

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

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What we know about COVID-19 and COVID-19 vaccines has evolved since the pandemic first began. We now have more information about the potentially serious impact of COVID-19 on pregnant woman. We also now have more information on the safety of COVID-19 vaccines in pregnancy. 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 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 when compared with non-pregnant women. Recently, there has been a significant increase in the number of pregnant women admitted to hospital and the ICU with COVID-19. Most women admitted to ICU with severe COVID-19 were not vaccinated.

Pregnant women with COVID-19 are at higher risk of preterm birth, high blood pressure, postpartum haemorrhage and stillbirth than those who are not infected with COVID-19.

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

In recent months there has been an increase in ICU admissions of pregnant women with COVID-19. If a woman is admitted to ICU, her baby may be affected by the life-saving care provided in ICU or the medications given to the woman 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.

Is the Delta variant of COVID-19 more dangerous for pregnant women?

The Delta variant of the COVID-19 virus is more contagious compared with previous strains of the virus. This means that pregnant women are more likely to get COVID-19 if exposed to the virus. The Delta variant of the COVID-19 virus may also cause more severe illness than previous virus strains. Information from Ireland and the UK shows that the Delta variant causes more moderate to severe COVID-19 disease in pregnant women and that more pregnant women require hospital treatment when infected with the Delta variants compared with variants circulating earlier in the pandemic.

The available mRNA vaccines are highly effective against preventing moderate to severe infection, even against the Delta variant.

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

Most pregnant women who become severely ill from COVID-19 are in their third trimester of pregnancy (28 weeks or more). Pregnant women from Black, Asian and ethnic minority backgrounds are more likely than other pregnant women to be admitted to hospital with COVID-19. Pregnant women aged 35 years and older, those who have a BMI of 30 or more, and those women who have additional medical problems, such as high blood pressure and diabetes, also appear to be at higher risk of developing severe illness. In Ireland, women in the third trimester are more likely to become ill if they get COVID-19 than those in early pregnancy. However, pregnancy alone is a risk factor for severe COVID 19. In other words, healthy young pregnant women with none of the above risk factors have a significant increased risk of severe COVID-19.

What is placentitis?

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. 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 present to their maternity unit if they notice a significant reduction in movement. We have no evidence that COVID-19 early in pregnancy is a risk to the baby later on in pregnancy.

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

Yes. The National Immunisation Advisory Committee (NIAC), a group of independent experts in Ireland, recommends that pregnant women should be offered mRNA COVID-19 vaccination at any stage of pregnancy. This recommendation is echoed by many other reputable organisations across the world, including the Institute of Obstetricians and Gynaecologists in Ireland, the European Network of Teratology Information Services (ENTIS), the Royal College of Obstetricians and Gynaecologists and Royal College of Midwives in the UK, and the American College of Obstetricians in the US.

When the vaccine first became available, there were differing recommendations about the use of the vaccine in different countries. Since then, we have more information about the potentially serious impact of COVID-19 on pregnant women and their infants. We now also have more information which shows these vaccines are safe in pregnancy. As a result, the protection that the vaccine offers both mother and baby outweighs any risk of getting the vaccine in pregnancy.

Hundreds of thousands of women worldwide have now received the COVID-19 vaccine in pregnancy. The most recent figures from the US surveillance system for COVID-19 vaccines report that more than 160,000 pregnant women have been vaccinated. In addition, the medicines regulator in the UK report that more than 72,000 pregnant women in the UK have received their vaccine.

Why should pregnant women get the COVID-19 vaccine?

COVID-19 can be dangerous for pregnant women, especially in the third trimester. COVID-19 vaccines have been shown to reduce the risk of developing moderate to 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. It may reduce the chance of pregnancy complications, such as

preterm birth, caesarean delivery and stillbirth, which are associated with COVID-19 illness. Vaccination may also reduce the spread of the infection within the community.

We now have good information to show that the COVID-19 vaccine is safe during pregnancy. Getting the COVID-19 vaccine is the best way to protect mother and baby from COVID-19. Choosing not to get the vaccine puts both mother and baby at risk of adverse outcomes.

What COVID-19 vaccines are recommended for pregnant women?

mRNA vaccines are recommended for pregnant women in Ireland. Two vaccines are available: Comirnaty (manufactured by Pfizer/BioNTech) and Spikevax (manufactured by Moderna). Both are mRNA vaccines that do not contain the live virus and cannot cause COVID-19. mRNA vaccines stimulate 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.

Spikevax is only recommended for those aged 30 years or older.

What are the potential side effects?

Common side effects of either of the COVID-19 vaccines recommended for pregnant women 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. These symptoms are more common after the second dose. 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. It is important to remember that these symptoms may not necessarily be caused by the vaccine; medical advice may need to be sought.

Have the COVID-19 vaccines been tested in pregnant people?

Pregnant women were not specifically included in the initial clinical trials of COVID-19 vaccines. This is mainly due to historical restrictions on including pregnant people in clinical trials. However, since the roll out of COVID-19 vaccination programmes across the world, many pregnant women have received the COVID-19 vaccine.

A number of studies assessed side effects and pregnancy outcome in women who received the COVID-19 vaccines when they were pregnant. These studies collected information from women themselves, from healthcare professionals through reports submitted to medicines regulators and from information recorded as part of the care they received in hospital when they had their baby.

To date, hundreds of thousands of women worldwide have received a COVID-19 vaccine in pregnancy and no unexpected pregnancy or infant outcomes have been observed. There has been no increased risk of miscarriage, no increased risk of congenital malformations or birth defects, no increased risk of stillbirths, no increased risk of growth problems and no increased risk of preterm birth associated with COVID-19 vaccination.

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

Are there risks to the fetus from vaccinating the mother?

There is no evidence of an increased risk to the fetus from vaccinating mothers. These are not live vaccines, so cannot infect either mother or fetus. The mRNA is rapidly broken down in the 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 potential risks. There is no known plausible biological mechanism which would affect the fetus or fertility.

Available data do not indicate an increased risk of miscarriage, birth defects, stillbirths, growth problems or preterm birth.

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

Here is a brief summary of the current evidence:

- One study from the US published in April 2021 included data on the 827 women enrolled in the V-SAFE pregnancy register who had completed their pregnancy by 30 March 2021. The rates of adverse events including stillbirth, preterm birth, small for gestational age and congenital anomalies were the same in those who received a COVID-19 vaccine during pregnancy as the rates in non-vaccinated pregnant women. Another study using the V-SAFE pregnancy register reported that the rate of miscarriage among 2,456 women who received the COVID-19 vaccine before 20 weeks' gestation was no different to the rate of miscarriage seen in non-vaccinated women.
- A study which included 105,446 pregnancies from the Vaccine Safety Datalink in the US reported that women who experienced a miscarriage were no more likely to have received a COVID-19 vaccine compared with those who did not experience a miscarriage. A similar study from Norway which included 18,477 pregnancies, also found no evidence of an increased risk for early pregnancy loss or miscarriage after COVID-19 vaccination.
- A registry from Canada included 30,892 women had received the COVID-19 vaccine in pregnancy. No increased risk of stillbirth, preterm birth or small for gestational age was reported among the 3,236 women who had given birth at the time of the study.
- A study from the UK compared pregnancy outcomes in 141 women who received a COVID-19 vaccine in pregnancy with 1187 women who did not receive a COVID-19 vaccine in pregnancy. The rate of adverse pregnancy outcomes was similar in both groups.
- No notable differences were noted when the rate of miscarriage, stillbirth and growth restriction was compared between 1387 vaccinated and 1427 unvaccinated women in Israel.

Together these studies show there is no increased risk of miscarriage, no increased risk of congenital malformations or birth defects, no increased risk of stillbirths, no increased risk of growth problems and no increased risk of preterm birth associated with COVID-19 vaccines.

Further studies will continue to be published on COVID-19 vaccines in pregnancy. These additional studies will further contribute to our knowledge on the safety of COVID-19 vaccines in pregnancy.

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

At present, there are no long term safety data. However, there is no scientifically plausible reason why COVID-19 vaccination should on the fetus or baby. Although these vaccines are new, we know they do not cross the placenta. Only the antibody crosses the placenta. On the other hand, there are

known consequences of severe COVID-19 infection and associated adverse pregnancy outcomes on the mother and her baby.

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

An mRNA COVID-19 vaccination can be given at any stage of pregnancy. The Immunisation Guidelines for Ireland recommend two doses of mRNA COVID -19 vaccine at least 21-28 days apart. This is the same for both Comirnaty® and Spikevax®.

Why is it now recommended to get the COVID-19 vaccine at any stage in pregnancy?

Women were previously recommended to get the COVID-19 vaccine between 14 and 36 weeks' gestation. This was a precaution to avoid a high fever in early pregnancy which may be associated with a slight increase in the risk of miscarriage. Studies now show that there is no increased risk of miscarriage in women who receive a COVID-19 vaccine.

Getting the vaccine as soon as possible will maximise protection from COVID-19 for a pregnant woman and her baby. If a fever of more than 38°C develops after vaccination, paracetamol can be taken. Ibuprofen and aspirin are not recommended.

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.

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

All people who are immunocompromised, including pregnant women, are advised to get the COVID-19 vaccine. They are also advised to observe public health and social measures.

Pregnant women who had a weakened immune when they received their initial COVID-19 vaccines are recommended an additional dose of mRNA vaccine to improve protection against COVID-19. This should be administered at least 2 months after the last COVID-19 vaccine.

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 as there may be more local side effects.

If a person had one dose of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca®), should a second Vaxzevria vaccine be given?

It is now recommended that an mRNA vaccine be given as the second dose. This gives a stronger immune response than two doses of Vaxzevria.

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

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.

Do COVID-19 vaccines have any impact on the menstrual cycle?

Menstrual disorders are very common in the general population and can occur without an underlying medical condition.

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency has looked into reports of menstrual disorders occurring after COVID-19 vaccination. Based on the assessment of all data, PRAC concluded that there is currently no evidence to suggest that COVID-19 vaccines can cause menstrual disorders.

There is also evidence that one in four women who were infected with COVID-19 also experienced changes to their menstrual cycle. It may be that activation of the immune system, for example, an infection or vaccination, affects the menstrual cycle.

These menstrual changes are temporary and most people who report a change to their period after vaccination find that it returns to normal the following cycle.

There is no evidence to suggest that COVID-19 vaccines can cause menstrual disorders.

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

There have been some suggestions that the COVID-19 vaccine affects fertility. This may be concerning for those who are pregnant or want to get pregnant in the future. There is no evidence that vaccines affect male or female fertility and

There is also some misinformation about the COVID-19 vaccine affecting fertility due to similarities between the COVID-19 spike protein and proteins which are responsible for the growth and attachment of the placenta during pregnancy. Laboratory studies have shown that these proteins are not similar enough to cause fertility problems. If this was the case, we would expect to see miscarriages in pregnant women who become infected with COVID-19 or who have received the COVID-19 vaccine, but this is not the case.

A number of scientific studies have shown that COVID-19 vaccines do not reduce fertility.

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

Secondly, there were a number of women enrolled in clinical trials who became pregnant after getting the vaccine. The number of women who unintentionally became pregnant during the clinical trial was equal among women who received the vaccine and those who did not receive the vaccine. A large number of women have become pregnant since receiving the vaccine.

The COVID-19 vaccine does 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. The British Fertility Society (BFS) have a dedicated Q&A document on COVID-19 vaccines and fertility. It is available here:

<https://www.britishfertilitysociety.org.uk/2021/07/27/bfs-arcs-covid-19-vaccines-fertility-2/>

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

There is no evidence that the 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.

There is no need to leave any interval after having the COVID-19 vaccine and becoming pregnant. If a woman becomes pregnant after the first dose, there is no requirement to delay the second dose.

Should those planning on getting vaccinated delay getting pregnant?

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)?

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 the 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 the 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

Are booster doses of COVID-19 vaccines recommended?

The National Immunisation Advisory Committee (NIAC) has recommended booster doses of mRNA COVID-19 vaccines in all those aged 16 years and older who have completed their primary COVID-19 vaccination course with any vaccine type.

This includes all pregnant or breastfeeding women. The booster dose should be given after an interval of three months or longer following the last COVID-19 vaccine dose.

COVID-19 booster vaccines can be given at any stage in pregnancy. COVID-19 booster vaccines can be given at the same time or at any interval before or after other vaccines recommended in pregnancy, including the seasonal influenza (flu) or pertussis (whooping cough) vaccine.

Are additional doses of COVID-19 vaccine recommended?

People with weakened immune systems may not develop enough immunity after two doses of the COVID-19 vaccine. The National Immunisation Advisory Committee (NIAC) recommends a third dose of an mRNA COVID-19 vaccine to improve protection against COVID-19 for those with a weakened immune system.

This may include pregnant women with kidney disease, those who have had an organ transplant and those on medication which may suppress the immune system.

If a woman had a weakened immune system when given her initial COVID-19 vaccine, she may require a third dose of an mRNA vaccine. This should be given a minimum interval of two months after the last COVID-19 vaccine dose. Either brand of mRNA COVID-19 vaccine can be given as a third dose. This can be given at a HSE COVID-19 vaccination centre, a pop-up vaccination clinic or a healthcare provider.

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

If an unvaccinated person has had laboratory confirmed COVID-19 infection or a positive COVID-19 antigen test, they should wait at least four weeks and until they are well before getting their COVID-19 vaccine.

If a vaccinated person has had laboratory confirmed COVID-19 infection or a positive COVID-19 antigen test with symptoms, they should wait at least three months and until they are well before getting their booster COVID-19 vaccine.

