Royal College of Obstetricians & Gynaecologists

Coronavirus (COVID-19) Vaccination in Pregnancy

Information for healthcare professionals

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Contents

1. Purpose and scope

This document is intended as temporary guidance on COVID-19 vaccination in pregnancy. It aims to summarise, in a format useful for maternity care, the evidence presented in existing COVID-19 vaccination guidance from the Public Health England/Department of Health Green Book,[1] as well as leaflets and information from Public Health England and the NHS. The document will be incorporated into the next version of the Royal College of Obstetricians and Gynaecologists (RCOG) *Coronavirus (COVID-19) Infection in Pregnancy* guidance expected to be published in autumn 2021.

2. Background on COVID-19 vaccines available in the UK

COVID-19 vaccine background (in non-pregnant population)

Key findings

- The phase 3 trials of the four currently-approved vaccines assessed protection against COVID-19 after two doses in three, and after a single dose in one.
- The Pfizer-BioNTech vaccine has an efficacy of 95% (95% CI 90.0–97.9%) against symptomatic COVID-19.[2]
- The Oxford-AstraZeneca vaccine has an efficacy of 66.7% (95%CI 57.4–74.0%) against symptomatic COVID-19.[3]
- The Moderna vaccine has an efficacy of 94.1% (95% CI 89.3–96.8%).[4]
- The Janssen vaccine has an efficacy of 66.1% (95% CI 55.0–74.8%).
- Real-world monitoring has confirmed that one dose of the Pfizer-BioNTech or Oxford-AstraZeneca vaccines confers about 60% protection against symptomatic COVID-19.[6]

Available vaccines in the UK and their mechanisms of action

As of June 2021, four COVID-19 vaccines are approved for use in the UK: the Pfizer-BioNTech vaccine, the Oxford-AstraZeneca vaccine, the Moderna vaccine and the Janssen vaccine. The MHRA approved the Pfizer-BioNTech vaccine in the UK on 2 December 2020, the Oxford-AstraZeneca vaccine on 30 December 2020, the Moderna vaccine on 8 January 2021 and the Janssen vaccine on 28 May 2021.

The **Pfizer-BioNTech** and **Moderna** vaccines are messenger RNA (mRNA) vaccines in which mRNA encoding SARS-CoV-2 spike protein is introduced into the person when they are vaccinated via a lipid nanoparticle coat. The mRNA does not go into the nucleus of the host cell, so it remains separate from the host DNA. The host cell produces the spike protein, as for the Oxford-AstraZeneca and Janssen vaccines below, and this protein elicits a protective immune response. The mRNA from the vaccine is broken down by the host cell within a few days.[1]

The **Oxford-AstraZeneca** and **Janssen** vaccines are viral-vector vaccines in which DNA encoding the SARS-CoV-2 spike protein is introduced into the person when they are vaccinated using a modified adenovirus vector. The adenovirus vector has been modified so that it cannot replicate, and the spike protein is not expressed on the adenovirus itself.

Rather, the adenovirus vector serves only to deliver the spike DNA into the host cell. The host cell then produces the spike protein, and this elicits a protective immune response.

Vaccine safety

The adverse effect profiles of the four available vaccines were similar in their phase 3 trials. Most participants in the trials had a minor local reaction (pain, redness or swelling at the injection site). Mild systemic adverse effects like fatigue, headache or myalgia were also common; these were typically short-lived (less than a few days). About 10–20% of participants had a fever after vaccination. In general, adverse events are more common after the first dose than the second dose for the Oxford-AstraZeneca vaccine and more common after the second dose than the first dose for the Pfizer-BioNTech and Moderna vaccines.

These vaccines have continued to be monitored for safety after their authorisation, and an association has emerged between the Oxford-AstraZeneca vaccine and rare cases of serious thrombosis in the context of thrombocytopenia (see 4.2.1 below). There have also been very rare reports of myocarditis and pericarditis following vaccination with Pfizer-BioNTech and Moderna vaccines.[7]

3. Eligibility for the vaccine in pregnancy

Advice

- Vaccination should be offered to pregnant women at the same time as the rest of the population, based on age and clinical risk.
- Pregnant women should be offered the Pfizer-BioNTech or Moderna vaccines unless they have already had one dose of the Oxford-AstraZeneca vaccine, in which case they should complete the course with Oxford-AstraZeneca.

The eligibility criteria are based on recommendations from the Joint Committee on Vaccination and Immunisation.[8] The choice of vaccine is based on the recommendations from the Green Book,[1] and reflects the fact that most of the safety data regarding vaccination in pregnancy comes from the USA where pregnant women were usually offered the Pfizer-BioNTech or Moderna vaccines.

4. Potential fetal and maternal effects

Pregnant women were not included in the large randomised controlled trials testing the safety and adverse effect profiles of the COVID-19 vaccines. However, as of 7 June 2021, over 120 000 pregnant women from diverse ethnic backgrounds in the USA have received either a Pfizer-BioNTech or Moderna COVID-19 vaccine, with no evidence of harm being identified.[9] In general, there are no known risks from giving inactivated or recombinant vaccines in pregnancy, or while breastfeeding,[10] and there is therefore no reason to suppose that the adverse effects from these COVID-19 vaccines should be different for pregnant women compared to non-pregnant women.

4.1 Common minor adverse effects

Minor and short-lived adverse effects such as soreness at the injection site, headache and fatigue are common in the general population after a COVID-19 vaccine. A report[11] on the first 35 000 pregnant women to receive a COVID-19 vaccine in the USA showed similar patterns of reporting for common minor adverse effects. Systemic features such as fever appeared more commonly in non-pregnant women, but pregnant women did report nausea and vomiting more frequently after the second dose of the Pfizer-BioNTech and Moderna vaccines.[11] Smaller observational studies[12,13] have also reached similar conclusions showing no significant difference between pregnant and non-pregnant women in their symptoms post vaccination, and a reduced incidence of systemic features such as fever in pregnant women.

4.2 Maternal effects

4.2.1 Vaccine-induced thrombosis and thrombocytopenia (VITT)

The rare syndrome of vaccine-induced thrombosis and thrombocytopenia (VITT) has been reported after the Oxford-AstraZeneca vaccine; it has also been reported after the Janssen vaccine.[14] VITT is an unpredictable idiosyncratic vaccine reaction (not dissimilar to heparin-induced thrombocytopenia and thrombosis associated with heparin therapy) and it is not associated with any of the usual venous thromboembolism risk factors. It has been described as presenting 5–28 days after the first dose, particularly in adults younger than 50 years old. Although pregnancy increases the risk of coagulopathy there is no evidence that pregnant or postpartum women are at higher risk of VITT than non-pregnant women.[1,15]

The risk of VITT is therefore extremely low with a first dose of the Oxford-AstraZeneca vaccine, and even lower with a second dose for those who were well after the first dose. The UK government[15] has advised that individuals younger than 40 years old should be offered an alternative vaccine to the Oxford-AstraZeneca vaccine based on the risk/benefit ratio for this age group. There is no known risk of VITT with the Pfizer-BioNTech and Moderna vaccines.

4.2.2 Other maternal effects

Preliminary findings from the USA[11] have not identified any safety problems with regards to maternal and neonatal risks. The most frequently reported pregnancy-related adverse event was spontaneous miscarriage (104/827, 12.6% – which is in keeping with published background rates), with 92.3% of these miscarriages occurring in the first trimester.

4.3 Fetal effects

Pregnancy outcomes following mRNA vaccination (Pfizer-BioNTech and Moderna) appear similar to comparator groups prior to the onset of COVID-19.[11] The most common adverse outcomes among 724 livebirths in the study by Shimabukuro et al.[11] were preterm birth (9.4%), small-for-gestational-age (3.2%) and major congenital anomalies (2.2%) – all consistent with published rates. None of the mothers whose babies were born with congenital anomalies had received the COVID-19 vaccine in the first trimester or the periconception period.

4.3.1 Antibody transfer

Studies[16,17] have demonstrated the presence of SARS-CoV-2 antibodies in neonatal cord blood and in breast milk produced in response to COVID-19 infection in pregnancy. These findings suggest the development of passive immunity in the neonate. In one of these studies[16] 87% of neonates (n = 83) had immunoglobulin G (IgG) conferred in cord blood following COVID-19 infection in pregnancy. Furthermore, the other cohort study[17] of 2312 lactating women in the Netherlands reported that 23.1% of women had IgA antibodies in their breast milk, which remain present for 10 months following infection in pregnancy.

Similar findings have been reported following the administration of the COVID-19 vaccine. Two cohort studies[10,11] of over 100 women establish the presence of vaccine-elicited antibodies in infant cord blood and breast milk. Both studies were conducted in the USA and utilised Pfizer-BioNTech or Moderna vaccines. There is some suggestion that timing of vaccination in pregnancy or during lactation may have an effect on the level of passive immunity conferred to the neonate, and two studies[11,18] found that production of IgG antibodies and their subsequent transfer were improved following a second dose of either vaccine. Similar to natural infection, IgA titres appear to remain stable for several weeks following vaccination with mRNA vaccines suggesting continual transference of antibodies during lactation.[18] The degree of protection these antibodies confer to the neonate, however, is not yet known.

5. Recommended vaccine timing in relation to stage of pregnancy or breastfeeding

Advice

- COVID-19 vaccines can be given at any time in pregnancy.
- In low-risk situations some women may choose to delay vaccination until 12 weeks of gestation, aiming for vaccination as soon as possible thereafter.
- If there is a higher chance of contracting infection, or a woman is at a higher risk of severe illness from COVID-19, the vaccine should be offered at the earliest opportunity, including in the first trimester.
- Breastfeeding women can receive a COVID-19 vaccine; there is no need to stop breastfeeding to have the vaccine.
- Women planning a pregnancy or fertility treatment can also receive a COVID-19 vaccine and do not need to delay conception.

Timing of vaccination in pregnancy

There is no robust evidence to guide the timing of vaccination in pregnancy: the advice above is based on expert opinion rather than experimental data. The COVID-19 vaccines should be effective at any stage of pregnancy. Some women may choose to delay their vaccine until after the first 12 weeks of gestation, which is the period during which the embryo or fetus is most vulnerable to teratogens. Pregnant women are more likely to become seriously unwell when compared to non-pregnant women and have a higher risk of their baby being born prematurely if they develop COVID-19 in their third trimester (after 28 weeks of gestation). It is therefore reasonable to aim to have the vaccine before the third trimester, bearing in mind that it takes time for immunity to develop and protection is higher after the second dose of the vaccine. Women who had a first dose of vaccine before becoming pregnant should complete the course with the same vaccine (including if their first dose was with the Oxford-AstraZeneca vaccine).[1]

Timing in the postpartum period

Women in the immediate postpartum period should be offered vaccination in line with the general (non-pregnant) population.[1]

Timing with breastfeeding

The Joint Committee on Vaccination and Immunisation (JCVI) advice[8] published on 30 December 2020 stated there is no known risk in giving available COVID-19 vaccines to breastfeeding women. Breastfeeding women should be offered vaccination at the time when they become eligible (as for the general non-pregnant population). Although there are a lack of safety data for the available vaccines relating to breastfeeding, there is no plausible mechanism by which any vaccine ingredient could pass to a breastfed baby through breast milk. Women should, therefore, not stop breastfeeding in order to be vaccinated against COVID-19.

Timing for women who are planning a pregnancy/undergoing fertility treatment

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.[8] There is no evidence to suggest that COVID-19 vaccines affect fertility, and there is no biologically plausible mechanism by which current vaccines could cause any impact on women's fertility. Animal studies[19,20] of the Pfizer-BioNTech and Moderna vaccines showed that administering these vaccines in rats had no effect on fertility. Preliminary animal studies[21] also showed no effect on fertility from the Oxford-AstraZeneca vaccine. 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 antibody to the spike protein and there is no evidence of fertility problems in people who have already had COVID-19. The British Fertility Society and Association of Reproductive and Clinical Scientists[22] advise people of reproductive age to have a COVID-19 vaccine, including those individuals who are trying to get pregnant or planning a pregnancy in the future. Furthermore, they advise that women can have the COVID-19 vaccine during fertility treatment, and that there is no need to delay fertility treatment after receiving a COVID-19 vaccine.

6. How should women be counselled

Advice

- Pregnant women should be supported, if necessary, to come to an informed decision about vaccination.
- An informed decision-making process should cover the options for timing of vaccination, the benefits and risks of vaccination, and the risks of declining vaccination.
- The RCOG Information sheet and decision aid can be used to aid counselling.

It is a pregnant woman's choice to have a vaccination against COVID-19. If a pregnant woman is undecided whether to get the COVID-19 vaccine, the role of the healthcare provider is to enable the pregnant woman to make her decision through an informed shared decision-making process. It is not necessary to show evidence of this discussion prior to the pregnant women receiving their vaccination (as is the case for the general population presenting for COVID-19 vaccination).

A pregnant woman should have the opportunity to read or view reliable information about COVID-19 vaccine in pregnancy, for example from the NHS, Public Health England or the RCOG. An informed decision-making process involves supporting a pregnant woman to understand the options available (including the risks and benefits of those options) and to make a decision based on the evidence and her personal preference.[23,24]

Counselling may cover the following points.

1. The options available to the pregnant woman:
    - To receive vaccination against COVID-19 now.
    - To decline the vaccine, with the option of having it in future (either later in her pregnancy, or after the birth of her baby) once more information about the vaccine is available.
    - To decline to have the vaccine altogether; this is a woman's individual choice.
2. The benefits of vaccination:
    - Reduction in severe disease for a pregnant woman.
    - Potential reduction in the risk of preterm birth associated with COVID-19.

- Potential reduction in transmission of COVID-19 to vulnerable household members.
- Potential reduction in the risk of stillbirth associated with COVID-19.
- Potential protection of the newborn from COVID-19 by passive antibody transfer.

3. The risks of vaccination (see section 4 for further detail):

- Minor local reaction (pain, redness or swelling at the injection site).
- Mild systemic adverse effects like fatigue, headache or myalgia, typically short-lived (less than a few days).
- Rare thrombotic adverse events following use of the Oxford-AstraZeneca vaccine.
- There has been no evidence to suggest fetal harm following vaccination against COVID-19, and fetal harm is considered to be extremely unlikely based on evidence from other non-live vaccines. Risk of fetal harm cannot be completely excluded until largescale studies of vaccination in pregnancy have been completed.

4. The risks from COVID-19 if the pregnant woman declines vaccination:

- The risks from COVID-19 to mother and fetus are covered in detail in section 1.5 of the RCOG *Coronavirus (COVID-19) infection and pregnancy* Version 13 guidance,[25] and are summarised below.
    - Maternal risks:
        - Most women with COVID-19 in pregnancy will have no symptoms. However, some women will develop critical illness from COVID-19.
        - The risk of severe illness from COVID-19 is higher for pregnant women than for non-pregnant women, particularly in the third trimester.
        - There is consistent evidence that pregnant women are more likely to be admitted to an intensive care unit than non-pregnant women with COVID-19.

- Fetal risks
    - Symptomatic maternal COVID-19 is associated with a two to three times greater risk of preterm birth.
    - Although the overall risk of stillbirth is small, the risk is approximately doubled with SARS-CoV-2 infection.[26,27]

- These risks should be personalised to each individual pregnant woman:
    - Risk of exposure due to occupation: for example (and not limited to) healthcare and social workers, public-facing roles and education settings.
    - Risk of severe illness: medical conditions (hypertension, diabetes), body mass index above 30 kg/m^2, Black or Asian ethnicity or from other minority ethnicity backgrounds.

7. Research on COVID-19 vaccines in pregnant women

There is ongoing research on COVID-19 vaccines in pregnant women, addressing aspects of immunity, safety, different vaccines and optimal schedules for protecting women. More information can be found on the RCOG website. These include a randomised controlled trial funded by Pfizer[28] being conducted worldwide including several UK National Institute for Health Research sites, in which pregnant women are being randomly assigned to receive either the Pfizer-BioNTech vaccine or a placebo. Those who receive the placebo during the trial will then be offered the vaccine once they give birth to ensure all participants have the opportunity of being vaccinated. The HORIZON1 study is also being planned by Janssen,[29] in which all participants will receive the Janssen vaccine (no one will receive a placebo). Finally, there is the PregCOV-19LSR pragmatic trial[30] in which pregnant women are receiving different vaccines on different schedules, depending on their gestational age at enrolment. The aim is to identify the most effective schedule in order to protect pregnant women, as well as other aspects such as whether or not vaccines improve immunity conferred by breast milk.

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