

The Perceptions of Infertility Patients Regarding the COVID-19 Vaccine: A Mixed Methods Analysis of Patient Readiness

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ABSTRACT

Introduction: We sought to elucidate infertile patient perceptions regarding the novel COVID-19 vaccine as it pertained to fertility treatments and future pregnancies.

Methods: Patients visiting the Froedtert North Hills Health Center for Fertility and Reproductive Medicine in Menomonee Falls, Wisconsin from July 1, 2020, through June 6, 2021, were invited to participate in a mixed methods survey assessing infertile patient perceptions regarding clinic closures, delays in treatment, and the COVID-19 vaccine. The main outcomes measured were readiness to receive the COVID-19 vaccine in the setting of trying to conceive.

Results: There were 760 surveys sent with a total of 192 completed surveys (response rate = 25.3%). Respondents who reported having a college or post graduate education were more likely to consider the COVID-19 vaccine when it became available to them ($P < 0.001$). When participants' responses were stratified by the number of previous completed fertility treatments (either embryo transfers or intrauterine inseminations), there was a statistically significant trend of increasing willingness to receive the COVID-19 vaccine as the number of completed fertility treatments increased even when considering a pregnancy or while breastfeeding ($P = 0.004$ and $P = 0.001$, respectively). Qualitative themes included participants' fear of the unknown due to existing perceptions, beliefs, and mistrust; interpretations of medical knowledge, and desire for provider guidance and mindful communication.

Conclusions: This study suggests that despite identified hesitancy of the COVID-19 vaccine, patients with higher levels of education and those who completed an increasing number of infertility treatments were more willing to consider the COVID-19 vaccine.

INTRODUCTION

Infertility is defined as trying to conceive for at least 1 year without a successful pregnancy. It is well established that the diagnosis of infertility and the need for infertility treatments can result in significant psychosocial distress.¹⁻⁵

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The SARS-CoV-19 virus (COVID-19) pandemic started in late 2019 and caused disruptions on a global scale. This disease led to mandated physical distancing, widespread enforcement of personal protective equipment, and closures of institutions worldwide. The pandemic also delayed medical treatments that were considered elective, including infertility treatments.

On March 17, 2020, the American Society for Reproductive Medicine (ASRM) published guidelines recommending the cessation and suspension of new and ongoing fertility treatments, except for urgent, medically indicated fertility preservation procedures.⁶ This included intrauterine insemination (IUI) and in vitro fertilization (IVF), including egg retrievals and frozen embryo transfers.

Recently, data have shown that fertility clinic closure during the COVID-19 pandemic was associated with a sharp increase

in the prevalence of anxiety and depression among infertile patients undergoing treatment and was perceived as an uncontrollable and stressful event.⁷⁻⁸

On April 24, 2020, ASRM released an update on its recommendations that included resumption of care in individual clinics based on state and disease risk.⁹ On December 11, 2020, the Pfizer-Biotech COVID-19 vaccine was authorized by the US Food and Drug Administration under an emergency use authorization for limited populations, with public-wide release shortly after.¹⁰ Although numerous studies have shown statistically significant increased levels of anxiety and depression in infertility patients whose evaluations and treatments were delayed, these studies did not include questions regarding patient perceptions of the

COVID-19 vaccine.⁷⁻⁸ Studies in general populations showed that pregnant women are less likely to receive the COVID-19 vaccine than nonpregnant and breastfeeding women.¹¹ The most common reasons for “declining” the vaccine included concern for short- or long-term side effects, the speed of the development of the vaccine, fear of harming the pregnancy, previous allergy or anaphylaxis, lack of sufficient research, and potential interaction with other medical comorbidities.¹¹ Online rumors about the vaccine’s potential negative impact on fertility regularly appeared after the vaccine rollout—particularly during its early phases—which was a source of hesitancy to the vaccine, specifically in patients seeking treatment for infertility and those of reproductive age.¹² To the best of our knowledge, prior to this study, there has been no data to represent the patient perspective towards the COVID-19 vaccine among those seeking infertility treatment.

The primary aim of this study was to assess the readiness of infertility patients to receive the COVID-19 vaccine in the setting of trying to conceive.

METHODS

Study Design

This survey study is a single-center convergent mixed methods study that involved the distribution of a 60-question survey assessing infertile patient perceptions regarding clinic closures, treatment delays, and the COVID-19 vaccine.

Recruitment and Data Collection

The study was performed at the Froedtert North Hills Health Center for Fertility and Reproductive Medicine in Menomonee Falls, Wisconsin. All patients who visited this clinic from July 1, 2020, through June 30, 2021, were invited to participate in the survey. Exclusion criteria included any patient under the age of 18 and prior completion of the survey. This survey was developed based on an existing survey out of Stanford University elucidating perceptions of how the COVID-19 pandemic affected the care of patients with cancer.¹³ Three different versions of the survey were offered to patients including a hard copy paper survey, online Google form survey, and Qualtrics survey. Initially, the survey was conducted in person only starting February 22, 2021. Given the limited availability of researchers to present the survey study to in-person patients on March 22, 2021, it was expanded to online platforms. Two reminders were sent to participants if they had not completed the survey during the study period. The survey was offered to a total of 760 patients resulting in 192 responses (25.3% response rate). Online surveys were distributed to patients through MyChart Messaging system (a patient portal) through the electronic medical record (Epic Systems Corporation, Verona, Wisconsin). No patient identifiers were obtained in this anonymous survey. Approval was obtained from the Medical College of Wisconsin’s Institutional Review Board, IRB Reference Number PRO00039946.

Table 1. Demographic Data, N=192

Variable	n	% ^a
Age		
≤35	86	44.8
>35	85	44.3
Did not answer	21	10.9
Gender		
Male	5	2.6
Female	187	97.4
Ethnicity/race		
White	177	92.2
Hispanic	7	3.6
African American	3	1.6
Asian	2	1.0
Jewish	1	0.5
Prefer not to answer	1	0.5
Did not answer	1	0.5
Marital status		
Married	178	92.7
Never married	8	4.2
Member of an unmarried family	6	3.1
Education		
No college degree	32	16.7
College degree	90	46.9
Postgraduate degree	67	34.9
Did not answer	3	1.6
Employment status		
Employed	178	92.7
Unemployed/disabled	11	5.7
Student	1	0.5
Did not answer	2	1.0
Health insurance		
Private	187	97.4
Badgercare	1	0.5
Obamacare	1	0.5
Military	1	0.5
Medicare	2	1.0
Household income		
<\$30 000	3	1.6
\$30 001–\$50 000	4	2.1
\$50 001–\$100 000	47	24.5
>\$100 000	96	50.0
Did not answer	42	21.9
Infertility diagnosis^b		
Polycystic ovary syndrome/anovulation	23	12.0
Endometriosis	9	4.7
Male factor	21	10.9
Low ovarian reserve	17	8.9
Same sex couple	2	1.0
Uterine abnormality	3	1.6
Tubal abnormality	4	2.1
Genetic	2	1.0
Unexplained	22	11.5
Did not answer	89	46.4

^aPercentages may not add up to 100 due to rounding.

^bQualitative data from survey that was summarized after data collection.

Data Analysis

Quantitative Analysis Methods

Data were presented as n (%). Chi-square or Fisher exact tests were used to examine the associations between categorical variables. Linear trend in proportion was tested by Cochran-Armitage trend test. SAS version 9.4 (SAS Institute Inc, Cary, North Carolina) and SPSS version 28.0 (IBM Corporation, Armonk, New York) were used for statistical analyses. $P < 0.05$ was considered statistically significant.

Qualitative Analysis

The survey questions analyzed included 2 free-text questions to further ascertain the perspectives and insights of those participating in the study. These qualitative questions aimed to explore patients' underlying motivations and were used to help amplify the patient experience. Written responses were extracted verbatim from the survey and inserted into an Excel document. Using inductive content analysis of the free-text survey responses, 2 members of the research team assigned individual codes to capture and classify recurring patterns. The same team members compared responses to negotiate discrepancies and ensure trustworthiness of analysis. Those patterns were grouped together into 3 themes to elucidate the individual perceptions and beliefs regarding the COVID-19 vaccine.

RESULTS

Quantitative Analysis

A total of 192 patients responded to the survey. Of those who responded, 187 identified as female, and 5 identified as male. A large majority identified as White, married individuals. Many respondents had a college or postgraduate degree and private health insurance. Not all questions were answered by all respondents. Therefore, to accurately convey the response rate, each question shows the total number of responses (Table 1).

Participant willingness to accept the COVID-19 vaccine was analyzed in conjunction with different demographic variables to see if there was an association between these variables and vaccine acceptance. The survey results suggest that respondents' age, marital status, income level, and insurance status did not correlate with willingness to accept the vaccine in any significant way (Supplementary Table 1). Participants with a higher educational level (college or postgraduate degree) were more likely to accept the COVID 19 vaccine when it became available to them (Cochran-Armitage trend test $P = 0.001$) (Table 2). Interestingly, when asked

Table 2. Education as Variable Affecting Respondents' Willingness to Receive COVID-19 Vaccine

	No/Unknown, n (%)	Yes, n (%)	Total N	P value
Question: Would you like to get the coronavirus (COVID-19) vaccine when it is available?			187	0.0010 ^a
No college degree	14 (47)	16 (53)		
College degree	25 (28)	65 (72)		
Postgraduate degree	10 (15)	57 (85)		

^aCochran-Armitage trend test.

Table 3. Number of Infertility Treatments Associated With Respondents' Willingness to Receive COVID-19 Vaccine

	No/Unknown, n (%)	Yes, n (%)	Total N	P value
Would you like to get the coronavirus (COVID-19) vaccine when it is available?			188	0.040 ^a
0 infertility treatments	1 (50)	1 (50)		
1 infertility treatment	42 (30)	100 (70)		
2 infertility treatments	7 (18)	31 (82)		
≥3 infertility treatments	0 (0)	6 (100)		
If you are pregnant or breastfeeding when the vaccine becomes available to you will you get it?			180	0.0010 ^a
0 treatments	1 (50)	1 (50)		
1 treatment	82 (61)	53 (39)		
2 treatments	18 (49)	19 (51)		
≥3 treatments	0 (0)	6 (100)		

^aCochran-Armitage trend test.

to consider a future pregnancy or breastfeeding and the COVID-19 vaccine, the significant trend between level of education of vaccine acceptance disappeared ($P = 0.92$) (Supplementary Table 2). When the number of completed treatment cycles (either IUI or embryo transfer) were analyzed with the respondents' willingness to accept the vaccine, there was a statistically significant trend of increasing willingness to receive the COVID-19 vaccine as the number of infertility treatments increased (Cochran-Armitage trend test $P = 0.040$), even when considering future pregnancy or breastfeeding (Cochran-Armitage trend test $P = 0.0010$) (Table 3).

Qualitative Analysis

From the analysis of free-text responses, we identified 3 primary themes: (1) fear of the unknown due to perceptions, beliefs, and historical mistrust; (2) patient interpretations of medical knowledge and self-generated benefit-risk assessments; and (3) seeking provider guidance and mindful communication.

Theme 1: Fear of the Unknown

Patients report a multifaceted fear of the unknown. Between concerns about harming a future child or fetus, the impact on fertility, and worries regarding breastfeeding risks, respondents described inadequate counseling on what to expect during a vulnerable time. Specifically, a female patient, age 34, said, "After all we have been through to get pregnant, it is not worth the risk." Another female patient, age 36, agreed, "I have been trying to become pregnant for

over 2 years, and I would be devastated if a reaction to the vaccine affected my pregnancy.” Additionally, patients describe how negative outcomes due to COVID-19 may influence their response and cited a lack of guidance or communication from medical professionals during the pandemic. Stemming from historical medical mistrust, a male patient, age 40, said, “[I am] not comfortable with how it [the vaccine] was developed and being targeted to minorities.”

Theme 2: Patient Interpretations of Medical Knowledge, and Self-Generated Benefit-Risk Assessments

Many patients provide insight into their experience when developing an understanding of new medical information, whether disseminated by their clinician or obtained through outside means. Primarily, patients cited a lack of clinical evidence for the use of the COVID-19 vaccine in pregnancy. A female patient, age 41, said, “[the] vaccine is new and hurriedly made, so I don’t trust it.” Other patients shared similar sentiments of mistrust due to the seemingly rapid production and dissemination of the COVID-19 vaccine. “Not enough time has passed to determine potential long-term effects,” said another female respondent, age 35. Regarding fertility specifically, a female respondent, age 43, said, “[I’m] worried about effects on fertility. Other members of my family will get the vaccine to protect me.”

For patients who are in higher-risk categories at baseline during their pregnancy, respondents described a greater sense of unpredictability and concern with COVID-19. A female patient, age 43, said, “I have an autoimmune disorder, and I worry about sufficient studies having been done with women who were pregnant and doubly with my disorder.” Another female patient, age 31, reported similar worries, stating “I am waiting until after I deliver to get the vaccine, as my husband had a significant reaction to the vaccine, and I do not know if that would affect my baby.”

Respondents also indicated that they perceived the lack of clinical research as harmful, advancing their mistrust surrounding COVID-19. “I’m not a lab rat, and my unborn child won’t be either,” said a female patient, age 39. Less explicitly, another female patient, age 32, agreed, stating that they would not receive the vaccine due to “the unknowns involved, and the fact that pregnant women were not a part of the testing.”

Without access to clinical trials that include pregnant women, patients reported creating a self-generated benefit-risk assessment based on their emotions and insufficient evidence. Respondents detailed an increased risk of being within a vulnerable population, as well as feelings of inadequacy and guilt that may arise if their pregnancy is unsuccessful due to the consequences of COVID-19. One female patient, age 41, said, “Infertility is a rollercoaster. If I did become pregnant, got the vaccine, and then lost the baby, I would feel immense guilt.”

Theme 3: Seeking Provider Guidance and Mindful Communication

Patients described an increase in desire to communicate with their

clinicians during COVID-19. They reported wanting direct information and individualized assessments tailored to their needs. As illustrated by this response from a female patient, age 33, “I would consult with my doctor, and if they said it was safe, I would [receive the vaccine],” patients are influenced by trust in their clinician’s recommendations. Another female patient, age 32, said, “I’m not sure I want to get the vaccine while pregnant. I will need to discuss with my doctor before I will decide.” Many patients additionally detailed that these conversations are important and have changed their opinion on receiving the vaccine. For example, a female respondent, age 37, said, “I’m pregnant and got vaccinated yesterday. OB was supportive.”

DISCUSSION

This study took place at the height of the COVID-19 pandemic and at the beginning stages of vaccine release to the public. Therefore, this timely study sheds light for fertility providers on patient hesitations regarding the COVID-19 vaccine and provides insights into evidence-based practice and targeted education regarding the vaccine. While education and number of completed infertility treatments appeared to significantly increase acceptance of the vaccine, it is evident there is still vaccine hesitancy—especially when related to pregnancy and breastfeeding—among the infertility population.

Previous studies have shown that less than 1 in 4 pregnant people were vaccinated against COVID-19, despite retrospective data showing safety, efficacy, and vaccine-generated antibody passage through umbilical cord blood and breastmilk.¹⁴⁻¹⁸ Our results suggest that as the number of infertility treatments increased, the acceptance of the vaccine also increased. The likely explanation for this is that participants in this study may do more to secure a viable and safe pregnancy. It is also possible that patients who have undergone more treatment cycles have spent more time with their clinician and have established a stronger rapport and level of trust. Further noted in our qualitative responses, patients appreciated detailed guidance and conversations with clinicians regarding the COVID-19 vaccine to help them make informed decisions regarding vaccine acceptance. However, many respondents who received 1 to 2 fertility treatments altered their answer from “yes” to “no or don’t know” responses when considering the COVID-19 vaccine during a pregnant state or breastfeeding, which highlights the hesitancy of respondents to accept the vaccine while pregnant or breastfeeding (Table 3). This perceived hesitancy correlates with the themes of fearing the unknown, mistrust in health care, and patient-driven benefit-risk assessments as found in our qualitative analysis. Patients who received less guidance were less likely to receive the vaccine.

Higher education significantly increased overall acceptance of the vaccine. However, when considering vaccination while pregnant or breastfeeding, the impact of education was no longer significant (Table 2 and Supplemental Table 2). This transition occurred in all

3 categories of education. Vaccine hesitancy in health care workers (the majority of individuals having at least some college degree) considering pregnancy/lactation and the COVID-19 vaccine has been reported previously.¹⁴ In that study, while the majority of respondents were not hesitant about the vaccine, respondents who were pregnant, breastfeeding, or actively pursuing pregnancy were significantly more hesitant to receive the vaccine.¹⁴ This suggests that education does not fully combat the hesitancy of the vaccine in pregnancy or breastfeeding and suggests that other factors play a role in helping patients make informed decisions regarding the vaccine. In our study, income, insurance status, age, and marital status showed no impact on vaccine acceptance.

There were a few limitations to our study. The survey distributed to participants was long (60 questions), which may have contributed to survey fatigue, variability between questions, and potentially lower response rate. Also, the study population was limited to a single academic center located in a state without an insurance mandate to cover infertility treatments. With this in mind, the authors recognize that the patient population surveyed was likely skewed with patients having higher levels of education and more resources to support infertility treatments.

To our knowledge, this is the first mixed method study elucidating the perspectives of the COVID-19 vaccine in an infertile population. Our study was timely in that it was initiated when most of the public were not eligible to receive the COVID-19 vaccine and continued until the vaccine was widely available.

CONCLUSIONS

This study demonstrates that despite identified hesitancy regarding the COVID-19 vaccine, patients with higher levels of education and those who completed an increasing number of infertility treatments were more willing to consider the vaccine. Patients unwilling to receive the vaccine reported mistrust in health care, lack of communication with clinicians, and medical misunderstanding while formulating benefit-risk assessments. Our study highlights the ongoing hesitations regarding the COVID-19 vaccination in patients seeking infertility evaluation and those undergoing treatment. Higher quality patient-clinician communication is essential for infertility patients with less than a college degree and for patients in the early stages of their fertility journey.

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Appendix: Supplemental Tables are available at www.wmjonline.org.

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Supplementary Table 1. Demographic variables association with willingness to receive COVID-19 vaccine

Question	Variable	No and Unknown, n (%)	Yes, n (%)	Total n	P Value
Would you like to get the coronavirus (COVID-19) vaccine when it is available?	Age			168	0.16
	Age ≤35	26 (30)	60 (70)		
	Age >35	17 (21)	65 (79)		
Would you like to get the coronavirus (COVID-19) vaccine when it is available?	Marital status			188	0.76
	Unmarried	3 (21)	11 (79)		
	Married	47 (27)	127 (73)		
Would you like to get the coronavirus (COVID-19) vaccine when it is available?	Income			148	0.49
	Income ≤ \$100,000	15 (28)	38 (72)		
	Income > \$100,000	22 (23)	73 (77)		
Would you like to get the coronavirus (COVID-19) vaccine when it is available?	Insurance coverage			186	
	Insurance would not cover treatments	33 (28)	87 (72)		
	Insurance would cover treatments	15 (25)	46 (75)		
	Unsure if insurance would cover treatments.	1 (20)	4 (80)		

Supplementary Table 2. Level of education impacting respondent willingness to receive COVID-19 vaccine in pregnancy and/or breastfeeding

Question	Variable	No and Unknown, n (%)	Yes, n (%)	Total n	P Value
If you are pregnant or breastfeeding when the vaccine becomes available to you will you get the novel coronavirus (COVID-19) vaccine?	Education			179	0.92
	No College Degree	16 (57)	12 (43)		
	College Degree	48 (55)	40 (45)		
	Post-Graduate	36 (57)	27 (43)		