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ORIGINAL ARTICLE

COVID-19 vaccination rate and factors affecting non-vaccination in pregnant women

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Abstract

Examining the Coronavirus disease 2019 (COVID-19) vaccination rates and associated factors for acceptance of vaccination in pregnant women during the pandemic. The present study has a cross-sectional survey-based design that evaluated 448 pregnant women, and data were collected between October 1 and December 31, 2021. A composite questionnaire with an instrument was utilized in the survey to examine vaccine rates, including socio-demographic data, maternal characteristics, vaccination history, and reasons for not vaccinating. The vaccination rate was 48% (n=216). The main concerns and barriers to non-vaccination were: (i) concerns about pregnancy (82.9%), (ii) possible vaccine side effects (76.3%), and (iii) insufficient trust in the reliability of the vaccine (20.3%). A multiple logistic regression analysis revealed that following factors affect COVID-19 vaccination rate: first trimester of pregnancy [Odds ratio (OR): 3.40 (95% *confidence interval* (CI):1.84-6.27), $p<0.001$], age 35 and over [OR: 2.96 (*95% CI*:1.40-6.27), $p=0.004$], active working status [OR: 4.88 (*95% CI*:2.57-9.23), $p<0.001$]. Our study indicated that rates of COVID-19 vaccination are still low in pregnant women. Pregnant females constitute a special vulnerable part of the community. Therefore, targeted communication is needed to raise awareness of vaccine safety in healthcare professionals and pregnant women, and strategies to solve vaccine hesitation. In addition, post-vaccination monitoring is required to collect additional data.

Keywords: COVID-19, vaccination, pregnancy, vaccine hesitancy, perinatal

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Introduction

Maternal-child health is the most important indicator of the quality of health care. The historic challenge facing quality healthcare is the global pandemic. The main way out of the pandemic is social vaccination, starting with the vulnerable population. Out of the populations that are most vulnerable to the virus, pregnant women are considered a highly vulnerable population. Vaccination is introduced as an efficient way to stop severe medical conditions in vulnerable people [1].

While 'Severe Acute Respiratory Syndrome Coronavirus-2' (SARS-CoV-2) vaccination was not available at the beginning of the pandemic, having Coronavirus disease 2019 (COVID-19) during pregnancy leads to serious medical conditions such as premature birth, preeclampsia, cesarean section, and perinatal death [2]. The findings of these studies show that fetal and maternal death is reduced due to vaccination in those who intend to become pregnant or pregnant patients. On the other hand, due to the exclusion in the initial phase 3 clinical trials, little was known about the COVID-19 vaccines' effectiveness and safety [3]. It is stated that any authorized vaccine can be used for people who are breastfeeding or are pregnant without choosing the vaccine type. In addition, cumulative observational data from the vaccination initiation have shown no adverse effects and showed that after maternal vaccination with mRNA vaccines, the maternal immune response is generated, and maternal antibodies are conveyed to the breast milk and placenta, which causes SARS-CoV-2 passive immunity in infants [4].

Furthermore, recent research has established that the mortality rate is higher in pregnant patients compared to non-pregnant patients of the same age (9 versus 2.5 deaths per 1000 COVID-19). And, none of moreover patients were fully vaccinated [5]. The Centers for Disease and Prevention (CDC) and Advisory Committee on Immunization Practice guidelines advise COVID-19 vaccines for pregnant females [6-8]. From January 2021, vaccination practices against SARS-CoV-2 began in Türkiye, and vaccination studies continue worldwide. In Türkiye; inactivated virus vaccines and mRNA vaccines are administered. In mRNA vaccines, the portion of the SARS-CoV-2 genome encoding the spike (S) protein is embedded in lipid nanoparticles together with the mRNA molecule. When given to the person in this way, mRNAs cause S protein production by entering the cells. Antigen-presenting cells detect these produced antigenic structures and present them to the immune system and cause the development of antibodies against S proteins [9]. The way inactivated virus vaccines work is by using beta-propionylactone and inactivating SARS-CoV-2 viruses. After vaccination, it is expected for the body to produce particular antibodies for the SARS-CoV-2 S protein, neutralizing the virus and preventing it from binding to its specific receptor [10,11].

Injection site pain or tenderness, rash, muscle pain, fatigue, fever, chills, headache, and joint pain are the most common side effects of COVID-19 vaccines. These side effects are usually self-limiting and mild [12]. Unfortunately, the probability of being vaccinated is significantly lower in pregnant women than in non-pregnant women of reproductive age [13]. Furthermore, there is little published data on vaccine hesitations or attitudes in pregnant women. Therefore, this study investigates the situation of pregnant women in our province about being vaccinated against COVID-19, their opinions on this issue, and how we should better inform pregnant women about vaccination by learning the reasons for their reservation.

Materials and Methods

This cross-sectional survey-based study was conducted from October 1 to December 31, 2021. The study population consisted of pregnant women followed in family health centers in Afyonkarahisar city center. The logistic regression test's sample size was calculated, which allows for 95% statistical power and 5% alpha error. Unfortunately, no study in Türkiye was conducted in a similar setting, so we assumed the prevalence to be 50% to reach the maximum sample. The sample size of the present study was 462, which was calculated by taking the pattern

effect as 1.2 for the largest sample size (n=385). Four hundred forty-eight patients were enrolled, with a 96.9% success rate.

Afyonkarahisar city center was divided into low, middle and high based on socioeconomic family health centers were randomly selected from each stratum. Criteria for eligibility of participation were: (1) being over 18 years of age, (2) being pregnant, and (3) filling out the informed consent form for participation. Fourteen pregnant women were excluded from the recruitment process; who did not want to participate in the research.

The survey was structured from 13 components, including socio-demographic data, maternal characteristics, vaccination history, and reasons for not getting vaccinated. The questionnaire form was applied to 448 pregnant women by taking pandemic measures. In addition, participants were informed about the COVID-19 vaccine.

Statistical Analysis

Statistical analyses were performed using SPSS version 22.0 (IBM Corp., Chicago, Illinois, USA). Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine the data's suitability for normal distribution. Numerical variables with normal distribution were presented as mean±standard deviation and categorical variables as percentages (%). Any variable (*i.e.*, age, education level, working status, trimester, having children, previous COVID-19 diagnosis, and chronic disease history) with a p-value<0.05 in a univariate model was accepted as a candidate for the multiple models along with all variables of possible vaccine hesitance cause. Odds ratios and 95%*CI* for each independent variable were also calculated. Statistical significance was accepted as p<0.05.

Ethical Considerations

The study was approved by the Ethical Committee of the Afyonkarahisar Health Sciences University (Registration Number: 2021/493). Also, research approval was taken from the Scientific Research Commission of the General Directorate of Health Services of the Turkish Ministry of Health (2021-09-30T15-42-08) and the Health Directorate of Afyonkarahisar Province (2021/20).

Results

In the survey of our study, 448 pregnant women with a 96.9% response rate were included. The mean [standard deviation (SD)] age of the participants was 27.5±5.3; 61.6% (n=276) of the pregnant had children, 35.9% (n=161) of the participants were university school degrees, 23.4% (n=105) of the participants diagnosed for COVID-19, 56% (n=251) of the participants were in the third trimester, 27% (n=121) of the participants were employed (Table 1).

Table 1. Characteristics of the study group.

	Characteristics	**n**	
	Age (mean±SD)	27.5±5.3	
	Pregnancy week (mean±SD)	27.2±9.9	
	Characteristics	**n**	**%**
Educational Status	*None*	6	1.4
	Primary school	20	4.5
	Secondary school	127	28.3
	High school	134	29.9
	University	161	35.9
Children	*Yes*	276	61.6
	No	172	38.4
Chronic Disease	*Yes*	25	5.6
	No	423	94.4
Employed	*Yes*	121	27
	No	327	73
Diagnosed for COVID-19	*Yes*	105	23.4
	No	343	76.6
Gestational Age	*1st trimester*	63	14.1
	2nd trimester	134	29.9
	3rd trimester	251	56
Total		448	100

SD: *Standard deviation*

Furthermore, only 16% (n=73) of the pregnant women took a single dose of vaccine, 32% (n=143) were vaccinated with at least two doses considered fully vaccinated, and 52% (n=232) were not vaccinated (Figure 1).

The full-dose vaccination of the study population with Pfizer-BioNTech (n=98) and Sinovac-CoronaVac (n=45) was 68.5% and 31.5%, respectively. In addition, most of the third dose was preferred as Pfizer-BioNTech (n=11, 84.6%). Another interesting finding was that 94% (n=423) of participating pregnant women received or intended to receive a tetanus vaccine.

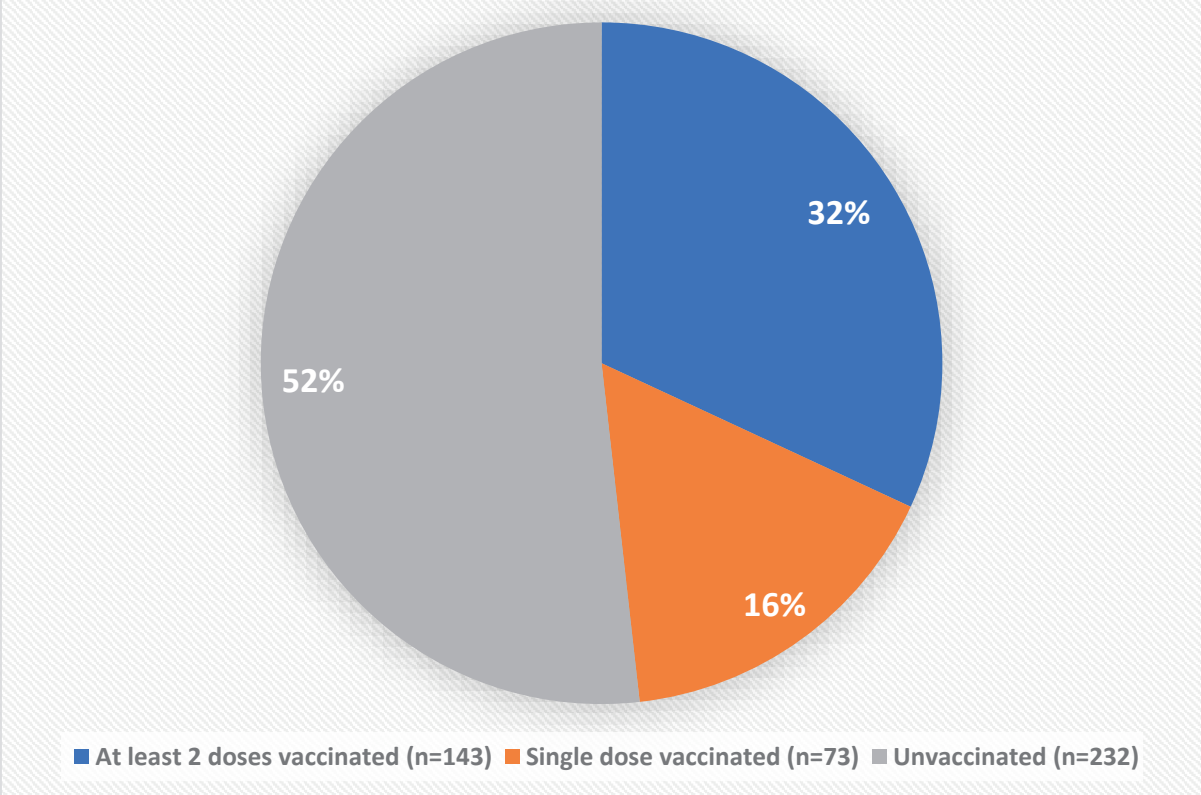

Figure 1. COVID-19 vaccination rate illustration.

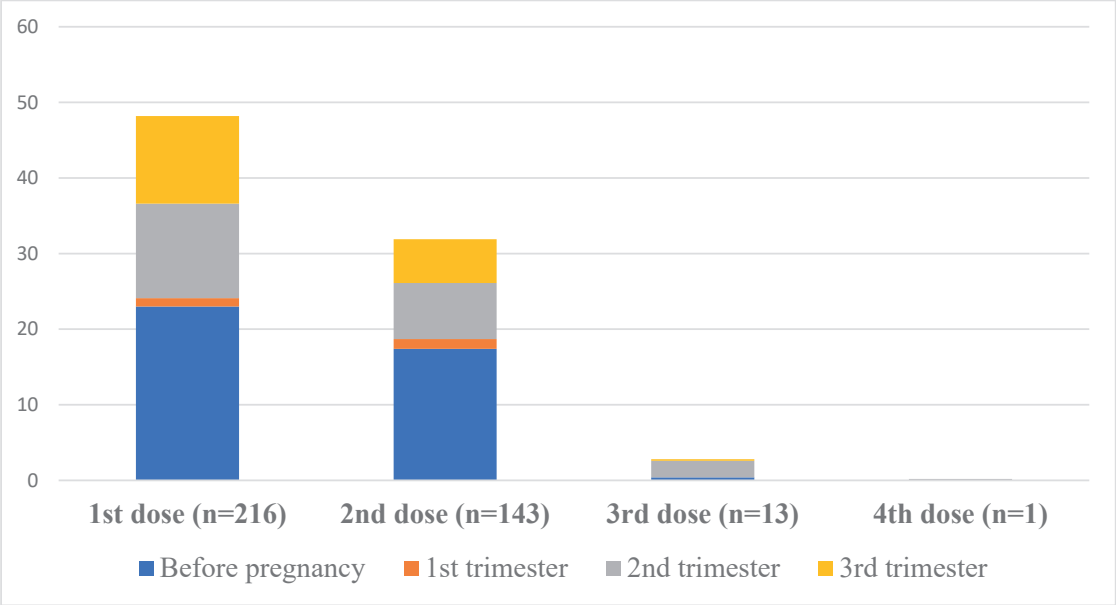

Figure 2. Vaccination times in pregnant women according to trimester.

However, only 1.3% (n=6) of the participants had received the flu vaccine for 2021. A total of 3.6% (n=16) of the pregnant women did not have any vaccination. When we look at the vaccination time of the subjects according to trimester, we see that 17.2% of them were fully vaccinated before pregnancy (Figure 2). Although most of our study population consisted of third-trimester pregnant women (56.0%, n=251), this group was also at least COVID-vaccinated (38.6%, n=97). Table 1 shows a steady fall in the vaccination number while the pregnancy trimester increases.

In response to "What was the reason for not getting vaccinated?" 82.3% of non-vaccinated respondents said they had concerns about pregnancy, especially safety issues about their fetus coming to the fore. Another important comment was the vaccine's reluctance to face possible side effects, with 76.3%. In addition, 20.3% of the respondents say: They do not trust the reliability of the vaccination. At the same time, 12.1% said they did not have sufficient information about the vaccine (Figure 3).

When we look at the affecting factors for the status of vaccination in pregnant women, significant relationships were found with age groups, educational status, trimester and employment status (p<0.001 for all, Table 2). According to the logistic regression analysis in Table 3; vaccination was higher; 4.88 times in working pregnant [*95% CI*= 2.57-9.23], p<0.001), 2.96 times in the ≥35 age group compared to the 18-24 age group (*95% CI* = 1.40-6.27, p=0.004), 3.4 times in the first trimester compared to third trimester (*95% CI* = 1.84-6.27, p<0.001), 1.76 times in the second trimester compared to third trimester (*95% CI* = 1.09-2.83, p=0.019). A positive correlation between education level and vaccination rate was found, while no correlation could be demonstrated in the multiple logistic regression model.

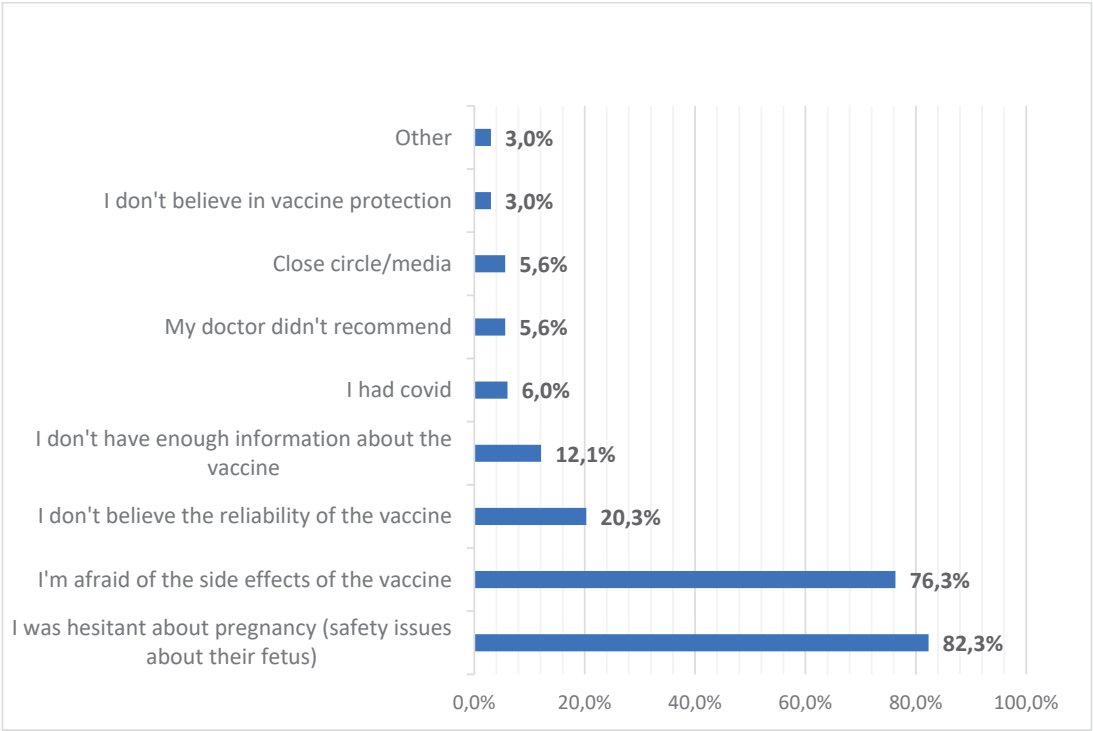

Figure 3. Factors for not getting vaccinated in the study population (n=232).

Table 2. Factors affecting vaccination status in the study group.

	Variables	n	Have you had the COVID 19 vaccine?			
			Yes (%)	No (%)	χ2	*p*-value*
Age	*18-24*	141	33.3	66.7	21.781	0.000
	25-34	258	52.7	47.3		
	≥35	49	67.3	32.7		
Children	*Yes*	276	51.8	48.2	3.726	0.054
	No	172	42.4	57.6		
Education Level	*None/Prim/Sec School*	153	35.3	64.7	28.839	0.000
	High School	134	43.3	56.7		
	University	161	64.6	35.4		
Trimester	*1st Trimester*	63	65.1	34.9	21.743	0.000
	2nd Trimester	134	58.2	41.8		
	3rd Trimester	251	38.6	61.4		
Working Status	*Yes*	121	76.9	23.1	54.48	0.000
	No	327	37.6	62.4		
COVID-19 History	*Yes*	105	45.7	54.3	0.343	0.558
	No	343	49	51		
Chronic Disease History	*Yes*	25	52	48	0.152	0.697
	No	423	48	52		

*: Analyses chi-squared

Discussion

This survey-based, cross-sectional study reports that 52% of pregnant women did not vaccinate against COVID-19. Moreover, 16% of the participants were vaccinated with a single dose and 32% with a full dose. Our regression models shed light on the positive factors influencing vaccine uptakes, such as first-trimester pregnancy, age over 35, and active employment. In particular, we found that active working pregnant women were more likely to take the COVID-19 vaccination. Therefore, it is quite surprising that 94.4% of participants received or planned to receive the tetanus vaccination. However, the flu shot rate for that year was very low. Finally, we found definite vaccine refusal at only 3.6% (n=16).

Compared to the general population or non-pregnant women, it is known that pregnant women have a higher risk of developing severe illness, intensive care hospitalization and the necessity for mechanical ventilation due to COVID-19 [14]. Moreover, various studies on pregnant women populations have shown that SARS-CoV-2 infection during pregnancy increases complications, including preterm delivery, preeclampsia, and several other clinical complications [15,16]. Vaccination of pregnant

Table 3. Factors affecting vaccination status according to Univariate and multiple logistic regression analysis results.

Variables		Univariate Logistic				Multiple Logistic			
		OR	*95% CI*		*p*-value	OR	*95% CI*		*p*-value
			Lower bound	*Upper bound*			*Lower bound*	*Upper bound*	
Working Status: Yes		5.5	3.41	8.88	0.000	4.88	2.57	9.23	0.000
Trimester	*2nd*	2.21	1.44	3.38	0.000	1.76	1.09	2.83	0.019
	1st	2.95	1.66	5.26	0.000	3.4	1.84	6.27	0.000*
Age	*25-34*	2.23	1.45	3.41	0.000	1.53	0.95	2.47	0.077
	≥35	4.12	2.06	8.24	0.000	2.96	1.4	6.27	0.004*
Education	*High School*	1.39	0.86	2.25	0.167	1.28	0.77	2.12	0.326
	University	3.34	2.1	5.31	0.000	1.02	0.54	1.92	0.941*

OR: Odds ratio, ***CI:*** Confidence interval

*Those who are not employed, are in the third trimester, are between the ages of 18-24, and are none/primary/secondary school graduates are taken as reference.

people against COVID-19 is therefore very important and effective health policies should be developed to increase vaccination rates. Identifying these people's concerns about the vaccine, informing them effectively about this issue, and raising awareness about the possible complications of the disease will be effective in encouraging vaccination.

In Türkiye, COVID-19 vaccines are free and easily accessible healthcare services. Further, the public health units inform and remind people who have not been vaccinated. Despite this, we found that the overall rate of non-vaccination among pregnant women is 52%. These findings were lower than recent studies showing acceptance or willingness for SARS-CoV-2 vaccination of pregnant women (respectively 49.1% and 52%) [17,18]. This discrepancy could be attributed to our research methodology assessing confirmed vaccination status. The difference between demand and execution may have brought us to this interpretation.

The three main factors behind vaccine reluctance in pregnant women were: (i) concern about pregnancy, particularly potential harm to the fetus, (ii) doubts about possible side effects of the vaccine, and (iii) disbelief in the vaccine's reliability. In a similar study conducted in Türkiye, insufficient confidence in the vaccine was found to be the most common cause of not getting the vaccine for COVID-19 [19]. In another study, the most important reason pregnant women refused the COVID-19 vaccine, even though it was proven safe, was that they feared hurting their developing babies because of side effects [20]. The biggest issue regarding the vaccination in the refusal group was hesitation due to its possible harmful effect on the fetus. Although CDC and health authorities in Türkiye declared that COVID-19 infection has devastating consequences in pregnant women, participants were unanimous in the view that potential long-term effects on the baby rise from the antivaccine qualitative data and arguments [21,22]. The mentioned hesitation may have been fueled somewhat by insufficient safety considerations in pregnant women in the initial phase 3 vaccine trials [3]. However, at the time of the study, there were no doubts or worrying signals regarding the vaccine's safety in peripartum women [23-25]. In addition, cumulative observational data provide an important foundation, such as the V-Safe registry [26].

Among participants, the highest COVID-19 vaccination rate was almost five-times among employed pregnant women. This is probably caused by working people seeing themselves as riskier. Working life causes inevitable social contact. In addition, the proximity of vaccination centers to work areas may have prompted pregnant women to vaccinate impulsively. This finding also accords with our earlier observations, which showed a high vaccination rate among working pregnant women [27,28].

If we compare gestation times, first-trimester women have the highest vaccination after the second and third trimesters. This result is consistent with Goncu Ayhan et al. [6]. Moreover, the 35-age group pregnant women were about 2.96 times more likely to have COVID-19 vaccination compared to pregnant women in the 18-24 age group. This result agrees with previous studies [20,29,30]. There are several possible explanations for these results. First, mature pregnant females could be aware of the severe COVID-19 complications and more focused on the protective effects of the vaccines. This finding may reflect that pregnant women of younger maternal ages have less experience with pregnancy-related losses and complications. In addition, comorbidities such as diabetes, and hypertension can emerge with age, lowering pregnant mothers' immunity and increasing COVID-19 morbidity and mortality rate. Consequently, this may cause anxiety in older pregnant and may encourage them to get the COVID-19 vaccine.

A positive correlation was found between education level and vaccination rate, while this relation disappeared in the multiple logistic regression model. Pregnant females with higher education levels might have partial information about COVID-19 vaccines, leading to a negative attitude. Studies on this subject in Türkiye, Italy, and Qatar found similar results [31-33]. Therefore, we should strengthen the transparency of vaccine trials and increase health literacy.

Regarding influenza vaccination, we found that the flu shot rate was very low for that year. This hesitation may arise from miscarriage observations reported in vaccinated pregnant persons during the H1N1 pandemic in 2009 [25]. However, in contrast to the COVID-19 and flu vaccination rates, 94.4% of the participants received or intended to receive the tetanus vaccine. Tetanus vaccine is usually administered to pregnant women in our country and vaccine applications are followed and recorded by family physicians. Therefore, the willingness for tetanus vaccines was significantly higher among study participants compared to influenza and COVID-19 vaccines.

Contrary to expectations, the rate of tetanus vaccination in our study did not differ between individuals with and without COVID-19 vaccination. This observation could support the hypothesis that most pregnant women are not against the vaccine but have reluctant toward the COVID-19 vaccine [34]. This result supports our view that pregnant women are worried for the possible vaccine side effects and should be informed about it.

Study Limitations

Due to some limitations, this study's findings should be interpreted cautiously. The first limitation is that the study's questionnaire was not tested for validity and reliability. Second, we examined the reasons and rates of vaccination but did not follow the unvaccinated group, who may change their beliefs in the future. Thus, all possible problems in real situations may not have been addressed in this study, which indicates the need for further studies in this field.

Conclusion

It is very important to vaccinate the pregnant population, which is at high risk of developing a severe condition against COVID-19, to protect it from the complications of this disease. However, pregnant women are unsure about getting vaccinated for fear of possible side effects, concern that it will harm the baby, and lack of knowledge about the vaccine. Informing them about possible complications of the disease and vaccine side effects will be effective in increasing vaccination rates in these people.

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Conflict of Interest

Authors report no conflict of interest.

Data Availability Statement

The dataset collected and analyzed for the current study is available from the corresponding author and can be obtained upon reasonable request.

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