(International Print/Online Journal)

SJIF IMPACT FACTOR: 5.565
PUBMED-National Library of Medicine ID-101739732

ISSN (Print): 2209-2870
ISSN (Online): 2209-2862

International Journal of Medical Science and Current Research (IJMSCR)
Available online at: www.ijmscr.com
Volume 5, Issue 2, Page No: 199-212
March-April 2022

IJMSCR

Evaluation of Adverse Events following Covid -19 Vaccination (Vaccine Vigilance) among the Health Care Professionals – A Multicentred Questionnaire Based Study

Shruthi Priyanka R[1], Saravana Kumar M[2], Rajam Ramasamy N[3]

[1]Final year MBBS Student, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur

[2]Professor and Head, Department of Pharmacology Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur

[3]Professor, Department of Mechanical Engineering Coimbatore Institute of Technology, Coimbatore

***Corresponding Author:**
Shruthi Priyanka R

[1]Final year MBBS Student, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur

Type of Publication: Original Research Paper
Conflicts of Interest: Nil

Abstract

Background: The COVID-19 pandemic has crippled down human health in alarming ratios globally including all the developed and developing countries as a whole. The pandemic situation has pushed the entire health care system in many countries to critical and most challenging testimony. The virus has claimed the lives of 3,884,890 people, with still 179,393,174 confirmed live cases among 220 countries as of June 2021[(1)]. The main aim of this study is to assess the adverse events on administration of vaccines among healthcare professionals and their approach towards vaccination[(2)].

Methods: A retrospective study conducted among the healthcare workers from June 2021 to August 2021 to analyze and introspect the AEFI post Covid 19 vaccination in Tamil Nadu, India. The local and systemic side effects post both the 1st and 2nd dose of Covid19 vaccination was collected through questionnaire.

Results: A total of 700 potential health care workers were approached, out of which 661 participated and provided value insights regarding the side effects of vaccination. The most common side effect reported were the fever, head ache, body pain and pain at the site of injection. Young population, majorly involving the females, were affected than the older population. All the reported side effects were mild to moderate in nature without requiring any hospitalization

Conclusion: The adverse events post Covid19 vaccination are tolerable and manageable while they can be mitigated with simple home remedies and administration of paracetamol.

Keywords: Adverse events, vaccination, Covid 19 pandemic, immunization, vaccine vigilance

Introduction

The novel Coronavirus has been reported in more than 120 countries and has claimed more than 2 million lives as of March 2021. Globally, there have been about 430 million confirmed cases of COVID-19, including 6 million deaths, reported to WHO.[(8)]

The development of vaccines has greatly proven to knock down the disease load and curb the spread in large numbers. Several updates have been reviewed including General recommendations on immunization, Recommendations of the Advisory Committee on Immunization Practices (ACIP)[(5).]

However, the vaccine administration was associated with some unfavorable side effects which greatly impacted the motivation for administration among people.

The WHO has proposed the following definition, adverse event following immunization (AEFI) is any untoward unfavorable unintended medical occurrence

which follows immunization and does not have a causal relationship with usage of vaccine.

Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, prevention and communication of AEFI or of any other vaccine or immunization related issues.[6]

The main aim of initiating pharmacovigilance was to ensure the safety of people taking the vaccine and promote safer administration practices of vaccines. As a consequence, the AEFI surveillance guidelines have been initiated and updated by many countries periodically.

INDIAN SCENARIO

India being the global hub for vaccine production and exports, run a explicit and intricate surveillance system to monitor the AEFI. And also taking into consideration that India runs one of the largest and widely covered immunization programs, the above becomes inevitable.

The AEFI surveillance program was initiated by the government of India in the year 1986 which was subjected to numerous revisions, the last being in 2015.[7]

The guidelines updated in 2015 has classified AEFI into 3 main classes:

1. Common minor AEFI including local reactions, fever and systemic symptoms
2. Serious AEFI those which result in hospitalization, death or significant disability
3. Severe AEFI these which are not minor but do not result in disability or death and do not require hospitalization

The intensive tracking documenting and reporting of AEFI is carried out by a team of stakeholders including:

1. Peripheral health workers
2. Peripheral medical officers
3. Private practices
4. DIO - District Immunization Officers
5. State Immunization Officers
6. Role of AEFI secretariat
7. Role of national AEFI committee
8. Role of marketing authorization holder

AIM OF STUDY

To evaluate the adverse events following Covid 19 vaccination (vaccine vigilance) among the health care workers- a multicenter questionnaire based study.

OBJECTIVE

To analyze the type of adverse events, onset and duration of post vaccination and the various methods of management adopted to overcome the same**.**

METHODOLOGY

Study Design: Cross sectional study

Study Area: Government and private medical colleges and hospitals including the nurses and paramedical staffs.

Study Population: Health care professionals including doctors, nurses, paramedical staffs and medical students

Inclusion Criteria: Health care professionals who are above 18 years of age and willing to participate and have given the consent.

Exclusion Criteria: Health care professionals who are not willing to participate or give consent.

Sampling Technique: Convenient sampling

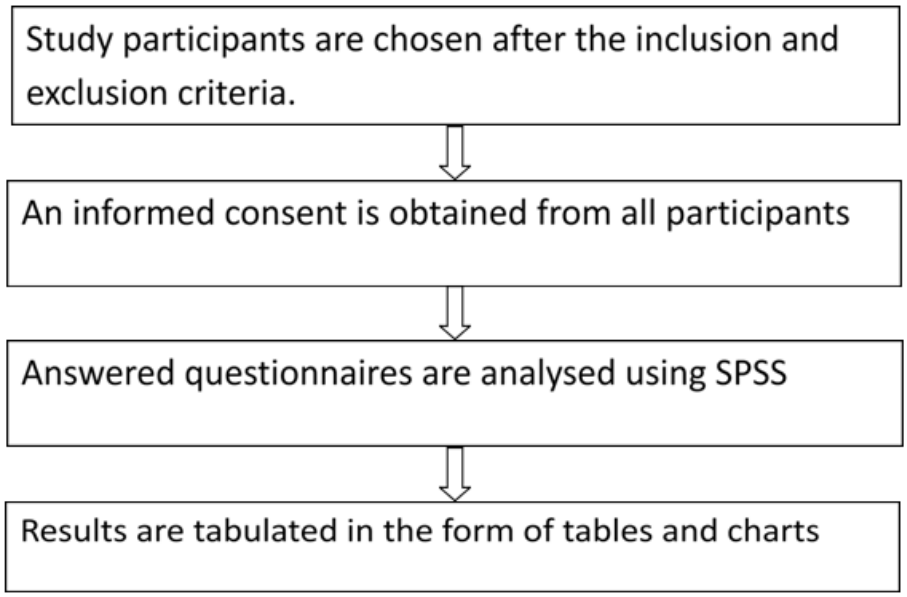
Sample Size: 661

Data Collection Methods: Questionnaire through Google forms in 21 days

Duration of Study: 6 months from the date of approval from IEC (August 2021 to February 2022)

Volume 5, Issue 2; March-April 2022; Page No 199-212

DATA ANALYSIS PROCEDURE:



RESULTS

A study on the effect of COVID vaccination and its impact on the medical industry was examined. A questionnaire was developed for the purpose of study and was circulated among various personnel in the field of medical sciences. The population for investigation comprised medical students, doctors, paramedical and allied industries in state of Tamil Nadu, India.

The questionnaire is circulated using email, WhatsApp and other social media. The response from the target group was collected for a period of 1 month. As many as 700 potential participants were approached out of which 661 participated and provided valuable information for the study, the following are the results of the analysis.

A total of 437 females and 224 males of different age groups had contributed for the study.

At the time of analysis, out of 661 participants, 622 had taken the first dose accounting to a 94.7% success rate of the vaccination program.

The information collected for the questionnaire were tabulated to conclude on the findings of the survey.

Table1. Details of the participants

Occupation	*Sex*	18 to 25	26 t0 35	36 to 50	51 to 65	65 and above	Total
Doctor	Female	1.98%	5.18%	3.04%	2.89%	0.30%	13.39%
	Male	1.22%	2.74%	2.44%	2.59%	0.15%	9.13%
Total		3.20%	7.91%	5.48%	5.48%	0.46%	22.53%
Medical student	Female	42.62%	0.15%				42.77%
	Male	22.37%					22.37%
Total		64.99%	0.15%				65.14%

Volume 5, Issue 2; March-April 2022; Page No 199-212

Paramedical staff	Female	3.20%	0.46%	0.15%			3.81%
	Male	0.46%					0.46%
Total		3.65%	0.46%	0.30%			4.41%
Paramedics	Female	3.81%	0.76%	1.52%	0.15%		6.24%
	Male	0.76%	0.46%	0.15%	0.30%		1.67%
Total		4.57%	1.22%	1.67%	0.46%		7.91%

From table 1, it is inferred that a good population of medical students in the age of 18 to 25 have actively participated in the survey. Among the overall student population, 42.62% were female medical students and 23.37% were male medical students. On the other hand, the participation from doctors and paramedical staff is quite remarkable.

Choice of the vaccine

Influence of the various vaccines on the factors considered for the study.

Table 2. Factors influencing the choice of vaccine

Factor	Covaxin	Covid Shield	Moderna	Pfizer	Sputnik
Availability	15.7%	82.67%	0.2%	1.07%	0.3%
Clinical trial	16.5%	81.4%	0,2%	1.2%	0.5%
Peer influence	18.2%	76.1%	1.7%	2.4%	1%
Social Media	16.94%	81.9%	0.24%	0.6%	0.1%
Recommendation @ workplace	16.30%	82.02%	0.26%	1.13%	0.26%
Cost per Dose	14.79%	83.51%	0.29%	0.80%	0.58%
Data efficacy	18.6%	79.75%	.247%	0.89%	0.49%
Travel restrictions	14.03%	83.48%	0.34%	1.78%	0.34%
importance	16.38%	81.35%	0.47%	1.23%	0.45%

Volume 5, Issue 2; March-April 2022; Page No 199-212

Ranking of the parameters by the participants

Table 3. Ranking of factors considered for choice of vaccine

	Availability	Clinical trial	Peer influence	Social Media	Recommendation @ workplace	Cost per Dose	Data efficacy	Travel restrictions
Absolute weight	3.60	3.25	2.85	2.505	2.87	2.10	3.12	1.864
Rank	**1**	2	5	6	4	7	3	8

We can analyze the factors influencing the choice of vaccines from table 2 and the factors considered while choosing the vaccine from table 3.

From the above two tables it is evident that the most preferred vaccine among all is the covishield (81.35%) over Covaxin (16.38%). Other vaccines such as Moderna, Pfizer and Sputnik did not contribute significantly to the study.

The main two factors considered during the selection of vaccination by the healthcare workers are cost effectiveness (83.51%) and restrictions on international travel across countries (83.48%).

The other factors which were considered are availability (82.67%) and influence of social media (81.9%) influencing the choice of vaccines.

EFFECT OF VACCINATION

Initial investigation on the data collected from the questionnaire provided a great insight on the post vaccination effect. The various factors considered for the study were grouped into two categories namely Type -I and Type -II. Type -I comprises factors such as Fever, Headache and body pain which had adverse effects on the population, while Type- II - namely pain at site of injection, redness/swelling at site of injection, vomiting, nausea, dizziness and others has mild or moderate effects.

Table 4. Gender wise side effects of vaccines

Sex	Type 1 factors (fever, headache, body pain)	Type 2 factors (pain at the site, redness, swelling, vomiting, nausea and others)
Female	77.6%	41.1%
Male	74%	37%

Table 4 gives us the details regarding the effects of vaccination for each gender. Females reported higher incidence of Type 1 factors (77.6%) followed by males (74%). Same trend was observed for type 2 factors as well, females (41.1%) and males (37%).

Volume 5, Issue 2; March-April 2022; Page No 199-212

Table 5. Percentage of Type-I factors on the population classified based on the gender and age group

Sex	Age	Not Reported	Mild	Moderate	Severe	Very severe
Female	**18 to 25**	18.24%	20.42%	26.00%	22.25%	13.09%
	26 t0 35	35.51%	18.12%	25.36%	13.77%	7.25%
	36 to 50	38.10%	25.00%	26.19%	7.14%	3.57%
	51 to 65	36.81%	24.31%	29.17%	7.87%	1.85%
	65 and above	66.67%	--	33.33%	--	--
Total		22.14%	20.41%	26.14%	19.85%	11.46%
Male	**18 to 25**	21.81%	17.90%	31.07%	22.02%	7.20%
	26 t0 35	41.67%	20.83%	20.83%	10.42%	6.25%
	36 to 50	54.17%	16.67%	29.17%	---	---
	51 to 65	50.00%	33.33%	--	16.67%	---
	65 and above	66.67%	33.33%	---	---	---
Total		25.61%	18.42%	29.47%	19.82%	6.67%

Table 5 gives us the percentage of Type-1 factors (fever, headache, body pain) on the population classified based on the gender and age group.

It is clear that participants of the age group 18 to 25, suffered from fever of different degrees and headache due to vaccination, while the older group participants did not report high temperature or fever. Within the age group of 18 to 25, it was found that the female participants (33%) were found to be most affected (severe and very severe), when compared to male participants (28.8%).

Young Female population tend to react more to the vaccination when compared to the young adult males. While the overall side effect on the elders is significantly less.

Volume 5, Issue 2; March-April 2022; Page No 199-212

Table 6. Percentage of Type-II factors on the population classified based on the gender and age group

Sex	Age	Not Reported	Mild	Moderate	Severe	Very severe
Female	18 to 25	55.80%	22.44%	11.22%	6.58%	3.96%
	26 t0 35	68.94%	14.29%	13.67%	1.24%	1.86%
	36 to 50	83.67%	7.14%	7.14%	2.04%	--
	51 to 65	54.17%	24.20%	18.25%	1.79%	1.59%
	65 and above	78.57%	7.14%	14.29%	--	---
Total		58.82%	20.69%	11.50%	5.57%	3.42%
Male	18 to 25	59.61%	17.81%	13.23%	6.52%	2.82%
	26 t0 35	82.14%	7.14%	8.93%	1.79%	0.00%
	36 to 50	78.57%	17.86%	3.57%	--	---
	51 to 65	85.71%	---	---	14.29%	---
	65 and above	85.71%	14.29%	--	--	--
Total		62.86%	16.69%	12.18%	5.87%	2.41%

Likewise, table 6 gives us the percentage of Type 2 factors (pain at the site of injection, redness or swelling at the site, nausea, vomiting, dizziness) the population classified based on gender and age group and they were found to have minimal or no significance on the population.

TIMELINE OF PRESENCE OF SIDE EFFECTS:

The data collected from the survey are grouped and the observations are tabulated.

Table 7. Timeline of onset of the symptoms- side effects for I dose

Timeline	Sex	Age (in years)	Immediate	1 to 2 hours	2 to 6 hours	6 to 12 hours	12 to 24 hours	24 to 48 hours
fever	Female	18 to 25	0.52%	3.14%	22.51%	32.98%	18.85%	5.76%
		26 t0 35	--	13.04	17.39%	34.78%	8.70%	--

Volume 5, Issue 2; March-April 2022; Page No 199-212

				%				
		36 to 50	--	14.29 %	14.29%	14.29%	28.57%	---
	Male	18 to 25	--	4.94%	18.52%	34.57%	22.22%	4.94%
		26 t0 35	--	---	12.50%	25.00%	25.00%	12.50%
		36 to 50	--	--	---	--	25.00%	--
	average		0.52	35.41	85.21	141.62	128.34	23.2
headache	Female	18 to 25	0.52%	8.90%	18.32%	24.61%	13.61%	3.14%
		26 t0 35	--	13.04 %	13.04%	21.74%	4.35%	--
		36 to 50	--	21.43 %	--	14.29%	7.14%	--
	Male	18 to 25	1.23%	4.94%	17.28%	20.99%	14.81%	4.
		26 t0 35	--	--	12.50%	--	--	---
	average		1.75	48.31	61.14	81.63	39.91	8.08
Fatigue & body pain	Female	18 to 25	1.57%	7.85%	23.56%	25.13%	17.80%	9.
		26 t0 35	4.35%	13.04 %	13.04%	30.43%	13.04%	---
		36 to 50	---	21.43 %	14.29%	7.14%	28.57%	---
	Male	18 to 25	---	8.64%	12.35%	22.22%	23.46%	1
		26 t0 35	---	---	25.00%	25.00%	25.00%	12.50%
		36 to 50	---	---	---	50.00%	50.00%	---
	average		5.92	41.96	88.24	159.92	157.87	34.8
Joint pain	Female	18 to 25	4.19%	7.33%	8.90%	17.28%	13.09%	4.19

Volume 5, Issue 2; March-April 2022; Page No 199-212

		26 t0 35	4.35%	4.35%	8.70%	13.04%	4.35%	---
	Male	18 to 25	--	6.17%	6.17%	18.52%	14.81%	6.17%
		26 t0 35	---	---	12.50%	12.50%	--	---
	average		8.54	17.85	36.27	61.34	32.25	10.36
Muscle pain	Female	18 to 25	2.09%	13.61 %	17.80%	18.32%	16.75%	
		26 t0 35	4.35%	17.39 %	17.39%	26.09%	4.35%	
	Male	18 to 25	---	9.88%	11.11%	27.16%	18.52%	6.17%
		26 t0 35	---	---	12.50%	12.50%	12.50%	25.00%
	average		6.44	40.88	58.8	84.07	52.12	38.5
Pain at site of injection	Female	18 to 25	13.61%	20.94 %	18.85%	15.71%	10.47%	1
		26 t0 35	13.04%	21.74 %	26.09%	8.70%	8.70%	4.35%
	Male	18 to 25	12.35%	16.05 %	18.52%	20.99%	9.88%	14.81%
		26 t0 35	12.50%	12.50 %	25.00%	12.50%	---	---
	average		51.50	71.23	88.46	57.9	29.05	32.77

Very few subjects have reported immediate side effects of the vaccination as fever, headache, fatigue/body pain etc.

Nearly 13% of the subjects reported immediate pain at the site of injection. This could be accounted for by the improper procedure followed during the injection.

About 20% of the subjects developed fever in the time interval of 6-12 hours.

Volume 5, Issue 2; March-April 2022; Page No 199-212

Duration of the Prevalence of the symptoms

Table 8. Onset interval of symptoms

	Sex	Age	2 to 6 hours	6 to 12 hours	12 to 18 hours	18 to 24 hours	24 to 48 hours	48 to 36 hours
Fever	Female	18 to 25	9.42%	13.09%	14.66%	18.85%	23.56%	4.19%
		26 t0 35	8.70%	30.43%	4.35%	13.04%	17.39%	4.35%
		36 to 50		21.43%	7.14%	21.43%	21.43%	
	Male	18 to 25	11.11%	12.35%	20.99%	19.75%	14.81%	4.94%
		26 t0 35		22.22%	25.00%	25.00%	12.50%	12.50%
		36 to 50		25.00%				
	average		9.74	20.75	72.14	98.07	89.69	26
Headache	Female	18 to 25	13.09%	14.14%	13.61%	15.18%	12.57%	3.14%
		26 t0 35		17.39%	4.35%	8.70%	13.04%	4.35%
		36 to 50		14.29%	7.14%	14.29%	7.14%	
	Male	18 to 25	13.58%	11.11%	12.35%	9.88%	11.11%	2.47%
		26 t0 35				12.50%		
		36 to 50		25.00%				
	average		26.67	81.93	37.45	60.55	43.86	9.96
Pain at site of injection	Female	18 to 25	5.76%	11.52%	8.90%	11.52%	30.89%	21.99%
		26 t0 35	8.70%	8.70%	4.35%	4.35%	43.48%	8.70%
		36 to 50		21.43%		28.57%	50.00%	
	Male	18 to 25	11.11%	11.11%	11.11%	14.81%	27.16%	17.28%
		26 t0 35		12.50%		12.50%	12.50%	12.50%
		36 to 50	25.00%		25.00%		50.00%	
	average		50.57	65.26	49.36	71.75	214.03	60.47
Fatigue and body pain	Female	18 to 25	10.47%	12.04%	10.47%	16.75%	22.51%	11.52%
		26 t0 35	4.35%	17.39%	8.70%	8.70%	30.43%	4.35%
		36 to 50		14.29%	7.14%	21.43%	28.57%	

Volume 5, Issue 2; March-April 2022; Page No 199-212

	Male	18 to 25	9.88%	6.17%	14.81%	12.35%	27.16%	4.94%
		26 t0 35			12.50%	25.00%	37.50%	12.50%
		36 to 50		25.00%	25.00%		50.00%	
	average		24.7	74.89	78.62	84.23	245.67	33.31
Muscle pain	Female	18 to 25	8.38%	8.38%	11.52%	14.66%	19.90%	7.33%
		26 t0 35		13.04%	8.70%	17.39%	17.39%	4.35%
		36 to 50	7.14%	7.14%			21.43%	
	Male	18 to 25	7.41%	6.17%	12.35%	14.81%	23.46%	4.94%
		26 t0 35			12.50%	12.50%	25.00%	12.50%
		36 to 50						
	average		22.93	34.73	45.07	59.36	107.18	29.12
Joint pain	Female	18 to 25	7.85%	6.81%	7.85%	9.42%	17.28%	6.81%
		26 t0 35		8.70%		8.70%	8.70%	
		36 to 50					14.29%	
	Male	18 to 25	3.70%	8.64%	7.41%	13.58%	12.35%	4.94%
		26 t0 35			12.50%		12.50%	
		36 to 50						
	average		11.55	24.15	27.76	31.7	65.12	11.75

The above table provides an insight to the duration of the persistence of the symptoms experienced by the subjects reported for investigation.

A closer observation of the structured information provides the following insight aged subjects experiencing these symptoms under study was significantly very low.

Majority of the subjects reported fever, headache and muscle pain started ranging from 6 to 12hrs, while fatigue, pain at site of injection and joint pain ranges from 24 to 48 hours

Volume 5, Issue 2; March-April 2022; Page No 199-212

REMEDIAL ACTION

Table 9. Remedial actions to overcome the side effects

SEX	AGE	Emeset, pantoprazole	Antiallergic medications	Home remedies	None	Paracetamol	remedies, visited doctor for help, Hospitalized	Paracetamol, None	Paracetamol, Visited doctor for help	Paracetamol, Visited doctor for help, Antibiotics	Grand Total
Female	18 to 25	2			23	161	2	2	1		191
	26 t0 35		1		4	17					23
	36 to 50			1	5	8					14
	51 to 65				4	5					9
	65 & above				1	1					2
Male	18 to 25			1	17	61	1			1	81
	26 t0 35				5	3					8
	36 to 50					4					4
	51 to 65				1						1
	65 & above				1						1

More than 70% of the subject did not undergo any treatment, they treated themselves with paracetamol(more than 70%). No hospitalization was reported

II stage vaccination

The vaccine administered at the second stage was the same as that of the first.

Table 10. Consolidated effect of the second dose

Did you feel any side effects after SECOND DOSE OF VACCINATION?				
SEX	***AGE(in years)***	**No**	**Yes**	**Grand Total**
Female	18 to 25	72.99%	27.01%	100.00%
	26 t0 35	72.97%	27.03%	100.00%

Volume 5, Issue 2; March-April 2022; Page No 199-212

	36 to 50	73.33%	26.67%	100.00%
	51 to 65	57.89%	42.11%	100.00%
	65 and above	50.00%	50.00%	100.00%
Female Total		71.76%	28.24%	100.00%
Male	18 to 25	83.53%	16.47%	100.00%
	26 t0 35	95.00%	5.00%	100.00%
	36 to 50	100.00%		100.00%
	51 to 65	100.00%		100.00%
	65 and above	100.00%		100.00%
Male Total		89.05%	10.95%	100.00%

From the above data, 80.40% of the subjects under study did not have any adverse side effects due to second vaccination. Very few had reported mild to severe rise in temperature, body pain, fatigue and muscular pain, when compared to the stage one vaccination.

It is also evident that females reported more side effects (28.24%) than the males (10.95%). It is also remarkable to mention that the female above the age of 65 years had reported in significant percentage (50%).Second dose of the vaccination has minimal to very low side effects when compared to the first dose on the subjects.

DISCUSSION

A highly potent and effective vaccine has the ability to mitigate the serious sequel of covid 19 infection in humans. However, this comes along with some unfavorable side effects of vaccination with additional studies conducted [(9)] which question the acceptance among people and eventually tapering the drive for vaccination. The reported side effects are however mild and treatable under proper supervision with very few cases requiring intensive care and approach. In a study conducted by Wu Q et al, it was suggested that the available evidence indicates that eligible COVID-19 vaccines have an acceptable short-term safety profile[(3).]

The most common side effects encountered were fever, body pain, pain at the site of injection and head ache. Other side effects like nausea, vomiting, arthralgia, myalgia, anaphylaxis were less commonly reported [(10).]

Majority of the side effects reported were mild to moderate in nature which resolved over a few days' post vaccination. This finding was similar to a study done by Kaplan RM et al in which Expected benefit was more influential in respondents' decision making than expected side effects[(4)]. No serious events requiring hospitalization was reported

The side effects were reported higher among the younger population comprising females on a large scale than males. The incidence and severity of side effects declined as the age advanced.

CONCLUSION

From our study, it is evident that the benefits of the vaccination outweigh the risks significantly. This has to be propagated to the public so that the fear of AEFI is reduced and more people volunteer for vaccination. The healthcare system must be equipped and alert with all facilities for tackling any serious AEFI outbreak in the community.

ACKNOWLEDGEMENT

I would like to acknowledge and give my warmest thanks and gratitude to my guide Dr. M. Saravana Kumar who helped me undertake this research and furnish this report with all his guidance and constant support, my statistician Dr.N. Rajam Ramasamy for

Volume 5, Issue 2; March-April 2022; Page No 199-212

helping us with most accurate and elaborate data regarding the study and helped us interpret the results wisely.

Last but not the least I would like to thank all the respondents and participants who contributed their valuable time for this study.

REFERENCES

1) Meher BR. Vaccine pharmacovigilance in India: Current context and future perspective. Indian J Pharmacol. 2019;51(4):243-247. doi:10.4103/ijp.IJP_53_19

2) Jeon M, Kim J, Oh CE, Lee JY. Adverse Events Following Immunization Associated with Coronavirus Disease 2019 Vaccination Reported in the Mobile Vaccine Adverse Events Reporting System. J Korean Med Sci. 2021;36(17):e114. Published 2021 May 3. doi:10.3346/jkms.2021.36.e114

3) Wu Q, Dudley MZ, Chen X, Bai X, Dong K, Zhuang T, Salmon D, Yu H. Evaluation of the safety profile of COVID-19 vaccines: a rapid review. BMC medicine. 2021 Dec;19(1):1-6.

4) Kaplan RM, Milstein A. Influence of a COVID-19 vaccine's effectiveness and safety profile on vaccination acceptance. ProcNatlAcadSci U S A. 2021 Mar 9; 118(10): e2021726118. doi: 10.1073/pnas.2021726118. PMID: 33619178; PMCID: PMC7958192.

5) John C. Watson JC, LeBaron CW, Hutchins SS, Hadler SC, Williams WW. CDC General Recommendations on Immunization Recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR. January 28, 1994 / 43(RR01);1-38

6) Definition and Application of Terms for Vaccine Pharmacovigilance. Report of CIOMS/WHO Working Group on Pharmacovigilance. Council for International Organizations of Medical Sciences (CIOMS) 2012

7) National Quality Assurance Standards for AEFI Surveillance Program. Ministry of Health & Family Welfare Government of India (2016).

8) World Health Organization. WHO Coronavirus (COVID-19) Dashboard. 2022

9) Voysey M, Clemens SAC, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK [published correction appears in Lancet. 2021 Jan 9;397(10269):98]. Lancet. 2021;397(10269):99-111. doi:10.1016/ S0140-6736 (20)32661-1

10) CDC COVID-19 Response Team and Food and Drug Administration. "Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021." MMWR. Morbidity and mortality weekly report vol. 70,4 125-129. 29 Jan. 2021, doi:10.15585/mmwr.mm7004e1

Volume 5, Issue 2; March-April 2022; Page No 199-212