

Acceptance of COVID-19 Vaccination Across India: How Concerned are the Health Care Workers?

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Abstract

Background and objectives: In COVID19 vaccination drive, Healthcare workers (HCWs) were first to receive the vaccine. But their concern about the safety of the vaccine prompted us to conducted this survey.

Methods: A questionnaire-based online survey was conducted to know post-vaccination symptoms in vaccinated and reasons of refusal in non-vaccinated HCWs.

Results: Among 2036 eligible respondents 1589 were vaccinated. In vaccinated group 665 experienced at least one post-vaccination symptom while remaining had no symptoms. Most commonly experienced post-vaccination symptom was pain at injection site (31.8%) and myalgia (31.7%) and were mild to moderate. Age showed inverse relationship with the post vaccination reactogenicity ($p < 0.001$) whereas gender and brand of vaccine showed no significant association. Respondents with comorbidities experienced significantly less symptoms ($p < 0.001$) whereas those with prior COVID19 infection showed significantly higher incidence of post-vaccination symptoms ($p < 0.046$). Among non-vaccinated 447(22.0%) respondents, lack of availability was the major reason cited (29.7%).

Interpretation and conclusion: Apart from few mild to moderate, transient, self-limiting symptoms, no HCW reported any major post-vaccination symptom, including elderly with comorbidities, assuring safety of vaccine. We can encourage and appeal general public to participate in vaccination drive without any apprehension, and strengthen the fight against COVID19 pandemic.

Keywords: COVID19, COVID19 vaccine, COVID 19 vaccine safety, Healthcare workers, Post-vaccination symptom

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Introduction

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), in December 2019, has imposed devastating consequences globally. Even with the rapid strides made in the technology for development of vaccines after Edward Jenner vaccinated a child in 1796, it took the scientific community more than a year to produce vaccines against COVID 19. So far, at least seven different vaccines have been rolled out with potential to protect against COVID-19[1]. The Indian government rolled out the vaccination drive for frontline medical workers on the 16th January 2021, among the most vulnerable populations, the health care workers (HCWs) being given the highest priority. All vaccines are being given clearance under Emergency Use Authorization (EUA) due to paucity of data about long term safety and efficacy. This paucity of data and doubts about post-vaccination symptoms; understandably led to lot of concerns, skepticism, and apprehensions, about the acceptance of COVID 19 vaccines, particularly among physicians. These concerns prompted us to conduct this online survey to evaluate post-vaccination symptoms, probable reasons for vaccine refusals and their relationship with sociodemographic characteristics among HCWs across India. We hope this survey will enlighten, and alleviate the anxiety of the HCWs and encourage them to accept vaccination. Here we evaluated for the profile of post-vaccination symptoms, and probable reasons for refusal of vaccine.

Material and Methods

Study Design

Approval for survey was obtained from an independent ethics committee. We carried out this prospective, cross-sectional, online survey to evaluate the potential acceptance of COVID 19 and to elicit causes of refusal for vaccination among HCWs over 5 weeks

(31st January 2021 to 6th March 2021). The questionnaire was created using Google form which was self-explanatory. We sent an introductory note along with the questionnaire, which explained the intent of the survey. Though there was an option to disclose the e-mail address of the respondent, we ensured strict anonymity and thus confidentiality of data. A completed questionnaire was considered to be an implied consent. The questionnaire had initial segment of general questions about age, gender, job profile, comorbidities and overall opinion of respondents about the effectiveness of vaccine. At the end of general questions, we had two domains: Vaccinated and Non-vaccinated. In vaccinated domain we asked about the type of vaccine they received, prior history of COVID 19 infection and also their willingness for the second dose. Vaccinated domain was with either post-vaccination symptoms or without post-vaccination symptoms. The respondents with post-vaccination symptoms were asked profile of questions mentioning about symptomatology of post-vaccination, onset, duration and need of hospitalization. In Non-vaccinated domain, we mentioned the probable reasons of vaccine refusal and respondents were asked to select a suitable reason or reasons. At the end of Vaccinated and non-vaccinated domain description box was made for special mention of their experiences. All these responses were noted down and analysed.

Study population

The questionnaire was sent to the contacts of all the investigators, using text messages, WhatsApp Messenger, emails etc. We included all HCWs (doctors, medical students, paramedics (nurses), administrative and hospital support staff). Reminder note of request to participate was sent twice at an interval of 1 week.

Statistical analysis

Data was analysed using IBM SPSS Statistics V21.0. The qualitative variables are described using frequency (%). The difference between proportions was tested using z test or chi square test (χ^2). Level of significance at 5% was considered statistically significant ($p < 0.05$).

This survey was conducted over 5 weeks and 2037 respondents completed the survey. One survey sheet was incomplete and was removed, therefore data was analysed for 2036 respondents. Nearly half the respondents were 31 – 50 years of age, with almost equal participation from males and females (table 1).

Results

Table 1: Demographic Characteristics of the respondents

Age (years)	
15 – 20	49 (2.4%)
21 – 30	329 (16.2%)
31 – 40	577 (28.3%)
41 – 50	478 (23.5%)
51 – 60	330 (16.2%)
> 60	273 (13.4%)
Gender	
Male	990 (48.6%)
Female	1046 (51.4%)
Job profile	
Doctor	1522 (74.8%)
Medical student	114 (5.6%)
Paramedical staff	244 (12.0%)
Administrative staff	101 (5.0%)
Hospital support staff	55 (2.7%)
Comorbidities	
Hypertension	399 (19.6%)
Diabetes mellitus	243 (11.9%)
Ischemic Heart Disease	70 (3.4%)
Others	163 (8.0%)
None	1359 (66.7%)
Perception of COVID19 vaccine	
Would be effective	1546 (75.9%)
Would not be effective	101 (5.0%)
Don't know	389 (19.1%)

Majority of the respondents were doctors (74.8%) followed by paramedical staff (12.0%), medical students (5.6%), administrative staff (5.0%) and hospital support staff (2.7%). Comorbid conditions were present in 677 (33.3%) respondents, of which 168 had more than one comorbidity. Hypertension was the most common comorbidity (399, 19.6%),

followed by diabetes mellitus (243, 11.9%), and Ischemic Heart Disease (70, 3.4%). A smaller proportion of respondents (163, 8.0%) had some other comorbid condition. Majority of the respondents (75.9%) believed that the vaccine would be effective against COVID19 and around 20% were not sure of its efficacy. A small proportion (5.0%) said that the vaccine would not be

effective. A large no. of respondents (1589, 78.0%) had received the first dose of vaccine (figure I). Most respondents (1496, 94.2%) received “Covishield”, while the others (93, 5.8%) had received “Covaxin” brand of the COVID19 vaccine. Nearly all (97%) respondents were willing to complete the vaccination schedule with the second dose. About 10th of the respondents (259) had COVID19 infection before getting vaccinated. Out of 1589 vaccinated respondents, 665 (41.8%) experienced at least one post-vaccination symptom, while remaining had no symptoms. The details of the post-vaccination symptoms are given in table 2. Most commonly experienced post-vaccination symptom was pain at injection site (31.8%) and myalgia (31.7%). Very few respondents reported arthralgia, sore throat, gastro-intestinal symptoms, cough, and skin rash away from injection site as post-vaccination symptoms. Generally, the symptoms were mild-to-moderate. Sixteen respondents experienced symptoms immediately after receiving vaccine. Post-vaccination symptoms occurred within 12 hours in 290 (18.2%) respondents, while

the remaining (244, 15.3%) experiencing them in 24 hours. Sixty-three respondents experienced post-vaccination after 24 hours. The symptoms lasted for 1-2 days for majority of the respondents. Only nine (0.6%) HCWs required hospitalization for management of post-vaccination symptoms (table 2).

In the entire survey, 20 respondents described unusual symptoms post-vaccination. Eight respondents one symptom of the following: cold extremities, difficulty in breathing, palpitations, distressing dry cough, excessive sweating, occipital headache, running nose, supraorbital pain and excessive weakness. Two respondents each reported excruciating pain at back, neck and shoulder, loss of appetite, loose motions, lymphadenopathy. One respondent (doctor) developed herpes zoster after vaccination and required antiviral treatment for 10 days. Another respondent reported persistent high-grade fever for 5 days after vaccination, caused by periapical tooth abscess.

Table 2: Post-vaccination Symptoms

(n=1589)

Symptoms	Nos. (%)
Local site pain	506 (31.8%)
Myalgia	504 (31.7%)
Lethargy	461 (29.0%)
Fever	375 (23.6%)
Headache / Dizziness	373 (23.5%)
Chills	331 (20.8%)
Arthralgia	183 (11.5%)
Sore throat	101 (6.4%)
Nausea / Vomiting / Abdominal pain	89 (5.6%)
Cough	72 (4.5%)
Skin rash away from injection site	30 (1.9%)
Onset of symptoms post-vaccination	
Immediately	16 (1.0%)
Within 6 hours	98 (6.2%)
Within 12 hours	290 (18.2%)
Within 24 hours	244 (15.3%)
More than 24 hours later	63 (3.9%)

Duration of symptoms post-vaccination	
Less than 1 day	127 (8.0%)
1 day	230 (14.5%)
2 days	226 (14.2%)
More than 2 days	82 (5.2%)
Required hospitalization post -vaccination	
Yes	9 (0.6%)
No	1580 (99.4%)

There were 447 unvaccinated respondents and nearly 30% (133) were unvaccinated due to lack of availability (table 3). One-third (114) respondents cited more than one reason for not taking the vaccine. The reasons for refusal varied from logical reasons such as uncertainties about the duration of protection by vaccine 41(9.2%) and hoping for vaccine of better brand 28(6.3%). Some respondents believed that their own immunity was strong enough to fight the vaccine. Other reasons for not taking the vaccine were pregnancy (3.6%), lactation (9.9%) and planning pregnancy in the immediate future (9.8%).

Table 3: Reasons for not taking vaccine

(n=447)

Non-availability of vaccine	133 (29.7%)
Lack of phase 3 trial	83 (18.6%)
Fear	65 (14.5%)
Possibility of side effects	59 (13.2%)
Breast feeding	43 (9.9%)
Planning pregnancy	44 (9.8%)
Belief in own immunity	41 (9.2%)
Uncertainty about duration of protection	41 (9.2%)
Known allergies	28 (6.3%)
Possibility of mutations	28 (6.3%)
Waiting for vaccine of another brand	28 (6.3%)
Sore throat and fever	20 (4.5%)
Antenatal care	16 (3.6%)
Plan of immediate travel	14 (3.1%)
Skin rash	8 (1.8%)

Table 4: Demographic characteristics and post-vaccination symptoms

Variable	Experienced symptoms n = 665	Did not experience symptoms n = 924	p value
Age (years)			
15 – 20	26 (3.9%)	10 (1.1%)	<0.001
21 – 30	112 (16.8%)	118 (12.8%)	0.022
31 – 40	195 (29.3%)	205 (22.2%)	0.001
41 – 50	169 (25.4%)	224 (24.2%)	0.596
51 – 60	109 (16.4%)	183 (19.8%)	0.083
> 60	54 (8.1%)	184 (19.9%)	<0.001
Gender			
Male	314 (47.2%)	480 (51.9%)	0.067

Female	351 (52.8%)	444 (48.1%)	
Comorbidities			
Present	188 (28.3%)	351 (38.0%)	<0.001
Absent	477 (71.7%)	573 (62.0%)	
Brand of vaccine received			
Covaxin	43 (6.5%)	50 (5.4%)	0.388
Covishield	622 (93.5%)	874 (94.6%)	
Infected with COVID19 before taking the vaccine			
Yes	123 (18.5%)	136 (14.7%)	0.046
No	542 (81.5%)	788 (85.3%)	

Post-vaccination symptoms showed significant association with age. A high proportion of respondents between 15-40 years of age experienced significantly more post-vaccination symptoms, as compared to older patients. Among the respondents older than 60 years, the incidence of post-vaccination symptoms was significantly lower. Respondents with comorbidities also experienced significantly less symptoms than those without. Respondents with COVID19 infection before vaccination showed significantly higher incidence of post-vaccination symptoms. There was no predilection of either gender or brand of the vaccine with post-vaccination symptoms (table 4).

Discussion

Vaccines such as mRNA, adenoviral vectored, inactivated virus, spike glycoprotein and adjuvanted vaccine etc. after undergoing clinical trials are proving to be critical new tools in the battle against COVID19 [1]. As per WHO, vaccine should have minimum 50% efficacy to create an impact on public health [2] which is endorsed by Food and Drug Administration guidelines of USA for licensing the vaccines [3]. Covishield, is a viral vector vaccine by AstraZeneca with Oxford university in the UK and is manufactured by the Serum Institute India (SII) in India. They have used weakened, non-replicating strain of Chimpanzee cold virus (adenovirus) to carry genetic material of the spike protein of SARS-CoV-2 into

human cells[4]. In a pooled interim analysis of safety and efficacy of Covishield, Vorsey et al analysed data of 11636 participants from Brazil and UK. Vaccine efficacy was 70.4% after two doses and 64.1% after one standard dose[5]. Covaxin is India's first home produced vaccine against covid-19. It is an inactivated SARS-CoV-2 virus (Strain: NIV-2020-770) extracted from asymptomatic patients and is disabled for replication. It is developed by Hyderabad based Bharat Biotech along with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) with efficacy of 81% as per interim analysis of phase III trial [6].

At the time this survey was undertaken, Covishield and Covaxin were made available at majority of the centres in India [7]. In this survey, 94.2% respondents had received "Covishield" and 5.8% had received "Covaxin". We observed that majority of the respondents, 924 (58.2%) had not reported any post-vaccination symptoms and 665 (41.8%) had some local and systemic symptoms. These symptoms were mild and lasted for 12 to 24 hours in 18.2% and more than 24 hours in 15.3% respondents respectively. A phase 1 double-blind, randomized trial on safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, (Covaxin's phase) was published in January 2021[8]. Total 827 participants were screened, and 375 were enrolled. They observed mild symptoms such as injection site pain (17

[5%]), headache (13 [3%]), fatigue (11 [3%]), fever (9 [2%]), and nausea or vomiting (7[2%]). Global Advisory Committee on Vaccine Safety (GACVS), a WHO subcommittee reported that these post-vaccination symptoms were localised, milder and transient [9]. Another single-blind, randomised, controlled, phase 2/3 trial among 560 respondents trial was conducted on safety and immunogenicity of ChAdOx1 nCoV-19 vaccine[10]. The findings were that there were no severe, local or systemic symptoms but that reactogenicity was reduced with increasing age. Local reactions were more common in younger age groups (88%) than older people (73%). However immunogenicity as measured by anti-spike SARS-CoV-2 IgG responses, neutralising antibody titres and T-cell responses after two doses was preserved [10]. Thus, Covishield is better tolerated in elderly with preserved immunogenicity in both age groups after a booster dose. In our survey we also found this reduced reactogenicity in respondents with older age. Younger age groups (15 to 40 years) had significantly more post-vaccination symptoms. Age group between 41-60 showed non-statistically significant decline in the symptoms. while those over 60 years showed statistically significant decline in post-vaccination symptoms. The same was true for respondents with comorbidities. Overall, these reactogenicity events were transient and resolved within a couple of days after onset. This makes this vaccine safer and effective even with advanced age, where the risk of symptoms is the major concern. Low reactogenicity with advance age was seen in another Indian study published by Rajeev et al[11]. There was a decline in the frequency of symptoms from 81% (3rd decade), 80% (4th decade), 68% (5th decade), 58% (6th decade), 45% (7th decade), 34% (8th decade) and 7% (9th decade). In those with prior history of COVID-19, we found that only 41.8% of the respondents were symptomatic post-vaccination, in contrast

to the study by Rajeev et al, where 66% respondents were symptomatic post-vaccination. We did not find any gender difference in post-vaccination symptoms whereas Rajeev et al found that women had higher incidence of post-vaccination symptoms (74.7% vs. 58.6%, $p < 0.001$).

In our survey, none of the respondents had any unexpected serious adverse events [5]. One trial volunteer died first dose of Covaxin, but the cause of death was unrelated to the vaccine. [12]. Acute neuroencephalopathy developing after Covishield was reported, but Serum Institute of India ruled that this was an unrelated to vaccine[13]. We found that two of the respondents had lymphadenopathy, which has also been reported earlier [4]. One respondent reported reactivation of herpes zoster in our survey, however, it may or may not be related to vaccination. Though all the above complaints appeared atypical and found in those specific individuals, we don't feel justified in totally ignoring them as they are coming from HCWs. Further studies and high number respondents on larger scale for vaccination will decide about their significance.

Though we found that most of the post-vaccination symptoms were mild to moderate and self-limiting, but possibility of severe events cannot be ruled out after vaccination, but that will even rarer. We recommend that such incidences should be reported to the agencies such as Vaccine Adverse Event Reporting System (VAERS) [14]. Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov.in>. CDC has developed a new tool, "**v-safe**" to make reporting easy. It is voluntary, smartphone-based tool. GACVS by WHO also reviews such events regularly with active surveillance [9]. Such steps help in taking preventive measures so as to avoid the repetition of similar instances and create

faith among the general population to actively participate in vaccination drive.

We also documented the reasons for refusal of getting vaccinated against COVID19. Non availability of the vaccine was the most common amongst all reasons. Possibly, when this survey was conducted, this was the major concern in the community. Lack of phase III trials, fear and possibilities of side effects were other major reasons for vaccine refusal.

This survey has some limitations. First, being an anonymous survey, a possibility of lack of uniformity, variability of responses, and self-reporting bias cannot be ruled out. There is always a possibility of subjective variability in individual symptoms and we could not confirm the symptoms reported by respondents. Second, as this is a post-vaccination online survey, we could not monitor the pre-vaccination events such as maintenance of cold chain, administration of correct dose of vaccine etc. Third limitation is that although less than 50% respondents reported post-vaccination symptoms, there is a possibility of overestimation bias, as those who had post-vaccination symptoms might have preferentially taken this survey. Fourth limitation is that we have not documented post-vaccination incidence of COVID 19 infection and also were unable to check anti-spike antibody titre, neutralising anti-vector antibody titers to evaluate immunogenicity. Fifth, we could not get details of those rare events such as herpes zoster or lymphadenopathy. Our survey is not large enough to evaluate these rare adverse events and larger size and follow up studies are required to analyze their association. Lastly long term effects of vaccination were beyond the scope of our survey.–Further larger randomised studies are essential to confirm the safety and efficacy of the available vaccines.

Conclusion:

Vaccination will be a game changer in the control of covid-9 pandemic. Rapid development of vaccines has created anxiety about its safety and efficacy among general population. This was fuelled by misinformation, leading to cautious response towards the acceptability of vaccine. But through this open online survey among the HCWs, we could clear many doubts. In our survey, most respondents experienced none to minor post-vaccination symptoms which were mostly self-limiting. The intensity of the reactogenicity was inversely proportional to age, regardless of comorbid conditions. Refusal to take vaccine was due to mainly unavailability, lack of phase 3 trails and fear. Though we cannot comment much on efficacy, we can be sure about the safety of vaccines. This should help in alleviating the anxiety, removing the fear and hesitation, thereby help making the vaccination drive successful.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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