

Update on WHO Interim recommendations on COVID-19 vaccination of pregnant and lactating women

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AFRO Webinar
June 2, 2021

Outline of Presentation

- Background on evidence
- WHO interim recommendations
 - Pregnancy
 - Lactation
- Global tracking of policies
- Safety Surveillance
- Tools and resources



Process for WHO Policy Recommendations on Immunization



Strategic Advisory Group of Experts on Immunization (SAGE)

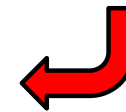
International experts; independent review of evidence

SAGE video meetings monthly since January 2021
SAGE COVID-19 Working Group/sub-groups (2-3 times/week)

Reports to WHO Director General

www.who.int/groups/strategic-advisory-group-of-experts-on-immunization

COVID-19 Technical Documents



- | | |
|---|---|
| <ul style="list-style-type: none">✓ Product specific documentation (6 EUL vaccines approved)✓ Generic guidance for policy-making on COVID-19 vaccines✓ Further resources – Vaccine Introduction Toolkit | <ul style="list-style-type: none">✓ WHO SAGE Roadmap For Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply✓ Other COVID-19 related guidance (e.g. Gender; Influenza) |
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www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials

Background evidence on COVID-19 vaccines and pregnant/lactating women

- Pregnant and lactating women were not included in the initial clinical trials of COVID-19 vaccines.
- Studies are underway* but long-term safety data are not yet available
- Available COVID-19 vaccines are not live virus vaccines
- Data from animal studies and post-introduction surveillance data have not shown harmful effects in pregnancy
- Vaccine effectiveness likely to be comparable to non-pregnant women; initial immunogenicity data similar



WHO Interim Recommendations

Interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222, SII Covishield, SK Bioscience)

Interim guidance
First issued 10 February 2021
Updated 21 April 2021



Background
This interim guidance has been developed on the basis of the advice issued by the Strategic Advisory Group of Experts (SAGE) on Immunization at its extraordinary meeting on 8 February 2021 (1), and updated on 21 April 2021.
Declarations of interests were collected from all external contributors and assessed for reported interests can be found on the SAGE meeting website and SAGE Website.
These interim recommendations refer to a generic group of COVID-19 vaccines that are produced by different manufacturers (AstraZeneca, SII, SK Bioscience), but which all rely on the same technology (ChAdOx1-S).
This background document was developed to inform the interim recommendation making process. It is not updated on a regular basis. The latest Grade and ETR tables can be obtained here: <https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>

Background document on the AZD1222 vaccine against COVID-19 developed by Oxford University and AstraZeneca

Background document to the WHO Interim recommendations for use of the AZD1222 (ChAdOx1-S [recombinant] vaccine against COVID-19 developed by Oxford University and AstraZeneca
1 March 2021



In the interim, WHO recommends vaccination in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks.

For example:

- pregnant women at high risk of exposure to COVID-19
- pregnant women with comorbidities that place them in a high-risk group for severe COVID-19

<https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>

Enabling Pregnant Women's Choice: Benefit/Risk Assessment

- Pregnant women should be provided with information about the:
 - risks of COVID-19 in pregnancy
 - likely benefits of vaccination in the local epidemiologic context
 - current limitations of the safety data in pregnant women
- Not necessary to conduct pregnancy testing prior to vaccination
- No need to delay or terminate pregnancy because of vaccination

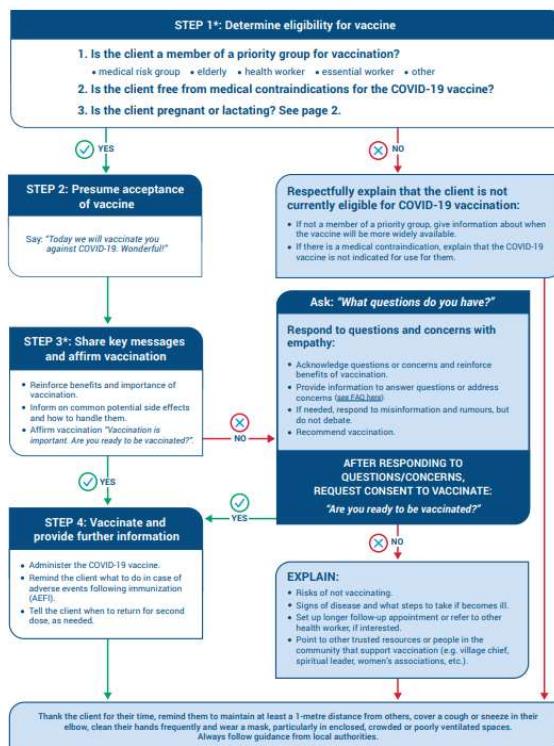


Health worker Job Aid

HEALTH WORKER COMMUNICATION FOR COVID-19 VACCINATION

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Flow diagram for communicating during COVID-19 vaccination sessions



*These steps can be carried out prior to the vaccination event, in-person or via virtual platform, at a group educational session, community meeting, or one-on-one interaction. These steps may need to be briefly repeated on the day of vaccination to affirm vaccination.

COVID-19 VACCINATION: PREGNANT AND LACTATING WOMEN

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Before vaccination, pregnant women should be provided with information about:

- the risks of COVID-19 in pregnancy
- the likely benefits of vaccination in the local epidemiologic context, and
- the current limitations of the safety data in pregnant women.

It is not necessary to conduct pregnancy testing prior to vaccination. There is **NO** need to delay or terminate pregnancy because of vaccination.

COMMONLY ASKED QUESTIONS AND KEY MESSAGES:

Are pregnant women at higher risk for complications of COVID-19?

- Pregnant women who get COVID-19 are more likely to have complications (e.g. admitted to intensive care, needing a machine to help them breathe, etc.) compared to non-pregnant reproductive aged women.
- COVID-19 in pregnancy has also been associated with increased risk of pre-term birth and neo-natal intensive care.
- Pregnant women who are older (≥35 years) or have high body mass index (≥30), or an existing co-morbidity such as diabetes or hypertension, are at particular risk of serious outcomes of COVID-19.

Can COVID-19 vaccines harm babies in the womb?

- Pregnant and lactating women were not included in the initial clinical trials of COVID-19 vaccines, and long-term safety data are not yet available. However, studies are underway.
- The information we have so far shows that the vaccines do not have any negative effect on babies in the womb.
- They are not live vaccines, so they cannot infect either mother or baby with COVID-19.

Are COVID-19 vaccines recommended for pregnant women?

- WHO recommends the vaccination of pregnant women when the benefits outweigh the potential risks (e.g. pregnant women at high risk of exposure to COVID-19, or with comorbidities that place them in a high-risk group for severe COVID-19).
- Pregnant and lactating women were not included in the initial clinical trials of COVID-19 vaccines, and long-term safety data are not yet available. However, studies are underway.
- Available data from animal studies have not shown harmful effects in pregnancy.
- Large numbers of pregnant women have chosen to be vaccinated in the USA, UK and other high-income countries. Safety surveillance has not found any pregnancy-related issues.
- Vaccination should protect pregnant women like everyone else. Vaccine effectiveness is likely to be comparable to non-pregnant women; initial studies show that immune responses following vaccination are similar.

Are COVID-19 vaccines recommended for lactating women?

- WHO recommends the vaccination of lactating women just like other adults (vaccine effectiveness and safety are expected to be similar).
- Breastfeeding has substantial benefits for both for babies and mothers.
- Currently there are no data on the safety of COVID-19 in lactating women or their breastfed infants. However, COVID-19 vaccines are unlikely to pose a risk to the breastfeeding infant.
- WHO recommends continuing breastfeeding after vaccination.

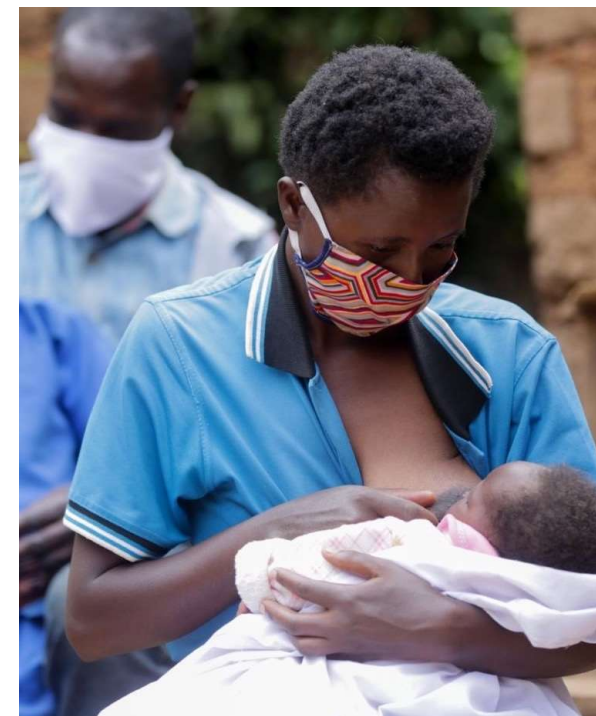
In what way will getting the COVID-19 vaccine help pregnant or lactating women?

- Since pregnant or lactating women may be at higher risk of exposure and/or severe disease (due to being a health worker or having a specific co-morbidity), choosing to get the vaccine will help protect them against COVID-19.

<https://www.who.int/publications/m/item/health-worker-communication-for-covid-19-vaccination-flow-diagram>

WHO Interim recommendations Breastfeeding and COVID-19 vaccination

- Breastfeeding = substantial health benefits to mother & infant
- Vaccine effectiveness expected to be similar in lactating women as in other adults
- Currently no data on the safety of COVID-19 vaccine in lactating women or their breastfed infants
- However, unlikely to pose a risk to the breastfeeding child
- On the basis of these considerations, WHO recommends vaccination in lactating women as in other adults
- WHO does **not** recommend to discontinue breastfeeding because of vaccination

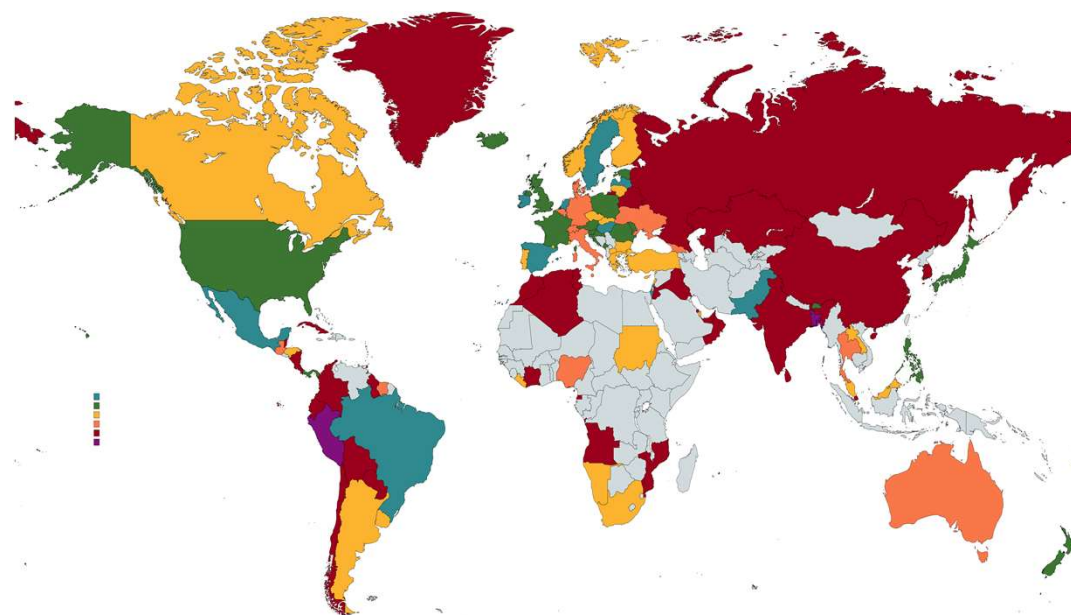


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Hdoes <https://www.who.int/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf>
<https://www.who.int/publications/i/item/9789240011588>
<https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/who-recommendations-for-routine-immunization---summary-tables>

Global tracking of national policies on COVID-19 vaccination of pregnant women - **DRAFT June 1/21**

-  **Recommended for some or all:**
Pregnant people should be offered vaccine...
-  **Permitted for all:**
Pregnant people may receive vaccine
-  **Permitted with qualifications:**
Pregnant people may receive the vaccine only if...
-  **Not recommended but with exceptions:** Pregnant people should not receive the vaccine unless...
-  **Prohibited:**
Pregnant women should not receive the vaccine
-  **Conflicting information**

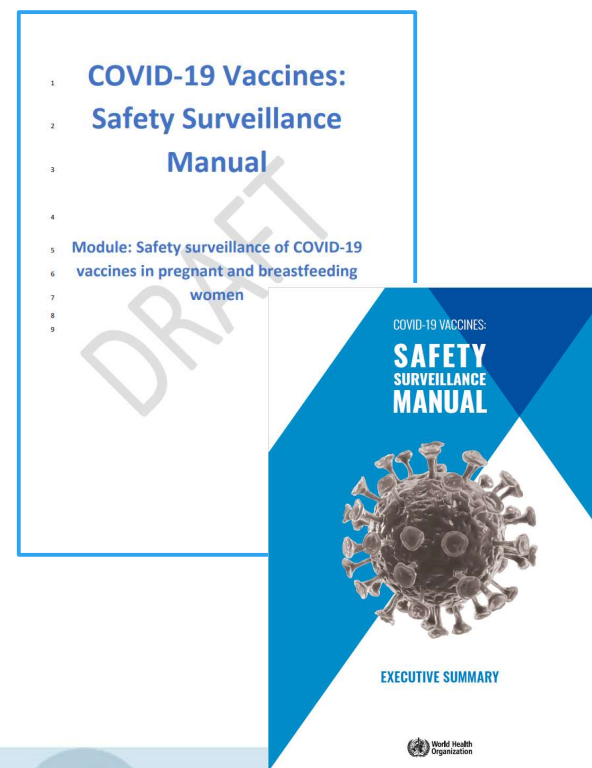


Created with mapchart.net

<https://www.comitglobal.org/>

Safety surveillance for pregnant & breastfeeding women

- WHO COVID-19 vaccine safety surveillance manual: **NEW** pregnancy module
- Immunization programmes to establish surveillance of women who have been vaccinated either intentionally or inadvertently during pregnancy, and their infants
- Both active and passive surveillance approaches recommended to assess adverse events following immunization (AEFI), incl during pregnancy



Additional resources



- Living systematic reviews on pregnancy and breastfeeding

<https://www.who.int/news/item/01-09-2020-increasing-understanding-of-the-impact-of-covid-19-for-pregnant-women-and-their-babies>
<https://nyaspubs.onlinelibrary.wiley.com/doi/10.1111/nyas.14477>

- Q&As: COVID-19 & pregnancy and childbirth

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-pregnancy-and-childbirth>

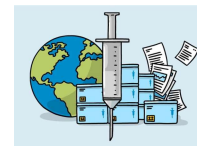
- Q&As: COVID-19 & breastfeeding

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-breastfeeding>

- Infographics and videos

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-breastfeeding>

<https://www.youtube.com/watch?v=OFGiy6t7k5E>



- WHO COVID-19 vaccines technical documents

<https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>

- Scientific briefs

➤ Breastfeeding and COVID-19

https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Breastfeeding-2020.1

➤ Timing of mother-to-child transmission of SARS-CoV-2

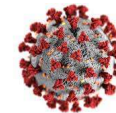
<https://www.who.int/publications/i/item/WHO-2019-nCoV-mother-to-child-transmission-2021.1>

- WHO Unity Studies

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations>

- Measuring COVID-19 vaccines effectiveness

- A prospective cohort study investigating maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2





Thank You!