

Vaccination against COVID-19 during Pregnancy and Lactation : An Overview

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Pandemic of SARS2- COVID-19 has caused disastrous impact globally in terms of sickness, deaths, and overburden on health infrastructure, employment, economy and psychological health. All countries are affected, to greater or lesser degree; be it from developed, developing or under-developed region.

Pregnancy has been identified as one of the risk factor for severe COVID-19 illness by Centre for Disease Control (CDC). About two-thirds of women who test positive for COVID-19 have no symptoms. But the data suggest that symptomatic pregnant patient with COVID-19 are at increased risk of more severe illness as well as have increased risk for ICU admission, ventilator support and deaths in comparison to their symptomatic non-pregnant peers.^[1] Pregnant patients with co-morbidities such as obesity and diabetes, hypertension, heart disease and asthma are further at higher risk of getting serious illness. Pregnant woman's Age above 35 years and pregnancy above 28 weeks makes women more at risk of severe COVID illness. Stillbirths and pre-term births are twice high in pregnant women with COVID -19 sickness as compared to pregnant women without COVID-19 infection.^[2] Ethnicity has also been found to affect the severity of COVID-19 illness. It has been found that Black and Hispanic pregnant women had disproportionately higher rates of COVID-19 infection and death. Further risk of ICU admission were higher in pregnant Asian, and Native Hawaiian/Pacific Islander women.^[1]


Looking to seriousness of COVID-19 illness among pregnant women and possibility of untoward outcome of pregnancy, it is imperative that in addition to COVID appropriate behavior – use of mask,

social distancing, hand hygiene etc., Vaccination of Pregnant and lactating women should be given priority attention.

CDC outlines that pregnant individuals are eligible for and can receive a COVID-19 vaccine. A discussion with their healthcare professional can help the patient make informed decision but is not precondition for getting vaccinated. Further, CDC states that lactating individuals can be vaccinated.^[1]

U.S. Food and Drug administration (FDA) has issued Emergency Use Authorization (EUA) for Pfizer-BioNtech mRNA vaccine, Moderna mRNA-1273 vaccine and Janssen Biotech Inc. Monovalent vaccine. According to EUA Fact Sheet for Health care Professionals for above mentioned three vaccines, available data on COVID-19 vaccine administered to pregnant women are insufficient to inform vaccine associated risks in pregnancy. EUA Fact Sheet for Recipients and Health care givers for these three vaccines states “If you are pregnant or breast-feeding discuss your options with your Care Provider”.^[1]

Recommendations by American College of Obstetrics and Gynecologists (ACOG) related to the use of COVID-19 vaccines in Pregnancy states that pregnant women were not included in vaccine clinical trials, however observational data from vaccinated pregnant individuals is being collected by CDC and manufacturer and to date no safety signals have been identified. Based on limited self reported information, and early data from CDC, no specific safety signals, or side effects or adverse events have been observed in pregnant people enrolled in v-safe pregnancy registry, however longitudinal follow up is needed. Animal model studies for all three vaccines

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have also not demonstrated any safety concerns in pregnancy. Based on the mechanism of action of these vaccines and demonstrated safety and efficacy in Phase II and Phase III clinical trials, it is expected that the safety and efficacy profile of vaccine for pregnant individuals would be similar to that observed in non-pregnant individuals. As of June 7, 2021, there have been over 123000 pregnancies reported in CDC's V. Safe after vaccination health checker. There is limited data on efficacy of COVID-19 vaccine in pregnancy, but so far vaccine appears to be equally effective in pregnant individuals and non-pregnant individuals. All currently available COVID-19 vaccines have demonstrated high efficacy among their respective clinical trials end points. COVID-19 vaccine may prevent severe COVID-19 disease.^[1]

As per information sheet and decision aid updated 28 May 2021 brought out by Royal College of Obstetrician & Gynecologists, UK, Pregnant women should be offered Pfizer BioNtech or Moderna vaccine as most of safety data from United States relates to these two vaccines. Also it states that Government of UK, has advised that individuals under age of 40 should be offered alternative vaccine to the AstraZeneca vaccine, based on the risk / benefit ratio for that age group.^[2]

As per FOGSI Position Statement 2021–COVID vaccination for Pregnant and Breastfeeding women there is no data on immunization of pregnant or lactating women with Covishield or Covaxin of April 2021. FOGSI recommends protection through COVID-19 Vaccine to pregnant and lactating women, stating that the very real benefits of vaccinating pregnant and lactating women far outweigh any theoretical and remote risks of vaccination. There is no potential risk to newborn of vaccinated women who breastfeed their baby, also there is passage of maternal antibody to baby through breast-milk. Additionally, protective antibodies were also isolated in umbilical cord blood and breast milk, implying protection to the fetus and newborn. FOGSI through its above-stated document has recommended to Ministry of Health & Family Welfare, GOI, that Obstetricians and Gynecologists and Women's Health care Providers should be allowed to administer COVID vaccines in Pregnant and breastfeeding women with preparation to manage adverse events.^[3]

Ministry of Health and Family welfare, Government of India, through its notification dated

19th May 2021; has recommended COVID-19 Vaccination for lactating women.^[4] It is a welcome and much needed decision.

Notification of COVID-19 vaccination to pregnant women in many countries is awaited. Limitation being, non availability of data relating to administration of vaccine. As per FAQ on Covishield vaccine on Website of Serum Institute of India Private Limited, updated till 21st May 2021, Covishield vaccine carries a serious but rare risk of arterial and venous thrombosis and; incidence of it being less than 1 per 100,000 cases who got Covishield vaccine.^[5] During pregnancy a hypercoagulable state is developed which aggravates possibility of thrombosis. All these facts cause dilemma to arrive at clear cut decision. But data for use of mRNA vaccine during pregnancy has shown no adverse concerns. And same mRNA vaccines (Pfizer BioNtech and Moderna mRNA vaccine) if made available for administration to pregnant woman in our country, it will protect this high risk group against COVID-19. Although issues relating to cold chain and issues of storage at -70 degree Celsius remains with these mRNA vaccines but ways have to be found out.

References:

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