

- 1. Home (https://www.gov.uk/)
- 2. Health and social care (https://www.gov.uk/health-and-social-care)
- 3. Public health (https://www.gov.uk/health-and-social-care/public-health)
- 4. Health protection (https://www.gov.uk/health-and-social-care/health-protection)
- 5. Immunisation (https://www.gov.uk/health-and-social-care/health-protection-immunisation)
- 6. Safety of COVID-19 vaccines when given in pregnancy (https://www.gov.uk/government/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy)
- Public Health

England (https://www.gov.uk/government/organisations/public-health-england)

#### Guidance

# The safety of COVID-19 vaccines when given in pregnancy

Published 18 December 2020

#### Contents

Background COVID-19 vaccine in pregnancy COVID-19 disease in pregnancy The UK Vaccine in Pregnancy surveillance programme References

Print this page

# OGL

#### © Crown copyright 2020

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3 (https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3) or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gov.uk.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at https://www.gov.uk/government/publications/safety-of-covid-19-vaccineswhen-given-in-pregnancy/the-safety-of-covid-19-vaccines-when-given-in-pregnancy

#### Background

COVID-19 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**

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). If a COVID-19 vaccine is given to a pregnant woman, she should be reassured that the vaccine does not contain live <u>SARS-CoV-2</u> virus and therefore cannot cause COVID-19 infection in her or in her baby. Some COVID-19 vaccines contain a different harmless virus to help deliver the vaccine – whilst this virus is live, it cannot reproduce and so will not cause infection in a pregnant woman or her baby.

Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (<u>MHRA</u>), the UK regulatory agency responsible for licencing medicines including vaccines, raise no concerns for safety in pregnancy (https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). Because of the new formulation of some COVID-19 vaccines the <u>MHRA</u> wants to see more non-clinical data before finalising the advice in pregnancy. It is standard practice when waiting for such data on any medicine, to avoid use even in women who are planning pregnancy (https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). This will be kept under review as more evidence becomes available.

The data for each licensed COVID-19 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, like that applied to trials of most other medicines. Therefore, as a precautionary approach, COVID-19 vaccines are not currently recommended in women at any stage of pregnancy (https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020).

If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy before finishing the recommended schedule.

## **COVID-19 disease in pregnancy**

Available evidence suggests that COVID-19 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.

There is some evidence that babies can be born prematurely to women who are very unwell with coronavirus (https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/covid-19-virus-infection-and-pregnancy)<sup>[footnote 1]</sup>. In a UK study of pregnant women with COVID-19 disease serious enough to require hospital admission (most infected in the second or third trimester), only 6 of 265 babies tested positive for COVID-19 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 COVID-19 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.

## The UK Vaccine in Pregnancy surveillance programme

All exposures to COVID-19 vaccine 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. These data will be used to help better inform pregnant women who are inadvertently 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

 Knight Marian, Bunch Kathryn, Vousden Nicola, Morris Edward, Simpson Nigel, Gale Chris et al. 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

Print this page