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Guidance

The safety of COVID-19 vaccines when given in pregnancy

Updated 30 April 2021

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This publication is available at 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/

Background

<u>COVID-19</u> disease is caused by the <u>SARS-CoV-2</u> virus (a new coronavirus) that emerged in China in December 2019. Disease symptoms at the time of diagnosis vary from those who have the infection but suffer no ill effects or have minor illness to those requiring breathing and intensive care support. Severe disease is more common with increasing age, particularly from 65 years and over.

COVID-19 vaccine in pregnancy

The <u>COVID-19</u> vaccines available in the UK have been shown to be effective and to have a good safety profile. These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb. There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding (https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html).

The Joint Committee on Vaccination and Immunisation (<u>JCVI</u>) has advised that pregnant women should be offered <u>COVID-19</u> vaccines at the same time as people of the same age or risk group.

Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK regulatory agency responsible for licencing medicines including vaccines, has raised no specific concerns for safety in pregnancy. Evidence on <u>COVID-19</u> vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

In the USA, over 100,000 pregnant women have been vaccinated, mainly with Pfizer and Moderna vaccines, and no safety concerns have been identified. Pfizer and Moderna vaccines are therefore the preferred vaccines for pregnant women of any age who are coming for their first dose. If a different <u>COVID-19</u> vaccine is given to a pregnant woman, she should be reassured that the vaccine does not contain live coronavirus and therefore cannot cause <u>COVID-19</u> infection in her or in her baby. Some <u>COVID-19</u> vaccines contain a different harmless virus to help deliver the vaccine – this virus cannot multiply and so will not cause infection in a pregnant woman or her baby.

The data for each licensed <u>COVID-19</u> vaccine in pregnancy is limited because pregnant women are not included in vaccine trials. This is not because of any specific safety concerns but as a matter of caution (https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020), like that applied to trials of most other medicines.

Further information can be found in the <u>COVID-19</u> vaccination: a guide for all women of childbearing age, pregnant or breastfeeding (https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding) and <u>COVID-19</u> vaccines and pregnancy (https://www.rcog.org.uk/covid-vaccine).

COVID-19 disease in pregnancy

Available evidence suggests that <u>COVID-19</u> infection in pregnancy is unlikely to lead to problems with a baby's development (https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/covid-19-virus-infection-and-pregnancy) and there have not been any reports of this. There is also no evidence of an increased risk of miscarriage if you become infected during pregnancy.

Although the overall risk from <u>COVID-19</u> disease in pregnant women and their new babies is low, in later pregnancy some women may become seriously unwell and need hospital treatment.

Pregnant women with <u>COVID-19</u> in later pregnancy have a higher risk of intensive care admission than women of the same age who are not pregnant. Women with <u>COVID-19</u> disease are also 2 to 3 times more likely to have their babies early than women without <u>COVID-19</u> [footnote 1]. Pregnant

women with certain underlying clinical conditions are at even higher risk of suffering serious complications from <u>COVID-19</u>.

In a UK study of pregnant women with <u>COVID-19</u> disease serious enough to require hospital admission (most infected in the second or third trimester), only 6 of 265 babies tested positive for <u>COVID-19</u> immediately after birth. In line with other studies, this suggests it is uncommon for the natural infection to pass from a woman to her baby. When babies have developed <u>COVID-19</u> soon after birth (https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/covid-19-virus-infection-and-pregnancy) they have been well.

Getting pregnant

There is no need to avoid pregnancy after <u>COVID-19</u> vaccination. There is no evidence that <u>COVID-19</u> vaccines have any effect on fertility or your chances of becoming pregnant.

The second dose

<u>COVID-19</u> vaccines offer pregnant women the best protection against <u>COVID-19</u> disease which can be serious in later pregnancy for some women.

The first dose of <u>COVID-19</u> vaccine will give you good protection. You need the second dose to get longer lasting protection. You do not need to delay this second dose. If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy.

If you have already had a first dose of <u>COVID-19</u> vaccine without suffering any serious side effects, you can have your second dose with the same vaccine when this is offered.

If you recently had a first dose of the AstraZeneca (AZ) vaccine there is further information in the <u>COVID-19</u> vaccination and blood clotting leaflet (https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting).

The UK Vaccine in Pregnancy surveillance programme

All <u>COVID-19</u> vaccines given inadvertently (that is, where the woman did not know she was pregnant at the time of vaccination) from the first day of last menstrual period to any time in pregnancy should be reported to the UK Vaccine in Pregnancy surveillance programme (https://www.gov.uk/guidance/vaccination-in-pregnancy-vip) run by the Immunisation Department of Public Health England.

The objectives of the UK vaccine in pregnancy surveillance are to compile additional information on women who are immunised with specified vaccines whilst pregnant to monitor the safety of such exposures. This data will be used to help better inform pregnant women who are immunised, their families and health professionals who are responsible for their care.

This surveillance is being undertaken in collaboration with the <u>MHRA</u>, the UK teratology information service (UKtis) and with Public Health Scotland, Public Health Wales and Public Health Agency in Northern Ireland.

References

1. Knight Marian, Bunch Kathryn, Vousden Nicola, Morris Edward, Simpson Nigel, Gale Chris and others. Characteristics and outcomes of pregnant women admitted to hospital with confirmed <u>SARS-CoV-2</u> infection in UK: national population based cohort study BMJ 2020; 369:m2107

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