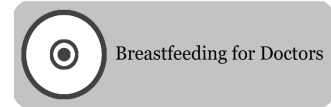## Factsheet on use of Covid-19 vaccinations in breastfeeding and pregnancy

In the UK there have been some changes surrounding the use of Covid-19 vaccinations in breastfeeding and pregnancy, which has led to confusion for some. This factsheet will outline the current position (January 2021) and some background information.
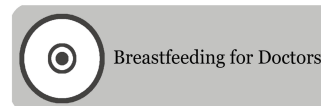
Current position

- All three Covid-19 vaccinations currently authorised for use by the UK Medicines & Healthcare products Regulatory Agency (MHRA) **can be given to people who are breastfeeding**
- All three Covid-19 vaccinations currently authorised for use by the MHRA **can be given to people who are pregnant where the potential benefits outweigh any potential risks**
- There is little information available about risk of vaccination in pregnancy and breastfeeding. The non-clinical evidence reviewed by the MHRA has raised no concerns about safety. Clinical evidence will now be collected.
- People who are breastfeeding can be vaccinated in the same way as anyone else and should be informed of the lack of safety data available. People who are pregnant will need to have their vaccination prescribed after a personalised risk/benefit discussion
- No pressure should be applied to people who are pregnant or breastfeeding to be vaccinated against Covid-19. Any protection provided for at-risk groups, such as a change in working location, should continue for those who choose not to be vaccinated due to pregnancy or breastfeeding.
- The original authorisation of the Pfizer-BioNtech Covid-19 vaccination advised that it should not be used in pregnancy or breastfeeding, meaning that some professionals and members of the public may be confused about the current position.

Recommendations in full (up to date on 11th January 2021):

The Joint Committee on Vaccination and Immunisation (JCVI) states:

"…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."

And "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."[1]

Government guidance also states that non-clinical evidence (usually studies in cells or animals) "has raised no concerns about safety in pregnancy"[2] but that before clinical evidence (studies in humans) is available "it is usual to not recommend routine vaccination during pregnancy".[2] It is also noted that "Adenovirus vectors, similar to those used in the AstraZeneca COVID-19 vaccine, have been widely used to vaccinate [pregnant/breastfeeding] women against Ebola without raising any concern".[3]
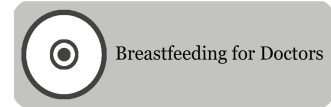
Information for health professionals on the Moderna vaccine recommends the same position for pregnancy and acknowledges the lack of data relating to breastfeeding.[4]

Legal constraints:
Covid-19 vaccinations are prescription only medicines. However, there are two legal mechanisms for them to be given by non-prescribing professionals in order to increase efficiency of the mass vaccination programme – a Patient Group Direction (PGD) and a National Protocol. In both of these cases non-prescribers can give specific vaccinations to a group of people with described characteristics. People who are breastfeeding can be given Covid-19 vaccinations in this way.[3]

Because of the current advice that use of Covid-19 vaccination in pregnancy should be only where potential benefit exceeds potential risk, people who are pregnant cannot be vaccinated under a PGD or national protocol arrangement. They should be prescribed the vaccination either with an individual signed prescription or a Patient Specific Direction (PSD) by an independent prescriber, after consideration of their individual circumstances.[3]

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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[5]. 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[6].

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[7] – allowing pregnant and breastfeeding priority populations (predominantly health and social care workers) to make their own risk/benefit analysis with their health care provider. The MHRA subsequently aligned their authorisation with this approach and the World Health Organisation has taken a similar approach[8]. There are several English language decision aids available to help guide a discussion on risks and benefits in pregnancy[9-10].

References:

1. https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020/joint-committee-on-vaccination-and-immunisation-advice-on-priority-groups-for-covid-19-vaccination-30-december-2020
2. https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding
3. https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)
4. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna
5. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948101/Temporary_Authorisation_HCP_Information.pdf
6. https://www.acog.org/en/Clinical/Clinical%20Guidance/Practice%20Advisory/Articles/2020/12/Vaccinating%20Pregnant%20and%20Lactating%20Patients%20Against%20COVID%2019
7. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
8. https://www.who.int/news-room/feature-stories/detail/who-can-take-the-pfizer-biontech-covid-19--vaccine
9. https://www.rcog.org.uk/globalassets/documents/guidelines/2021-01-12-covid-19-vaccine-info-sheet.pdf
10. https://www.rcpi.ie/news/releases/covid-19-vaccine-decision-aid-for-pregnant-women/