# ADVERSE EVENTS FOLLOWING IMMUNIZATION ASSOCIATED WITH COVID VACCINES AMONG HEALTHCARE WORKERS IN TERTIARY CARE CENTRE IN A DISTRICT

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### ABSTRACT

**INTRODUCTION:** Myths regarding AEFI associated with covid vaccines caused fear among general population to take up vaccination against covid.

### **OBJECTIVES:**

1.To study the socio-demographic factors associated with AEFI following COVID vaccination among healthcare workers.

2. To study the AEFI following covid vaccination.

**MATERIALS AND METHODS:** The study is a cross-sectional study with minimum sample size of 178 and the study was done on 377 healthcare workers using simple random sampling method. Data was collected using pre-structured questionnaire and analyzed using proportions, bar charts & chi-square test of significance.

**RESULTS:** AEFI after first dose and second dose was highest among 21-30 years age group and least among 61-70 yrs age group and below 20 years. AEFI reporting was highest in females compared to males both after first dose and second dose. AEFI after first dose was highest among nursing staff followed by doctors whereas after second dose it was vice-versa. Fever and body pains were the most common adverse events after first dose (within 1-5 days) whereas after second dose, pain at the site of injection and body pains were more common.

**CONCLUSION:** Majority of the adverse events reported after covid vaccination in the study were only minor not needing any hospitalization.

KEY WORDS: AEFI, COVAXIN, COVISHIELD, FIRST DOSE, SECOND DOSE

**INTRODUCTION:** First COVID 19 case had been reported in Wuhan, china on 31<sup>st</sup> Dec 2019<sup>(1)</sup>.In India first case of COVID was reported in 20 year old female from Kerala on January 20<sup>th</sup>, 2020<sup>(2)</sup>. Corona virus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Corona virus had badly disrupted the social, economic and psychological aspects of humankind in several countries all over the world. In this scenario several protective measures have been advocated. Inspite of the protective measures being followed by the public, several deaths occurred due to corona virus. Several research works were started all over the world to combat the virus. Finally the scientists could prepare vaccines which can be used for prevention and control of the virus. India initially approved the Oxford-AstraZeneca vaccine (manufactured under license by Serum Institute of India under the trade name Covishield) and Covaxin (a vaccine developed locally by Bharat Biotech)<sup>(3)</sup>. Vaccine administration started in India on 16<sup>th</sup> January 2021<sup>(4)</sup>. Initially only two doses were given. Later on WHO advised booster dose for healthy individuals and additional booster doses for certain health conditions also. But there have been a several myths regarding vaccination and the public hesitated to take vaccine because of AEFI. "An AEFI is any untoward medical occurrence and which does not necessarily have a causal relationship with the usage of the vaccine  $^{(5)}$ ."

The World Health Organization, with the support of the Strategic Advisory Group of Experts (SAGE) on Immunization and its COVID-19 Vaccines Working Group, continues to review the emerging evidence on the need for and timing of a booster dose for the

currently available COVID-19 vaccines which have received Emergency Use Listing (EUL) <sup>(6)</sup>. In order to reduce the spread and severity of corona virus, WHO suggested public to take vaccination along with the protective measures. The present study aimed to study the adverse events following immunization associated with covid vaccines and to counsel the participants regarding vaccination.

## **OBJECTIVES:**

1.To study the Socio-demographic factors associated with AEFI following COVID vaccination among healthcare workers.

2. To study the adverse events following first and second doses of covaxin and covishield vaccines among healthcare workers.

**MATERIALS & METHODS:** The study is a cross-sectional study. Assuming prevalence to be 50% as there is limited literature available regarding the prevalence of AEFI in India by the time of data collection and similar to Subedi P etal study<sup>(7)</sup> and allowable error of 15% of P. Minimum sample size of 177 has been calculated as follows-

Sample size =  $4PQ/L^2 = 4X50X50/7.5X7.5 = 177$ 

Around 377 healthcare workers in tertiary care centre of a District were selected using simple random sampling method. All the healthcare workers who were willing to participate and took at least one dose of vaccine were included in the study. Healthcare workers of age below 18 years and above 70 years were excluded from the study. A pre-tested pre-structured questionnaire has been administered to the health care workers in tertiary care centre. The data collection has been done from august 2021 to November 2021.The data thus collected has been entered into MS Excel and statistical analysis was done using Open Epi software using chi-square tests, bar charts and 2x2 tables.

**Ethical committee :** Ethical approval was obtained from the Institutional Ethics Committee with project No.41-A/2021 dated 12/07/2021 and an informed consent was taken from all participants.

**RESULTS:** The total sample size in the present study was 377. Subjects who received single dose of Covid vaccine of any brand were 22 while subjects who received two doses of vaccine of any brand were 355; Subjects who received same brand for two doses were 362 and those who received different brand for two doses were around 15.

### Table 1: AEFI after first dose of covid vaccine in relation with brand of vaccine

Vaccine brand	AEFI	AEFI not	Total	
	reported	reported		
Covishield	223 (68.4%)	103 (31.6%)	326 (100%)	
Covaxin	33 (64.7%)	18 (35.3%)	51 (100%)	
Total	256 (67.9%)	121 (32.1%)	377 (100%)	
Chi squara $= 0.277$ , $p = 0.508$ Not significant				

Chi-square = 0.277, p = 0.598, Not significant

Out of 377 respondents who received first dose of vaccine, 326 subjects received Covishield and 51 subjects received Covaxin. Among 326 subjects, 223 (68.4%) reported

AEFI after first dose of Covishield while 33(64.7%) subjects reported AEFI after first dose of Covaxin. More adverse reactions were reported with covishield vaccine following first dose compared to covaxin but the difference was not statistically significant (Table1).

## Table 2: AEFI after second dose of covid vaccine in relation with brand of vaccine

Vaccine brand	AEFI	AEFI not	Total
	reported	reported	
Covishield	93 (29.6%)	221 (70.4%)	314 (100%)
Covaxin	11 (26.8%)	30 (73.2%)	41(100%)
Total	104 (29.3%)	251 (70.7%)	355(100%)

chi-square = 0.136, p = 0.712, not significant

Out of 355 respondents who received second dose of vaccine, 314 subjects were vaccinated with Covishield and 41 subjects with Covaxin. Among 314 subjects who received second dose 93 (29.6%) reported AEFI with covishield vaccine while around 11(26.8%) subjects reported AEFI with Covaxin. More adverse reactions were reported with covishield vaccine following second dose compared to covaxin but the difference was not statistically significant (Table 2).

# Table 3: Socio-demographic factors associated with AEFI following covid vaccination after first dose among health care workers

Category	Sub-category	AEFI	AEFI not	p value
		reported	reported	
		(n=256)	(n=121)	
Age	21-30 vrs	119(46.4%)	40(33.05%)	
8	31-40 yrs	72(28.1%)	42(34.7%)	
	41-50 yrs	35(13.6%)	18(14.8%)	Chi-square = 7.689,
	51-60 yrs	20(7.8%)	13(10.7%)	df = 5, p = 0.17 (>0.05),
	61-70 yrs	3(1.1%)	4(3.3%)	Not significant
	18- 20 yrs	7(2.7%)	4(3.3%)	
Gender	Male			Chi-square = 0.128,
		83 (32.4%)	37(30.5%)	df =1, p = 0.72 (>0.05),
	Female			Not significant
		173(67.5%)	84(69.4%)	
Education	Graduate or			
	postgraduate	166(64.8%)	72(59.5%)	
	High school certificate	19(7.4%)	7(5.7%)	
	Illiterate	4(1.5%)	3(2.4%)	Chi-square = 6.237,

	Intermediate/ post high			df=6, p=0.397(>0.05),
	school diploma	42(16.4%)	19(15.7%)	Not significant
	Middle school	5(1.9%)	3(2.4%)	
	Primary school	4(1.5%)	1(0.8%)	
	Profession/honors	16(6.2%)	16(13.2%)	
Occupation	Doctors	62(24.2%)	32(26.4%)	Chi-square= 1.74,
	Interns & pgs	33(12.8%)	14(11.5%)	df = 4, p = 0.78(>0.05),
	Nursing staff	78(30.4%)	42(34.7%)	Not significant
	Para medical	50(19.5%)	18(14.8%)	
	Sanitation workers &			
	others	33(12.8%)	15(12.3%)	
Family income	≥ rs.1,99,862	22(8.5%)	9(7.43%)	Chi-square = 5.15,
per month	Rs.99,931-rs.199,861	41(16%)	17(14%)	df= 6, p = $0.52(>0.05)$ ,
	Rs.74,755-rs.99,930	28(10.9%)	13(10.7%)	Not significant
	Rs.49,962-rs.74,755	21(8.2%)	18(14.8%)	
	Rs.29,973-rs.49,961	53(20.7%)	19(15.7%)	
	Rs.10,002-rs.29,972	64(25%)	33(27.2%)	
	≤ rs.10,001	27(10.5%)	12(9.9%)	
<b>Co-morbidities</b>	<b>Co-morbidities present</b>	59(23%)	25(20.6%)	Chi-square = 0.27,
				df =1, p = 0.60(>0.05),
	Co-morbidities absent	197(76.9%)	96(79.3%)	not significant

Reporting of AEFI after first dose was highest in the age group of 21-30 years (46.4%), followed by 31-40 years age group (28.1%) and least among 61-70 years age group (1.1%). Reporting of AEFI after first dose was highest among females (67.5%) compared to males (32.4%). Coming to educational status, AEFI after first dose was highest in graduates or postgraduates (64.8%), followed by Intermediate (16.4%) and least among Profession or honors (6.2%). Among Occupational cadres, nursing staff (30.4%) reported highest AEFI after first dose followed by doctors (24.2%) and least among interns/ post-graduate students (12.8%) and sanitation workers (12.8%) AEFI after first dose reporting was highest among income group of Rs.10,002 -Rs.29,972 (25%), and least AEFI reported among Rs.49,962-Rs.74,755(8.2%). Subjects having co-morbidities like hypertension, diabetes, thyroid disorders etc. reported slightly higher proportion of AEFI after first dose compared to those who did not have co-morbidities, but this finding was falling short of statistical significance (Table 3).

Category	Sub-category	AEFI	AEFI not	p value	
		reported	reported		
		(n=104)	(n=251)		
Age	21-30 yrs	38(36.5%)	113(45%)		
	31-40 yrs	34(32.6%)	72(28.6%)	Chi-square = 4.689,	
	41-50 yrs	19(18.2%)	31(12.3%)	$\mathbf{df}=5,$	
	51-60 yrs	8(7.6%)	23(9.1%)	p = 0.45 (>0.05),	
	61-70 yrs	3(2.8%)	4(1.5%)	Not significant	
	18-20 yrs	2(1.9%)	8(3.1%)		
Gender	Males	34(32.6%)	79(31.4%)	Chi-square = 0.0502 ,	
				df= 1,	
				p = 0.82 (>0.05), not	
	Females	70(67.3%)	172(68.5%)	significant	
Education	Graduate or				
	postgraduate	65(62.5%)	157(62.5%)		
	High school			Chi-square = 7.37,df = 6,	
	certificate	11(10.5%)	14(5.5%)	p = 0.29 (>0.05), not	
	Illiterate	0	7(2.7%)	significant	
	Intermediate/ post				
	high school				
	diploma	13(12.5%)	43(17.1%)		
	Middle school	3(2.8 %)	5(1.9%)		
	Primary school	1(0.9%)	4(1.5%)		
	Profession/honors	11(10.5%)	21(8.3%)		
Occupation	Doctors	31(29.8%)	57(22.7%)	Chi-square = 10.39,	
	Interns & pgs	6(5.7%)	41(16.3%)	df= 4 ,	
	Nursing staff	29(27.8%)	83(33%)	p = 0.034 (p<0.05),	
	Para medical	23(22.1%)	39(15.5%)	significant	
	Sanitation workers				
	& others	15(14.4%)	31(12.3%)		
Family income	≥ rs.1,99,862	16(15.3%)	12(4.7%)	Chi-square =18.93, df= 6	
per month	Rs.99,931-			,	
	rs.199,861	21(20.1%)	32(12.7%)	<b>p</b> = 0.004( <b>p</b> <0.05),	
	Rs.74,755-rs.99,930	12(11.5%)	27(10.7%)	significant	
	Rs.49,962-rs.74,755	8(7.6%)	29(11.5%)		
	Rs.29,973-rs.49,961	18(17.3%)	49(19.5%)		
	Rs.10,002-rs.29,972	18(17.3%)	75 (29.8%)		

# Table 4: Socio-demographic factors associated with AEFI following covid vaccination after second dose among health care workers

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	≤ rs.10,001	11(10.5%)	27(10.7%)	
<b>Co-morbidities</b>	<b>Co-morbidities</b>			Chi-square = 3.99 , df= 1
	present	24(23%)	36(14.3%)	,
	<b>Co-morbidities</b>			<b>p</b> = 0.045( <b>p</b> <0.05),
	absent	80(76.9%)	215(85.6%)	significant

Reporting of AEFI after second dose was highest among the age group of 21-30 yrs (36.5%), followed by 31-40 yrs (32.6%), 41-50 yrs(18.2%), 51-60 yrs(7.6%), 61-70 yrs (2.8%) and below 20 yrs(1.9%). Similarly, reporting of AEFI after second dose was highest in females (67.3%) compared to males(32.6%). AEFI after second dose was reported more among doctors (29.8%) followed by nursing staff (27.8%), paramedical staff(22.1%), sanitation workers (14.4%) and interns/ post-graduate students (5.7%) and this finding was statistically significant (p<0.05). AEFI after second dose were reported more among income group of Rs.99,931-Rs.1,99,861(20.1%),followed by Rs.29,973-Rs.49,961(17.3%),Rs.10,001-Rs.29,972(17.3%). AEFI after second dose were reported least among the income group  $\geq$  Rs.1, 99,862 (15.3%), Rs.74,755-Rs.99,930(11.5%) and  $\leq$ Rs.10,001(10.5%). There was a statistical significance between income and AEFI after second dose with p < 0.01.

AEFI after second dose were reported among 23% of the participants with comorbidities and this finding was statistically significant (p<0.05) (Table 4).



Fig 1: Bar chart showing common adverse events reported after receiving first dose of covid vaccine

Fever (66.70%) and body pains/myalgia (66.4%) were the most common post vaccination symptoms after first dose of COVID vaccine followed by pain at the site of injection(60%).Headache was reported among 28% of the participants followed by

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tiredness(17%),chills(9.70%),nausea (5%) and giddiness(4.60%).Least reported symptoms were syncope(1.1%),sore-throat (1.1%) and allergic rash(0.7%) (Fig 1).



# Fig 2: Bar chart showing time interval between vaccination and occurrence of AEFI after first dose of covid vaccine but before second dose of vaccine

Majority of the AEFI were reported among the participants within 1-5 days(97.6%)following vaccination and no AEFI were reported after 16-25 days of vaccination (Fig 2).



# Fig 3: Bar chart showing common adverse events reported after receiving second dose of covid vaccine

Pain at the site of injection (45.10%) and body pains/myalgia(43.20%) were the most common adverse events reported after receiving second dose of COVID vaccine followed by headache (19.20%) & tiredness(6.70%).Least reported adverse events were nausea(3.8%),sore throat (2.8%),chills(1.90%) and fever(0.4%) after second dose of covid vaccine (Fig 3).



# Fig 4 : Bar chart showing time interval between vaccination and occurrence of AEFI after second dose of covid vaccine (within 1 month of receiving vaccine)

Majority of the AEFI reported among the participants in the time interval of 11-15 days of vaccination(89.40%) followed by the time interval of 6-10 days(8.60%).Least AEFI reported among the participants in the time-interval of 1-5 days(0.9%) and 26-30 days(0.9%).No reactions were reported among the participants in the time interval of 16-20 days and 21-25 days (Fig 4).

**DISCUSSION:** In the present study more adverse events were reported after first dose compared to second dose similar to Parida SP etal study  $^{(8)}$  and Chakraborthy etal study $^{(9)}$ .

The present study among healthcare workers showed more AEFI's in the age group of 21-30 years after both first and second dose and least in 61-70 years, which is similar to a study conducted in Nepal<sup>(7)</sup> and Suhagiya P etal study<sup>(10)</sup>.

AEFI reporting showed higher female preponderance after both the doses which is similar to the studies of Subedi P etal, Chakraborthy etal and Basavarajaetal study<sup>(7,9,11)</sup>. Adverse events were reported more among the doctors after first dose whereas after second dose more number of events were reported among nursing staff. A study done by Kamal D etal<sup>(12)</sup> among healthcare workers had more adverse events reported among the paramedics than doctors but it might be because of more paramedics in that study(selection bias might be the reason).

This study shows a new finding of association between income and adverse events following covid vaccination. AEFI after first dose reporting was highest among subjects of lower income group i.e Rs.10,002 -Rs.29,972 (25%), whereas least adverse events were reported among subjects of middle income group i.e.Rs.49,962-Rs.74,755(8.2%). More adverse events were reported among subjects of higher income group i.e. Rs.99,931-Rs.1,99,861(20.1%) and less adverse events were reported among the subjects of lower income group i.e. Rs.10,001(10.5%). There was a statistical significance between income and AEFI after second dose with p<0.01. This study also shows other new finding i.e. more adverse events were reported among graduates or postgraduates both after first dose (64.8%)

and second dose (62.5%) as far as education is concerned. Further research is required to study whether these socio-economic factors like education and income have any influence on AEFI with covid vaccination among healthcare workers as well as general population.

Subjects with co-morbidities like diabetes, hypertension, thyroid disorders etc. had reported more adverse events after receiving second dose of vaccine and there was a statistical significance with p = 0.045(p<0.05). This was similar to Parida SP etal study<sup>(8)</sup> and Sultana etal study<sup>(13)</sup>.

The most common adverse events reported were fever and body pains/myalgia and very rarely allergic rash after first dose was reported similar to Konda etal study<sup>(14)</sup>, Rajpurohit etal study <sup>(15)</sup> and Kavita etal study<sup>(16)</sup> whereas local reactions were more in other studies <sup>(7,8,13)</sup>. Body pains /myalgia was the most common symptom reported following second dose of vaccination <sup>(14)</sup>.

Most of the adverse events were reported within 1-5 days after vaccination with first dose of covid vaccine and within 11-15 days after vaccination with second dose. These reactions were only minor and there were no serious events reported similar to the studies where there were only minor adverse events reported that too within 48 hrs <sup>(12,13,16)</sup>.

#### LIMITATIONS :

1. There were more females in the study which might have led to the selection bias in the results implicating female preponderance in case of AEFI following covid vaccination. Also the history of menstruation and menopause among female subjects was not taken which might play role in the occurrence of adverse events.

2. The data about any medication history, rare conditions like autoimmune disorders was not taken.

3. History of covid positive test both before and after the first and second dose of covid vaccination was not collected.

4. In this study, the data regarding lifestyle related habit of smoking, alcoholism, substance abuse etc. of the subjects was not taken which may influence the AEFI following covid vaccination. 5. The data regarding any history of allergic reactions of the subjects was also not taken.

**CONCLUSION & RECOMMENDATIONS:** There is a need to create awareness wherever possible at all public platforms about the need to take vaccine in the present situation as there had not been severe reactions reported till date (though reported in some individuals as projected by certain studies, the percentage of AEFI were less) as this had been the only severe pandemic so far which had affected mankind in almost every aspect all over the world. The people can be given suggestions about the vaccination but cannot be compelled as the vaccination had started recently and the longterm side effects are not known. The decision to take vaccination (be it first, second or booster doses) must be left to the choice of the individuals. Further research works may be conducted to know the longterm side-effects of covid vaccination, the reasons for adverse events and their prevention.

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