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 Questions & Answers document has been updated to reflect current evidence and recommendations in Ireland.

What are the risks to me as a pregnant woman 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.

If you get COVID-19 when you are pregnant, you may be 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.

There is also increasing evidence that COVID-19 can affect your pregnancy. For example, 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 have implications for their baby. For example, if you contract COVID-19 infection in pregnancy, this may lead to pre-term delivery of your baby, due to deterioration in your health, or concerns about your 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 infant 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 units 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 you are more likely to get COVID-19 if you are 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 than 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 COVID19?

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 minority ethnic backgrounds are more likely than other pregnant women to be admitted to hospital with COVID-19. Pregnant women over the age of 35, 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, we have noticed 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 cases 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. Continue to monitor fetal movements and present to your maternity unit if you 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 was differing recommendations about the use of the vaccine in different countries. Some women decided to wait until after they had their baby to get the vaccine. 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 you and your infant 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 I get the COVID-19 vaccine in pregnancy?

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 your baby from COVID-19. Choosing not to get the vaccine puts you at risk of getting this potentially serious disease.

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. 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. You cannot get COVID-19 from the vaccine.

What are the potential side effects?

Common side effects of any of the vaccines include fatigue, headache, sore arm, fever and muscle or joint pains. There is no evidence 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 after vaccination, is generally mild (<39^{o}C) and usually resolves within 2 days without treatment. Fever after vaccination can be managed with paracetamol. Do not take ibuprofen or aspirin. Remember if you are unwell after getting a vaccine, it could be for some other reasons - don't assume it's the vaccine and seek medical advice if needed.

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 have been published which assessed side effects and pregnancy outcomes in women who received the COVID-19 vaccines when they were pregnant. These studies collected information from women themselves, through smartphone apps, 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.

Together these studies show there is no increased risk of adverse pregnancy outcomes associated with COVID-19 vaccines. Available studies report 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. Clinical trials assessing COVID-19 vaccines in pregnant women are currently ongoing.

Are there risks to the fetus from vaccinating the mother?

Studies to date have shown no 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 body. It cannot become part of your or your 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.

To date, hundreds of thousands of women worldwide have received a COVID-19 vaccine in pregnancy. No unexpected pregnancy or infant outcomes have been observed in women who received COVID-19 vaccination during pregnancy. 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?

Like COVID-19, the COVID-19 vaccines are new. However, we now have data from hundreds of thousands of women who have received this vaccine across the world. There are now numerous scientific studies which show that the COVID-19 vaccines are safe in pregnancy.

Here we provide a brief summary of the evidence which is currently available:

- One study from the US published in April 2021 included data on the 827 woman enrolled in the V-SAFE pregnancy register and had completed their pregnancy by March 30th 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 vaccinate during pregnancy as in the general pregnant population. 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 the general population.
- 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 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 were 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.

There is currently no reason to believe these additional studies will change recommendations on the use of COVID-19 vaccines in pregnancy.

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

Some people are concerned that there are no long term data on the use of these vaccines. Although these vaccines are new, we know they do not cross the placenta. Only the antibody crosses the placenta. There is no scientific plausible reason why this would have any long-term negative impact on your infant. On the other hand, there are potential long term 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?

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. 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. However, studies now show that there is no increased risk of miscarriage in women who receive a COVID-19 vaccine.

Recommendations have now changed and pregnant women can get their COVID-19 vaccine at any stage in pregnancy. Getting the vaccine as soon as possible will maximise protection from COVID-19 for you and your baby. If you develop a fever >38^{o}C after your vaccination you may choose to take paracetamol.

I have had my Anti -D recently. Can I still get the vaccine?

Yes. There is no interval that you have to wait for the vaccine.

I have an underlying condition that means I am immunocompromised should I get the vaccine?

Immunocompromised people are advised to get the vaccine. Pregnant women in these groups are also advised to get the vaccine as well as observing public health 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), be given at the same time as a COVID-19 vaccine?

Yes. NIAC recommends that COVID-19 vaccines and any other vaccines can be given at the same time or at any interval. The vaccines should be given in different limbs as there may be more local side effects.

I had a first dose of Vaxzevria® (formerly COVID-19 Vaccine AstraZeneca®), what about my second dose?

If you already received your first dose of Vaxzervia®, it is now recommended that you get a second dose using an mRNA vaccine. This is due to the availability of mRNA vaccines in Ireland and evidence to support the mixing of COVID-19 vaccines, also called heterologous vaccination.

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

Yes. If you were vaccinated while pregnant, antibodies against COVID-19 disease may pass into the breastmilk and give some protection to your baby. This has now been shown in published papers.

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

Yes. You can get the vaccine at any stage after your baby is born. 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.

Do I need to wait any amount of time after giving birth before getting my COVID-19 vaccine?

You can get the COVID-19 vaccine as soon as you feel well enough to get the vaccine. There is no need to wait any amount of time between giving birth and getting the vaccine.

Do the vaccines have any impact on the menstrual cycle?

A recent publication stated that over 30,000 women in the UK reported changes to periods and unexpected vaginal bleeding shortly after vaccination (up to 2nd September 2021). 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 that COVID-19 vaccination adversely affects fertility or your chances of getting pregnant.

Will the vaccine cause infertility or reduce my 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.

As described above, a recent study reported that some noted changes in their menstrual cycle after getting the vaccine. These menstrual changes are temporary. Most people who report a change to their period after vaccination find that it returns to normal the following cycle. This is unlikely to affect your chances of getting pregnant.

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.

Second, 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 who have reported that they have gotten 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 I delay getting a COVID-19 vaccine if I am thinking about getting pregnant?

There is no reason to believe the COVID-19 vaccine will affect your 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.

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, there is no requirement to delay the second dose.

Should I delay getting pregnant if I'm planning on getting vaccinated?

There is no reason to delay pregnancy if you planning on getting the vaccine or if you have recently gotten the vaccine. If you become pregnant after your first dose of the COVID-19 vaccine, you should get the second dose as scheduled.

Should I delay getting the vaccine if I am undergoing or planning fertility treatment (including IVF)?

There is no need to delay getting the vaccine if you are planning fertility treatment or are 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 your protection against COVID-19. However, you may wish to consider the timing of your COVID-19 vaccine if you want to avoid any mild vaccine side effects at particular stages in your treatment. For example, you may also 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. You should still get the vaccine as early as possible to ensure full protection against COVID-19

Are COVID-19 vaccine additional doses or boosters recommended?

People with weakened immune systems might not develop enough immunity after 2 doses of the COVID-19 vaccine. The National Immunisation Advisory Committee (NIAC) recommends a third dose of mRNA COVID-19 vaccine to improve protection against COVID-19 for individuals who have weakened immune system.

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

If you had a weakened immune system when you receive your initial COVID-19 vaccines you may require a third dose of an mRNA vaccine. This should be given a minimum interval of 2 months after the last COVID-19 vaccine dose. Either brand of mRNA COVID-19 vaccine can be given as a third dose. You should make an appointment for vaccination at a HSE COVID-19 vaccination centre, attend a pop-up vaccination clinic or contact your healthcare provider.

What if I have had COVID-19 in the last 6 months?

If you have already had COVID-19 you should still consider getting the mRNA COVID-19 vaccine. Although previous COVID-19 infection does provide some protection, vaccination is still recommended. If you have had laboratory-confirmed COVID-19 in the previous 6 months, you will only need one dose of vaccine.