

# COVID-19 Vaccine Acceptance and its Associated Factors among Pregnant and Lactating Women in Coastal Karnataka, India: A Cross-sectional Study

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## ABSTRACT

**Introduction:** Coronavirus Disease-2019 (COVID-19) has become a global threat. Despite the hazard of the pandemic and availability of COVID-19 vaccines, a major hindrance exists related to vaccine hesitancy. The acceptance of vaccine among pregnant and lactating women widely differs in countries.

**Aim:** To assess the COVID-19 vaccine acceptance and the factors influencing it among pregnant and lactating women.

**Materials and Methods:** A cross-sectional study was conducted at four selected Primary Health Centres (PHCs) of Dakshina Kannada district, Karnataka, South India, from October 2021 to December 2021 among 350 pregnant and lactating women. A questionnaire was developed based on the literature review and validated by two subject experts regarding knowledge of COVID-19 vaccines, perceptions, attitude and their vaccination status and information was collected using questionnaire. Perceptions and attitude were scored based on Likert scale. Predictors of COVID-19 vaccine acceptance were identified using univariate analysis. Further, multivariate regression model was used to

obtain the Adjusted Odds Ratios (AOR) and Confidence Intervals (CI) using Statistical Package for the Social Sciences (SPSS) software version 27.0.

**Results:** Study participants included 247 (70.6%) pregnant women and 103 (29.4%) lactating women. Among them 218 (62.3%) were aware that pregnant women can take the vaccine and 184 (52.6%) were aware that lactating women can take the vaccines. Overall vaccine acceptance among the study participants was 208 (59.4%). Vaccine acceptance was significantly higher among pregnant women (AOR: 3.02; CI: 1.58-5.77), women living in nuclear families (AOR: 4.27; CI: 2.31-7.89) and those with a positive attitude (AOR: 17.48; CI: 9.52-32.09) as compared to their counterparts.

**Conclusion:** The study highlights that vaccine acceptance was higher in pregnant women as compared to lactating mothers. Improving the awareness and acceptance of COVID-19 vaccination to overcome the fear of vaccination would help to control the disease.

**Keywords:** Attitude, Coronavirus disease-2019, Lactation, Pregnancy, Pandemics, Vaccination, Vaccine-hesitancy

## INTRODUCTION

Coronavirus Disease-2019 (COVID-19), the outbreak of Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2) was declared as a Public Health Emergency of International Concern (PHEIC) in January, 2020 [1]. Since, then it has become a global threat and has been crippling the health system worldwide. On 2<sup>nd</sup> December 2021, the cumulative number of confirmed cases had reached approximately 26.3 crore, with more than 52.2 lakh deaths worldwide [2].

Coronavirus disease-2019 infection during pregnancy may rapidly deteriorate the health of pregnant women and increase the risk for preterm deliveries and caesarean section. In addition to these, it has brought about an increase in the incidence of Intensive Care Unit (ICU) admissions, mechanical ventilations and even deaths due to COVID-19. Besides the rise in maternal morbidity and mortality, there has been an increase in Neonatal ICU (NICU) admissions, intrauterine foetal deaths, perinatal and neonatal deaths among children born to pregnant women with COVID-19 infection [3].

In order to curb the pandemic, major efforts by the scientific research and pharmaceutical industry backed by political will were directed towards developing safe and efficacious vaccines [4]. These efforts led to the approval of three COVID-19 vaccines for emergency use in India [5]. Further, vaccination for pregnant and lactating women with two of the vaccines namely, Covishield and Covaxin were introduced from 25<sup>th</sup> June 2021 [6]. The country had successfully vaccinated over 2,30,000 such women with their first dose by first

week of December, 2021 [7]. The most common adverse effect of vaccination among pregnant women was injection site pain, which was reported in 90% of cases, while some others experienced fatigue, headache and myalgia [8]. Breastfeeding women showed similar side-effects as non breastfeeding women. The infants of the breastfeeding women who got vaccinated did not show any serious side-effects, though some breastfed infants showed irritability and poor sleep for short period [9].

Despite the hazard of the pandemic and availability of COVID-19 vaccines, a major hindrance may exist related to vaccine hesitancy [10]. The various barriers of vaccine acceptance in the previous studies included worrying about COVID-19, misinformation about the benefits, lack of confidence in vaccine effectiveness and safety, and persistent compliance to infection prevention guidelines even after vaccination [11,12]. COVID-19 acceptance rates across Low and Middle-income Countries (LMIC) according to surveys ranged between 66.5% to 96.6% [13]. Similarly, the acceptance of COVID-19 vaccine among pregnant and lactating women widely differs in countries [14].

Acceptance of COVID-19 vaccine among pregnant and lactating women is not well-established in India, particularly in the study area [15,16]. Understanding the acceptance of COVID-19 vaccine and the reasons for refusal would help to design a strategy to overcome the vaccine hesitancy. Therefore, this study was aimed to assess the COVID-19 vaccine acceptance and the factors influencing it among such women residing in coastal Karnataka in India.

## MATERIALS AND METHODS

A cross-sectional study was conducted in four selected Primary Health Care (PHC) Centres of Dakshina Kannada district of Karnataka, South India, which was under the field practice areas of a teaching hospital, Kanachur Institute of Medical Sciences, Natekal, Mangaluru, Karnataka, India, from October 2021 to December 2021. The study was commenced after obtaining ethical clearance from Institutional Ethics Committee (IEC no. KIMS/IEC/A017/2021).

**Sample size calculation:** Sample size was calculated based on the findings of the study by Mose A and Yeshaneh A, where 70.9% acceptance to COVID-19 vaccine was seen [17]. Hence, considering 70.9% as prevalence with 95% CI using formula,  $n=(1.96)^2pq/d^2$  with 5% margin of error and 10% non response rate. So, total sample size was 350.

**Inclusion criteria:** All pregnant and lactating women who attended the Outpatient Department (OPD) from selected PHCs under the teaching hospital, selected by simple random sampling method using the table of random numbers were included in the study.

**Exclusion criteria:** Emergency obstetric cases and women with serious illnesses were excluded from the study.

### Procedure

After taking informed consent from the study participants, the information was collected on a questionnaire which was developed based on the literature review and validated by two subject experts [18-21]. Questionnaire was initially prepared in English language and translated to local language which was back translated to ensure the accuracy of the translation. Further, the questionnaire was pilot tested and suitable modifications were done before its use in the study. The Cronbach's alpha coefficient for reliability was 0.768. Each study participant was informed about the purpose, aims and objectives of the study and confidentiality of the information was assured.

The questionnaire was divided into four sections. The first section included socio-demographic details like age, educational status, religion, occupation, family status, socio-economic status, whether pregnant or lactating women, trimester of pregnancy or age of the infant in lactating women. Socio-economic status was classified based on Modified BG Prasad updated for the year 2021 [22].

The second section included knowledge related questions such as, whether they were aware of the COVID-19 vaccines, whether they were aware that pregnant and lactating women could take the vaccines and awareness regarding continuing wearing a mask and physical distancing after vaccination. A total of six questions were knowledge related and their response was recorded as 'yes' or 'no'.

The third section assessed the perceptions and attitude about COVID-19 vaccines in which participants answered six questions and it was based on five item Likert scale from strongly agree to strongly disagree. The attitude was scored from six to one for positive response questions (six for strongly agreed) and in the reverse order for negative questions (one for strongly agreed). The highest score was 30 and the least was six. A score of less than 18 (the median value) was considered to be negative attitude while a score of 18 or more is considered as positive attitude.

In the last section, the vaccination status with first and second dose of the vaccine was assessed and reasons for not taking the vaccine were also assessed among those who were not vaccinated even with a single dose. In this study the participants who were vaccinated with atleast one dose of COVID-19 vaccine were considered to have vaccine acceptance.

## STATISTICAL ANALYSIS

Data collected was entered and coded in Microsoft Excel software and analysed using a Statistical Package for the Social Sciences

(SPSS) software version 27.0. Descriptive statistics was presented for continuous variables and, frequency and percentage for categorical variables. Predictors of COVID-19 vaccine acceptance were identified using univariate analysis which evaluated the association between vaccine acceptance and its determinants like type of family, educational status, employment status, whether pregnant or lactating, socio-economic status and attitude towards vaccination. A p-value <0.05 was considered statistically significant. Further, explanatory variables from univariate analysis were entered into multivariate regression model to obtain the Adjusted Odds Ratio (AOR).

## RESULTS

Among 350 study participants, 247 (70.6%) were pregnant women and 103 (29.4%) were lactating women. Majority of them, 161 (46%) were in the age group of 23-27 years, followed by 28-32 years age group, that is 121 (34.5%) participants. The educational status of 161 (46%) participants were upto 10<sup>th</sup> standard and 118 (33.7%) women were working. Majority, 220 (62.9%) women lived in nuclear families. With regard to socio-economic class, according to modified BG Prasad classification for the year 2021, 146 (41.7%) and 118 (33.7%) participants belonged to class IV and class V, respectively [Table/Fig-1].

Variables	Categories	Number	Percentage
Pregnant/Lactating	Pregnant	247	70.6
	Lactating	103	29.4
Age group (years)	18-22	50	14.3
	23-27	161	46.0
	28-32	121	34.5
	33-37	16	4.6
	>37	2	0.6
Educational status	Upto SSLC	161	46.0
	PUC and above	189	54.0
Religion	Hindu	170	48.6
	Muslim	170	48.6
	Christian	10	2.8
Occupation	Homemaker	232	66.3
	Working women	118	33.7
Type of family	Nuclear	220	62.9
	Joint	130	37.1
Socio-economic status	Class I (>Rs 7770)	18	5.2
	Class II (Rs 3808-7769)	20	5.7
	Class III (Rs 2253-3808)	48	13.7
	Class IV (Rs1166-2253)	146	41.7
	Class V (<Rs 1166)	118	33.7

**[Table/Fig-1]:** Socio-demographic profile of the study participants (N=350).  
SSLC: Secondary school leaving certificate; PUC: Preuniversity course

Further, among the 247 pregnant women, 50 (20.3%), 149 (60.3%) and 48 (19.4%) were in first, second and third trimesters, respectively. Also, among the 103 lactating women, 72 (69.9%) had infants less than six months and remaining 31 (30.1%) had infants above six months of age.

All the study subjects had heard about the vaccine Covishield and 319 (91.1%) participants had heard about the vaccine Covaxin against COVID-19. When enquired about vaccinating pregnant and lactating women, 218 (62.3%) were aware that pregnant women can take the vaccine and 184 (52.6%) were aware that lactating women can take the vaccines. Majority, which is 280 (80%) women were aware that they need to continue wearing mask and 278 (79.4%) of them were aware that they need to continue physical distancing after vaccination [Table/Fig-2].

Knowledge of COVID-19 vaccine	Yes n (%)	No n (%)
Are you aware/heard about a vaccine named Covishield?	350 (100)	0
Are you aware/heard about a vaccine named Covaxin?	319 (91.1)	31 (8.9)
Can pregnant women take the COVID-19 vaccine?	218 (62.3)	132 (37.7)
Can lactating women take the COVID-19 vaccine?	184 (52.6)	166 (47.4)
Postvaccination one needs to continue wearing a mask.	280 (80)	70 (20)
Postvaccination one needs to maintain physical distancing.	278 (79.4)	72 (20.6)

**[Table/Fig-2]:** Knowledge of study participants regarding COVID-19 vaccination (N=350).

Among the participants, 229 (65.5%) and 233 (66.5%) agreed that pregnant women and lactating women should be vaccinated against COVID-19, respectively. When the participants were asked regarding health education about vaccination, 242 (69.1%) agreed that it was necessary, further 281 (80.3%) participants agreed that motivation by healthcare workers would lead to better acceptance. With regard to vaccine side-effects, 103 (29.4%) women perceived as not dangerous and 176 (50.3%) gave a neutral response. It may be noted that, 213 (60.9%) women were of the opinion that compliance to vaccination schedule was important [Table/Fig-3]. Lowest and highest total score of attitude were nine and 25, respectively; with a mean score of 18.45±3.30. Overall, 203 (58%) women had a positive attitude towards vaccination.

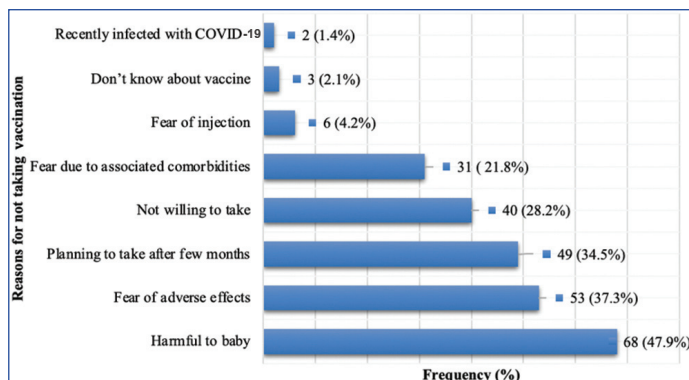
Perceptions and attitude	Strongly agree n (%)	Agree n (%)	Neutral n (%)	Disagree n (%)	Strongly disagree n (%)
Pregnant women should be vaccinated against COVID-19	143 (40.9)	86 (24.6)	75 (21.4)	46 (13.1)	0
Lactating women should be vaccinated against COVID-19	138 (39.4)	95 (27.1)	78 (22.3)	36 (10.3)	3 (0.9)
Health education to pregnant and lactating women regarding vaccine is NOT necessary	6 (1.7)	7 (2)	95 (27.2)	193 (55.1)	49 (14)
Health workers motivating mothers about vaccines help in better acceptance of vaccines	89 (25.4)	192 (54.9)	62 (17.7)	5 (1.4)	2 (0.6)
Vaccine side-effects are dangerous	13 (3.7)	58 (16.6)	176 (50.3)	85 (24.3)	18 (5.1)
Compliance to the vaccination schedule is NOT important	3 (0.9)	13 (3.7)	121 (34.5)	164 (46.9)	49 (14)

**[Table/Fig-3]:** Perceptions and attitude of study participants regarding COVID-19 vaccination (N=350).

Overall vaccine acceptance among the study participants was 208 (59.4%) (that is vaccinated with atleast one dose of COVID-19 vaccine). Further, 165 (47.1%) women had taken their 1<sup>st</sup> dose and 43 (12.3%) women completed both the doses of vaccination. Also, of the 247 pregnant women, 165 (66.8%) women were vaccinated and out of the 103 lactating mothers, 43 (41.7%) women were vaccinated.

Out of the 142 women who had not received the vaccine, the most common reasons for refusal of vaccine were fear of harm to the baby because of the vaccine 68 (47.9%) and fear of adverse effects of vaccine 53 (37.3%) [Table/Fig-4].

Univariate analysis showed that pregnant women, women with higher education, residing in nuclear families, working women and those with positive attitude had statistically significant association (p-value <0.05) with vaccine acceptance than their counterparts [Table/Fig-5].



**[Table/Fig-4]:** Reasons for not taking the vaccine among unvaccinated participants (n=142).

Predictors	Vaccinated with atleast one dose, n (%)	Unvaccinated n (%)	Chi-square value	p-value
<b>Status</b>				
Pregnant	165 (66.8)	82 (33.2)	18.924	<0.001
Lactating	43 (41.7)	60 (58.3)		
<b>Educational status</b>				
Upto SSLC	78 (48.4)	83 (51.6)	14.912	<0.001
PUC and above	130 (68.8)	59 (31.2)		
<b>Type of family</b>				
Joint	51 (39.2)	79 (60.8)	34.993	<0.001
Nuclear	157 (71.4)	63 (28.6)		
<b>Occupation</b>				
Homemaker	129 (55.6)	103 (44.4)	4.176	0.041
Working women	79 (66.9)	39 (33.1)		
<b>Socio-economic status</b>				
Class I to III	183 (58.7)	129 (41.3)	0.715	0.398
Class IV and V	25 (65.8)	13 (34.2)		
<b>Attitude towards vaccination</b>				
Positive	171 (84.2)	32 (15.8)	123.370	<0.001
Negative	37 (25.2)	110 (74.8)		

**[Table/Fig-5]:** Association of vaccination status and various factors among the participants (N=350). p-value <0.05 considered significant

Further, unadjusted associations of the factors influencing vaccination status were analysed. It was observed that pregnant women {Crude Odds Ratio (COR): 2.81; 95% CI: 1.75-4.51} were associated with the higher odds ratio of getting atleast one dose of vaccine as compared to lactating women. Vaccination status was considerably better in women with higher education (COR: 2.35; 95% CI: 1.52-3.63), those residing in nuclear families (COR: 3.86; 95% CI: 2.44-6.10) and working women (COR: 1.62; 95% CI: 1.02-2.57). Participants who had a positive attitude had significantly higher odds of getting vaccinated (OR: 15.89, 95% CI: 9.35-27.00) [Table/Fig-6].

Multivariate analysis revealed that vaccine acceptance was significantly higher among pregnant women (AOR: 3.02; CI: 1.58-5.77), women living in nuclear families (AOR: 4.27; CI: 2.31-7.89) and those with a positive attitude (AOR: 17.48; CI: 9.52-32.09) as compared to their counterparts [Table/Fig-6].

Predictors	COR (95% CI)	AOR (95% CI)
<b>Status</b>		
Pregnant	2.81 (1.75-4.51)*	3.02 (1.58-5.77)**
Lactating	1	1
<b>Educational status</b>		
Upto SSLC	1	1
PUC and above	2.35 (1.52-3.63)*	1.60 (0.87-2.96)

Type of family		
Joint	1	1
Nuclear	3.86 (2.44-6.10)*	4.27 (2.31-7.89)*
Occupation		
Homemaker	1	1
Working women	1.62 (1.02-2.57)**	1.68 (0.88-3.20)
Attitude towards vaccination		
Positive	15.89 (9.35-27.00)*	17.48 (9.52-32.09)*
Negative	1	1

**[Table/Fig-6]:** Logistic regression analysis for vaccination status and associated factors (n=350).

COR: Crude odds ratio; AOR: Adjusted odds ratio; CI: Confidence interval; \*p-value  $\leq 0.001$ ; \*\*p-value  $\leq 0.05$ ; p-value  $\leq 0.05$  considered significant

## DISCUSSION

With introduction of a vaccine, hesitancy towards vaccination has been reported previously and the main reasons for the same may include the compulsory nature of immunisation with vaccines, their coincidental temporal relationships to adverse health outcomes, religious reasons and unfamiliarity [23]. This multifaceted vaccine hesitancy is a major obstacle that needs to be overcome for controlling a pandemic such as COVID-19.

This study assessed the COVID-19 vaccine acceptance and factors influencing vaccination among pregnant and lactating women. Among the participants, 229 (65.5%) and 233 (66.5%) agreed that pregnant women and lactating women should be vaccinated against COVID-19, respectively. Overall, at least one dose of the vaccine was received by 59.4% of the participants. Findings were similar to a study by Mose A and Yeshaneh A, where willingness to receive COVID-19 vaccine was found to be 61% and study by Riad A et al., where two-thirds of the participants (66.6%) indicated their acceptance [17,24].

This study also showed that pregnant women had higher acceptance of vaccine (66.8%) as compared to lactating women (41.7%). Similar results were observed in studies by Riad A et al., where acceptance among pregnant women (76.6%) was higher than lactating women (48.8%) [24]. Vaccine acceptance was much lower in the study by Jayagobi PA et al., (30.3% in pregnant and 16.9% in lactating women), however acceptance was higher in pregnant women [18]. The acceptance of COVID-19 vaccine among pregnant and lactating women widely differs in countries as stated by Skjefte M et al., (range: 28.8-84.4%) [14]. The discrepancy in the different studies may be attributed to the differences in study population, awareness of COVID-19, access to healthcare services in different regions and the study period. Further, this study assessed acceptance after the expert committee approved the vaccination of pregnant and lactating women, as the vaccination programme is ongoing. Majority (80%) were aware that they need to continue COVID-19 protocols and appropriate behaviours after vaccination. Similar findings were observed in a study by Anil A et al., where 98% were ready to follow COVID-19 prevention protocols even after vaccination [25].

Studies have reported that public perception of the benefits and risks of vaccination is a major obstacle for vaccine acceptance [15,18,24]. Studies done in Singapore by Jayagobi PA et al., and Germany by Schaal NK et al., state that limited vaccination-specific information, limited scientific evidence on vaccination safety were the major concerns [18,19]. However, these studies assessed the vaccine hesitancy reasons prior to the approval of its use among pregnant and lactating women. Anxiety about adverse reactions appears to be the most common reason for hesitancy in the majority of the studies as stated by Sharun K et al., [26]. This was supported by these study findings which showed that fear of vaccine associated harm to the baby (47.9%) and adverse effects of vaccine (37.3%) were major hindrances for vaccine acceptance. Report of Ayhan SG et al., stated that 41.7% perceived that the

vaccine will harm the baby [20]. Further report of Sutton D et al., showed similar findings [21].

Vaccination acceptance was considerably better in women with higher education (COR: 2.35; 95% CI: 1.52-3.63) and women who were employed (COR: 1.62; 95% CI: 1.02-2.57), however multivariate analysis did not show statistical significance. Studies done across different countries project the association of education and employment status with vaccine acceptance [17,18,20,24]. This could possibly be explained that having higher educational status and being employed makes them have better awareness regarding the benefits of vaccination. This study also found that, those who had a positive attitude towards vaccination had significantly higher odds of getting vaccinated (AOR: 17.48; CI: 9.52-32.09). Similar were the findings of Skjefte M et al., and Mose A and Yeshaneh A [14,17]. This study also found that women in nuclear families had higher vaccination rates (AOR: 4.27; CI: 2.31-7.89). It could be seen that over two-third of the participants lived in nuclear families, also as the onus of decision making in nuclear families lies in the couple, there may be better chance of acceptance.

This study has identified the possible determinants of COVID-19 vaccine acceptance. Further, it is the first of its kind in the setup after the rolling out of COVID-19 vaccine for pregnant and lactating women and thus provides good information for different stakeholders. The determinants of vaccine acceptance studied are of interest as they may influence introduction of any new vaccine like COVID-19 vaccine for this segment of vulnerable population.

## Limitation(s)

This study was a health institution based, conducted in PHCs, hence possibility of inflation of the findings cannot be ruled out due to ongoing mitigation measures. This study was conducted in selected PHCs in a single district which may limit the generalisability of the study. Similar large scale community-based study across different districts to understand the factors for vaccine hesitancy among pregnant women and lactating women may help to address them.

## CONCLUSION(S)

The study highlights that COVID-19 vaccine acceptance was higher in pregnant women as compared to lactating mothers. Higher education status, being working women, residing in nuclear families and having a positive attitude towards vaccination were the major determinants of vaccine acceptance. Fear of vaccine associated harm to the baby and adverse effects of vaccine were found to be the major hindrances for vaccine acceptance. Increasing the awareness and acceptance of vaccination is essential especially for this segment of vulnerable population so as to control the pandemic.

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