



# The practice of COVID-19 vaccination among the pregnant and lactating women: the present global scenario and decisions taken in India and Nepal

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**ABSTRACT:** During COVID-19 pandemic till date, millions of women have become pregnant, given birth and breastfed their babies. But, due to the lack of experience-based knowledge about the adverse effects of COVID-19 vaccine, if any, it was not simple to take decision to vaccinate pregnant women and lactating mothers. The outcome of results of vaccination during at any trimester, on delivery, on neonates and on babies was uncertain. With the advancement of time, on the basis of experience and extensive studies global health bodies suggested and gradually recommended for administration of COVID-19 vaccine to pregnant and lactating women to protect from COVID-19 virulent attack and also assured that registered COVID-19 vaccines will not contraindicate neonates and breastfed babies. From first approval of COVID-19 vaccine in December 2020 by WHO to recommend vaccination to high risk and comorbidity pregnant women and lactating mother on June, 2021 was not an easy task. In this juncture we summarize the milestones of successful endeavor to vaccinate pregnant women and breastfed mothers against COVID-19.

**KEYWORDS:** COVID-19, COVID-19 vaccine, SARS-CoV-2, Pregnant women, Lactating mother.

## I. INTRODUCTION

Although hundreds of vaccine platforms have been taken utmost initiative to develop COVID-19 vaccine to fight SARS-CoV-2, but few of these were examined to elicit immunity in pregnant and lactating women. The main hindrance to vaccinate pregnant women and breastfed mothers was safety and liability concern [1]. COVID-19 vaccines were developed rapidly than any other vaccines in the medical history of vaccine-development [2]. Lack of scientific trials, reports, evidences did not help to support and recommend vaccination to pregnant women by the advisory medical councils throughout the globe. Even, after recommendation and free vaccination by concern medical councils, pregnant and lactating women were refused to volunteer themselves. A recent systemic review and meta analysis on 40,978 pregnant women (19,108 vaccinated and 21,870 unvaccinated) revealed no adverse events of COVID-19 vaccination on pregnant, fetal, or neonatal outcomes [3]. Therefore, there would be any serious adverse effect on mother and baby had not been established following a long term and extensive studies [4] Hence, it is important to draw extra attention to compulsorily vaccinate all pregnant and lactating women to reduce their risk of severe illness during pregnancy. Table 1 highlighted the last updated (January 12, 2022) Emergency Used Listed COVID-19 vaccines recommended and approved by WHO [5].

**Table 1. WHO Emergency Used Listed COVID-19 Vaccines**

COVID-19 Vaccine	Approval
Pfizer/BioNTech Comirnaty	31 Dec, 2020
SII/COVISHIELD and AstraZeneca/AZD1222 vaccines	16 Feb, 2021
Janssen/Ad26.COV 2.S vaccine by Johnson & Johnson	12 Mar, 2021
Moderna COVID-19 vaccine (mRNA 1273)	30 Apr, 2021



Sinopharm COVID-19 vaccine	7 May, 2021
Sinovac-CoronaVac vaccine	1 Jun, 2021
Bharat Biotech BBV152 COVAXIN vaccine	3 Nov, 2021
Covovax (NVX-CoV2373)	17 Dec, 2021
Nuvaxovid (NVX-CoV2373) vaccine	20 Dec, 2021

### **Pregnancy And Covid-19 Vaccination: Global Scenario**

Nevertheless, gradually, the available data showed no alarming adverse side effects of COVID-19 vaccine on them and this population, that avoided vaccination when first vaccination all over the world started are not showing apathy for COVID-19 vaccination. Till February 2022, according to US based V-Safe, 198000 pregnant ladies in United States [6] and more than 100000 in UK [7], received COVID-19 vaccine and did not shown any serious adverse effect caused by or strictly related to vaccination [8]. It has been noted that administration of COVID-19 vaccine did not cause higher incidence of premature birth, small for gestational age, congenital malformation [9] and spontaneous abortion from conception to 19<sup>th</sup> week of pregnancy, [10] compared to their non-vaccinated counterparts. Scandinavian countries also registered the same type of results following the administration of COVID-19 vaccine during pregnancy [11]. Studies in Canada, Sweden and Norway done amongst more than 3 million pregnant women, who received COVID-19 vaccines in even second or third trimester of pregnancy, and did not exhibited any higher risk of postpartum hemorrhage, chorio-amnionitis, cesarean delivery, neonatal ICU-admission or low Apgar score in comparison to non-vaccinated pregnancy cases [12].

### **BREASTFED INFANTS AND COVID-19 VACCINE**

Breast milk contains protective maternal immunoglobulins that contribute to the protection against infections by boosting up immunity. Dilemma cropped up amongst common people and health professionals about whether the vaccination against COVID-19 would be harmful for the pregnant ladies, lactating mothers and/or the breastfed baby. Initially in any countries, pregnant women and lactating mothers were excluded from the vaccination program. Nevertheless, this resulted in significant population along with frontline workers to remain unprotected from COVID-19 [13]. After that, several studies have been conducted throughout the globe on lactating women. Gray and his colleagues (2021) reported

lactating women elicited comparable COVID-19 vaccine-induced humoral immune responses with non-pregnant controls and antibodies were present in their breast milk after maternal vaccination [14]. Subsequent consistent observations and finding leads Centers for Disease Control and Prevention to announce there is practically no differences in post vaccination reactions in pregnant and lactating mothers compare to non-pregnant women at the age of 16 to 54 years [15]. Recently, all countries concerned and admitted that administration of COVID-19 vaccine to breastfeeding women should not render any harm to the breastfed infant rather benefit them.

### **Recommendations By International Agencies / Bodies**

Gynecological and Pediatrics bodies of individual States are mainly responsible to draw, check, revised and approved any guidelines to the pregnant and lactating mothers. Most of the similar agencies in the developed and under developed countries, throughout the globe considered all precautions and liabilities before recommend COVID-19 vaccine to pregnant and lactating mothers. These agencies and bodies included Royal College of Obstetricians and Gynecologists, UK; American College of Obstetricians and Gynecologists, US; The Society of College of Obstetricians and Gynecology of Canada, The Royal Australian and New Zealand College of Obstetricians and Gynecologists and advised to administration of COVID-19 vaccination to pregnant women of any trimester as early as possible [16].

### **PREGNANT / LACTATING MOTHERS AND COVID VACCINE IN INDIA:**

During the COVID-19 pandemic in 2021, India registered 24.02 million births (65797/day) highest in the world [17]. Till now (August 13, 2022) India fully vaccinated 938 million which is 67.9% of its population [18]. Indian Government allowed COVID-19 vaccination to pregnant women and breastfed mothers on July 2, 2021 and published an operational guideline (Ref). In India Covaxine™ and Covishield™ were predominantly administered to fight against COVID-19.



Covaxin™ (BBV152) was developed by Bharat Biotech and Indian Council of Medical Research, Govt. of India. Covaxin™ is a whole-virion inactivated SARS-CoV-2 antigen (NIV-2020-770) attenuated or weakened by biotechnical methods [19]. On the contrary, Covishield™ is a viral vector vaccine (chimpanzee adenoviral vector) which was developed and manufactured by Oxford University, Astra Zeneca and Serum Institute of India. Covishield™ (ChAdOx1 nCoV-19) suggest a long-term high-level antigenic protein expression through triggering prime cytotoxic T cells to eliminate virus infected cells [20-22]. Moreover, there is no report on adverse effects of both the vaccinations in pregnant and lactating mothers.

#### **PREGNANT / LACTATING MOTHERS AND COVID-19 VACCINE IN NEPAL**

Nepal launched COVID-19 vaccination campaign on January 27, 2021. Nepal's Ministry of Health and Population, National Immunization Advisory Committee of Nepal, Integrated Health Information Management Section of Nepal, WHO, UNICEF, Water-Aid and Red Cross were worked together in the COVID-19 vaccination in Nepal. In Nepal, all nine COVID-19 vaccines have been approved for emergency use and recent data (August 12, 2022) suggested 200 million vaccinations have been completed [23]. One clinical trial (Phase 3) on Clover-SCB (NCT04672395), COVID-19 vaccine has now being conducted in Nepal. Clover-SCB is an adjuvant recombinant SARS-CoV-2 vaccine developed by Clover Biopharmaceuticals, Australia [24]. Although, it is very difficult to distinguish the number of COVID-19 vaccinations of pregnant women and breastfed mothers in Nepal, but till date there is no single report on adverse events after vaccination.

#### **RECOMMENDATIONS BY THE NATIONAL / INTERNATIONAL BODIES IN INDIA AND NEPAL**

In India, Federation of Obstetrics and Gynecological Societies of India, Indian Academy of Pediatrics and Advisory Committee on Vaccination and Immunization Practices – all favors and strongly recommends the idea of administration of COVID-19 vaccine to all lactating mothers [13,25]. Besides these national bodies of India, International bodies of health committees also supported and recommended COVID-19 vaccination to pregnant women and lactating mothers. WHO advice not to discontinuing breastfeeding after vaccination [26], American College of Obstetricians and

Gynecologists suggested vaccination to both lactating and non-lactating women [27]. International Federation of Gynecology and Obstetrics supported COVID-19 vaccination to pregnant and breastfeeding women [28]. Australian and New Zealand Health authorities also strongly recommended it [29-30]. WHO, UNICEF, Water-Aid and Red Cross not only recommend but also take active part in COVID-19 vaccination to pregnant and breastfeeding women in Nepal. No recommendation would be effective without proper planning and execution. In last one year vaccination drive successfully conducted by both the nations with the tireless efforts.

#### **SURVEILLANCE OF COVID-19 VACCINE**

Before COVID-19 vaccination, an analysis of surveillance on pregnancy status of 409462 women with symptomatic COVID-19 illness reported the adjusted risk ratio in pregnant women compared to similar age and not pregnant was 3.0 for intensive care unit admission, 2.9 for mechanical ventilation and 1.7 for death [31]. Other studies also showed similar findings that COVID-19 vaccines induce immunogenicity in pregnant women against SARS-CoV-2 infection, which is similar in nonpregnant women [32-33]. Given the importance of reducing risk of COVID-19 for pregnant and lactating women and their neonates, it is essential to determine the safety profile of COVID-19 vaccination. Though, it has been established fact that except small-pox and yellow fever vaccine no other vaccine contra-indicated during breastfeeding [34]. Surveillance study reported that administration of m-RNA vaccines in lactating mother resulted in high titer of RBD-IgG binding antibodies and neutralizing antibodies in mother's serum and milk [35]. Another surveillance study revealed, COVID-19 vaccines administered in lactating woman resulted in elevation of SARS CoV2- specific IgG, IgA titer in breast milk after a week of vaccination with IgG dominant response [36]. Indian Academy of Pediatrics Advisory Committee clearly advised that lactating women vaccinated with Covaxine™ and Covishield™ which are inactivated/ non-living vaccine should not render any harm to breastfed infant [13]. Although, due to heterogeneity in population, vaccine research guidelines, and regulations among various countries comparison of various other COVID-19 vaccines on pregnant women and lactating mothers are complex tasks. Till date, there is no report on adverse effects of COVID-19 vaccination were found on pregnant, fetal, or neonatal outcomes in India and Nepal. But, complete pregnancy outcomes data from people



vaccinated in the first and early second trimesters are not yet available.

## II. CONCLUSION

COVID-19 vaccination is the most promising means of controlling the spread of the COVID-19 global pandemic. It can protect pregnant women and lactating mothers by boosting up immunity. Moreover, it is safe in the vast majority of cases for mothers and their infants. Therefore, we need to keep up to date with the new information to provide evidence-based information and effective counselling to pregnant and lactating women in both the countries.

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