

On 30th December 2020 the UK Medicines & Healthcare products Regulatory Agency (MHRA) announced that both the Pfizer-BioNtech and Astra Zeneca Covid-19 vaccinations can be used during pregnancy and lactation, after considering the individual risks and benefits involved and with more caveats associated with use in pregnancy than in lactation.

This factsheet will outline options for pregnant and breastfeeding women obtaining Covid-19 vaccination in the interim period while full documentation of this decision is put into place by Public Health England (PHE). The information has been collated with reference to relevant NHS England documentation[1] and will be superseded by definitive recommendations from PHE.

Covid-19 vaccinations are prescription only medicines (POMs) which PHE have recommended be administered in most cases with the use of a Patient Group Direction (PGD) as this is an efficient method for mass vaccination. PGDs are written instructions for the administration of medicines by registered healthcare professionals to a pre-defined group of patients without the need for a prescription. The current national PGD[2] explicitly states that the vaccine cannot be given to women who are breastfeeding or pregnant (in line with the MHRA authorisation at the time of PGD publication).

Until the National PGD is updated, the most appropriate options for NHS trusts and PCN hubs to vaccinate breastfeeding and pregnant high priority populations are therefore likely to be the use of either an individual signed prescription or a Patient Specific Direction (PSD) by an independent prescriber.

The use of a PSD may be the most efficient way to deal with this issue in large staff vaccination settings. In a PSD, an independent prescriber gives an authorised instruction to administer a medicine to a list of individually named patients where each patient on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of the patient's health and be satisfied that the medicine to be administered serves the individual needs of each patient on that list. A template PSD is provided within national guidance,[1] which can be used locally with the information on use in pregnancy and lactation amended in line with updated Covid-19 Green Book chapter 14a[3]. Women must be informed of the absence of safety data available.

Given that the PGD may not be able to include pregnancy due to the recommended detailed discussion of individual benefit and risk, this may remain the most appropriate avenue after the PGD update as well.

Updated Recommendations in full:

The MHRA issued amendments to the UK authorisation of the Pfizer-BioNtech Covid-19 vaccination on 30th December 2020, at the same time as authorising the Astra Zeneca Covid-19 vaccination. The MHRA stated that for both vaccines:

“the vaccine should only be considered for use in pregnancy when the potential benefits outweigh any potential risks for the mother and baby. Women should discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances. Women who are breastfeeding can also be given the vaccine”[4]

The JCVI has given further detail:

“There is no known risk associated with giving non-live vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. Although the available data does not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.”

“...There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. 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.”[5]

There is slightly more detail on pregnancy in the full Green Book chapter.[3]

Background:

Initial authorisation of the Pfizer-BioNtech Covid-19 vaccine by the MHRA included a highly precautionary statement that the vaccine was not recommended in pregnancy, for those trying to conceive or those who were breastfeeding[6]. This

was due to a lack of available data on safety in these populations, as they were not included in phase III trials. However it was widely acknowledged that there is minimal theoretical risk with non-live vaccines, particularly in lactation[7].

In contrast, other locations such as the USA, Canada and the EU authorised the Pfizer-BioNtech vaccine with an acknowledgement of the lack of data but no contraindication to its use[8] - this allowed pregnant and breastfeeding priority populations (predominantly health and social care workers) to make their own risk/benefit analysis with their health care provider. This is particularly important for those who are at very high risk of Covid-19 infection or severe complications of infection.

References:

1. <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0923-legal-mechanisms-for-administration-of-the-covid-19-vaccines-v2-10-december-2020.pdf> (see Appendix B for PSD template)
2. <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0956-Patient-Group-Direction-for-COVID-19-mRNA-vaccine-BNT162b2-Pfizer-BioNTech-11-December-2020.pdf>
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8. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>