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

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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

- Product specific documentation (6 EUL vaccines approved)
- Generic guidance for policy-making on COVID-19 vaccines
- Further resources – Vaccine Introduction Toolkit
- 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)

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

* [https://clinicaltrials.gov/ct2/show/NCT04754594](https://clinicaltrials.gov/ct2/show/NCT04754594)
  [https://clinicaltrials.gov/ct2/show/NCT04765384](https://clinicaltrials.gov/ct2/show/NCT04765384)
WHO Interim Recommendations

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
Flow diagram for communicating during COVID-19 vaccination sessions

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 ventilator, or requiring cardiovascular support).
- Pregnancy is a risk factor for severe COVID-19, especially in the third trimester and for women with pre-existing conditions.

Are pregnant or lactating women at risk for birth defects from COVID-19 vaccines?
- Pregnant and breastfeeding 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 effects on babies in the womb.
- They are not live vaccines, so they cannot infect other mothers or babies 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. This is a conservative approach to managing high-risk groups and ensuring that pregnant women are protected.
- Pregnant and breastfeeding 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 been vaccinated in the USA and other high-income countries, where several outbreaks have been linked to pregnant women.
- 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 is expected to be similar).
- Breastfeeding has substantial benefits for both babies and mothers.
- Currently, there is no evidence on the safety of COVID-19 in lactating women or on breastfeeding. However, COVID-19 vaccines are unlikely to cause a risk to the breastfeeding infant.
- WHO recommends continuing breastfeeding after vaccination.

In what ways will getting the COVID-19 vaccine help pregnant or lactating women?
- Some pregnant or lactating women may be at higher risk of severe illness than other women due to being a health worker or having a specific comorbidity (e.g., diabetes, high blood pressure). Vaccines may be the only way to protect them from severe 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
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**

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

https://apps.who.int/iris/handle/10665/338400
Additional resources

• Living systematic reviews on pregnancy and breastfeeding

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

• Q&As: COVID-19 & breastfeeding

• Infographics and videos
  https://www.youtube.com/watch?v=cOGLeGd7KSj

• WHO COVID-19 vaccines technical documents
  https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials

• WHO Unity Studies
  • Measuring COVID-19 vaccines effectiveness
  • A prospective cohort study investigating maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2

• Scientific briefs
  ➢ Breastfeeding and COVID-19
  ➢ Timing of mother-to-child transmission of SARS-CoV-2
Thank You!