



A questionnaire-based survey on experience of side effects of COVID-19 vaccination among healthcare workers in Andhra Pradesh, India

Aleti Lakshmi Manohari¹, Lohitha Polisetty^{ 2}, Smita Padhy³, D.S.S. Girjavani⁴*

ABSTRACT

Introduction

Immunization is one of the most effective and cost-effective health measures for controlling infectious diseases. This study developed and implemented a questionnaire to determine COVID-19 vaccine acceptance among healthcare workers (HCWs) in Visakhapatnam, India, and to study the influence of medically attended adverse events (MAEs) experienced by them on their willingness to consider taking the second vaccine dose. The purpose of the study was to evaluate safety and immunogenicity of the COVAXIN® and COVISHIELD® vaccines in HCWs aged ≥ 18 years and their attitudes towards vaccination based on their own experiences.

Methods

During January to March 2021, a cross-sectional questionnaire survey was conducted among healthcare staff and medical students at a tertiary care teaching hospital in Visakhapatnam, India. A total of 265 HCWs were evaluated using a standardized questionnaire that captured data on demographics.

Results

The participants in our study took two different vaccines: COVAXIN® or COVISHIELD®. Most 250 (94%) took COVISHIELD®. Of these, 32% reported experiencing no side effects, 25% reported mild side effects (including fever, headache, weakness and fatigue), 37% reported moderate side effects, and 6% reported side effects severe enough to disrupt day-to-day activities inside and outside the home for a period of five or more days. None of the study participants required hospital attention. The majority of the participants (n=238, 90%) were prepared to take a second dose of vaccine but 2% said they would not take the second dose of the vaccine based on the side effects they experienced and a further 8% expressed reluctance.

Conclusion

The majority of participants experienced either no symptoms (32%), mild (25%) or moderate (32%) side effects and none were hospitalized, showing that vaccines are safe with no long-term side effects. However, the number of those who expressed reluctance or unwillingness to take a second dose based on the side effects they experienced is concerning and warrants further attention to determine how confidence can be supported.

Keywords: Healthcare Workers, Side Effects, COVID-19 Vaccines, Sanitization, Hygiene, Safety

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¹ Department of Biochemistry, GITAM Institute of Medical Sciences and Research, GITAM (Deemed to be University), Rushikonda, Visakhapatnam – 530045, Andhra Pradesh, India

2*Corresponding author Lohitha Polisetty, Department of Biochemistry, GITAM Institute of Medical Sciences and Research, GITAM (Deemed to be University), Rushikonda, Visakhapatnam – 530045, A.P, India, drlohithao6@gmail.com

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INTRODUCTION

Coronavirus (CoV) is a type of RNA virus, the name for which is derived from the Latin word corona, meaning 'crown', due to the distinctive crown appearance caused by the virions on its surface¹ A number of coronaviruses cause infections in humans and animals, with symptoms ranging from a simple cold to extreme respiratory distress that can be fatal.² The novel CoV disease that has become an emerging global health threat³ since the first recorded outbreak began in Wuhan, China near the end of December 2019 is also known as SARS-CoV-2 (Severe Acute Respiratory Syndrome 2) and the disease it causes, COVID-19 (coronavirus disease of 2019).

Shortly after it was first recording in China, the virus spread quickly to Thailand, Japan, South Korea, Singapore, Iran and eventually around the world across the following months,⁴⁻⁶ with widespread viral distribution in countries including Spain, Italy, the United States, the United Arab Emirates and the United Kingdom.⁷ COVID-19 was declared a global pandemic by the World Health Organization on 11 March 2020^{8,9} and had resulted in 244,897,472 officially confirmed cases of COVID-19 and 4,970,435 deaths by the end of October 2021. Since its emergence, SARS-CoV-2 has presented numerous challenges, including virus isolation, identification, prevention and the need for rapid vaccine production and distribution.¹⁰

Seven separate coronaviruses, from alpha and beta genera, have been identified as infecting and causing disease in humans. SARS-CoV, Middle East respiratory syndrome (MERS-CoV), and SARS-CoV-2 are beta coronaviruses that cause extreme acute respiratory syndrome and result in high mortality rates. SARS-CoV-2 is a particular public health issue because its transmission rates are higher than those of the other beta coronaviruses. It thus has the potential to overwhelm intensive care units, which could cause health systems to collapse.^{11,12}

Vaccination against COVID-19 is very important for preventing COVID-19. Immunization is one of the most effective and cost-effective health measures for preventing infectious diseases.^{13,14} Countries all over

the world have sped up the research and production of COVID-19 vaccines. As of October 2021, 23 had already been approved or authorized for use, with a further 12 in phase III trials, 17 in phase II trials, 15 in phase I clinical trials and 13 in pre-clinical trials.¹⁵

Several studies have identified a variety of factors that affect vaccine acceptance when a new vaccine is introduced. These include questions about the vaccine's safety and effectiveness; perceived negative health effects; misunderstandings about the need for vaccination; a lack of confidence in the health system; and a lack of community awareness about vaccine-preventable diseases. Misinformation or confusion that lead to vaccine hesitancy could jeopardize public health in the face of the current crisis.¹⁶⁻¹⁹

Since the COVID-19 pandemic is more severe in terms of transmissibility and/or mortality than previous pandemics, for example of influenza or AIDS, countries all over the world, including India, are under intense pressure to contain the current pandemic and avoid the damaging impacts of epidemic waves. Understanding the factors that affect COVID-19 vaccination acceptance, as well as recognizing common obstacles and facilitators to vaccination decisions, are essential aspects of developing successful strategies to increase vaccine coverage in the general population.²⁰⁻²³

Individual reactions to immunization vary greatly, ranging from mild local reactions to – in a handful of extremely rare cases, often no more than one in several million – fatal outcomes. Vaccine-induced adverse reactions; adverse reactions caused by storage, manipulation and/or administration errors; and coincidental reactions (adverse health outcomes that happen shortly after vaccination but which have no causal association with the immunization) can all adversely affect confidence in vaccination amongst healthcare workers (HCWs) and the public. The current study therefore aimed to record healthcare workers' experience of the side-effects of vaccination and to examine how these experiences influence their attitudes towards further vaccination, specifically their willingness to take the second dose of the 2-dose

COVID-19 vaccination schedule. This is the first study to determine the degree to which vaccine acceptance might be negatively affected by experiences of side-effects following first vaccination.

METHODS AND MATERIALS

The present study developed and implemented a questionnaire to study any adverse effects produced by the COVID-19 vaccine during the post-vaccination period and to determine the acceptance of vaccination by healthcare workers resulting from their personal experience of these adverse effects. The questionnaire collected demographic data, details of the brand of vaccination received (COVAXIN® or COVISHIELD®, both of which were available at the time of the study), post-vaccination symptoms and which precautions (such as mask wearing, hygiene and social distancing) study participants were willing to take after vaccination.

During January to March 2021, we undertook a cross-sectional survey, using a questionnaire developed for this study, among healthcare staff and medical students at a tertiary care teaching hospital in Visakhapatnam, Andhra Pradesh, India. At that time, vaccines had been prioritized for healthcare workers (HCWs) but were not available to the general public.

A total of 265 healthcare workers were evaluated using a standardized questionnaire that included 20 closed-ended questions (see Tables 2-5) that captured information on demographics (age, gender and professional role), vaccination details, experience of side effects and willingness to take the second dose needed to provide full and lasting protection. An exploratory session was conducted to explain the motive of the study and an online link was given to those willing to participate in the study. Web-based support was provided to those who needed it.

Our questionnaire was used as a novel approach to study medically attended adverse events (MAEs) including mild to serious adverse events (SAEs) and thus to describe not only the long-term safety and immunogenicity of COVAXIN® and COVISHIELD® in healthcare workers aged ≥ 18 years, but also how their

experience of side-effects might influence their confidence in vaccines and willingness to take the second dose.

Vaccines Used in the Study

The vaccines received by the healthcare workers were COVAXIN® and COVISHIELD®. COVAXIN® is India's indigenously-developed COVID-19 vaccine, an inactivated vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR), National Institute of Virology (NIV). From the results of Phase I, II, and III clinical trials involving around 27,000 participants, COVAXIN® demonstrates a high clinical efficacy against COVID-19 and also significant immunogenicity against the rapidly emerging variants. The BBV152 vaccine is being developed on a platform derived from whole-virion inactivated vero cells: it contains 6g of whole-virion inactivated SARS-CoV-2 antigen (strain: NIV-2020-770), as well as aluminium hydroxide gel (250 g), TLR 7/8 agonist (imidazoquinolinone) (15g), TM 2-phenoxyethanol (2.5 mg), and phosphate buffer saline (up to 0.5 ml).

Since inactivated vaccines do not replicate, they cannot revert and cause disease. The dead viruses they contain instruct the immune system to launch a protective response in the face of infection, which will be remembered if subsequent infection with a live virus occurs. Immuno-potentiators, also known as vaccine adjuvants, are applied to the vaccine to improve and enhance its immunogenicity. COVAXIN® is a two-dose vaccine, with the two doses usually offered 28 days apart. It does not require sub-zero freezing, nor reconstitution, and comes in ready-to-use liquid form in multidose vials that can be stored safely at 2-8°C. The vaccine received DCGI (Drug Controller General of India) approval for Phase I & II Human Clinical Trials in July, 2020.

COVISHIELD® is a locally-produced version of the Oxford-AstraZeneca vaccine, which uses an adenoviral vector. It is manufactured by the Serum Institute of India (SII), the world's largest vaccine producer and contains the following ingredients: L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80,

ethanol, sucrose, sodium chloride, disodium edetate dihydrate (EDTA) and water for injection. COVISHIELD® is highly successful, according to the SII, and this is backed by Phase III trial evidence from Brazil and the United Kingdom.²⁴ Clinical trials are a IV-phased process used to see if a vaccine produces healthy immune responses, if it has any unfavourable side effects (Phases I-III) and its long-term value, particularly when compared with existing products on the market (Phase IV – this is less relevant to COVID-19 vaccines as there were no existing treatments for it to replace). COVISHIELD® was found to be 90% effective in international clinical trials. The vaccine requires two separate doses of 0.5 ml each, given intramuscularly in deltoid muscle. The second dose should be administered 4–6 weeks after the first dose.

Study population

Those deemed at risk of occupational exposure to the COVID-19 and who were thus eligible for priority vaccination were included in the study. This included medical students and HCWs including interns, doctors, nurses and paramedical staff working at the study site hospital. All male and female healthcare workers at the hospital who were over 18 years of age at the time of the first vaccine dose, who had shown stable health for at least 30 days prior to enrollment, and who gave informed consent of willingness to participate were included in the study. Exclusion criteria were patients with a history of allergy, fever or bleeding disorders and pregnant women. Medical students under 18 years of age, anyone who did not

work at the study site hospital in a healthcare worker role, and those who did not give informed consent. Informed consent was taken from participants before the start of the survey. Out of a total 289 potential participants, 265 (92%) gave voluntary consent to participate and 24 (8%) were not willing to participate in the survey; reason(s) for non-participation were not recorded.

Tables 2-5 show the post-COVID-19 vaccination survey questionnaire questions. The questionnaire contained 20 questions related to demographic data, vaccination details, post-vaccination symptoms and willingness (or not) to take a second dose of the vaccine.

Classification of Symptoms

We divided post-vaccination symptoms into three categories (mild, moderate or severe) based on type of symptoms, duration, medication taken after vaccination and ability to perform normal day-to-day activities. Mild symptoms were categorized as those that that persisted for less or equal to 2 days but which did not interfere with normal day-to-day activities. Moderate symptoms were categorized as lasting for 2-4 days, but which still did not interfere with daily activities. Severe symptoms were characterized as those that persisted for five or more days and/or which interfered with daily activities such as completing household duties, driving or going to work. Some participants did not record any symptoms and this, too, was recorded.

Table 1 Post-vaccination symptoms

Category	Description	Symptoms
Mild	Any of the symptoms lasting for less than or equal to 2 days, which subsided without any medication and which did not interfere with daily household or outdoor activities.	Fever<100°F, headache, dizziness, weakness, pain and redness at the injection site, urticaria, myalgia.
Moderate	Any of the following symptoms or symptoms from the mild category lasting for 2–4 days, which subsided with over-the-counter medication and which did interfere with outdoor activities such as driving or going to work.	Fever>100°F, chills, severe weakness, vertigo, nausea, vomiting, plus and of the symptoms from the 'mild' category
Severe	Any symptoms belonging to the mild or moderate category lasting for greater than or equal to 5 days; and/or which required doctor consultation; and/or hospitalization; and/or rendered the recipient incapable of daily household activities and activities outside of the home, e.g. driving and attending work.	All symptoms from 'mild' or 'moderate' categories plus blurring of vision

RESULTS

The majority of the individuals involved in the study (n=198, 75%) were in the 18–25 years age group, which reflected the study sample being drawn largely from medical students, who made up 72% of the study sample. 156 (58.9%) were female and 109 (41.4%) male; this ratio reflects the workplace demographics.

Results of the demographic questions, and willingness to participate in the study are shown Table 2. The vaccines received by the healthcare workers were COVAXIN® (received by 94%) and COVISHIELD® (received by 4%); 2% did not know which vaccine they had received (Table 3).

Table 2 Demographics of the study population and willingness to participate

Questions	n=	%
Q1. Consent for participation in survey		
Yes	265	92%
No	24	8%
Q2. Age (years)		
18-25	198	75%
26-40	47	18%
41-60	16	6%
≥60	4	1%
Q3. Gender distribution		
Male	109	41%
Female (1 breastfeeding)	157	59%
Q4. Professional role		
Medical students	191	72%
Healthcare workers	74	28%
Q5. Co-morbidities		
None	233	88%
Bronchial asthma	12	4%
Thyroid disorders	9	3%
Hypertension	7	2%
Diabetes mellitus	4	1%
Sinusitis [1], migraine [1], TB lymphadenitis [1], obesity [1], prostate hypertrophy [1], penicillin allergy [1]	1 each	2%

Table 3 Vaccination details of the study population

Questions	N (Received vaccine)
Q6. Month of vaccination	
Jan 2021	100 (38%)
Feb 2021	165 (62%)
Q7. When are you filling out the survey	
After 1st dose	265 (100%)
Q8. Type of vaccine	
COVISHIELD®	250 (94%)
COVAXIN®	10 (4%)
Don't know	5 (2%)
Q9. History of allergy (Food/dust allergy)	
Yes	12 (4.5%)
No	253 (95.5%)
Q10. Were you kept for observation after 30 minutes immediately after vaccination?	
Yes	260 (98%)
No	5 (2%)

Amongst the 265 individuals, 180 (68%) reported some post-vaccination symptoms (Table 4), of which the most common were fever (reported by n=143, 79% of the 180 who reported symptoms/53% of the total sample), weakness/fatigue (n=119, 66%/46%) and headache (n=110, 62%/42%). Just over half (n=99, 55% of those who reported symptoms/37% of the total sample) reported moderately severe symptoms that lasted longer than two days. The majority of those who reported symptoms did not consult a medical practitioner for treatment (n=156, 95%) but some used over-the-counter medication for symptom relief, such as antipyretics (used by n=89) and analgesics (n=58).

A small minority (n=15, 6%) of the sample described their symptoms as severe enough to disrupt day-to-day household tasks and outdoor activities such as driving and attending work, and 24 (9%) consulted a medical practitioner regarding the symptoms they experienced. It is important to stress, however, that none of the 265 study participants experienced

symptoms severe enough to require hospitalization (Table 4).

The majority of the study participants (n=238, 90%) expressed their intention to take the second dose of vaccine and 260 (n=98%) intended to maintain a high standard of precautions, such as hand sanitization, mask wearing and social distancing, after vaccination. However, 6(2%) participants, all of whom had experienced symptoms they reported as 'severe', said that they were not willing to take the second dose of the vaccine due to the side effects, which had included high fever, severe weakness, blurring of vision, myalgia, urticaria for more than five days (all these symptoms did eventually, in some cases after medical consultation). A further 21 (8%) participants, all belonging to the moderate category, were not sure whether they would take the second dose as they were apprehensive after the side effects of the first dose, which had included nausea, vomiting, high fever, myalgia and/or weakness lasting for 2–4 days, as indicated in Table 6.

Table 4 Representing side effects of vaccination in study cases

Questions	n=	%
Q11. Symptoms after vaccination		
Yes	180	68%
No	85	32%
Q12. Symptoms		
Fever	143	79% (53%)
Weakness/Fatigue	119	66% (44%)
Headache	110	62% (42%)
Pain/redness at injection site	93	52% (35%)
Chills	78	43% (30%)
Myalgia	58	32% (12%)
Vertigo	85	47% (32%)
Dizziness	55	30% (21%)
Nausea	27	15% (9%)
Blurring of vision	10	7% (4%)
Vomiting	10	7% (4%)
Diarrhea	9	5% (3.5%)
Urticaria	5	3% (2%)
Others (non-specific)	1	0.6% (0.4%)
Q13. Severity of symptoms		
Mild	66	37% (25%)
Moderate	99	55% (37%)
Severe	15	8% (6%)

Table 5 Other details recorded in the questionnaire

Questions	n=	%
Q14. Consulting medical practitioner for symptoms		
Yes	24	13% (9%)
No	156	87% (59%)
Q15. Medication taken for symptom relief		
Antipyretics	89	49% (34%)
Analgesics	58	32% (22%)
No-medication	58	32% (22%)
Anti-inflammatory drugs	12	7% (4%)
Anti-histamines	8	4% (3%)
Antacids	6	3% (2%)
Steroids	1	0.6% (0.4%)
Q16. History of family members getting infected by covid-19		
Yes	13	5%
No	252	95%
Q17. Infection by covid-19 prior to vaccination		
Yes	22	8%
No	243	92%
< 1 month	1	5%
1-3 months	4	18%
4-6 months prior	11	50%
> 6months prior	6	27%
Q18. Plasma therapy when infected with covid-19		
Yes	1	5%
No	21	10%
Q19. Willing to take a second dose of covid-19 vaccination		
Yes	238	90%
No	6	2%
May be	21	8%
Q20. Will continue to take precautions such as hand sanitization, social distancing and wearing mask after vaccination.		
Yes	260	98%
No	2	1%
May be	3	1%

Table 6 Willingness to take 2nd dose of vaccine based on 1st dose experience

Experience of 1st dose side-effects	Yes	No	May be	P Value
None	85	0	0	0.0001; Highly significant
Mild	66	0	0	
Moderate	78	0	21	
Severe	9	6	0	

DISCUSSION

Throughout the pandemic, healthcare staff and medical students who attend COVID-19 patients have been at a higher risk of contracting COVID-19 disease than the general public. As a result, it is important that they should have a thorough understanding of all aspects of the disease, the vaccines that protect against it, available treatment and prevention

strategies. It is important that they themselves are also vaccinated, and for this our study shows that it is also important that they are well-informed as to the likelihood of post-vaccination symptoms and what these symptoms may be, as this can affect their willingness to complete the vaccination schedule. As patients are likely to look to them for guidance on this

issue, such patients may be discouraged from taking the vaccine themselves if HCWs are unable to answer any questions they have, give the impression that side-effects are likely to be unpleasant or dangerous, or share their reluctance to undergo the second scheduled vaccination based on their own experience of the side effects experienced after the first.

The participants in our study took two different types of vaccines: 94% took COVISHIELD® and 6% took COVAXIN®. Of these, 62% reported mild to moderate severity, with 15 participants (6%) experiencing symptoms severe enough to interfere with their day-to-day functioning, impacting on household tasks, driving and ability to go to work; 13% consulted a medical practitioner for symptom relief. The findings of the present study are important as they show that while the majority of healthcare workers who received the vaccine experienced either no side effects at all (32%) or only mild side-effects that soon pass (25%), a significant group experience moderate (37%) or severe (6%) symptoms that interfere with their ability to perform day-to-day household tasks, drive or go to work. As a result of this, as many as 10% may be apprehensive of taking the second dose based on the symptoms they experienced, with 2% saying they definitely would not take the second dose; all of those who expressed concern with taking the second dose had reported experiencing moderate or severe symptoms. This suggests that those who experience such symptoms may require further support and education to help them weigh the temporary discomfort of COVID-19 vaccine side-effects against the risk of severe symptoms from COVID-19 infection more likely to be experienced by the unvaccinated.

Within the general public, rates of hospitalization amongst the unvaccinated who contract COVID19 are approximately 20-25%, with a mortality rate of 1-3%,²⁵ however, these are much lower in the 18-25 age group that was most commonly represented in the study. Messages regarding the importance of vaccination to this group may need some more nuanced messaging; it is important for young HCWs to be vaccinated to help prevent them from passing the virus onto more vulnerable patients they are attending and requires them to bear the temporary

but nonetheless inconvenient and uncomfortable side-effects reported. While the results of our study will help to communicate to the public and to other HCWs that in the vast majority of cases side-effects are mild or moderate, if they are experienced at all, and thus that the vaccine is safe, the impact of those side-effects on HCW attitude to the second vaccination must not be under-estimated. This is especially important as HCWs who have safely received the vaccine can be used to build confidence amongst the rest of the public. The 10% who may be unwilling to do this, or who may actively undermine confidence by sharing their own negative experiences and warning friends and family against vaccination, could seriously undermine vaccination efforts.

This study therefore contributes to the quantification of vaccine and post-vaccination symptoms during a crucial phase of the pandemic. Healthcare workers (HCWs) in India have a generally positive attitude towards vaccination and vaccine confidence scores for the country as a whole are generally very high for vaccines being safe, important and effective.²⁶⁻³⁰ This makes the reasonably high rates of vaccine hesitancy in this study concerning and warrants further investigation. The authors of the current study made a wide literature survey but did not find any previously published data from India on the influence of side-effects of Covid-19 vaccines on confidence in continuing to the second dose. This is the first attempt at explaining the COVID-19 vaccine experience in India, its influence on acceptance by healthcare workers, and how this may be influenced by post-vaccination symptoms.

CONCLUSION

The present study concludes that while post-vaccination symptoms were mild in most of the participants and none were hospitalized, experience of moderate or more severe side effects can undermine confidence in continuing with the vaccination schedule. Vaccines are overwhelmingly safe and most people, even if they experience side effects, are willing to take a second dose, but more attention may need to be given to how best to support and build confidence in a significant minority who show resistance based on their personal experience.

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