

Operational Guidance for COVID-19 Vaccination of Pregnant Women

Dated: 02/07/2021

Background

COVID-19 infection during pregnancy may result in rapid deterioration of health of pregnant women and could also affect the fetus. Experts are of the view that the benefits of vaccination to the pregnant women outweigh its potential risks. Based on the recommendations from National Technical Advisory Group on Immunization (NTAGI), MoHFW has approved vaccination of pregnant women against COVID-19 with the condition that the pregnant women may be informed about the risks of exposure to COVID-19 infection along with the risks and benefits associated with the COVID-19 vaccines available in the country. Based on the information provided, a pregnant woman will have the choice to take the vaccination.

The COVID-19 vaccination has been expanded to include all citizens from 18 years of age onwards, making more than 69% of population eligible, of which nearly half (48%) are women. Pregnant women who develop COVID-19 are more likely to require intensive care than their non-pregnant counterparts. COVID-19 infection during pregnancy may result in rapid deterioration of health of pregnant women and might affect the fetus also. Information related to COVID-19, the impact of the disease on pregnancy and data related to COVID-19 vaccines are rapidly evolving. In the context of current situation of the SARS-CoV-2 pandemic, experts have suggested that the COVID-19 vaccine may be offered to the pregnant women if no contraindications exist. The intent is to weigh risk versus benefit on individualized basis, so that a pregnant woman can take an informed decision. This decision is based on the woman's understanding that the risk of infection and/or morbidity from COVID-19 outweighs the undescribed risk of being vaccinated during pregnancy.

In India, at present three vaccines have received approval for restricted use in emergency situation. One of them is an inactivated vaccine (Covaxin) and other two are based on non-replicating viral vector platform (Covishield and Sputnik V).

A pregnant woman who opts for vaccination, could be vaccinated at any time of the pregnancy. To help pregnant women make an informed decision to be vaccinated, they should

be provided with information about the risks of COVID-19 infection in pregnancy, the benefits of vaccination, along with the likely side effects of vaccination.

This guidance note enables states to develop a Counseling and Vaccination plan for pregnant women.

Section I: Preparing for COVID-19 vaccination of pregnant women

(i) Orientation and Capacity Building

Orientation of programme staff: States would undertake an orientation of programme managers responsible of the COVID vaccination programme at district, block and sub block levels, including Health and Wellness Centres and vaccinators at the health facilities in the public and private sector and also of all FLWs and health care providers at all the levels including medical colleges, DH, SDH, CHCs, PHCs, private clinics etc. who provide ANC services to women. The orientation would be conducted virtually and would broadly cover the areas in the attached sheet (Annexure I).

Training of FLWs and Vaccinations: From the above category, states would identify a pool of individuals (PHC-MOs, Staff Nurses, District Programme managers, and Community Health Officers etc.) who would be directly be responsible for training of frontline workers and vaccinators on counseling of pregnant women and providing them with accurate information regarding the benefits and risks of the vaccine, including guiding them on registration and the location of the appropriate vaccination site. This training can be accomplished in two hours. It would need to be conducted in small batch (10-15) at the level of the PHC, ensuring COVID appropriate behaviors. The material to be used is at Annexure II.

(ii) Engagement of medical professionals in the private sector

The state would conduct an orientation of members from professional bodies such as FOGSI, IMA, IAP & NNF, and any other state specific professional bodies they would be requested to ensure that this information is transmitted to all members. This could also be done virtually.

Section II: Counseling pregnant women for COVID Vaccination

There are several points at which interface of the pregnant woman and the FLW occurs and where pregnant women could be counselled. These include:

- Household visits by frontline workers;
- Antenatal checkup at health facility, outreach immunization sessions, Village Health and Nutrition Days (VHNDs) and Urban Health and Nutrition Days (UHNDs).
- Facility visits by pregnant women for other reasons;
- Any other site where there is interaction with the pregnant woman
- COVID-19 Vaccination Centers (CVCs);

During the counselling, the FLW or vaccinator (if the women reaches the CVC directly and has questions related to COVID 19 vaccination) should explain to the pregnant women the potential risks of COVID-19 on their health or that of the baby, benefits of vaccination, potential side effects and precautions they need to take following vaccination.

Section III: Vaccination of Pregnant Women

If the pregnant woman decides to get vaccinated, the process of registration for COVID-19 vaccination needs to be explained to her and the accompanying family member. She also needs to be informed about the nearest COVID vaccination center

The modality for registration of beneficiaries, reporting of vaccination, generation of certificate etc. remains the same as general population. Operational guidelines and standard operating procedures for COVID-19 vaccination are available at:

<https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf>

<https://www.mohfw.gov.in/pdf/GuidancedocCOWIN2.pdf>

Section IV: Adverse Events following Vaccination

The full impact of COVID-19 disease on pregnancy outcomes for mother and fetus as well as for new-born is still unclear. Therefore, pregnant women require special considerations and systematic reporting of adverse events following immunization (AEFI). National AEFI surveillance operational guidelines and Covid-19 vaccination operational guidelines will be

followed for AEFI surveillance related to Covid-19 vaccination of pregnant women. Following are the additional specific activities and action points under this:

1. Obstetrician and gynecologist, pediatrician or neonatologist to be included in AEFI committees and be sensitized on Covid-19 vaccination of pregnant women
2. Members of local FOGSI chapter and IAP should be oriented on Covid-19 vaccination of pregnant women
3. All the medical officers, private practitioners and frontline health workers to be trained on their role in AEFI surveillance related to Covid-19 vaccination of pregnant women.

During vaccination:

1. The vaccinator or medical officer must consider the fact that women in reproductive age group might be unaware of the pregnancy at the time of vaccination. Therefore, the vaccinator must inform her for immediate reporting of AEFI, if any, following Covid-19 vaccination. In such cases, women will need to report immediately to the vaccinator or nearest health facility.

Reporting:

1. The pregnancy status of women should be recorded into the AEFI notification form while reporting AEFI cases.
2. All Adverse Event following vaccination of pregnant women should be reported immediately into Co-WIN.
3. All serious and severe adverse events following vaccination of pregnant women should be reported immediately to concerned Medical Officer / District Immunization Officer.

Investigation of cases:

1. Obstetrician and gynecologist, pediatrician or neonatologist should be part of District AEFI Committee investigating all serious and severe AEFI cases following vaccination of pregnant women.
2. The investigation of all such cases to be expedited. Cytopathological examination of aborted/ perinatal death if any occurring in vaccinated women may be done.
3. The adverse event and the pregnancy outcome must be noted on the ANC/MCH card. Pregnancy registry can be used to track such cases and to determine pregnancy outcome.

4. All antenatal, post-natal and other relevant clinical records must be sought for and collected during investigation and gathered from the treating physician.

Causality assessment:

Causality assessment of all adverse events following Covid-19 vaccination of pregnant women to be expedited.

Section V: Monitoring (as for current vaccination for COVID)

State Task forces (STF) will review planning, capacity building and implementation of pregnant women vaccination in the state.

District Task Forces (DTF) / Urban Task Forces (UTF) will be responsible for ensuring training of health workers, sensitization of professional bodies, and monitoring of vaccination activities for pregnant women.

Annexure I

Counselling pregnant women for COVID vaccines Fact-Sheet to guide the Medical Officers

As a Medical Officer, you need to build capacity of Frontline Workers and Vaccinators to counsel pregnant women and their families about the risks of COVID-19 in pregnancy (including, for example, that some pregnant women are at increased risk of infection, or have comorbidities that add to their risk of severe disease and adverse pregnancy outcomes), the likely benefits of vaccination in the current epidemiological context, and the current limitations of the safety data in pregnant women. Based on it the pregnant woman can choose to get vaccinated or not for COVID-19. This would empower pregnant women to make an informed decision. This note provides you with the information to help you educate and support Frontline Workers and Vaccinators, so that they can assist pregnant women and their families make an informed decision on getting the COVID-19 vaccine.

1. Why is COVID 19 vaccine being recommended for pregnant women?

- Pregnancy does not increase the risk to COVID-19 infection, but current evidence indicate that pregnant women are at an increased risk for severe illness from COVID-19 compared to non-pregnant women in case they get infected.
- Additionally, pregnant women with COVID-19 are at increased risk for preterm birth and might have an increased risk of other adverse pregnancy outcomes¹ including higher chances of neonatal morbidity²
- Most pregnant women will be asymptomatic or have mild disease, BUT their health may deteriorate rapidly and that might affect the foetal outcome.
- It is important that they take all precautions to protect themselves from acquiring COVID-19, including taking vaccination against COVID-19.
- WHO recommends vaccination in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks, such as pregnant women at high risk of exposure to COVID-19 and pregnant women with comorbidities that place them in a high-risk group for severe COVID-19 disease.
- It is therefore advised that a pregnant woman should take COVID-19 vaccine.

¹Wei SQ, Bilodeau-Bertrand M, Liu S, Auger N. The impact of COVID-19 on pregnancy outcomes: a systematic review and meta-analysis. CMAJ. 2021 Apr 19;193(16):E540-E548. doi: 10.1503/cmaj.202604. Epub 2021 Mar 19. PMID: 33741725; PMCID: PMC8084555.

²Outcomes of Neonates Born to Mothers with Coronavirus Disease 2019 (COVID-19) – National Neonatology Forum (NNF) India COVID-19 Registry; early online version, Indian pediatrics

2. Who are at Higher Risk of getting infected with COVID-19?

- Someone who is a health care worker or a frontline worker.
- Community having high or increasing rate of COVID-19 infections.
- Frequently exposed to people outside the household.
- Difficulty in complying with social distancing if living in a crowded household.

3. How does COVID 19 affect the health of the pregnant woman?

- Although most (>90 percent) infected pregnant women recover without need for hospitalization, rapid deterioration in health may occur in a few.
- Symptomatic pregnant women appear to be at increased risk of severe disease & death.
- Compared with pregnant women without COVID-19, those with symptomatic COVID-19 are at increased risk of adverse pregnancy outcomes, including admission to the ICU, iatrogenic preterm birth, pre-eclampsia-like symptoms, Caesarean section and death ³.

4. How does COVID 19 infection of pregnant women affect the baby?

- Most (over 95 percent) of newborns of COVID-19 positive mothers have been in good condition at birth.
- However, Covid-19 in pregnancy increases the chances of preterm birth, increasing the possibility of hospitalization for the neonate and in some cases even death.

5. Which pregnant women are at higher risk of developing complication after COVID 19 infection?

Risk factors for developing complication after COVID 19 infection during pregnancy are:

- Pre-existing co-morbidities, advanced maternal age, and high body mass index are risk factors for severe COVID -19 in pregnancy⁴.
- Pregnant women with certain high-risk conditions have greater risk of severe illness from COVID-19 such as
 - Pre-existing medical conditions e.g. Diabetes
 - Organ transplant recipients
 - Chronic respiratory conditions like COPD, Asthma, Cystic Fibrosis
 - Homozygous sickle cell disease

³<https://www.heart.org/en/coronavirus/coronavirus-questions/questions-about-covid-19-vaccination>

⁴SAGE guidance for the development of evidence-based vaccination-related recommendations. Geneva: World Health Organization; 2017 (https://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf, accessed 19 April 2021).

- Receiving immunosuppression therapies (enough to significantly increase risk of infection)
- Dialysis or advanced chronic kidney disease
- Congenital or acquired heart disease

6. If a pregnant woman has already had COVID-19, when should she be vaccinated?

- In case a woman has been infected with COVID-19 infection during the current pregnancy, then she should be vaccinated soon after the delivery.

7. Are there any side effects of the COVID 19 vaccines that can either harm the pregnant women or her foetus?

- COVID 19 vaccines available are safe and vaccination protects pregnant women against COVID 19 illness/disease like other individuals.
- Based on current knowledge, experts believe that COVID -19 vaccines are unlikely to pose a risk to the pregnant person or foetus⁵.
- Like any medicine a vaccine may have side effects which are normally mild. After getting the vaccine, she can get mild fever, pain at injection site, or feel un-well for 1-3 days.
- The long-term adverse effects and safety of vaccine for foetus and child is not established yet.
- Very rarely, (one in 1-5 lakh persons) the beneficiary may after COVID 19 vaccination, experience some of the following symptoms within 20 days after getting the injection which may need immediate attention

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| <p style="text-align: center;">Symptoms occurring within 20 days after receiving any COVID 19 vaccine</p> <ul style="list-style-type: none"> - Shortness of breath (difficulty in breathing) - Chest Pain - Pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf) - Small pinpoint haemorrhages (petechial) or bruising of the skin beyond the vaccination site - Persistent abdominal pain with or without vomiting - Seizures in the absence of previous history of seizures with or without vomiting - Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache) <p>When should the vaccine be given to the pregnant woman?</p> <ul style="list-style-type: none"> - The COVID 19 vaccination schedule can be started anytime during pregnancy - Weakness/paralysis of limbs or any particular side of the body - Persistent vomiting without any obvious reason - - Blurred vision/ pain in eyes <p>Any other symptom or health condition which is of concern to the recipient or the family</p> |
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⁵ Interim Clinical Considerations for Use of COVID -19 Vaccines Currently Authorized in the United States; Centers for Disease Control and Prevention; <https://www.cdc.gov/vaccines/Covid -19/info-by-product/clinical-considerations.html#pregnant>; accessed on 16 May 2021.

8. Are there any specific contraindications for vaccination in Pregnancy?

As for the general population, pregnant women should avoid vaccination in the following conditions:

- Anaphylactic or allergic reaction to the previous dose of COVID-19 vaccine
- Anaphylaxis or allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc.
- Vaccine is temporarily contraindicated in the following conditions:
 - Diagnosed COVID-19 infection – defer for 12 weeks from infection or 4 to 8 weeks from recovery
 - Active COVID-19 infection
 - COVID-19 infection treated with anti-COVID-19 monoclonal antibodies or convalescent plasma

9. What are the global recommendations and practices on vaccination of pregnancy women in other countries?

Given the potential benefits and risks of the vaccine, International professional bodies have taken a positive stand on the COVID-19 vaccine in pregnancy. These bodies acknowledged lack of data in pregnancy.

- WHO recommends use of recombinant vaccine in pregnant women, provided the benefits of vaccination outweigh the potential risk. Pregnant women may also be exposed to COVID-19 vaccine before the woman knows she is pregnant.
- WHO does not recommend pregnancy testing prior to vaccination and delaying pregnancy or terminating pregnancy because of vaccination.
- International Federation of Gynecology and Obstetrics (FIGO) believes that risk-based approach to immunization might be of disadvantage to the pregnant woman.
- The Royal College of Obstetricians and Gynecologists (RCOG) states that pregnant women should be offered the vaccine as the general population⁶.
- The American College of Obstetricians and Gynecologists (ACOG) states that pregnancy testing should not be required prior to receiving vaccine and vaccine may be administered to the people who may consider future pregnancy. Women under age 50 including pregnant women can receive any COVID-19 vaccine. However, they should be

⁶Royal College of Obstetricians and Gynecologists (RCOG). COVID -19 vaccines, pregnancy and breastfeeding. [Online] 16 April 2021. <https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-Covid-19-pregnancy-and-womens-health/Covid-19-vaccines-and-pregnancy/Covid-19-vaccines-pregnancy-and-breastfeeding/>; Accessed: 16 May April 2021

aware of the rare risk of thrombosis with thrombocytopenia syndrome after receipt of mRNA vaccines.

- Countries such as **Australia, Canada, Israel, Singapore, United Kingdom and United State of America** are vaccinating pregnant women with COVID-19 vaccines.

Annexure II

Counselling pregnant women for COVID-19 vaccines

Fact-Sheet to guide the Frontline Health Care Workers and Vaccinators

As a Frontline Worker or a Vaccinator, you need to counsel pregnant women about the availability, value and precautions regarding COVID vaccine. This note provides you with the information that you need to educate and support pregnant women, so that they can take an informed decision on getting the COVID vaccine. Based on it the pregnant woman can choose to get vaccinated or not for COVID-19. The note is structured in the form of questions & answers to make it easier for you to inform pregnant women and their families about most important issues related COVID-19 vaccination.

For additional information please contact: Medical Officer of nearest Health Centre

1. Why is COVID-19 vaccine being recommended for pregnant women?

- Pregnancy does not increase the risk to COVID-19 infection
- Most pregnant women will be asymptomatic or have mild disease, **BUT their health may deteriorate rapidly and that might affect the foetus too.**
- It is important that they take all precautions to protect themselves from acquiring COVID-19, including taking vaccination against COVID-19.
- It is therefore advised that a pregnant woman should take COVID-19 vaccines.

2. Who are at higher risk of getting infected with COVID-19?

- Someone who is a health care worker or a frontline worker
- Community having high or increasing rate of COVID-19 infections
- Frequently exposed to people outside the household
- Difficulty in complying with social distance if living in a crowded household

3. How does COVID-19 affect the health of the pregnant woman?

- Although most (>90 percent) infected pregnant women recover without need for hospitalization, rapid deterioration in health may occur in a few.

- Symptomatic pregnant women appear to be at increased risk of severe disease and death. In severe disease, like all other patients, pregnant women may also need hospitalization.
- Pregnant women with underlying medical conditions e.g., high blood pressure, diabetes, obesity, age over 35 years are at higher risk of severe illness due to COVID-19.

4. How does COVID-19 infection of pregnant women affect the baby?

- Most (over 95 percent) of newborns of COVID-19 positive mothers have been in good condition at birth.
- In some cases, COVID-19 infections in pregnancy may increase the possibility of premature delivery, baby's weight might be less than 2.5 KG and in rare situations, baby might die before birth.

5. Which pregnant women are at higher risk of developing complication after COVID-19 infection?

- Pregnant women who are:
 - Older than 35 years of age
 - Obese
 - Have an underlying medical conditions such as diabetes or high blood pressure
 - Have a history of clotting in the limbs

6. If a pregnant woman has already had COVID, when should she be vaccinated?

- In case a woman has been infected with COVID during the current pregnancy, then she should be vaccinated soon after the delivery.

7. Are there any side effects of the COVID-19 vaccines that can either harm the pregnant women or her foetus?

- COVID-19 vaccines available are safe and vaccination protects pregnant women against COVID 19 illness/disease like other individuals.
- Like any medicine a vaccine may have side effects which are normally mild After getting the vaccine injection, she can get mild fever, pain at injection site, or feel unwell for 1-3 days.

- The long-term adverse effects and safety of vaccine for foetus and child is not established yet.
- Very rarely, (one in 1 to 5 lakh persons) the beneficiary may after COVID-19 vaccination, experience some of the following symptoms within 20 days after getting the injection which may need immediate attention.

| Symptoms occurring within 20 days after receiving any COVID 19 vaccine |
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| Any other symptom or health condition which is of concern to the recipient or the family |

8. When should the vaccine be given to the pregnant woman?

- The COVID-19 vaccination schedule can be started anytime during pregnancy.

9. What other precautions need to be advised to the pregnant woman after vaccination?

- You must counsel the pregnant woman and her family members to continue to practice COVID appropriate behaviour: wearing double mask, frequent handwashing, maintaining physical distance, and avoiding crowded areas, to protect themselves and those around from spreading the COVID-19 infection.

10. How does a pregnant woman register herself for Covid-19 vaccination?

- All pregnant women need to register themselves on Co-WIN portal or may get themselves registered on-site at the COVID-19 vaccination centre. The process of registration for pregnant women remains same as of the general population and as per the latest guidance provided by MoHFW from time to time.

Myth buster: You cannot get COVID-19 infection from vaccination