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## The impact of COVID-19 virus and vaccination on the pregnancy and breastfeeding women in Makkah region

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### Abstract

**Background:** Pregnant women usually have a lower acceptance rate and more concerns about vaccination than the general population. There aren't sufficient prior studies on the effect of COVID-19 vaccination on Saudi Arabian pregnant and breastfeeding women either on pregnancy outcomes or on the fetus status. Therefore, the purpose of this study is to identify the impact of the COVID-19 virus and vaccination on pregnancy, pregnancy outcomes, and fetus during the lactation period in women living in Makkah region, Saudi Arabia; in addition, it aims to assess the knowledge, perception, and attitude of pregnant women toward COVID-19 vaccine.

**Methods:** A cross-sectional study was conducted in four major hospitals in Makkah, Saudi Arabia, between January and October 2023. Data was collected through a valid questionnaire, The study included women aged 18-55, who provided informed consent and received the vaccine. Quantitative data analysis was performed using Excel software.

**Results:** The study involved 543 women, mainly younger than 50, with 50.1% expecting or breastfeeding, almost 25% had a history of COVID-19 infection and 55% had received immunization, The study reveals that 66.2% of women have received other vaccine brands in the past three years, with 90.1% believing they have sufficient information about the COVID-19 vaccine. However, 55.6%), lack knowledge about vaccine safety during pregnancy and breastfeeding, and 34.5% believe it causes complications. Overall, 46.0% received at least two doses.

**Conclusion:** The study found that hesitancy to COVID-19 vaccination was primarily due to concerns about vaccine safety among 543 women who met inclusion criteria.

**Keywords:** Pregnant women, Breastfeeding, Covid-19 infection, Vaccine, Perception.

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## **1. Introduction**

Pregnant women usually have a lower acceptance rate and more concerns about vaccination than the general population [1]. According to a review published in 2015, the vaccine-hesitant factors include vaccine safety and ineffectiveness, and insufficient vaccine awareness [2]. assessed pregnant women acceptability of the COVID-19 vaccination among 5294 pregnant women across 16 countries using an online survey. It revealed that the COVID-19 vaccine acceptance rate varied significantly by country; below 45% for pregnant women in USA, Russia, and Australia; and 80% for those in Mexico and India [3].

Fears about the safety of vaccines, fabricated or real, have the power to erode confidence and increase vaccine hesitancy. Pregnant women are likely to have particular questions and concerns about vaccination acceptance. Pregnant women are a unique demographic that may react differently to vaccination due to both the physiological changes that occur during pregnancy and the impact of vaccination on the placenta and fetus [4-6]. These uncertainties must be taken into account when evaluating the benefits-risk ratio and selecting the best course of action for pregnant women who are more likely to experience severe COVID-19 infection.

### ***Impact of coronavirus on pregnant women***

COVID-19 has a significant impact on fetal-maternal health due to the growing concern regarding the risk of COVID-19 vertical transmission (from mother to fetus) or associated malformations, as well as contagion during delivery and breastfeeding . Several studies revealed that clinical features of COVID-19 were similar to those described in non-pregnant women with mild to moderate symptoms [7-10].

Additionally, compared to non-pregnant women in the general community, pregnant women do not seem to be at an elevated risk of developing a severe disease from COVID-19 [11-13].

### ***Vertical transmission of COVID-19 to fetus***

Recent evidence indicates that there may be a possibility of a vertical transmission. This is still controversial because there aren't enough reported cases with intrapartum samples (amniotic fluid, placenta, and umbilical cord blood), and there is a lot of variation in the kind of biological material examined and the collection time. Rodrigues et al. conducted a systemic review study [14-17].

### ***Impact of COVID-19 on breastfeeding women***

Out of the 92 reported cases, the reviewed studies identified four cases exhibiting evidence of COVID-19 in association with breast milk samples. Nevertheless, insufficient scientific data exists to defensively declare that moms infected with COVID-19 may be able to pass the virus on to their infants through breast milk. As a result, recommendations ought to be based on the available data, historical

comparisons, and predictable costs and benefits. Breastfeeding is considered the optimal method of infant feeding as it improves the defense against respiratory and gastrointestinal diseases [18-26].

### ***Impact of vaccination on pregnant and breastfeeding women***

Surveillance during national immunization campaigns is yielding large-scale vaccine safety data. Safety results for the US mass vaccination program were published from several databases. The v-safe surveillance system included 35961 pregnant women who got the Moderna and Pfizer through February 28, 2021 [27-30].

A total of 221 reports from vaccine adverse event reporting system (VAERS) were made by pregnant women who had received the COVID-19 vaccine up until February 28, 2021. Of these reports, 66 (29.9%) suffered adverse effects related to pregnancy or the neonate, the most common of which was spontaneous abortion in the first trimester. [31-32] Reports of congenital abnormalities were absent.

A comparison between spontaneous abortions and ongoing pregnancies revealed no greater odds of exposure to COVID-19 vaccination among 105466 unique pregnancies, according to an analysis of data from Vaccine Safety Datalink through June 28, 2021. [33] The same findings were noted for the rates of stillbirth associated with antepartum COVID-29 vaccine exposure. [34]

### ***Perception of pregnant and breastfeeding women about COVID-19 vaccine***

In a recent study, the acceptance of the COVID-19 vaccination among pregnant, non-pregnant, and breastfeeding women was investigated in the United States. Among this study population, non-pregnant women were found to be the most likely to accept the vaccination (76.2%), followed by breastfeeding women (55.2%). The lowest rate of acceptance (44.3%) was among the pregnant population. [35] Only 41% of participants in different US studies with 939 pregnant women planned to have a vaccination, and 82% of them expressed concerns about the safety of vaccines during pregnancy. [36].

## **2. Subjects and Methods**

### **2.1 Study design and setting**

Cross-sectional study design was conducted from four major hospitals in the Makkah region of Saudi Arabia between January 2, 2023, and October 30, 2023.

### **2.2 Sampling and recruitment strategies**

We include Women who were pregnant or breastfeeding during the year 2021-22, aged (18-55), able to provide informed consent, and receiving the COVID-19 vaccine.

### **2.3 Study questionnaire and eligibility criteria**

Valid questionnaire used for data collection that needs 10 minutes to be completed. No personal identifiers were collected. Inclusion criteria were asked whether or not they had the COVID-19 vaccine

and the type of vaccine, their history of COVID-19 infection, how many episodes of COVID-19 they had to compare data with female who do not take the vaccine, and their history of COVID-19 infection during breastfeeding or in which trimester of pregnancy and then asked about problems in pregnancy and problems in breastfeeding through the questionnaire. measure all the variable questions needed to answer our research, using Arabic and English language.

## 2.4 Data collection and analysis

Quantitative data analysis operated using Excel software. Descriptive analysis and summary Continuous variables are described as means and standard deviations or median and range as appropriate, whereas categorical variables are described as frequency and percentage. 95% CI was used to quantify the perception around all estimates.

## 2.5 Ethical approval

Ethical approval was obtained from Umm Al-Qura university institutional review board Approval No. (HAPO-02-K-012-2023-06-1682), and informed verbal consent was also obtained from all participants.

## 3. Results

This study included 543 women in total who met the inclusion criteria. The majority, (77.9%, n=422), were younger than 50. Of the survey sample, about half (50.1%, n=272) said they were expecting a child or were breastfeeding during the years 21-22. Twenty-two percent of the 119 participants of the study sample, or almost one-quarter, had a history of COVID-19 infection. fifty-five percent of the study sample had received the COVID-19 immunization from around 374 participants. Table1

Table (1) Demographic Characteristics for the Study Participants

Demographic Variable	Frequency (%)
<b>Age</b>	
18–29 years	138 (32.0%)
30–39 years	180 (41.8%)
40–49 years	71 (16.5%)
50 years and over	42 (9.7%)
<b>Were pregnant or breastfeeding during 2021-22?</b>	
Yes	272 (50.1%)
<b>Previous COVID-19 infection history</b>	
Yes	217 (40.0%)
<b>COVID-19 vaccination history</b>	
No	196 (63.0%)
One dos	49 (9.0%)
Two doses	325 (46.0%)

Three doses	NA
Four doses	NA

The attitudes, perceptions, and practices related to vaccination of the participants are presented in [Table 2]. In the past three years, 359 (66.2%) women had received other vaccine brands. A total of 489 (90.1%) women believed that they had sufficient information about the COVID-19 vaccine, but 301 (55.6%) reported that they lacked knowledge about COVID-19 vaccine safety during pregnancy and/or breastfeeding. Moreover, 187 (34.5%) women thought that the COVID-19 vaccine carries the possibility of harm to their babies. However, 356 (65.7%) women reported that they did not fear the COVID-19 vaccine in their pregnant and breastfeeding journey. Overall, 325 (46.0%) women received at least two doses of the COVID-19 vaccine based on governmental requirements. [Figure 1] demonstrates the percentage of complications that occurred during pregnancy and breastfeeding where the mothers believe it's because of COVID-19 vaccine.

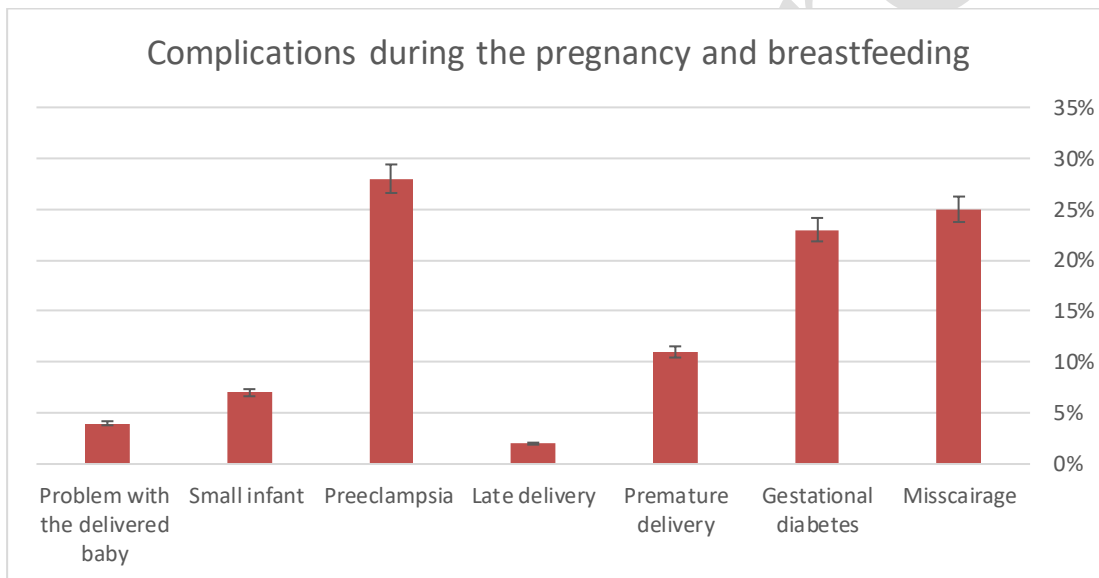


Figure (1) Complications during pregnancy and breast feeding to mothers who took the COVID-19 vaccine.

Table (2) Participants' Attitudes, Perceptions and Practices Related to Vaccination

Variable	n (%)
<b>Vaccinated in the last 3 years</b>	359 (66.2%)
<b>Have enough information about the COVID-19 vaccine</b>	489 (90.1%)
<b>Did not fear the COVID-19 vaccine in their pregnant and breastfeeding journey.</b>	356 (65.7%)
<b>COVID-19 vaccine carries the possibility of harm to your baby</b>	187 (34.5%)
<b>Think COVID-19 is not a serious disease</b>	112 (20.6%)
<b>Have a low risk for COVID-19 infection</b>	234 (43.0%)
<b>If they are sick, their baby will not encounter any negative events</b>	325 (59.8%)
<b>Think the vaccine will not work</b>	313 (57.6%)

<b>Did you suffer from any complications during your pregnancy or breastfeeding journey</b>	112 (20.6%)
<b>Lack of data about COVID-19 vaccine safety in pregnant and breastfeeding women</b>	540 (99.4%)

#### **4. Discussion**

The present study reported a moderate acceptance rate (65.7%) and high knowledge (90.1%) about COVID-19 vaccine. These findings are consistent with previous research, including a study conducted in Saudi Arabia that found almost half of the study's sample size refused to receive the vaccine. [37].

Additional Saudi Arabian study reported moderate scores in terms of COVID-19 vaccination perception, hesitancy, and perceived advantages, ranging from 53.3% to 65%. (38) However, the study results were different from another study conducted in Jordan using an online survey with over 3000 participants; the COVID-19 vaccine had a low rate of acceptance (37%). All these studies were conducted on the general population, with the same study design, data collection techniques, and geographic location. [38-39].

The lack of information regarding the COVID-19 vaccine's safety in the pregnant population was the refusal group's main issue. Pregnant women have not been the target of any COVID-19 vaccine trials, even though the CDC considers them to be a high-risk demographic. Despite being excluded from clinical trials, pregnant women are advised to receive the COVID-19 vaccine, according to a recommendation made by the Advisory Committee on Immunization Practices. [40-43].

The main study limitations include self-reported responses which can result in misreporting, recall bias, and social desirability. The study's sample, which was restricted to people with internet access, might be a biased subset of pregnant women, which could limit the conclusions' ability to be applied generally. Further studies with larger sample size will be useful for generalization of the study results and for creation of strategies that increase uptake among pregnant women during COVID-19 pandemic.

#### **5. Conclusion**

The present study reported moderate acceptance (65.7%) and knowledge (90.1%) about COVID-19 vaccination in a sample of 543 women who met the inclusion criteria. Concern about vaccine safety was the major reason for hesitancy.

#### **6. Declarations**

##### **6.1 Conflict of Interest Statement**

The authors have no conflict of interests to declare.

##### **6.2 Funding Disclosure**

This research did not receive any specific grant from funding agencies in the public, commercial,

or not-for-profit sectors.

Galley Proof

## 7. References

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