Published June 2021

Topic: The COVID-19 vaccination for women who are pregnant, planning pregnancy or breastfeeding.

This clinical briefing provides information about the coronavirus vaccine for those who are planning a pregnancy, are pregnant and/or breastfeeding.

Potential impact of COVID-19

More than half of women who test positive for COVID-19 in pregnancy have no symptoms at all, but some pregnant women can become severely unwell with COVID-19, particularly if they have underlying health conditions.

Current key guidance for this topic – advice for women

The updated advice from the Joint Committee on Vaccination and Immunisation (JCVI) is that COVID-19 vaccines should be offered to pregnant women at the same time as the rest of the population, based on their age and clinical risk group. Women should discuss the risks and benefits of having the vaccine with their midwife or health professional and reach a decision based on their individual circumstances. This discussion should make clear that although there is a lack of safety data for these specific vaccinations for pregnancy, there is no known risk associated with giving other non-live vaccines to pregnant women.

The Vaccines

COVID-19 vaccines do not contain ingredients that are known to be harmful to pregnant women or to a developing fetus. Studies of the vaccines in animals, looking at the effects on pregnancy, have shown no evidence that the vaccine causes harm to the pregnancy, or to fertility.

The COVID-19 vaccines being used in the UK are not 'live' vaccines and so cannot cause COVID-19 infection for women or their babies. Vaccines based on live viruses are avoided in pregnancy in case they infect the developing fetus and cause harm. However, non-live vaccines have previously been shown to be safe in pregnancy (for example, flu and pertussis).

The benefits of vaccination include:

- reduction in severe disease for the pregnant woman
- reduction in the risk of pre-term delivery of the baby
- potentially reducing transmission to vulnerable household members and others.

The vaccine should be effective at any stage of a woman's pregnancy. The JCVI advises that women do not need a pregnancy test before vaccination, and that women planning a pregnancy do not need to delay pregnancy after vaccination.

However, as COVID-19 has more serious complications in later pregnancy, women may choose to delay their vaccine until after the first 12 weeks (which are most important for the baby's development) and will plan to have the first dose at any time from 13 weeks onwards.

Risks of COVID-19 in pregnancy

Pregnant women with a range of risk factors are at higher risk of becoming severely unwell with COVID-19. These include being from a Black, Asian and minority ethnic background, aged over 35 years or having a high BMI. Some underlying health conditions, such as diabetes or hypertension also increase risk (see appendix below).

In the later stages of pregnancy, women are at increased risk of becoming seriously unwell with COVID-19. If this

happens, it is about three times more likely that their baby will be born prematurely, which can affect their long-term health.

As pregnant women with COVID-19 are more likely to be seriously unwell, with a higher risk of their baby being born prematurely during their third trimester (after 28 weeks), women may wish to have the vaccine before their third trimester. Women should be advised that immunity is not conferred within the first 2-3 weeks after the first dose of the COVID-19 vaccination.

Safety of the COVID-19 Vaccination

The large clinical trials that showed that COVID-19 vaccines are safe and effective did not include pregnant women. This means there is limited information about the effects of COVID-19 vaccination in pregnancy. However, approximately 90,000 pregnant women have been vaccinated in the United States, mainly with the mRNA vaccines, such as Pfizer-BioNTech and Moderna, and there have been no safety concerns. As a result of this real-world data, the JCVI advises that it is preferable for the Pfizer-BioNTech or Moderna mRNA vaccines to be offered to pregnant women, if possible.. As of 7th April 2021, this recommendation has been extended to include everyone under the age of 40, if doing so does not cause a substantial delay in accessing a vaccination.

Pregnant women who have had a first dose of the Oxford/AstraZeneca vaccine, are advised to get the same vaccine as their second dose In non-pregnant individuals, the COVID-19 vaccines are known to have mild and short-lasting side effects, such as a fever or muscle ache, lasting a day or two. More recently, there have been reports of rare but serious blood clots after vaccination. Up to 31st March 2021, over 20 million doses of the AstraZeneca vaccine had been given in the UK (to non-pregnant individuals). There have been 79 reports of serious thrombosis (blood clots) following vaccination, meaning that about four people have had these blood clots for every million doses of vaccine given. There is therefore an extremely low risk of the serious side effect of blood clots with this vaccine.

Furthermore, the JCVI has stated that “there are currently no known risk factors for this extremely rare condition, which appears to be an idiosyncratic reaction on first exposure to the AstraZeneca COVID-19 vaccine”. This means that someone is not necessarily at higher risk of this serious side effect just because they have a higher risk of other blood clots, for example because they are pregnant. This rare side effect has not been reported in any pregnant women and therefore we do not know the exact risk in pregnancy.

Vaccination and fertility

There is no evidence to suggest that COVID-19 vaccines will affect fertility.
There is no biologically plausible mechanism by which current vaccines would cause any impact on women’s fertility. Evidence has not been presented that women who have been vaccinated have gone on to have fertility problems.

The JCVI advises that women who are planning a pregnancy should not be advised to delay having the vaccination, or delay becoming pregnant after the vaccination course. Likewise, the theory that immunity to the spike protein could lead to fertility problems is not supported by evidence. Most people who contract COVID-19 will develop antibodies to the spike and there is no evidence of fertility problems in people who have already had COVID-19.

Vaccination and breastfeeding

The JCVI now advises that there is no known risk in giving these vaccines to breastfeeding women. Breastfeeding women should therefore be offered vaccination if they are otherwise eligible. The developmental and health benefits of breastfeeding should be considered along with the woman’s clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

RCM Advice

Based on the evidence presented by the JCVI, the RCM advises the following:

- Pregnant women should have an individualised discussion about the risks and benefits of vaccination during pregnancy with their midwife or health professional. They should have the option of having the vaccine if they choose.
- Pregnant women should seek advice through their GP, to support their direction to an appropriate vaccination centre that offers either Pfizer/BioNTech or Moderna vaccines.
- Non-pregnant women should be encouraged to take up the vaccine and reassured that there is no evidence that this will adversely affect their fertility. We do not advise routine pregnancy testing before receipt of a COVID-19 vaccine.
- Those who are trying to become pregnant do not need to avoid pregnancy after vaccination.
- Discussion with pregnant women about whether to take the vaccine should include acknowledgement of the lack of safety data for COVID-19 vaccinations for pregnant or breastfeeding women, but that there is no known risk associated with giving other non-live vaccines to pregnant women.
- If a woman decides not to have the vaccine during pregnancy, she should be offered the vaccine as soon as possible after birth.
- There is no known risk in giving these vaccines to breastfeeding women. However, women should be advised that there is lack of safety data for these specific vaccinations in breastfeeding.
- Pregnant women who receive the vaccine should inform their maternity team that they have been vaccinated, so that this can be recorded in their maternity records.

References

Clift, A. K., Coupland, C. A. C., Keogh, R. H., et al 2020 Living risk prediction algorithm (QCOVID) for risk of hospital admission and mortality from coronavirus 19 in adults: national derivation and validation cohort study *BMJ* October 371:m3731 Accessible at: doi**:** https://doi.org/10.1136/bmj.m3731

JCVI statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021 - GOV.UK (www.gov.uk)

Joint Committee on Vaccination and Immunisation (2020) Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination JCVI final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 - GOV.UK (www.gov.uk)

NHS Digital (2021) Coronavirus (COVID-19) risk assessment NHS Digital February https://digital.nhs.uk/coronavirus/risk-assessment

Links to online resources and guidance

British Fertility society information on COVID-19 vaccine and fertility. Accessible at: https://www.britishfertilitysociety.org.uk/2021/02/09/bfs-arcs-covid-19-vaccines-fertility/

COVID-19: vaccination programme guidance for healthcare practitioners. Accessible at: https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

Joint RCM/RCOG guidance for women on vaccination in pregnancy https://www.rcog.org.uk/globalassets/documents/guidelines/2021-01-12-covid-19-vaccine-info-sheet.pdf

Joint RCM/RCOG decision making guide to support discussions about potential vaccination in pregnancy https://www.rcm.org.uk/media/4714/2021-02-11-decision-aid.pdf

Public Health England have produced a range of guidance and information for women of childbearing age about the vaccine and fertility, pregnancy and breastfeeding, here: https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding

RCM website vaccination hub: https://www.rcm.org.uk/coronavirus-vaccines/

RCOG website vaccination hub: https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/

The UK Teratology information service (UKTIS) monograph on non-live COVID vaccine in pregnancy https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-NON-LIVE-VACCINES-IN-PREGNANCY/

UK Government, MHRA guidance on vaccination in pregnancy: https://www.gov.uk/government/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy/the-safety-of-covid-19-vaccines-when-given-in-pregnancy

Appendix

Advice was updated by the JCVI on 30th December 2020 to recommend certain priority groups to receive the AstraZeneca and the Pfizer-BioNTech vaccines. This included pregnant and breastfeeding women who met other criteria for priority vaccination.

The criteria at this point were those that were clinically extremely vulnerable, occupational exposure as a frontline health or social care worker, including a carer in a residential home.

These clinical vulnerabilities included:

- solid organ transplant recipients
- those with severe respiratory conditions including cystic fibrosis and severe asthma
- those who have 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.

A NHS Digital risk assessment tool, known as QCovid®, looks at absolute and relative risks of catching coronavirus and being admitted to hospital and catching coronavirus and dying. It reflects the fact that some risk factors have a bigger impact on risk than others such as ethnicity, BMI, smoking status, social deprivation and age (Clift, Coupland and Keogh et al 2020; NHS Digital, 2021).