure why some pregnant women have suffered from this. Anyone who has a COVID-19 diagnosis in pregnancy should inform their hospital to arrange follow up. Mothers should monitor fetal movements and go to their maternity unit if they notice a significant reduction in movement.

Should pregnant women get a COVID-19 vaccine?

Yes. The National Immunisation Advisory Committee (NIAC), a group of independent experts in Ireland, recommends that pregnant women should be offered one dose of an mRNA COVID-19 vaccine once in pregnancy. These recommendations have also been made by other reputable organisations, including the Institute of Obstetricians and Gynaecologists in Ireland, the European Network of Teratology Information Services (ENTIS), the European Medicines Agency (EMA), the Royal College of Obstetricians and Gynaecologists and Royal College of Midwives in the UK, and the American College of Obstetricians and Gynecologists in the US.

There is a lot of information about the potentially serious impact of COVID-19 on pregnant women and their babies. There is extensive information which shows mRNA COVID-19 vaccines are safe in pregnancy. We know that the protection that the vaccine offers both mother and baby outweigh any risk of getting the vaccine in pregnancy.

Hundreds of thousands of women worldwide have safely received COVID-19 vaccines in pregnancy. No studies have found any increased risk of birth defects, miscarriage, growth problems for the baby, preterm birth or stillbirth from COVID-19 vaccines.

Why should pregnant women get vaccinated against COVID-19?

COVID-19 infection can be dangerous for pregnant women, especially in the third trimester (28 weeks or more). COVID-19 vaccines reduce the risk of developing moderate or severe COVID-19 and reduce the risk of death from COVID-19. For pregnant women, getting the vaccine will reduce the chance of becoming severely unwell. In the UK between February and September 2021 more than 98% of women who required hospital admission with symptomatic COVID-19 in pregnancy were unvaccinated. Of 235 pregnant women admitted to intensive care, only three (1.3%) had received a single dose of vaccine, and none had received both doses.

COVID-19 vaccination may reduce the chance of pregnancy complications, such as preterm birth, caesarean delivery and stillbirth, which are associated with COVID-19 infection.

Getting a COVID-19 vaccine is the best way to protect mother and baby from COVID-19. Choosing not to get the vaccine could increase risks of harm for both mother and baby

What COVID-19 vaccines are recommended for pregnant women?

mRNA vaccines are the recommended COVID-19 vaccines for pregnant women. Both the original mRNA vaccine and the updated mRNA vaccines can be given in pregnancy.

mRNA vaccines that are available in Ireland for those aged 12 years and over include; **Comirnaty Original/ Omicron BA.4-5 bivalent** and **Comirnaty Omicron XBB.1.5** vaccine (manufactured by Pfizer/BioNTech).

COVID-19 vaccines cannot cause COVID-19 infection in anyone, including the mother or the baby. mRNA vaccines stimulate the body to produce antibodies against the virus. These antibodies block the virus from entering the cells and can prevent disease.

The adapted mRNA vaccines are recommended as booster vaccines in pregnancy. These vaccines have been adapted to target the more recent strains of COVID-19 and may offer better protection than the original mRNA vaccines.

Are there any other types of COVID-19 vaccines recommended in pregnancy?

There is another COVID-19 vaccine called **Nuvaxovid** which has recently been updated to Nuvaxovid XBB.1.5. The National Immunisation Advisory Committee (NIAC) has recommended that this vaccine may be given to a pregnant woman if she is not able to have or chooses not to have an mRNA vaccine.

While there are no known safety concerns associated with Nuvaxovid that are specific to pregnancy, breastfeeding or planning pregnancy, these vaccines have not yet been used in sufficient numbers of pregnant or breastfeeding women to detect rare events. mRNA vaccines have been used in greater numbers, providing more reassuring safety data for their use in pregnancy. Hence mRNA vaccines are the preferred type of vaccine for administration in pregnancy. However, in the rare circumstance that a pregnant woman is not able to have an mRNA vaccine, or if they choose not to receive an mRNA vaccine, Nuvaxovid XBB.1.5 may be used in pregnancy. A discussion with your healthcare provider may be helpful to decide if the benefits of vaccination with Nuvaxovid outweigh the potential risks.

What are the potential side effects of these vaccines?

Common side effects include fatigue, headache, sore arm, fever, and muscle and joint pains. There is no evidence that pregnant women experience more of these side effects than non-pregnant women. Fever after vaccines usually starts within 24 hours, is generally mild (<39°C) and usually resolves within two days without treatment. Fever can be managed with paracetamol. Ibuprofen and aspirin are not recommended during pregnancy. It is important to remember that these symptoms may not necessarily be caused by the vaccine; the woman may need to seek medical advice. Side effects of adapted mRNA COVID-19 vaccines are similar to those of the original mRNA vaccines.

Have COVID-19 vaccines been tested in pregnancy?

Since the roll out of COVID-19 vaccination programmes across the world, many pregnant women have received COVID-19 vaccines.

No unexpected pregnancy or infant outcomes have been observed. There has been no increased risk of congenital malformations or birth defects, miscarriage, growth problems in the baby, preterm birth, stillbirths or admission to the neonatal intensive care unit associated with COVID-19 vaccination.

Clinical trials assessing COVID-19 vaccines in pregnant women are ongoing.

Are there risks to the unborn baby from vaccinating in pregnancy?

mRNA COVID-19 vaccines are not live vaccines, so cannot infect either a mother or her unborn baby. The vaccine is rapidly broken down in a mother's body. It cannot become part of a mother's or baby's DNA. Animal studies of the mRNA vaccines did not show any unexpected risks. There is no known plausible biological mechanism which would affect the unborn baby or fertility.

Studies have shown that COVID-19 vaccination in pregnancy can reduce the risk of stillbirth by up to 15% and can reduce the risk of babies being admitted to hospital with COVID-19 in the first six months of life.

What information is available about the safety of COVID-19 vaccines in pregnancy?

Continuing evidence regarding vaccination during pregnancy has demonstrated it to be safe and effective. Studies have found that COVID-19 vaccination is not associated with an increased risk of congenital malformations or birth defects, miscarriage, growth problems in the baby, preterm birth, stillbirths or admission to the neonatal intensive care unit.

A number of studies from the UK, Israel and the US compared pregnancy outcomes among women who received a COVID-19 vaccine in pregnancy and women who did not receive a COVID-19 vaccine in pregnancy. None reported any increased risk of adverse pregnancy outcomes in women who received a COVID-19 vaccine. Some of these studies found evidence that vaccination reduces the risk of stillbirth and preterm birth.

Is there any information about the potential long-term effects of COVID-19 vaccines in pregnancy?

At present, there are no long term safety data as vaccination only began in late 2020. However, there is no scientifically plausible reason why COVID-19 vaccination should affect the baby. The vaccines do not cross the placenta. Only the antibody crosses the placenta. On the other hand, there are known consequences of severe COVID-19 infection which are associated with adverse pregnancy outcomes for the mother and her baby.

When should a COVID-19 vaccine be given in pregnancy?

An mRNA COVID-19 vaccine can be given at any stage of pregnancy.

For those who are up to date with their COVID-19 vaccines before pregnancy, a booster dose should be given once in pregnancy. This can be given at any stage of pregnancy. However, the ideal time is between 20-34 weeks of pregnancy as this offers optimal protection to both mother and baby. Vaccinating at this time provides a boost in protection for the third trimester when the risks of COVID-19 related complications are highest to the mother. It also provides the vaccine at the optimal time to allow antibodies to pass to the baby through the umbilical cord and help protect the baby from COVID-19 infection in the months after birth.

If it is more than 12 months since the last dose of COVID-19 vaccine, booster vaccination before 20 weeks of pregnancy can be considered. A booster dose before 20 weeks of pregnancy may also be considered in pregnant women with immunocompromise.

COVID-19 vaccination in the unvaccinated

Most adults in Ireland have had at least one dose of a COVID-19 vaccine. Pregnant women who have never had a dose of COVID-19 vaccine (i.e., **unvaccinated**) are recommended to receive one dose of an mRNA vaccine. This can be given at any stage in pregnancy.

If a fever of more than 38°C develops after vaccination, paracetamol can be taken. Ibuprofen and aspirin are not recommended in pregnancy.

Can other vaccines, such as pertussis (whooping cough) and seasonal influenza (flu), be given at the same time as a COVID-19 vaccine?

Yes. NIAC recommends that COVID-19 vaccines and any other recommended vaccines can be given at the same time or at any interval. The vaccines should be given in different arms.

There may be a slight increase in mild side effects when COVID-19 and flu vaccines are given at the same time. These include pain at the site of the injection, headache, muscle pain and tiredness which only last a few days and can be relieved with paracetamol.

When can a woman who had COVID-19 get a COVID-19 vaccine?

If an **unvaccinated woman** has had COVID-19 infection, they should wait at least four weeks before getting their first COVID-19 vaccine.

If a **vaccinated woman** has had COVID-19 infection they should wait four to six months before getting their COVID-19 booster vaccine.

Can COVID-19 vaccine be given to a pregnant woman who has an immunocompromising condition?

Yes. All people who are immunocompromised (have weakened immune systems) including pregnant women, are advised to get a COVID-19 vaccine. They are also advised to observe public health and social measures.

Are additional doses of COVID-19 vaccine recommended for a pregnant woman who has an immunocompromising condition?

Yes. People with weakened immune systems may require additional doses of COVID-19 vaccine to develop sufficient immunity against COVID-19.

The National Immunisation Advisory Committee (NIAC) recommends that pregnant women with immunocompromising conditions should get two doses of an mRNA COVID-19 vaccine if they have never been vaccinated against COVID-19 before. Those with more severe immunocompromise may need a third dose and should consult with their relevant specialist physician regarding the need for additional doses of COVID-19 vaccine.

In addition, if an immunocompromised person gets a COVID-19 booster dose early in pregnancy, they may need a second booster dose during the same pregnancy if six months has elapsed (i.e., if a booster was given at 8-10 weeks of pregnancy a second booster could be considered at 32-34 weeks of pregnancy).

Is breastfeeding safe for a woman given a COVID-19 vaccine during pregnancy?

Yes. If a pregnant woman is vaccinated, antibodies against COVID-19 disease may pass into the breastmilk and give some protection to her baby.

Can a breastfeeding mother get a COVID-19 vaccine?

Yes. There is no evidence that COVID-19 vaccination while breastfeeding causes any harm to breastfed children or affects the ability to breastfeed. Studies looking for vaccine mRNA in breast milk have been unable to detect it or have only detected it at very low levels. If remnants of the vaccine get into breastmilk they get digested in the baby's stomach.

A number of studies have shown that the protective antibodies the body makes get into breast milk at high concentrations and provide the baby with some protection against COVID-19 infection.

How soon after delivery can a COVID-19 vaccine be given?

There is no need to wait any amount of time between delivery and getting the vaccine.

Can a woman who has received Anti-D recently get a COVID-19 vaccine?

Yes. COVID-19 vaccines can be given at any interval before or after Anti-D.

Do COVID-19 vaccines have any effect on the menstrual cycle (periods)?

Menstrual disorders (period problems) are very common in the general population and can occur without an underlying medical condition. Some women have reported changes to their menstrual cycle after receiving the COVID-19 vaccine. The changes are small and temporary. Most women who report a change to their period after vaccination find that it quickly returns to normal. There is evidence that one in four women who were infected with COVID-19 experienced changes to their menstrual cycle. It may be that activation of the immune system, for example, by an infection or vaccination, affects the menstrual cycle.

Will the vaccine cause infertility or reduce the chances of getting pregnant?

No. Studies have shown that COVID-19 vaccines do not reduce fertility.

Studies have shown that COVID-19 vaccination does not affect ovarian function, egg quality, fertilisation or the number of women who became pregnant.

COVID-19 vaccines do not affect male fertility. Three studies have shown that vaccination does not impact sperm quality or sperm count. Some studies have, however, found that COVID-19 infection may reduce sperm quality.

Should those thinking about getting pregnant delay getting COVID-19 vaccine?

No. There is no need to leave any interval after having COVID-19 vaccine and becoming pregnant.

There is no evidence that COVID-19 vaccine will affect the chances of getting pregnant, now or in the future. People of reproductive age are advised to have the vaccine as soon as possible. This includes those who are trying to have a baby and those who are thinking about having a baby in the near future or in a few years' time.

Should those planning on getting vaccinated delay getting pregnant?

No. There is no reason to delay pregnancy if planning on getting the vaccine.

Should vaccination be delayed if undergoing or planning fertility treatment (including IVF)?

No. There is no need to delay getting the vaccine if planning fertility treatment or undergoing fertility treatment. A number of international bodies have recommended that those planning to conceive spontaneously or with assisted reproductive therapy such as IVF should get a COVID-19 vaccine. A recent study showed no difference in IVF success outcomes in people who had been vaccinated against or previously infected with COVID-19. Fertility measures and pregnancy rates are reported to be similar in vaccinated and unvaccinated women.

Getting the vaccine as soon as possible will maximise protection against COVID-19. However, a woman may wish to consider the timing of a COVID-19 vaccine to avoid any mild vaccine side effects at particular stages

in treatment. For example, she may want to separate the date of vaccination from some fertility procedures such as egg collection in IVF to avoid confusing side effects from the vaccine and the treatment procedure. The vaccine should be given as early as possible to ensure full protection against COVID-19.

