

Are Covid-19 Vaccines Safe For Pregnant And Lactating Women of Pakistan?

A Comprehensive Report

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Key Points

- Who declared covid-19 as pandemic on 11th march, 2020
- There is increased risk of adverse effects of covid-19 in pregnant patients
- Vaccines have been deemed safe for pregnant patients

Introduction:

The World Health Organization (WHO) declared COVID-19 as a pandemic on the 11th of March 2020¹ and since then almost 224 million cases have been reported worldwide with 4.6 million deaths². In Pakistan, there have been 1.2 million cases thus far with more than 26,580 deaths³. The malady imposed economic turmoil in addition to threatening health globally but its threat was doubly significant in Pakistan because of its status as a developing nation with limited resources^{4, 5}. This pattern is mirrored in the pregnant population as COVID-19 has been linked to elevating the severity of the disease in pregnant individuals^{6, 7}, especially those with underlying comorbidities, with pregnant people having COVID being more likely to die, as well as experiencing an increased risk of adverse pregnancy outcomes⁸. This is an issue ubiquitously but especially in Pakistan due to its long-standing history of having a disproportionately high maternal mortality rate owed to a lack of education and healthcare resources among other reasons⁹ (with the current rate being estimated at 186 deaths per 100,000 live births). Fortunately, when given

adequate care, materno-fetal outcomes are usually good¹⁰ but the overburdening of the healthcare system may exacerbate the mortality rate especially considering that the amount of pregnant COVID patients is only escalating following the first case that was reported in 2020. Although details of specific instances of pregnancy with COVID in Pakistan is scanty, atleast one case of miscarriage in the first trimester has been documented in detail¹¹ and 2 deaths of females with late-stage pregnancies recieved national media coverage. With the alarming frequency of infection as well as additional variants emerging, vaccination becomes imperative for the general population but especially for vulnerable sects like pregnant and lactating women.¹²

In Pakistan, about 66.4 million doses have been administered and 21.3 million individuals are fully vaccinated¹³, with the number of doses administered to pregnant women remaining unclear. The important question of the safety and efficacy of COVID vaccines in the pregnant and

lactating population arises because this high risk group was excluded from all clinical trials during vaccine development and authorisation¹⁴. Nevertheless, this article aims to concisely present the available data regarding vaccination in pregnancy so that Pakistani women can receive evidence-based counselling. An overview of the available vaccines is as follows; 3 main types of COVID vaccines have been developed and are being used worldwide including mRNA vaccines (Pfizer, Moderna), viral vector vaccines (AstraZeneca, SputnikV, J&J) and inactivated whole virus vaccines (SinoPharm, SinoVac)¹⁵. In general, vaccines have been deemed safe for pregnant individuals¹⁶ and are discussed separately below.

mRNA Vaccines:

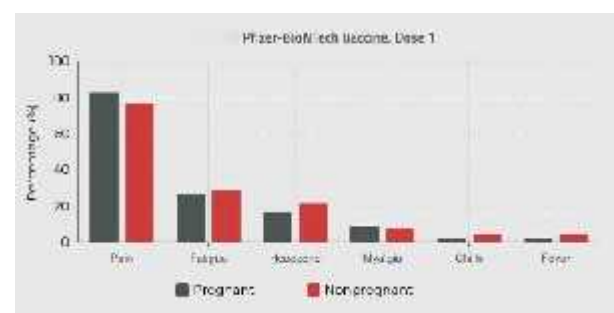
1. Pfizer: The Pfizer-BioNTech vaccine is one of the two mRNA vaccines currently in use. These utilize a lipid nanoparticle to enclose the mRNA that encodes for the SARS-CoV-2 spike protein, which is then delivered to a cell's cytoplasm where its cellular machinery generates the viral protein which triggers an appropriate immune response when introduced to lymphocytes. Pfizer is shown to be 95% effective in phase 3 clinical trials¹⁵ and has received FDA authorisation for non-pregnant people aged 12 years or above and pregnant individuals, aged 18 and above^{17, 18}. A breakdown of the available data with regards to its use in pregnant and lactating women is as follows:

A study included in the *American Journal of Obstetrics and Gynaecology*, featuring 131 women of reproductive age, aimed to quantitatively contrast the potency and safety of mRNA vaccines. The vaccine response in pregnant and lactating women

was compared with that of non-pregnant uninfected women (control group) as well as pregnant women that had naturally acquired the virus. Titers were compared in serum and breastmilk for SARS-CoV-2 spike proteins and IgA, IgM, IgG receptor binding domains. Results showed that vaccine induced antibody titers were identical in pregnant and lactating women when compared with the control group, while they were considerably higher than pregnant women that were naturally infected with COVID-19.¹⁹

Pre-partum mRNA vaccination using the Pfizer vaccine also showed antenatal immunization against COVID-19 as SARS-CoV-2 antibodies travelled from the maternal serum to the fetus via the transplacental route.²⁰

Another study published in the *New England Journal of Medicine* evaluated immunogenicity and reactogenicity profiles through the V-Safe vaccine registry in which participants self-reported symptoms after mRNA vaccine administration as



well as pregnancy outcomes. Reported reactions and

Figure 2 Pfizer dose 1²¹

adverse pregnancy outcomes to the vaccine were similar among pregnant and non-pregnant women²¹. The results of this study are further discussed and illustrated in the section on Moderna, with a comparison of the reported symptoms of

pregnant and non-pregnant women being represented below:

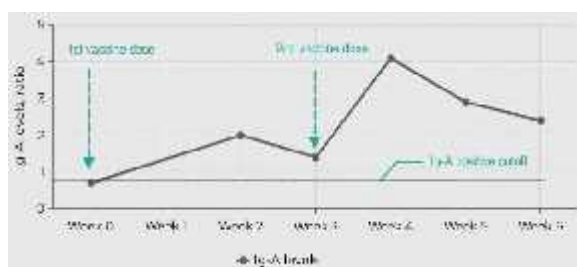


In a large retrospective cohort study, a statistically significant association between Pfizer vaccine administration and a lower risk of SARS-CoV-2 infection in pregnant women was found.²²

Furthermore, human studies of mRNA vaccines developed for other viruses like Influenza, Rabies, Zika show that these are safe for pregnant individuals^{15, 23}. Perhaps the strongest proponent for administration of vaccines is real world data as upwards of 185,000 pregnant people in the United States, Europe and Scotland have elected to be vaccinated without harm.⁵⁸

The rest of this section will focus on data pertaining exclusively to lactation. In general, viral spike proteins, fragments of mRNA²⁴ and PEG-2000²⁵ do not enter breastmilk and so infant exposure to these subsequent to maternal vaccination is not a concern.

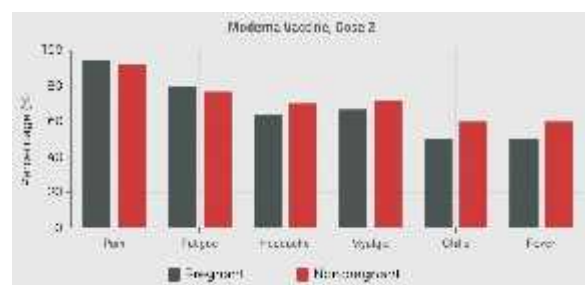
In an 84-participant study, breast milk samples were collected a week before receiving the 1st dose of the Pfizer vaccine and then in the following weeks with an interval of seven days in between



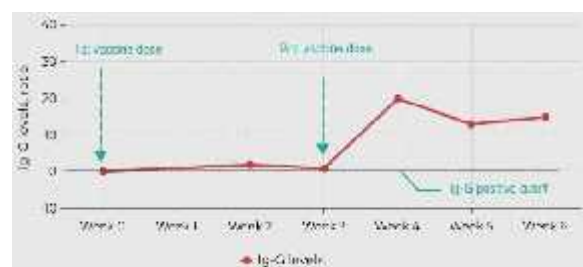
collection. IgA levels showed a documented increase from week 1 (61.8%) to week 4 (86.1%), with a relative decline (65.7%) at week 6, while IgG antibodies stayed low for the initial 3

weeks, burgeoning at week 4 (91.7%) and peaking at weeks 5 and 6 (97%)²⁶. This is diagrammatically presented below:

A study that measured different immunoglobulins showed no IgM antibodies in breastmilk even after the 2nd dose with IgG and IgA antibodies both peaking 7 days after the 2nd dose²⁷, while another study that had some participants with low anti-COVID antibodies before the first dose detected antibodies in the breastmilk of all participants after vaccination with increased levels in the participants with antibody positive milk before vaccination.²⁸ Lastly, the findings of a 61 participant study revealed that 38.3% of milk samples could neutralise SARS-CoV-2 infectivity and secretory IgA was present in 15% of the breastmilk specimens. These outcomes were in conjunction with other previously discussed findings such as an increase in baseline antibodies following maternal vaccination in serum and breast milk of the

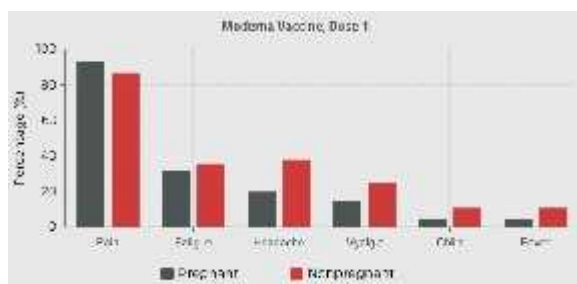


individual.²⁹



2. Moderna: This was the first vaccine to get the EU authorization by the FDA. It is also an mRNA vaccine with a reported efficacy of 94% and has been approved for people aged 18 years and above.^{30, 31}

According to preliminary data from the Vaccine Adverse Event Reporting System (VAERS) and the V-safe vaccine registry (previously discussed in the



section on Pfizer), injection site pain was more prevalent but other symptoms like myalgia, fever, headache, chills, etc. were reported less frequently in pregnant women. Thus, the reactogenicity profiles were again found to be similar.²¹

The percentage of adverse pregnancy outcomes also did not deviate from the normal range in these participants when compared to the occurrence of these outcomes in the general public (view the table below) with 12.6% participants reporting spontaneous abortion and 0.1% reporting still birth. The trend holds true for neonatal outcomes as well, with 0% neonatal death, 9.4% of neonates being born preterm, 3.2% of neonates being smaller than their gestational age and 2.2% of neonates showing congenital anomalies.

Pregnancy and Neonatal Outcomes in Published Studies and V-Safe Registry		
Participant Reported Outcome	Published Literature	V-Safe Registry
Pregnancy loss among participants with a completed pregnancy:		
Spontaneous abortion (n = 25 women)	10% (36%)	12.6%
Stillbirth (n = 11 weeks)	0.1%	0.1%
Neonatal outcomes at birth (n = 1000 infants)		
Preterm birth (0-1 weeks)	8% (15%)	9.4%
Low birth weight gestational age	3.5%	3.2%
Congenital anomalies	2.8%	2.2%
Neonatal Death	0.1%	0%

Furthermore, 13 inadvertent pregnancies were reported during Moderna's vaccine clinical trials. Out of these, 7 individuals were part of the placebo/control group (unvaccinated) and 6 individuals were vaccinated with Moderna. 1 miscarriage (14%) was reported in the control group and no miscarriages were seen in the vaccinated individuals.^{15, 32}

In addition to this, data from the Moderna developmental and reproductive toxicology (DART) studies, which were conducted on animals, found no detrimental effects on fertility, reproduction, miscarriage, fetal and postnatal development.^{30, 32}

A study of lactating women that received mRNA vaccines found COVID-19 antibodies in breastmilk. These IgA and IgG titers were relatively elevated in vaccinated people than in individuals who were naturally infected.³³

Baird et al. analyzed breast milk antibody levels of 7 nursing mothers who received mRNA vaccines at 11 time-points after the first dose. Levels of IgG and IgA antibodies were raised roughly 7 days after the initial dose with IgG antibodies showing marked and sustained elevation.³⁴

Inactivated whole virus vaccines:

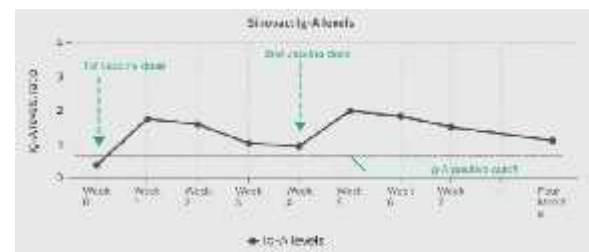
Sinopharm and CoronaVac (Sinovac): These vaccines operate by triggering an immunologic response in the host using an inactivated COVID-19 virus particle. Vaccines of this sort also make use of an adjuvant which is a substance that increases the immune response of a vaccine when given with an antigen. The adjuvant used is aluminum hydroxide³⁵. Reported efficacy for Sinovac is 50.7%³⁶ and for Sinopharm is 73%³⁵. Both of these percentages are derived from the phase 3 clinical trials.^{37, 38}

Although there have been no human studies that have investigated the safety and potency in the pregnant and lactating population, experiments on animals showed no adverse effects³⁶. Moreover, vaccines that use inactivated viruses, bacteria or toxoids have been administered to pregnant women for decades and show a good safety profile as they do not harm the fetus or the mother.³⁹

A case report detailing the account of maternal vaccination by CoronaVac in a 34 years old health care worker who completed her vaccine regimen at the gestational age of 32 weeks showed no vaccine related side effects after either dose. 3 weeks after the 2nd dose, her serum contained antibodies with anti receptor binding domains for the SARS-CoV-2 spike protein. She also proceeded to give birth to a healthy full-term girl whose cord-blood was positive for IgG antibodies.⁴⁰

A study was conducted on 20 nursing mothers with 16 of them being Covid-negative before vaccination. 10 of the participants presented with IgA antibody levels above the seroconversion value (i.e. transition from point of viral infection to the

detection of antibodies in blood) at the 7th week. 5 out of these 10 participants showed the same levels even around 4 months after the first dose. Furthermore, none of the breastfed infants showed any adverse effects.⁴¹



When Sinovac received emergency use authorization in China, 12 vaccine recipients reported pregnancy. 3 of these elected to terminate pregnancy while the remaining 9 reported no adverse effects and all maternal indicators were within the normal range.³⁶

Viral vector vaccines:

AstraZeneca, Janssen-Johnson&Johnson and Sputnik: These use a viral vector which is a modified version of the adenovirus that carries the viral spike protein RNA inside body cells to elicit an immune response. The mechanism is similar to mRNA vaccines but the efficacy is 66%⁴² and 63.1% for J&J and AstraZeneca respectively.⁴³

Although the drug and reproductive toxicology (DART) studies in animals show no safety concerns⁴³, there have been 28 reported cases of people developing thrombosis following administration of the AstraZeneca vaccine⁴⁴. These rare but potentially fatal cases of thrombosis alongside thrombocytopenia syndrome (TTS) and intracranial venous sinus thrombosis (IVST) are significant when considering the pregnant

population as pregnancy is already a pre-existing risk factor for developing blood clots⁴⁵. Therefore, the Joint Committee on Vaccination and Immunization (JCVI) endorsed mRNA vaccines in lieu of the AstraZeneca vaccine (unless one dose has already been administered)³⁹, which is in line with the overall scientific consensus^{46, 47}. This is also supported by robust real-world data from the United States and England where mRNA vaccines were predominantly used and no safety concerns were reported.

The following table shows the number of participants that accidentally got pregnant during the vaccine clinical trials. The miscarriage rates for the J&J and AstraZeneca vaccine were 25% and 17% respectively. Lastly, Sputnik (which has an estimated efficacy of 91.6%⁴⁸) is inadvisable for use in pregnant or lactating individuals.^{49, 50}

Vaccine Type	Control/Placebo Group			Vaccine Group		
	Participants	Pregnancies	Miscarriage Rate %	Participants	Pregnancies	Miscarriage Rate %
J&J	15,046	11	0.07%	15,090	11	0
AstraZeneca	11,001	7	0.06%	9,001	6	0
UK ⁵¹	21,000	4	0.02%	21,000	4	0.02%
AstraZeneca	5,829	5	0.08%	5,829	12	0.20%

Figure 10 miscarriage during trials¹⁵

Guidelines for vaccine administration in pregnant and lactating women:

The National Command and Operation Centre (NCOC) of Pakistan has issued vaccine guidelines which highly recommended that pregnant and lactating women receive any of the Covid-19 vaccines available in Pakistan (except J&J which is inaccessible) with AstraZeneca vaccine exclusively being recommended for people 40 years and older⁵¹ and the remaining vaccines available for people 18 years and above^{18,31,37,38} because these vaccines have proven to be effective and secure

after usage in the general public. Sputnik is an exception as it is not recommended and requires guidance from physicians.⁵⁰

WHO endorsed the administration of Covid vaccines in the population under discussion when the advantages exceed the prospective threats. Physicians should assess whether vaccines would be beneficial and provide the patient with all the necessary details regarding coronavirus, its vaccines and the constraints posed by currently available data. WHO also discourages delaying or terminating pregnancy and lactation due to vaccination.⁵²

The Royal College of Obstetricians and Gynecologists (RCOG) has issued additional guidelines that dictate that Covid-19 vaccines can be received anytime during pregnancy specifically if these women are at a higher risk of contracting Covid infection or experiencing severe illness from Covid-19, including in the first trimester. In low-risk cases, some women may choose to postpone vaccination to after 12 weeks of gestation, citing potential harmful effects of exogenous RNA and vaccine induced fever in the period of organogenesis. Furthermore, women receiving fertility treatment do not need to delay conception in view of vaccination.⁴⁷

Conclusion:

Pregnant and lactating women were omitted from all vaccine clinical trials owing to a historic pattern of exclusion⁵³ and an emphasis on treating even more vulnerable groups of people like those over the age of 50 or immunosuppressed individuals so that the devastating economic and healthcare impacts of the pandemic could be curbed. This

justifies why some pregnant women may be apprehensive towards vaccine administration^{54, 55} but it is imperative for all those that are pregnant or lactating to consult their healthcare provider so that they can be counselled on a case-to-case basis about the advantages and hazards of vaccine administration. It is generally accepted throughout the world that pregnant women should be vaccinated because the benefits tend to outweigh the risks for both mother and child in most scenarios^{46, 56}. Special focus should be placed on the fact that the threat of increasingly dangerous variants of the coronavirus that emerge periodically levy a more serious danger towards the pregnant population and that vaccines are shown to significantly decrease the general rate of hospitalisation and morbidity⁵⁷. Also, real world data shows that minimal adverse reactions were recorded in pregnant individuals with reactogenicity and immunogenicity profiles being similar in pregnant and non-pregnant women. Fortunately, many governments and private companies are planning to carry out large scale clinical trials for pregnant and lactating women⁵⁵ so that robust data can be available to alleviate the safety and efficacy concerns that are present currently.

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