Original Article

Adverse events following immunization of ChAdOx1 nCoV-19 vaccine among healthcare workers of a medicine-teaching institution of North India

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Abstract

Objective: This study sought to assess the prevalence of adverse events following immunization (AEFI) and factors associated with AEFI of the ChAdOx1 nCoV-19 vaccine (Covishield) among healthcare workers (HCW) of a medicine-teaching institution of North India. **Materials and Methods:** A cross-sectional study was conducted in the months of June and July 2021 among HCW ($N = 203$) of 18 years and above, vaccinated with at least the first dose of Covishield. A semi-structured, prevalidated, and pretested questionnaire was used to collect information through an interview schedule. The questionnaire was divided into five sections: the sociodemographic profile, behavioral characteristics, past medical history, COVID-19 awareness, and past infection and COVID-19 vaccine related information. Chi-squared test was applied to check the association of different factors with AEFI. **Results:** In our study, 73.89% of participants suffered from at least one AEFI after the first dose of the vaccine, while 48.66% had at least one AEFI after the second dose. Females reported significantly high AEFI for both doses ($P = 0.001$, 0.000). We found a significant association between the occurrence of AEFI and occupation (first dose $P = 0.015$), substance abuse (first dose $P = 0.002$), diet (first dose $P = 0.016$), and allergy (first dose $P = 0.027$). Other significant findings were headaches among HCW ≥40 years of age (dose $P = 0.034$) and systemic AEFI in participants with comorbidity (first dose $P = 0.020$). **Conclusion:** More AEFI were reported after the first dose as compared to the second dose. AEFI were more among females after both the doses. Occupation, substance use, diet, and history of allergy were significantly associated with AEFI.

Keywords: Adverse events following immunization, ChAdOx1 nCoV-19 vaccine, COVID-19, Covishield, healthcare workers

Introduction

On March 11, 2020, COVID-19, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was officially declared a pandemic by the World Health Organization (WHO). Confirmed COVID-19 cases and deaths reported till June 21, 2021 globally were 178.20 and 3.86 million,[1] respectively, whereas, in India, were 29.94 and 0.39 million,[2] respectively.

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There is no specific treatment available for COVID-19 to date, so vaccine seemed to be the most effective way to halt this pandemic. Within less than 12 months after the pandemic onset, several research teams took the challenge and developed vaccines that protect from COVID-19.[3] However, for this pandemic to end, there shall be equal access to safe and effective vaccines. Moreover, many are in the developmental phase. Up till June 20, 2021, total vaccine doses administered and fully vaccinated people globally were 2,645.71 and 545.79 million,[4] respectively, and in India were 274.3 and 49.7 million,[5] respectively.

As of June 20, 2021, there were 287 total vaccine candidates, 102 under the clinical phase and 185 under the preclinical phase,[6] and among clinical phase vaccine candidates, 22 are undergoing assessment for WHO Emergency Use Listing (EUL)/ prequalification evaluation.[7] In this evaluation, some of the vaccines along with their manufacturer/EUL holder are AZD1222 by AstraZeneca and University of Oxford or ChAdOx1_ nCoV-19 (Covishield) by Serum Institute of India (SII), COVAXIN by Bharat Biotech, Sputnik by the Gamaleya National Center of Epidemiology and Microbiology, etc.[7] Also, in India, eight COVID-19 vaccines are undergoing human clinical trials (HCT). Among these, phase II/III trials of Covishield were completed on June 2, 2021.[8] In contrast, COVAXIN and ZyCoV-D are undergoing phase III trials, and Sputnik V is undergoing phase II trials.[9] Out of these eight vaccines, three have been approved for restricted use in an emergency situation by the Drugs Controller General of India (DCGI), which are Covishield, a recombinant chimpanzee adenovirus vector vaccine, COVAXIN, a whole virion inactivated corona virus vaccine, both approved on January 3, 2021.[10] Sputnik V, a human adenovirus-based vector vaccine[11] approved on April 13, 2021.[12] In India, Covishield's phase II/III HCT on 1600 subjects is complete.[8] COVAXIN's phase III HCT on healthy human volunteers from age 18–99 years and phase II/III HCT in age group 2–18 years are ongoing for a total of 25,800[13] and 525[14] subjects, respectively. For Sputnik V, phase II HCT are ongoing on 1600 subjects.[15]

In phase I/II HCT of Covishield, adverse events following immunization (AEFI) were mild to moderate pain after vaccination in 67%, mild tenderness in 83%, fatigue in 70%, headache in 68%, muscle ache in 60%, malaise in 61%, chills in 56%, feeling feverish in 51% and transient neutropenia in 46% of participants in the vaccine group (without paracetamol).[16] On April 7, 2021, the European Medicines Agency (EMA) reported there were 222 cases of thrombosis after vaccination, with 18 fatalities.[17] In the phase II/III HCT in healthy Indian adults, the most common AEFI in the SII-ChAdOx1 nCoV-19 group were injection site pain and systemic symptoms, including pyrexia, body ache, headache, myalgia, malaise, asthenia, and fatigue.[18] In a study conducted in Bangalore, the most common local AEFI were pain, followed by swelling, then weakness of the arm, while the systemic AEFI were generalized weakness, followed by fever, headache, chills, dizziness, somnolence, and loss of appetite.[19] There was a single-center study that showed that Covishield and COVAXIN both had an association with coronary thromboembolic events.[20]

A study conducted at the vaccination center of SS Lal Hospital, BHU, Varanasi, UP, reported that the most common AEFI within 30 min were pain/tenderness at the injection site of the healthcare workers (HCW), followed by headache/dizziness, itching/rashes at the injection site, nausea/vomiting and fever/chills.[21] A study by Deb *et al.*[22] reported that the most common AEFI were fever, followed by myalgia. The most common symptoms found in a study in the tertiary hospital of Kerala were fever, local pain at the injection site, tiredness, chills, myalgia, headache, injection site stiffness, joint pain, and nausea/vomiting after the first dose.[23] National AEFI Committee of India, on June 4, 2021, reported the first death due to anaphylaxis to vaccine product of Covishield.[24] In phase II HCT of COVAXIN (6 μg with aluminum gels (Algel)-imidazoquinoline derivative **(**IMDG)), AEFI (expressed in percentage of total participants in 6 μg with Algel-IMDG group) for the first and second dose, respectively, were pain at the injection site, redness at the injection site, itching, stiffness in the upper arm, weakness in injection arm, body ache, fever, headache, malaise, weakness, rashes.[25]

Clinical trials perhaps detect common AEFI happening soon after vaccination, whereas rare and delayed AEFI have more chances to be revealed when large populations are immunized.[26] Furthermore, the AEFI of COVID-19 vaccines among HCW of North India remains underexplored. This study aims to report AEFI and factors associated with the AEFI of the ChAdOx1_nCoV-19 vaccine among HCW of a medicine-teaching institution of North India.

Materials and Methods

A cross-sectional study was conducted in the months of June and July, 2021 on the HCW of a medicine-teaching institution of North India. The required sample size was calculated by using the formula $n = \frac{z_{\alpha}^2 PQ}{l^2}$, and the average magnitude of local and systemic AEFI of the COVID-19 vaccine to be 10%[25] at a 95% level of significance and 5% error; the final calculated minimum sample size was 139. We have studied and analyzed data from 203 HCW. All the HCW above 18 years of age and who were administered with Covishield vaccine were included in the study. Participants who did not give consent were excluded from the study.

Questionnaire design and validation

A semi-structured, prevalidated, and pretested questionnaire was used to collect information. The questionnaire was validated by three senior professors of the Medicine and Community Medicine Departments. This validated questionnaire was pilot-tested on 20 subjects. The language of some questions was modified for better understanding and clarity for the participants. It was divided into five sections: the sociodemographic profile, behavioral characteristics, past medical history, COVID-19 awareness, and past infection and COVID-19 vaccine related information. The "sociodemographic profile" section consisted of questions regarding age, gender, occupation/designation,

marital status, education status, religion, and residence. The "behavioral characteristics" section consisted of questions to assess any substance use, diet, and physical activity. Substance use was considered as yes, if the participant used that substance during the last 1 month before vaccination. Physical activity was assessed according to WHO criteria.[27] The "past medical history" section consisted of questions regarding a history of asthma, hypertension/increased blood pressure, diabetes mellitus, chronic vascular disease, chronic liver disease (CLD), chronic kidney disease (CKD), any other allergy, and past vaccination details. The "COVID-19 awareness and past infection" section consisted of questions to assess knowledge about COVID-19, past diagnosis with COVID-19, date of diagnosis, symptoms that appeared, and complications associated (if any). Finally, the "COVID-19 vaccine related information" section consisted of questions to assess the beneficiary's perception and knowledge about the COVID-19 vaccine, the day, date, route, and site of administration of the vaccine, which vaccine, and how many doses were administered, adverse event(s) after vaccination, the medication used for AEFI.

Data collection

Data was collected through an interview schedule. The researcher introduced himself to the participants, and after taking their informed consent and explaining the purpose, possible outcomes and risks, discomforts, inconveniences, and benefits of our study, the researcher conducted the interview individually. They were free to decline or end their participation at any time for any reason or refuse to answer any particular question.

Data management and statistical analysis

Confidentiality of all the data was ensured by keeping the responses anonymous. Moreover, the collected data was stored under secure settings. The collected data was coded and recorded in a Microsoft Excel sheet. Qualitative data was analyzed using percentages and proportions, whereas quantitative data was summarized in mean and standard deviation. Chi-squared test was applied to check the association of different factors with AEFI. Significant deviation from the null hypothesis was calculated using Fisher's exact test. Data were analyzed using the trial version of Statistical Package for the Social Sciences (version 27.0; SPSS Inc., Chicago, IL). A *P* value less than 0.05 was considered significant.

Results

In this study, 203 subjects participated who had received at least the first dose of ChAdOx1 nCoV-19 vaccine. 73.89% (n = 150) and 48.66% (n = 91) of the subjects reported at least 1 AEFI after the first and second dose, respectively, and none of the subjects reported serious/severe AEFI. 46.3% (n = 94) of those who received the first dose (N = 203) and 18.7% (n = 35) of those who received the second dose (N = 187) reported more than one AEFI [Figures 1 and 2].

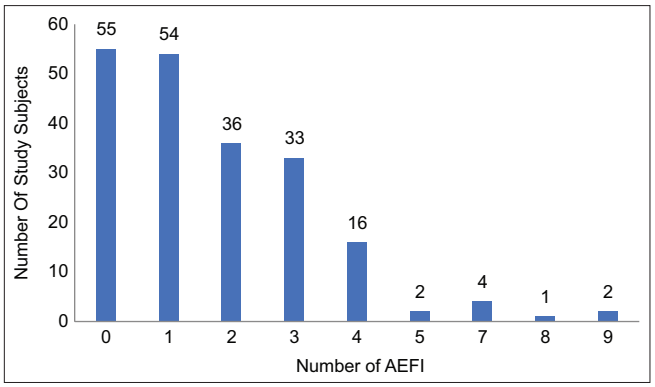

Figure 1: Distribution of the number of adverse events following immunization after the first dose of Covishield vaccine (N = 203). AEFI = adverse events following immunization

We found significantly high AEFI among females vis-à-vis males for both doses of the Covishield vaccine (P = 0.001, 0.000). We found a significant association between occupation and AEFI after the first dose (P = 0.015). Accredited social health activists (ASHA) showed the highest incidence of AEFI after the first dose of the Covishield vaccine among different occupations. We found a statistically significant association between substance use and AEFI (P = 0.002) after the first dose, as participants not abusing any substance reported a smaller number of AEFI compared to abusers. We found a statistically significant association between diet and AEFI after the first dose (P = 0.016), as subjects consuming a vegetarian diet reported more AEFI compared to nonvegetarians. We found a statistically significant association between allergy and AEFI after the first dose, and subjects having allergies reported more AEFI compared to nonallergic subjects (P = 0.027). We found no significant association between AEFI and age, education status, marital status, residential area inside the hospital campus, religion, physical activity, comorbidity, and prior COVID-19 infection [Table 1].

Females reported higher AEFI than males after both the doses (P = 0.001, 0.000). Less number of males reported AEFI after the second dose. Systemic AEFI were reported higher among females after both the doses (P = 0.000, 0.000). AEFI like tiredness (P = 0.001, 0.000), fever (P = 0.001, 0.002), feeling unwell (P = 0.001, 0.012), and headache (P = 0.000, 0.008) were higher among females after both the doses. Joint pain after the second dose was higher among females (8%) compared to males (1%) (P = 0.018). Nausea or vomiting was higher among females (8.7%) compared to males (0.9%) after the first dose (P = 0.007) [Table 2].

Headache after the second dose was higher among participants of ≥40 years of age (11.3%) compared to participants of <40 years of age (3.4%) (P = 0.034) [Table 3].

Participants not abusing any substance (78.8%) reported a significant incidence of AEFI after the first dose compared to abusers. (P = 0.002). Local (P = 0.003) and systemic (P = 0.002)

Table 1: Association of sociodemographic, behavioral, comorbid condition and COVID status of subjects with AEFI after the first and the second dose of Covishield vaccine

Variable	AEFI after first dose			AEFI (After second dose)		
	Yes (150)	No (53)	*P*	Yes (91)	No (96)	*P*
Age						
<40	99 (76.2)	31 (23.8)	0.327	55 (47.4)	61 (52.6)	0.662
≥40	51 (69.9)	22 (30.1)		36 (50.7)	35 (49.3)	
Gender						
Male	72 (64.9)	39 (35.1)	0.001	36 (36.0)	64 (64.0)	0.000
Female	78 (84.8)	14 (15.2)		55 (63.2)	32 (36.8)	
Education						
Postgraduation	21 (67.7)	10 (32.3)	0.295	16 (51.6)	15 (48.4)	0.953
Graduation	63 (80.8)	15 (19.2)		37 (50.0)	37 (50.0)	
Intermediate	21 (65.6)	11 (34.4)		13 (46.4)	15 (53.6)	
Up to 10th	45 (72.6)	17 (27.4)		25 (46.3)	29 (53.7)	
Occupation						
Doctor	23 (62.2)	14 (37.8)	0.015	16 (44.4)	20 (55.6)	0.712
Nursing officer	22 (88.0)	3 (12.0)		11 (45.8)	13 (54.2)	
Paramedical staff	45 (80.4)	11 (19.6)		24 (51.1)	23 (48.9)	
Housekeeping staff	28 (80.0)	7 (20.0)		17 (50.0)	17 (50.0)	
Supporting staff	23 (57.5)	17 (42.5)		17 (44.7)	21 (55.3)	
ASHA	9 (90.0)	1 (10.0)		6 (75.0)	2 (25.0)	
Marital Status						
Ever married	125 (74.0)	44 (26.0)	0.958	81 (50.9)	78 (49.1)	0.137
Never married	25 (73.5)	9 (26.5)		10 (35.7)	18 (64.3)	
Residence						
Inside hospital campus	7 (58.3)	5 (41.7)	0.206	6 (50.0)	6 (50.0)	0.924
Outside hospital campus	143 (74.9)	48 (25.1)		85 (48.6)	90 (51.4)	
Religion						
Hindu	142 (73.6)	51 (26.4)	0.652	85 (47.5)	94 (52.5)	0.128
Others	8 (80.0)	2 (20.0)		6 (75.0)	2 (25.0)	
Substance Use						
Yes	24 (55.8)	19 (44.2)	0.002	17 (44.7)	21 (55.3)	0.587
No	126 (78.8)	34 (21.3)		74 (49.7)	75 (50.3)	
Diet						
Vegetarian	77 (81.9)	17 (18.1)	0.016	46 (54.8)	38 (45.2)	0.132
Nonvegetarian	73 (67.0)	36 (33.0)		45 (43.7)	58 (56.3)	
Physical Activity						
Regular	45 (73.8)	16 (26.2)	0.987	28 (50.0)	28 (50.0)	0.064
Occasional	47 (74.6)	16 (25.4)		36 (59.0)	25 (41)	
Not at all	58 (73.4)	21 (26.6)		27 (38.6)	43 (61.4)	
Comorbidity						
Yes	39 (83.0)	8 (17.0)	0.106	22 (52.4)	20 (47.6)	0.584
No	111 (71.2)	45 (28.8)		69 (47.6)	76 (52.4)	
Allergy						
Yes	13 (100.0)	0 (0.0)	0.027	7 (63.6)	4 (36.4)	0.306
No	137 (72.1)	53 (27.9)		84 (47.7)	92 (52.3)	
COVID-19 Infection						
COVID group	58 (80.6)	14 (19.4)	0.109	33 (50.0)	33 (50.0)	0.787
Non-COVID group	92 (70.2)	39 (29.8)		58 (47.9)	63 (52.1)	

AEFI=Adverse events following immunization

AEFI after the first dose were statistically significant among participants not abusing any substance compared to abusers. Among systemic AEFI, tiredness was significantly more after the second dose than the first dose ($P = 0.017$). Among systemic AEFI, tiredness was significantly associated with AEFI after the second dose ($P = 0.017$) and subjects not abusing any substance reported more incidence of tiredness. AEFI like fever ($P = 0.005$) and feeling unwell ($P = 0.005$) were reportedly significant in participants after the first dose [Table 4].

Systemic AEFI after the first dose was significant in participants with comorbidity ($P = 0.020$). Among participants with comorbidity, AEFI like headache was significant after the first dose ($P = 0.008$). AEFI like loss of appetite was reported

Table 2: Association of self-reported AEFI with gender after the first and the second dose of Covishield vaccine

Variable	AEFI after first dose			AEFI (After second dose)		
	Male (111)	Female (92)	*P*	Male (100)	Female (87)	*P*
Any AEFI						
Yes	72 (64.9)	78 (84.8)	0.001	36 (36.0)	55 (63.2)	0.000
No	39 (35.1)	14 (15.2)		64 (64.0)	32 (36.8)	
Local AEFI						
Yes	55 (49.5)	52 (56.5)	0.332	26 (26.0)	34 (39.1)	0.056
No	56 (50.5)	40 (43.5)		74 (74.0)	53 (60.9)	
Systemic AEFI						
Yes	48 (43.2)	69 (75.0)	0.000	18 (18.0)	38 (43.7)	0.000
No	63 (56.8)	23 (25.0)		82 (82.0)	49 (56.3)	
Tiredness						
Yes	27 (24.3)	43 (46.7)	0.001	6 (6.0)	22 (25.3)	0.000
No	84 (75.7)	49 (53.3)		94 (94.0)	65 (74.7)	
Fever						
Yes	22 (19.8)	37 (40.2)	0.001	6 (6.0)	19 (21.8)	0 0.002
No	89 (80.2)	55 (59.8)		94 (94.0)	68 (78.2)	
Feeling unwell						
Yes	19 (17.1)	34 (37.0)	0.001	3 (3.0)	11 (12.6)	0.012
No	92 (82.9)	58 (63.0)		97 (97.0)	76 (87.4)	
Headache						
Yes	5 (4.5)	20 (21.7)	0.000	2 (2.0)	10 (11.5)	0 0.008
No	106 (95.5)	72 (78.3)		98 (98.0)	77 (88.5)	
Joint pain						
Yes	4 (3.6)	7 (7.6)	0.210	1 (1.0)	7 (8.0)	0 0.018
No	107 (96.4)	85 (92.4)		99 (99.0)	80 (92.0)	
Breathing difficulty						
Yes	1 (0.9)	3 (3.3)	0.228	0 (0.0)	1 (1.1)	0 0.282
No	110 (99.1)	89 (96.7)		100 (100.0)	86 (98.9)	
Sore throat						
Yes	2 (1.8)	1 (1.1)	0.674	1 (1.0)	1 (1.1)	0 0.921
No	109 (98.2)	91 (98.9)		99 (99.0)	86 (98.9)	
Loss of appetite						
Yes	0 (0.0)	3 (3.3)	0.055	1 (1.0)	1 (1.1)	0 0.921
No	111 (100.0)	89 (96.7)		99 (99.0)	86 (98.9)	
Abdominal pain						
Yes	1 (0.9)	2 (2.2)	0.454	1 (1.0)	1 (1.1)	0.921
No	110 (99.1)	90 (97.8)		99 (99.0)	86 (98.9)	
Rashes						
Yes	1 (0.9)	2 (2.2)	0.454	2 (2.0)	1 (1.1)	0.644
No	110 (99.1)	90 (97.8)		98 (98.0)	86 (98.9)	
Excessive sweating						
Yes	0 (0.0)	3 (3.3)	0.055	0 (0.0)	2 (2.3)	0.127
No	111 (100)	89 (96.7)		100 (100.0)	85 (97.7)	
Nausea or vomiting						
Yes	1 (0.9)	8 (8.7)	0.007	1 (1.0)	1 (1.1)	0.921
No	110 (99.1)	84 (91.3)		99 (99.0)	86 (98.9)	

AEFI=Adverse events following immunization

significantly in the participants of both the doses (P = 0.001, 0.008). AEFI like abdominal pain (P = 0.008) and excessive sweating (P = 0.008) were reported significantly after the second dose [Table 5]. We found no significant association between prior COVID-19 infection and systemic AEFI after both the doses (P = 0.881, 0.280) [Table 6].

Most frequently reported AEFI after the first dose, within 30 min were feeling unwell (25%) and local AEFI (44.44%). Between 30 min to 1 week were local AEFI (27.74%) and weakness (18.68%). Between 7 days to 15 days were fever or chills (14.81%) and muscle pain (14.81%). Between 16 days to 1 month were rashes (22.22%) and joint pain (22.22%). Furthermore, after 1 month from the first dose, there were fever or chills (33.33%), rashes (33.33%), and joint pain (33.33%) [Figure 3].

Most commonly reported AEFI after the second dose, within 30 min were feeling unwell (15.78%) and local AEFI (63.1%).

Between 30 min to 1 week were fever or chills (13.87%) and local AEFI (31.79%). Between 7 days to 15 days were fever or chills (23.81%) and weakness (19.05%). Between 16 days to 1 month were rashes (22.22%) and muscle pain (22.22%). After 1 month from the second dose, there were rashes (33.33%) and joint pain (33.33%) [Figure 4].

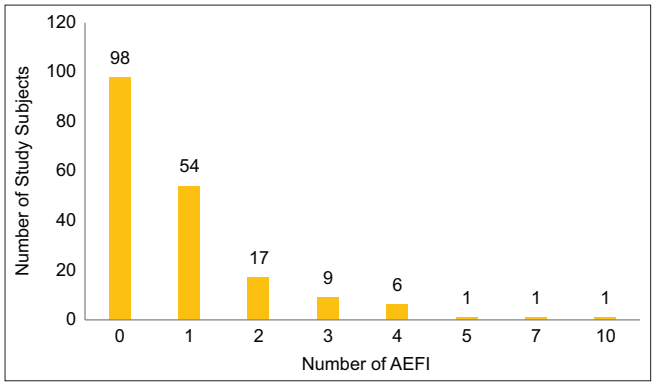

Figure 2: Distribution of the number of adverse events following immunization after the second dose of Covishield vaccine (*N* = 187). AEFI = adverse events following immunization

Discussion

We have found no significant association between age and AEFI, whereas some studies found age to be significantly associated with AEFI.[28,29] Mohakuda *et al.*[30] found that the odds of participants in the groups aged 29–39 years and 39–49 years developing minor reactions following exposure to the Covishield vaccine were 1.90 (P =0.029) and 2.37 (P =0.034), respectively, vs. those of participants in the group aged 19–29 years and Basavaraja *et al.*[31] found that the majority of the study population with AEFI belong to the age group of 18–45 years (82.53%). Jeon *et al.*[32] found that, after the first dose, all AEFI were reported to be significantly more severe in younger HCW than in older and decreasing trend with age, whereas after the second dose, there was no statistically significant difference across age groups except arthralgia. However, a study conducted by Kaur *et al.*[33] found that the risk of development of AEFI in participants ≥40 years was 27% less than in the <40 years age group. We have found a significant association between gender and AEFI, and the number of females have reported more AEFI after both the doses as compared to males, which is corroborated by some other studies.[31,34] Mahapatra *et al.*[35] found specific AEFI, like tiredness,

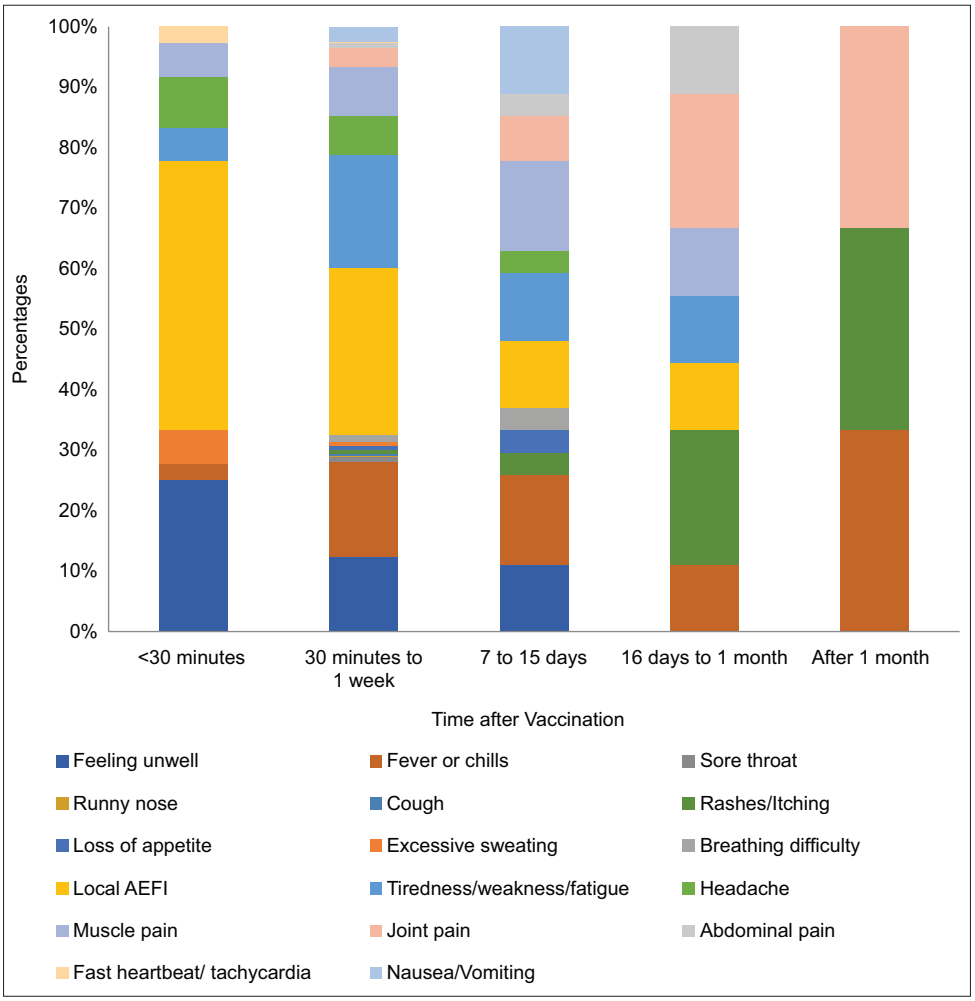

Figure 3: Distribution of adverse events following immunization after the first dose of Covishield vaccine during the mentioned time period. AEFI = adverse events following immunization

Table 3: Association of self-reported AEFI with age after the first and the second dose of Covishield vaccine

Variable	AEFI after first dose			AEFI (After second dose)		
	<40 Years old (130)	≥40 Years old (73)	*P*	<40 Years old (116)	≥40 Years old (71)	*P*
Any AEFI						
Yes	99 (76.2)	51 (69.9)	0.327	55 (47.4)	36 (50.7)	0.662
No	31 (23.8)	22 (30.1)		61 (52.6)	35 (49.3)	
Local AEFI						
Yes	73 (56.2)	34 (46.6)	0.190	38 (32.8)	22 (31.0)	0.801
No	57 (43.8)	39 (53.4)		78 (67.2)	49 (69.0)	
Systemic AEFI						
Yes	76 (58.5)	41 (56.2)	0.751	34 (29.3)	22 (31.0)	0.808
No	54 (41.5)	32 (16.7)		82 (70.7)	49 (69.0)	
Tiredness						
Yes	45 (34.6)	25 (34.2)	0.958	15 (44.4)	13 (18.3)	0.317
No	85 (65.4)	48 (65.8)		101 (87.1)	58 (81.7)	
Fever						
Yes	42 (32.3)	17 (23.3)	0.174	15 (12.9)	10 (14.1)	0.822
No	88 (76.5)	56 (76.7)		101 (87.1)	61 (85.9)	
Feeling unwell						
Yes	38 (29.2)	15 (20.5)	0.176	8 (6.9)	6 (8.5)	0.695
No	92 (70.8)	58 (79.5)		108 (93.1)	65 (91.5)	
Headache						
Yes	15 (11.5)	10 (13.7)	0.653	4 (3.4)	8 (11.3)	0.034
No	115 (88.5)	63 (86.3)		112 (96.6)	63 (88.7)	
Joint pain						
Yes	8 (6.2)	3 (4.1)	0.537	5 (4.3)	3 (4.2)	0.978
No	122 (93.8)	70 (95.9)		111 (95.7)	68 (95.8)	
Breathing difficulty						
Yes	4 (3.1)	0 (0.0)	0.130	1 (0.9)	0 (0.0)	0.433
No	126 (96.9)	73 (100.0)		115 (99.1)	71 (100.0)	
Sore throat						
Yes	2 (1.5)	1 (1.4)	0.924	1 (0.9)	1 (1.4)	0.724
No	128 (98.5)	72 (98.6)		115 (99.1)	70 (98.6)	
Loss of appetite						
Yes	2 (1.5)	1 (1.4)	0.924	1 (0.9)	1 (1.4)	0.724
No	128 (98.5)	72 (98.6)		115 (99.1)	70 (98.6)	
Abdominal pain						
Yes	3 (2.3)	0 (0.0)	0.191	1 (0.9)	1 (1.4)	0.724
No	127 (97.7)	73 (100.0)		115 (99.1)	70 (98.6)	
Rashes						
Yes	3 (2.3)	0 (0.0)	0.191	3 (2.6)	0 (0.0)	0.172
No	127 (97.7)	73 (100.0)		113 (97.4)	71 (100.0)	
Excessive sweating						
Yes	1 (0.8)	2 (2.7)	0.264	0 (0.0)	2 (2.8)	0.069
No	129 (99.2)	71 (97.3)		116 (100.0)	69 (97.2)	
Nausea or vomiting						
Yes	8 (6.2)	1 (1.4)	0.112	1 (0.9)	1 (1.4)	0.724
No	122 (93.8)	72 (98.6)		115 (99.1)	70 (98.6)	

AEFI=Adverse events following immunization

fever, headache, nausea, and decreased appetite, to be significantly more among females. Whereas a study conducted by Mohakuda *et al*.[30] found that the odds of men developing systemic AEFI to the Covishield vaccine were 2.08 times that of women. Some studies found no significant association of AEFI with gender,[29,36] but the prevalence was more among females.[29,33,37] However, some studies found the prevalence of AEFI to be more among males.[16,38] We found no significant association between education status and AEFI; this is corroborated by the study conducted by Jahan *et al*.[34] In our study, ASHA workers showed the highest prevalence of AEFI among different occupations after the first dose, whereas most of the studies found no significant association between occupation and AEFI.[29,30,34] We found no significant association between marital status, residential area, religion, and AEFI.

We have found a significant association between substance use and AEFI, and participants not abusing any substance reported a

Table 4: Association of self-reported AEFI with substance use after the first and the second dose of Covishield vaccine

Variable	Substance use					
	AEFI after first dose			AEFI (After second dose)		
	Yes (43)	No (160)	*P*	Yes (38)	No (149)	*P*
Any AEFI						
Yes	24 (55.8)	126 (78.8)	0.002	17 (44.7)	74 (49.7)	0.587
No	19 (44.2)	34 (21.3)		21 (55.3)	75 (50.3)	
Local AEFI						
Yes	14 (32.6)	93 (58.1)	0.003	9 (23.7)	51 (34.2)	0.214
No	29 (67.4)	67 (41.9)		29 (76.3)	98 (65.8)	
Systemic AEFI						
Yes	16 (37.2)	101 (63.1)	0.002	9 (23.7)	47 (31.5)	0.345
No	27 (62.8)	59 (36.9)		29 (76.3)	102 (68.5)	
Tiredness						
Yes	10 (23.3)	60 (37.5)	0.081	1 (2.6)	27 (18.1)	0.017
No	33 (76.7)	100 (62.5)		37 (97.4)	122 (81.9)	
Fever						
Yes	5 (11.6)	54 (33.8)	0.005	3 (7.9)	22 (14.8)	0.267
No	38 (88.4)	106 (66.3)		35 (92.1)	127 (85.2)	
Feeling unwell						
Yes	4 (9.3)	49 (30.6)	0.005	1 (2.6)	13 (8.7)	0.203
No	39 (90.7)	111 (69.4)		37 (97.4)	136 (91.3)	
Headache						
Yes	2 (4.7)	23 (14.4)	0.085	2 (5.3)	10 (6.7)	0.745
No	41 (95.3)	137 (85.6)		36 (94.7)	139 (93.3)	
Joint pain						
Yes	3 (7.0)	8 (5.0)	0.611	1 (2.6)	7 (4.7)	0.574
No	40 (93.0)	152 (95.0)		37 (97.4)	142 (95.3)	
Breathing difficulty						
Yes	1 (2.3)	3 (1.9)	0.850	0 (0.0)	1 (0.7)	0.613
No	42 (97.7)	157 (98.1)		38 (100.0)	148 (99.3)	
Sore throat						
Yes	1 (2.3)	2 (1.3)	0.604	1 (2.6)	1 (0.7)	0.294
No	42 (97.7)	158 (98.8)		37 (97.4)	148 (99.3)	
Loss of appetite						
Yes	0 (0.0)	3 (1.9)	0.366	0 (0.0)	2 (1.3)	0.473
No	43 (100.0)	157 (98.1)		38 (100.0)	147 (98.7)	
Abdominal pain						
Yes	1 (2.3)	2 (1.3)	0.604	0 (0.0)	2 (1.3)	0.473
No	42 (97.7)	158 (98.8)		38 (100.0)	147 (98.7)	
Rashes						
Yes	1 (2.3)	2 (1.3)	0.604	2 (5.3)	1 (0.7)	0.044
No	42 (97.7)	158 (98.8)		36 (94.7)	148 (99.3)	
Excessive sweating						
Yes	0 (0.0)	3 (1.9)	0.366	0 (0.0)	2 (1.3)	0.473
No	43 (100.0)	157 (98.1)		38 (100.0)	147 (98.7)	
Nausea or vomiting						
Yes	1 (2.3)	8 (5.0)	0.449	0 (0.0)	2 (1.3)	0.473
No	42 (97.7)	152 (95.0)		38 (100.0)	147 (98.7)	

AEFI=Adverse events following immunization

higher number of AEFI after the first dose compared to abusers. In our study, subjects consuming a vegetarian diet reported higher AEFI after the first dose. We found no significant association between physical activity and AEFI. In our study, systemic AEFI after the first dose were significantly more among subjects with comorbidity, which was also found in the study by Khalil *et al.*[28] In the study conducted by Ella *et al.*,[38] 22.2% had at least one comorbid condition. Whereas there was a statistically insignificant association between the development of AEFI and comorbidity in studies by Mohakuda *et al.*[30] and Kaur *et al.*[33]

In our study, subjects with allergies reported more AEFI. Similar results were found by Kaur *et al.*[33] We did not find any association between past COVID-19 infection and AEFI, which

Table 5: Association of self-reported AEFI with comorbidity after first and second dose of Covishield vaccine

Variable	Comorbidity					
	AEFI after the first dose			AEFI (After the second dose)		
	Yes (47)	No (156)	*P*	Yes (42)	No (145)	*P*
Any AEFI						
Yes	39 (83.0)	111 (71.2)	0.106	22 (52.4)	69 (47.6)	0.584
No	8 (17.0)	45 (28.8)		20 (47.6)	76 (52.4)	
Local AEFI						
Yes	28 (59.6)	79 (50.6)	0.282	14 (33.3)	46 (31.7)	0.844
No	19 (40.4)	77 (49.4)		28 (66.7)	99 (68.3)	
Systemic AEFI						
Yes	34 (72.3)	83 (53.2)	0.020	14 (33.3)	42 (29.0)	0.586
No	13 (27.7)	73 (46.8)		28 (66.7)	103 (71.0)	
Tiredness AEFI						
Yes	20 (42.6)	50 (32.1)	0.184	10 (23.8)	18 (12.4)	0.068
No	27 (57.4)	106 (67.9)		32 (76.2)	127 (87.6)	
Fever						
Yes	18 (38.3)	41 (26.3)	0.112	8 (19.0)	17 (11.7)	0.219
No	29 (61.7)	115 (73.7)		34 (81.0)	128 (88.3)	
Feeling unwell						
Yes	13 (27.7)	40 (25.6)	0.782	3 (7.1)	11 (7.6)	0.923
No	34 (72.3)	116 (74.4)		39 (92.9)	134 (92.4)	
Headache						
Yes	11 (23.4)	14 (9.0)	0.008	3 (7.1)	9 (6.2)	0.827
No	36 (76.6)	142 (91.0)		39 (92.9)	136 (93.8)	
Joint pain						
Yes	4 (8.5)	7 (4.5)	0.285	2 (4.8)	6 (4.1)	0.860
No	43 (91.5)	149 (95.5)		40 (95.2)	139 (95.9)	
Breathing difficulty						
Yes	0 (0.0)	4 (2.6)	0.268	0 (0.0)	1 (0.7)	0.589
No	47 (100.0)	152 (97.4)		42 (100.0)	144 (99.3)	
Sore throat						
Yes	0 (0.0)	3 (1.9)	0.338	1 (2.4)	1 (0.7)	0.348
No	47 (100.0)	153 (98.1)		41 (97.6)	144 (99.3)	
Loss of appetite						
Yes	3 (6.4)	0 (0.0)	0.001	2 (4.8)	0 (0.0)	0.008
No	44 (93.6)	156 (100.0)		40 (95.2)	145 (100.0)	
Abdominal pain						
Yes	1 (2.1)	2 (1.3)	0.674	2 (4.8)	0 (0.0)	0.008
No	46 (97.9)	154 (98.7)		40 (95.2)	145 (100.0)	
Rashes						
Yes	1 (2.1)	2 (1.3)	0.674	0 (0.0)	3 (2.1)	0.347
No	46 (97.9)	154 (98.7)		42 (100.0)	142 (97.9)	
Excessive sweating						
Yes	2 (4.3)	1 (0.6)	0.072	2 (4.8)	0 (0.0)	0.008
No	45 (95.7)	155 (99.4)		40 (95.2)	145 (100.0)	
Nausea or vomiting						
Yes	4 (8.5)	5 (3.2)	0.449	1 (2.4)	1 (0.7)	0.348
No	43 (91.5)	151 (96.8)		41 (97.6)	144 (99.3)	

AEFI=Adverse events following immunization

was also shown by the study conducted by Mohakuda *et al.*[30] whereas it was significant in the study by Shrestha *et al.*[36] The most commonly reported AEFI was fever in 29.06% after the first dose, which was quite high compared to 13.37% after the second dose; it is also reported as a common AEFI in various studies.[16,28,29,30,33,35,36,38] This high incidence of fever is usually due to the release of pyrogenic cytokines by white blood cells against vaccine constituents. People who felt unwell were 26.11% after the first dose, which is quite higher than 7.48% after the second dose. This finding is corroborated by Kamal *et al.*[29] and Folegatti *et al.*[16] Tiredness was also reported in a high number among participants, 34.48% after the first dose and 14.97% after the second dose. There have been similar findings in studies conducted by some other authors.[16,29,30,32,35,36,38] Headache

Table 6: Association of self-reported systemic AEFI with COVID status after the first and second dose of Covishield vaccine

Variable	AEFI (After first dose)			AEFI (After second dose)		
	COVID-19 group (72)	Non-COVID group (131)	*P*	COVID-19 group (66)	Non-COVID group (121)	*P*
Systemic AEFI						
Yes	42 (58.3)	75 (57.3)	0.881	23 (34.8)	33 (27.3)	0.280
No	30 (41.7)	56 (42.7)		43 (65.2)	88 (72.7)	
Tiredness						
Yes	28 (38.9)	42 (32.1)	0.327	12 (18.2)	16 (13.2)	0.364
No	44 (61.1)	89 (67.9)		54 (81.8)	105 (86.8)	
Fever						
Yes	20 (27.8)	39 (29.8)	0.765	11 (16.7)	14 (11.6)	0.328
No	52 (72.2)	92 (70.2)		55 (83.3)	107 (88.4)	
Feeling unwell						
Yes	17 (23.6)	36 (27.5)	0.548	6 (9.1)	8 (6.6)	0.538
No	55 (76.4)	95 (72.5)		60 (90.9)	113 (93.4)	
Headache						
Yes	6 (8.3)	19 (14.5)	0.201	5 (7.6)	7 (5.8)	0.633
No	66 (91.7)	112 (85.5)		61 (92.4)	114 (94.2)	
Joint pain						
Yes	4 (5.6)	7 (5.3)	0.949	2 (3.0)	6 (5.0)	0.533
No	68 (94.4)	124 (94.7)		64 (97.0)	115 (95.0)	
Breathing difficulty						
Yes	0 (0.0)	4 (3.1)	0.134	0 (0.0)	1 (0.8)	0.459
No	72 (100.0)	127 (96.9)		66 (100.0)	120 (99.2)	
Sore throat						
Yes	1 (1.4)	2 (1.5)	0.938	1 (1.5)	1 (0.8)	0.662
No	71 (98.6)	129 (98.5)		65 (98.5)	120 (99.2)	
Loss of appetite						
Yes	1 (1.4)	2 (1.5)	0.938	1 (1.5)	1 (0.8)	0.662
No	71 (98.6)	129 (98.5)		65 (98.5)	120 (99.2)	
Abdominal pain						
Yes	2 (2.8)	1 (0.8)	0.255	1 (1.5)	1 (0.8)	0.662
No	70 (97.2)	130 (99.2)		65 (98.5)	120 (99.2)	
Rashes						
Yes	0 (0.0)	3 (2.3)	0.196	0 (0.0)	3 (2.5)	0.197
No	72 (100.0)	128 (97.7)		66 (100.0)	118 (97.5)	
Excessive sweating						
Yes	1 (1.4)	2 (1.5)	0.938	1 (1.5)	1 (0.8)	0.662
No	71 (98.6)	129 (98.5)		65 (98.5)	120 (99.2)	
Nausea or vomiting						
Yes	1 (1.4)	8 (6.1)	0.118	0 (0.0)	2 (1.7)	0.294
No	71 (98.6)	123 (93.9)		66 (100.0)	119 (98.3)	

AEFI=Adverse events following immunization

was another common adverse event reported in 12.32% of participants after the first dose and 6.42% of participants after the second dose; this is corroborated with studies conducted by other researchers.[16,29,30,33,35,38,36]

Less common but severe AEFI reported after the first dose were chest pain in the 1st week and exacerbated back pain in the 1st month. Less common but severe AEFI observed in other studies were flu-like symptoms, diarrhea by Mohakuda *et al.*,[30] agitation by Konu *et al.*[37]

In our study, 73.89% of participants suffered from at least one AEFI after the first dose of the vaccine, while 48.66% had at least one AEFI after the second dose. Adverse events were quite high after the first dose. In addition, they were more severe and of longer duration after the first dose as compared to the second dose. Systemic AEFI were higher than local AEFI by 4.92% after the first dose, and after the second dose, local AEFI were higher by 2.14%. Comparing with other studies, Basavaraja *et al.*[31] had AEFI incidence rate of 4.32%. An adverse event rate of 54.1% after the first dose and 41.3% after the second dose respectively, with higher severity and duration after the first dose, were found by Khalil *et al.*[28] In a study by Jeon *et al.*,[32] 98.1% of participants reported more than one AEFI after the first dose, and 90.9% of participants reported AEFI following the second dose. Besides, this study also reported a close rate of local and systemic AEFI

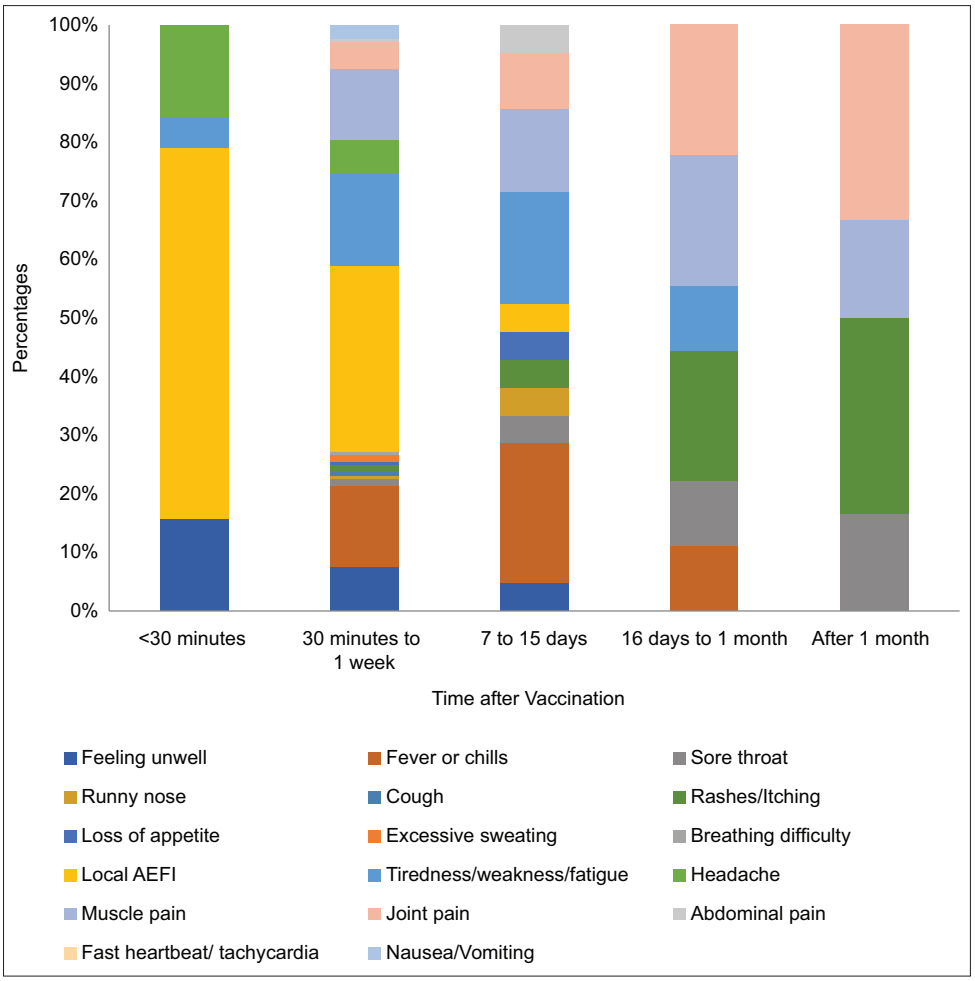

Figure 4: Distribution of adverse events following immunization after the second dose of Covishield vaccine during the mentioned time period. AEFI = adverse events following immunization

following the first dose but a lower systemic AEFI following the second dose. In a study by Kamal *et al.*[29] AEFI reported after the first dose, were among 57% of participants, and after the second dose, were among 14.1% of participants. In a study by Ella *et al.*[38] local AEFI were <0.3% following both doses. Shrestha *et al.*[36] reported that 85.04% of participants had AEFI after the first dose, and systemic AEFI were 77.7%. In another study by Kaur *et al.*[33] following the first dose, the AEFI rate was 40%, with systemic and local being 31% and 9%, respectively, and following the second dose, the AEFI rate was 16%, and systemic AEFI rate was 13.6%.

Our study has a few limitations. First of all, it is an observational cross-sectional study, and hence, the cause-and-effect relationship cannot be proved. This study is subject to some extent of recall bias in self-reported AEFI. It is a single-centric study, so multi-centric studies are needed to explore the effects of different sociodemographic factors on AEFI of the Covishield vaccine.

Conclusion

In our study, more AEFI were reported after the first dose as compared to the second dose of the Covishield vaccine. AEFI were more among females after both the doses. Occupation, substance use, diet, and history of allergy were significantly associated with the occurrence of AEFI. Incidences of more than one AEFI after the first dose were greater than the second dose. None of the study subjects had any Severe or Serious AEFI. A long-term follow-up study is recommended to assess the cause-and-effect relationship and delayed AEFI. Awareness should be created among the general population about the mild AEFI to reduce the vaccine hesitancy. There should be provision for follow-up of vaccinated persons for early detection of possible AEFI. Proper advice should be given to vaccinated candidates about adverse events of self-medication after AEFI.

List of Abbreviations

AEFI, adverse events following immunization; ASHA, accredited social health activist; CKD, chronic kidney disease; CLD, chronic liver disease; COVID-19, coronavirus disease of 2019; DCGI, Drugs Controller General of India; EMA, European Medicines Agency; EUL, Emergency Use Listing; HCT, human clinical trials; HCW, healthcare workers; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SII, Serum Institute of India; WHO, World Health Organization

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Ethics approval and consent to participate

Ethical approval was obtained from the ethical review committee of Dr Baba Saheb Ambedkar Medical College and Hospital, Delhi-110085, India (DBSAMC/EC-2/2021). Informed consent was taken from each participant.

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Conflicts of interest

There are no conflicts of interest.

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