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Original Research



COVID-19 vaccine hesitancy among caregivers of children under five years old in a pediatric emergency department

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ABSTRACT

Objective: Children under five years old have a high rate of SARS-CoV-2 (COVID-19) infection, yet rates of vaccination are relatively low. Our qualitative study investigated reasons why caregivers of children ages six months to four years old may be hesitant to vaccinate their children against COVID-19. Study design: Qualitative study.

Methods: We enrolled a convenience sample of caregivers of patients aged six months to four years who presented for care at a pediatric Emergency Department in southern California. We conducted face-to-face semi-structured interviews with caregivers to probe for themes regarding any hesitations they may have regarding vaccinating their children against COVID-19. Interviews were recorded, transcribed, translated if necessary, and coded. When thematic saturation was achieved, we applied grounded theory methodology to assess for themes and adapted the World Health Organization Strategic Advisory Group of Experts model of vaccine hesitancy determinants matrix to provide a framework for the identified themes.

Results: We conducted 20 interviews, two in Spanish, and achieved thematic saturation at 17 interviews. We categorized themes surrounding vaccine hesitancies into external, patient-centric, and vaccine-centric factors. External factors included sources of information and family/community influence. Patient-centric factors included the perceived risk versus benefit ratio, caregiver beliefs, and caregiver knowledge and awareness. Vaccine-centric factors included vaccine safety, vaccine efficacy, vaccine information, and barriers to vaccination.

Conclusions: Using qualitative methodology, we gained important insights into caregiver thoughts regarding the COVID-19 vaccine in children under five years old. We identified themes not previously published in the literature that may be specific to the COVID-19 vaccine in the young pediatric population.

1. Introduction

COVID-19 (SARS-CoV-2) has infected nearly two million children under five years old and was the fifth leading cause of death in this age group between 2020-2022. The emergency of the omicron variant raised particular concern because of worsening outcomes in young children. Children under five, even without underlying health conditions, are experiencing more hospitalizations than any other group. As of June 2023, it caused over 750 deaths in this age group. Despite this, vaccination rates in this population remain low.

On June 17, 2022, the United States Food and Drug Administration authorized the Pfizer-BioNTech and Moderna COVID-19 vaccines for

children aged six months to four years.⁵ Subsequently, the American Academy of Pediatrics issued a policy statement recommending these vaccines for all children above six months, including booster doses as per Center for Disease Control and Prevention (CDC) guidelines.³ However, vaccination coverage in this age group is low when compared to older age groups, with fewer than 10 % of eligible children receiving at least one dose.² Surveys reveal that 11.8 % of caregivers intend to vaccinate their children under five,² with 47.5 % expressing no intention to do so.¹

Vaccine hesitancy is defined by the World Health Organization (WHO) as the "delay in acceptance or refusal of vaccination despite availability of vaccination services." The WHO Strategic Advisory Group of Experts (SAGE) on Vaccine Hesitancy concluded that vaccine

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hesitancy is complex and is influenced by factors such as complacency, convenience, and confidence. Previous research relies primarily on large scale surveys, highlighting factors such as vaccine safety, efficacy, and caregiver knowledge. However, surveys often limit responses to predetermined categories, necessitating a deeper exploration of the nuanced factors contributing to vaccine hesitancy in this age group. This study aims to determine the factors associated with COVID-19 vaccine hesitancy in caregivers of children aged six months to four years.

2. Methods

2.1. Study setting and design

This qualitative study was conducted at a free-standing tertiary care hospital in urban southern California. Our Emergency Department (ED) provides care to approximately 95,000 patients per year and is the only pediatric-specific ED in San Diego County. COVID-19 vaccination rates in our county for children under age five is 7.2 $\%.\ ^{13}$

We conducted semi-structured individual interviews with caregivers whose children sought medical care in the ED. The interviews addressed caregiver hesitancies and barriers related to COVID-19 vaccination. Additionally, we collected self-reported demographic data to provide context

The data collection took place between July–November 2022. A key time point is the emergency use approval of Moderna and Pfizer-BioNTech vaccines on June 17, 2022 for ages six months and up. The Institutional Review Board granted this study an exemption under category 45CFR46.104. A partial waiver of individual authorization for use of Protected Health Information was granted for the recruitment component of this research by the IRB as this component meets the requirements of the HIPAA Privacy Rule, 45CFR164 section 512(I).

2.2. Sampling, recruitment, and enrollment

Caregivers were enrolled using convenience sampling when the research team was present in the ED. Eligible participants were caregivers of children aged six months to four years old who could provide informed consent in English or Spanish. Exclusions were made for children with life-threatening conditions or instances where participation could hinder medical care.

The research team approached caregivers while they were in their assigned exam room. Researchers collaborated with the primary care team to ensure that participation would not disrupt patient care. After verifying that caregivers had not yet participated in the study, researchers explained the purpose of the study and provided caregivers with a written document containing information on the study. Consent for audio recording was obtained. Each participant was assigned a study number for anonymity.

2.3. Data collection

Once enrolled, caregivers completed face-to-face interviews using a semi-structured interview guide (Appendix 1). The same pediatric emergency physician conducted all the interviews to provide consistency of how questions were asked and probed. Interviews were conducted in the caregiver's preferred language and were audio recorded. Caregivers then filled out a multiple-choice demographic survey. A bilingual, certified translator experienced in qualitative interviews transcribed the audio recordings and translated them into English when necessary. The team stored all audio files and documents on the hospital-approved secure network. All hard copies were destroyed.

After the first five interviews, investigators revised the interview questions to be more open-ended. The interview guide was revised again after the fourteenth interview to remove a confusing question.

2.4. Data analysis

Three pediatric emergency physicians with experience in qualitative analysis individually reviewed the transcripts to identify emerging themes and create a code book through open coding.¹⁴ They then compared codes and resolved discrepancies through discussion. They used the constant comparison method for code refinement and transcripts were re-coded using the final codebook. 15 Using a grounded theory approach, the investigators iteratively reviewed the final coded data for overarching themes. 15 Grounded theory is a theoretical framework focused on generating theory grounded in data. Through discussion and consensus building, investigators noted that themes mirrored the WHO SAGE Vaccine Hesitancy Determinants Matrix (Fig. 1) so they selected this as a conceptual model to explain caregiver COVID-19 vaccine hesitancy. Investigators determined that thematic saturation was met after completion of 17 interviews when the data generated no new themes. 16 They coded the data using Dedoose software (Los Angeles, California/United States)¹⁷ to facilitate the reporting of common themes and supporting quotations for constructing the conceptual framework. Techniques to ensure trustworthiness included iterative data collection, use of a coding framework, and keeping notes of coding decisions. Member checking was also performed by completing three additional interviews with new participants to verify and validate the themes obtained from interviews.¹

3. Results

3.1. Characteristics of study subjects

Our team completed 20 interviews; we achieved thematic saturation at interview number 17. Of the 20 interviews, 18 were in English and two were in Spanish. Most caregivers interviewed were female, between 20 and 39 years old, and had at least received a college degree. Half of the participants identified as Hispanic. Almost a quarter of participants were healthcare workers. None of the participants had vaccinated their child against COVID-19; 55 % reported that they would not vaccinate their child, 25 % intended to vaccinate, and 20 % remained undecided. Most children were up to date on their routine childhood vaccines. Additional details of subject characteristics are provided in Table 1.

3.2. Themes

Investigators assembled caregiver thoughts into a qualitative taxonomy and applied it to the WHO SAGE Vaccine Hesitancy Determinants Matrix to provide a conceptual model for viewing the themes surrounding caregiver COVID-19 vaccine hesitancy (Fig. 1). This model categorizes vaccine hesitancy into three main categories: 1) Contextual influences, 2) Individual/social group influences, 3) Vaccine and vaccination-specific issues. This model has been validated in several systematic literature reviews. ^{21,22} Three main themes emerged from our analysis: external influences, patient-centric factors, and vaccine-centric factors (Fig. 2). Illustrative quotes within each theme are provided in Fig. 3.

3.2.1. External influences

Caregivers trusted their healthcare providers for vaccine information. Their pediatrician was reported as their "go-to 100 %" (Participant #11). Others reported that they got information from the government, the CDC, and published research. They trusted scientists and researchers. Caregivers that worked in the healthcare system reported that they got information from their employers (for example, the University of California).

Several participants got information from the news, internet, and social media (specifically, Facebook and Tik-Tok). They also relied on television, billboards, and the radio. The political environment played a critical role in their beliefs, with one participant stating that "all of the



Fig. 1. WHO SAGE vaccine hesitancy determinants matrix.

politics that are involved now are not okay" (Participant #12). Several participants reported that they were hesitant to vaccinate their children because they could not find reliable information. They reported distrust in certain sources, specifically in the Food and Drug Administration (FDA), stating that they are "not going to trust anybody and anything just because you are FDA" as they "have heard bad things about FDA before too" (Participant #12). Participants further reported that their sources had conflicting information, making it hard to know which information to trust. They stated that all the "mixed information" (Participant #18) and "controversies" (Participant #19) made it difficult to know who and what to trust.

Family and community influence also played a role in the decision to vaccinate their children against COVID-19. Participants reported that family members' opinions played a role, specifically the caregiver's

partner and parents. One participant stated that they were "in favor of the vaccine but [her] husband is against the COVID vaccine" (Participant #10) which is why their child was not vaccinated. Peer influence came from friends, neighbors, and school members.

3.2.2. Patient-centric factors

3.2.2.1. Risk versus benefit. Participants believed that the risk of their child contracting COVID-19 was low due to lack of exposure. For example, one child was not in school or daycare so the perceived risk of their child getting infected with COVID-19 was low. They stated that they may consider vaccinating their child when they are older or are in school. Caregivers also believed that the vaccine was unnecessary in children under age five because they are not at high risk for severe

 $\label{eq:control_equation} \textbf{Table 1} \\ \text{Demographics of subject characteristics (n = 20)}.$

Demographics of subject characteristics (ii = 20).	
Child Age	
Less than 1 year	6 (30 %)
1 year old	3 (15 %)
2 years old	5 (25 %)
3 years old	3 (15 %)
4 years old	3 (15 %)
Child Ethnicity/Race	
Hispanic/Latino	7 (35 %)
Non-Hispanic	13 (65 %)
White	5 (25 %)
African American/Black	0 (0 %)
Asian	1 (5 %)
Other	7 (35 %)
Child Sex	
Male	13 (65 %)
Female	7 (35 %)
Caregiver Language	
English	18 (90 %)
Spanish	2 (10 %)
Caregiver Age (Years)	
Less than 20	2 (10 %)
20–29 years	7 (35 %)
30–39 years	8 (40 %)
40–49 years	2 (10 %)
Decline to answer	1 (5 %)
Caregiver Ethnicity/Race	
Hispanic/Latino	10 (50 %)
Non-Hispanic (NH)	10 (50 %)
White	7 (35 %)
African American/Black	0 (0 %)
Asian	2 (10 %)
Other	1 (5 %)
Caregiver Sex	E (0E 0/)
Male	5 (25 %)
Female	15 (75 %)
Caregiver Highest Level of Education	0 (0 0/)
Elementary School	0 (0 %)
Junior High School	3 (15 %)
High School	1 (5 %)
College/University	11 (55 %)
Graduate School/PhD	5 (25 %)
Caregiver Employment Healthcare Worker	4 (20.06)
Non-healthcare Worker	4 (20 %) 16 (80 %)
Household Annual Joint Income	10 (00 70)
Less than \$20,000	5 (25 %)
\$20,000 to \$50,000	3 (15 %)
\$50,000 to \$100,000	4 (20 %)
\$100,000 to \$200,000	1 (5 %)
Greater than \$200,000	4 (20 %)
Decline to answer	3 (15 %)
Caregiver Political Party	0 (10 70)
Democratic	4 (20 %)
Republican	4 (20 %)
Other	2 (10 %)
Decline to answer	10 (50 %)
Caregiver Intent to Vaccinate Child (COVID)	10 (50 70)
No	11 (55 %)
Yes	5 (25 %)
Undecided	4 (20 %)
Child Has Received COVID Vaccine	1 (20 70)
No	20 (100 %)
Yes	0 (0 %)
Child up-to-date on Childhood Immunizations	- (0 /0)
No	1 (5 %)
Yes	18 (90 %)
Unknown	1 (5 %)
	· · ·

disease. One participant stated that if their daughter was "exposed [and infected with COVID-19], she will be okay" (Participant #2). For this same reason, another caregiver was not planning on vaccinating their healthy child, however they were planning on vaccinating their child who had underlying respiratory issues because of their higher risk for severe disease.

Conversely, some parents were less likely to vaccinate their children

if they had chronic medical conditions, with the thought the vaccine might trigger an exacerbation of their underlying illness. For example, one caregiver was concerned because their child had lung issues and were not supposed to get live viruses (when in fact, it is a mRNA vaccine, not a live vaccine). Another reported that "if [their child] was a full term, completely healthy baby, I think we would have gone ahead and vaccinated him from the beginning" (Participant #10), however they believed that the vaccine may harm him because of his prematurity. Overall, participants felt that their children were too young and too sensitive. Caregivers expressed that the risk of COVID-19 infection is less than the risks associated with the vaccine. Participants expressed that they "trust their child's immune system more than they trust the vaccine." (Participant #9)

3.2.2.2. Knowledge and awareness. Several participants reported that they intended to vaccinate their child but had not because they did not know that it had been approved. They felt that "there is [not] enough communication, specifically to the public" (Participant #15). Caregivers expressed that they did not know enough about the vaccine to decide, for example whether it's "a live virus or a dead virus or anything on the COVID vaccine" (Participant #10). Knowledge regarding the vaccine was limited for some due to not having a trustworthy source for vaccine information and due to receiving conflicting information. They reported that "there is a lot of misinformation and people need to be careful about that" (Participant #11).

3.2.2.3. Caregiver choice. Several participants had not vaccinated their child because they felt that it was their personal choice to vaccinate their child. In fact, some felt even more hesitant to vaccinate their children because of the societal pressure to vaccinate. "The constant push of another vaccine, another vaccine, a booster" made them less likely to vaccinate because "it didn't seem right to push it so much" (Participant #12). They also stated that they were spacing out the vaccine from the other childhood vaccinations or that their child was on a delayed vaccination schedule. Lastly, they reported that they were unable to vaccinate their child because their child was recently sick or recently had a COVID-19 infection.

3.2.3. Vaccine-centric factors

3.2.3.1. Vaccine safety concerns. Participants reported that the vaccine was developed and approved too quickly, and that vaccines should take longer to gain FDA approval. They expressed that not enough research had been done and that they wanted to wait until the vaccine had been out longer before giving it to their child. They were afraid of any unknown long-term side effects and did not want their child to be a "guinea pig but would rather wait around for ten plus years" (Participant #9) before vaccinating.

Participants did not trust the vaccine ingredients and were afraid of side effects that it may have on their child. They were worried about short-term side effects such as fever, influenza-like symptoms, and muscle aches. They feared potential long-term side effects such as infertility, menstrual irregularities, heart problems, blood clots, seizures, autism, DNA alteration, cancer, as well as the possibility that it may affect the child's development or underlying medical condition. Some also believed that the vaccine caused death. For some, the belief that the vaccine was unsafe was based on their own adverse reactions to the vaccine while others did not want to vaccinate their child because they personally knew or heard of people with adverse reactions to the vaccine.

3.2.3.2. Vaccine efficacy concerns. Caregivers were hesitant to vaccinate their children because they believed that it does not actually prevent COVID-19, but only reduces the symptoms. They reported that they had gotten vaccinated themselves but still got COVID-19 and were "just as sick as everybody else, so what is the point?" (Participant #12). They

Fig. 2. Themes regarding COVID-19 caregiver hesitancy.

* specific side effects mentioned include: short term side effects (fever, influenza-like symptoms, muscle aches), long term side effects (the "unknown"), death, infertility, menstrual irregularities, heart problems, blood clots, seizures, autism, DNA alteration, cancer, and the fear that it will affect the child's development or underlying medical condition.

also reported that they were hesitant because the vaccine was not up to date for the current variant making it less efficacious.

3.2.3.3. Barriers to vaccination. Caregivers reported that they were hesitant to vaccinate their child because it took too much time or too much effort to get the vaccine. Appointments were difficult to get because "it can be tricky [to make an appointment] if you don't have access to [the internet]" (Participant #11). Caregivers cited the cost of the vaccine as a barrier. They also reported that they did not want to vaccinate their child while they were currently sick or if their child had recently been sick.

4. Discussion

This qualitative study identified themes that influence caregiver COVID-19 vaccine hesitancy in children less than five years old. While other studies have looked at the themes of vaccine hesitancy against COVID-19,¹⁹ this is one of the first studies that specifically explores hesitancy towards vaccinating children under five. There are different attitudes and beliefs toward vaccines, making it difficult to determine how to address vaccine hesitancy and help promote vaccinations. Vaccination decisions remain complex while some individuals accept vaccines, some remain concerned but still accept them, some delay vaccines, some refuse specific vaccines but accept others, and some refuse all vaccines.²⁰ Children under five years old are among the least vaccinated,^{2,3} thus, understanding factors that play a role in this is crucial in tackling vaccination and caregiver education strategies.

A commonly cited reason for lower acceptance of vaccination in children is the opinion that children are at lower risk for infection and for developing severe outcomes when compared to adults.²³ In line with other research,⁷ many participants did not perceive COVID-19 as a

serious health threat to their child. The assumption that COVID-19 is a mild condition in childhood is not supported by evidence. While children do have lower mortality rates from COVID-19 than adults, they still account for a large proportion of cases. 1,2,24 COVID-19 is also associated with life threatening manifestations such as multisystem inflammatory syndrome in children 25 and high rates of hospitalization with the omicron variant.

Low confidence in vaccine safety and efficacy played a large part in caregiver hesitation. Participants reported concerns about the expedited vaccine development and authorization process, which is a commonly cited reason for COVID-19 vaccine hesitancy. Conspiracy theories and general distrust in government, healthcare professionals, and variable sources contribute to even more unfounded doubts and objections to vaccination. Caregivers also were hesitant to vaccinate their children because the vaccine for under five was not specific to the current variant. Parents may even have different intentions for their children than they do for themselves. 19,26,27

Most of the study participants were female (75 %), however it is well documented that mothers are more likely to accompany their children to medical appointments. ²⁸ In addition, most of our population identified as Non-Hispanic white or Hispanic Latino and although this represents the demographics of our institution's catchment area, there is a known impact of race and ethnicity on decision to vaccinate. ²⁹ One recent survey indicated that caregivers identifying as female or Hispanic, or who had an education lower than a bachelor's degree having the lowest reported and intended COVID-19 vaccination. ³⁰ Our study also did not include any Black caregivers, and previous research indicates that non-Hispanic Black parents have higher hesitancy about vaccinating their children against COVID-19. ^{11,31,32} This finding is important given the disproportionate impact of the COVID-19 pandemic on Black communities. ³³ We may be missing key themes from this vulnerable

External Influences

Sources

"We go the pediatrician, or doctors, and we go to Yahoo too" (Participant #15)

"Social media just kind of scares you because [the users] tell you their experience but then you don't know if it was the vaccine, or it was probably just their medical thing so yeah it's just all mixed information..." (Participant #18)

"Sure enough COVID happens - this vaccine comes out and take it, take it, trust us, trust us... there hasn't been a long history of research so I'm not going to trust anybody and anything just because your FDA [recommends it]..., we have heard bad things about the FDA before too..." (Participant #12)

Individual/Group Influences

"I'm in favor of the vaccine but my husband is against the COVID vaccine." (Participant #10)

Patient-centric Factors

Risk vs Benefit

"[Children] are not at high risk, so I trust her immune system more than I trust the vaccine." (Participant #9)

"RSV kicked her way harder than COVID... she just got a fever and not even a cough, no respiratory issues...Do we really need to give her a vaccine for something that wasn't that bad for her?" (Participant #14)

<u>Caregiver Beliefs</u>
"It seems it was a good idea at first but then the fact that they get pushing more and more vaccines, one, two, three, four shots. I've never heard about other shots being pushed so much. ... Then the constant push of another vaccine, another vaccine, a booster, a booster, it just kind of felt like it didn't seem right to push it so much. It is bad enough that we as adults are taking it. What have we done to ourselves? Our next generation is coming, what is going to happen to them?" (Participant #12)

Knowledge/Awareness

"I don't hear enough news about it... I didn't know that it was available to six months old and older, so I don't feel there is enough communication specifically to the public." (Participant #15)

"I'm not sure what is in the COVID vaccine, I'm not sure if it's like a live virus or like a dead virus or anything on the COVID vaccine." (Participant #10)

Vaccine-centric Factors

Vaccine Safety

"I think they were just trying to get something out there quick...with the way the pandemic is and how fast [COVID-19] is spreading. It was too quick of a process for how soon it came out. [Vaccines] being out within a year is just mind-blowing to me." (Participant #16)

"I trust what they are doing, but I also don't know if I just want to give my child a vaccine that hasn't been studied for a long time, I think that is what it comes down to." (Participant #14)

"We heard that they are giving a vaccine to stop the population from growing, to make people disappear." (Participant #18)

Vaccine Efficacy

"With the new variant coming out they are kind of like pushing for an old variant vaccine, instead of giving something that is what we need to fight [the current strain]" (Participant #14)

"I took the vaccine, both shots and then I still have COVID-19 and mom, she had three of them, and she still got COVID-19 and she was super sick." (Participant #1)

Vaccine Information

"We don't even know what they are putting in the vaccine" (Participant #13)

Barriers

"Getting the appointment is the most difficult part of getting the vaccine." (Participant #15)

Fig. 3. Illustrative quotes regarding COVID-19 vaccine hesitancy.

population given that we did not have any Black families in our study. Future research could include a more diverse sample.

There are important limitations to this study. First, researchers enrolled a convenience sample therefore the data may be incomplete. Second, the interviews were all conducted in an ED. Thus, caregiver concern for the health of their child may have impacted their responses. There may also be a bias towards caregivers who are more concerned for their child's health at baseline given that research shows an association between parental COVID-19 vaccine hesitancy and their children having chronic health conditions. Also, several caregivers mentioned that their children had underlying medical conditions which may have influenced their responses. Finally, 20 % of participants worked in a healthcare setting which likely influenced their beliefs on vaccinating their children. Previous studies show that healthcare workers are more likely to vaccinate their children against COVID-19.

4.1. Conclusions

Using qualitative methodology, we gained important insights into caregiver thoughts regarding the COVID-19 vaccine in children under five years old. We identified themes not previously published in the literature that may be specific to the COVID-19 vaccine in the young pediatric population. Many caregivers expressed concern about how quickly the vaccine had been developed and approved for use in the pediatric population. The concern for vaccine safety was further exacerbated by the perceived low risk of COVID-10 morbidity in their young child as compared to the potential risk of the vaccine. More reliable dissemination of accurate and high-quality information could address these reasons for vaccine hesitancy. This is supported by research showing the association with caregiver knowledge and willingness to vaccinate their children. 12 Moving forward, strategies tailored to cultures and socio-psychological factors need to be developed to reduce vaccine hesitancy and aid informed decision-making.³⁴ It is also important to note that caregivers trust their healthcare providers thus information can be distributed on a small scale. Public health teams should consider a more targeted approach to improve vaccine hesitancy in their communities by exploring how these factors and others apply to the needs of their own local populations.

Author statements

Ethical approval

Our study was exempt from Institutional Review Board requirements under category 45 CFR 46.104. A partial waiver of individual authorization for use of Protected Health Information (PHI) was granted for the recruitment component of this research by the IRB as this component meets the requirements of the HIPAA Privacy Rule, 45 CFR 164 section 512(I). The PHI determined necessary to include the following: ED track board to identify potential subjects. This waiver was reviewed and approved using expedited review procedures (Approval #802490).

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Competing interests

None declared.

Contribution list

Dr. Van Woy conceptualized the study, designed the study, supervised data collection, analyzed the data, and drafted and critically revised the manuscript. Dr. Casas collected data and critically revised

the manuscript. Dr. Shah analyzed the data and critically revised the manuscript. Dr. Chang designed the study, analyzed the data, and critically revised the manuscript. All authors approved the final manuscript as submitted and agree to take public responsibility for the content of the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at $\frac{https:}{doi.}$ org/10.1016/j.puhe.2024.12.015.

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