ISSN No:-2456-2165

Surveillance Study of Adverse Events Following COVID-19 Vaccination in Enugu State, Nigeria

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Abstract:-

Background:Vaccination against COVID-19 virus is essential to curb the spread of the virus. Understanding the nature of adverse events following COVID-19 vaccination will help to improve vaccine reduce spread , and promote vaccine safety.

Objective:This study evaluated the adverse events following vaccination with the different types of COVID-19 vaccines, as well as people's response to such events.

Method:A cross-sectional online survey of persons aged 18 years and above who received at least, one dose of a COVID-19 vaccinae in Enugu state, Nigeria was conducted by convenient sampling method. Data was analysed using SPSS version 25 to determine the prevalence, characteristics, and predictors of adverse events following COVID-19 vaccination.

Result:A total of 657 respondents (mean age of 34.9 ± 13 years)completed the survey. Adverse events following immunization (AEFI) was reported by 29.4% of the respondents, mostly (96.3%) experienced after receiving their first dose. Muscle pain, headache, and fever were, respectively, the most frequently reported AEFI (33.5%, 22.7%, and 20.2%). Common response by the respondents after experiencing AEFI include taking paracetamol (36.5%), drinking plenty of water (13.5%), and application of wet cloth over the area (6.5%). AEFI were significantly associated with age and education of the respondents (*P*-value: 0.013 and 0.020), while no significant association was established between the type of vaccine received. Respondents between the age of 18 and 49 years were 1.871 more likely to admit having experienced AEFI than aged 50 years and above (95% CI: 1.086 – 3.222). Also, respondents with postgraduate and post-secondary education were 3.568 (95% CI: 1.348 – 9.541) and 2.688 (95% CI: 1.009 – 7.162) times more likely to admit that they have experienced AEFI.

Conclusion:It is necessary to improve active surveillance reporting system for COVID-19 in the state to better promote vaccine safety, management of cases and more effective public health advisory.

Keywords:- *COVID-19, surveillance, epidemiology, public health preparedness.*

I. INTRODUCTION

A. Implications for policy-makers

The data generated from this research could be useful in COVID-19 safety profile characterization and COVID-19 vaccine safety surveillance. Outcome of the research would identify gaps in adverse events reporting system and suggest strategies to improve on it. Further, identifying the events following COVID-19 vaccination would inform further global research on the COVID-19 vaccine safety.

B. Implications for public

Application of surveillance to COVID-19 vaccine will actively accelerate the early detection and rapid response of COVID-19 pandamic. The result from this study could serve as a reference for scientists andscholars in the field of vaccine development and management.

II. BACKGROUND

The spread of Corona Virus Disease 2019 (COVID-19) is on the increase. COVID-19 is caused by severe acute respiratory syndrome coronairus2 (SARS-CoV-2). The first novel case was recorded in China in December 2019. The first COVID-19 cases reported in Nigeria and reported in Enugu State, Nigeria were in February and March 2020 respectively. There have beencontinuous global effort to contain the spread of the SARS-CoV-2. These include surveillance and the manufacturing and distribution of vaccines.

The COVID-19 Vaccines Global Access (COVAX) facility was launched on the 24th February2021 to improve COVID-19 vaccine deliveries to Africa[]. AstraZenca, Mordena, Johnson Johnson, and Pfizer are the four different brands of COVID-19 vaccines available in Enugu. The Oxford–AstraZeneca vaccine was the most used because of its ease ofstorage at a temperaturerangeof +2 to +8 ◦C, however, it have itsadverse events, as observed for other COVID-19 vaccines[10]. There is an ongoing immunization campaign against the SARS-CoV-2 in Enugu. The mass immunization commenced in December, 2021.

Vaccines train immune system to recognize infectious agents likeviruses, create antibodies that protect the body from the virus by recognizing the antigen, then swinging into action to keep the bodyfree from infection by the virus. The body, upon receiving COVID-19 vaccine, is triggered

ISSN No:-2456-2165

into action..the body can recognize the SARS-CoV-2 virus and wingsinto actionbecause the body's immunologicalsystem is set to always recognize foreign and infectious agents, responding through humoral pathways resulting to adverse effect following vaccination[2]. These responses manifest as adverse events following vaccination, in some cases, are called side effects of a medicine. Adverse events following vaccination range from mild to severe depending on the individual. Mild adverse events usually goaway after few days, while severe effect could lead to hospitalization, and in few cases death.Adverse effect following immunization also, varies per vaccine.

Globally, research has shown that adverse events following COVID-19 vaccination are based on type of vaccine[13] However, most common symptoms reported includemuscle and joint pain,fatigue,headache, and chills,allergic skin reaction,while the most reported events include low-grade fever and pain or redness at the site of injection, often felt a fewdays after vaccination. [6-8]Further observations revealed that severe adverse events are possible, but the chances are low. [9]Adverse effect following immunization also, varies per vaccine. Globally, research has shown that adverse events following COVID-19 vaccination are based on type of vaccine[1]

Despite the effort devoted towards the development, and rapid approval ofthe different vaccines, there are low willingness to uptake (or high hesitancy to) COVID-19 vaccines acceptance inNigeria.[5]Furthermore, dearth of information, lack of reporting, and weak surveillance on adverse events following COVID-19 vaccination in Enugu makes it difficult to know the actual rate of occurrence of AEFI in the population.

Although efforts are made to promote safetiness of COVID-19 vaccines, there is still need for active surveillance and public healthresearch communication to improve health literacy for the populace to report adverse events following COVID-19 vaccination to any health facilty, vaccination post or hospital, following the guidelines[3]. Surveillancefor adverse events following vaccination is crucial to ensuring safety, maintaining trust, and guidingpolicy-makers. Therefore this public health study will evaluate the adverse events according to different COVID-19 vaccines administered in Enugu, Nigeria. The study will also evaluate people's response to the surveillance system designed for COVID-19 emergency response in Enugu State.

III. MATERIALS AND METHODS

A. *Study Design and Participants*

A descriptive cross-sectional study was carried out to monitor adverse events following COVID-19 vaccination in persons in Enugu State, Nigeria. An online survey instrument was used to collect data from persons aged 18 years and above, who had received at least one dose of a COVID-19 vaccine.We used convenient sampling method to recruit respondents from vaccination posts.[1]. Inclusion criteriawere being persons in Enugu State, 18 years of age and above, and having receivedany of the COVID-19 vaccines. An initial probable target of ≥250–≤500 respondents was plannedto be recruited. This strategy was selectedbecause it was difficult to get participants willing to respond to the study due to the general apprehension of the populace to COVID-19 vaccines.

B. *Questionnaire*

A semi-structured, multiple-choice questionnaire was designed was designed based on the US CDC classificationof common and uncommon COVID-19 vaccination reactions was used[2]to elicit information aboutrespondents' socio-economic and demographic characteristics, health status, adverse events following vaccination, and how those events were managed.Data was downloaded from the server in Microsoft Excel format and analysed using SPSS to determine the prevalence, characteristics, and predictors of adverse events following COVID-19 vaccination.With the consent of participants, thequestionnaire was administered through telephone interview because of the low response gotten from an online survey.

C. *Ethical Issues/Statement*

This survey data passed the ethical review by the Ethical Review Board of the Ministry of Health, Enugu State, Nigeria. The survey data was conducted according to the standard of the Ethical Review Board.

IV. RESULTS

A. *Sociodemographic Characteristics of the Respondents*

We collected data from 657 respondents with mean age of 34.9 ± 13 years. Majority 562 (85.5%) of the respondents were between 18 and 49 years old, while 14.5 (14.5%) were above 50 years old or higher. More than half of the responents already had post secondary education (36.5% and 33.9% for post-secondary postgraduate degree, respectively), whereas 5.9% have just primary education. Most respondents (35.5%) were unemployed, 2.6% retired, and the rest (3.8%, 31.1% and 27.1%) were artisans, business owners, or employees, respectively. Adverse events following immunization (AEFI) was reported by 29.4% of the respondents, mostly (96.3%) experienced after receiving their first dose (Table 2). Only 25.4% of the respondents have received their second dose of the vaccine.

ISSN No:-2456-2165

Variable	Frequency (N)	Percent (%)
Age Group		
18-49	562	85.5
50 and above	95	14.5
Educational Status		
Post graduate	223	33.9
Post-secondary	240	36.5
Secondary	155	23.6
Primary	39	5.9
Employment Status		
Business	229	34.9
Employed	178	27.1
Retired	17	2.6
Unemployed	233	35.5

Table 1: Sociodemographic Characteristics of Respondents

Mean age = 34.9 ± 13

Variable	Frequency (N)	Percent (%)
Type of Vaccine Received		
Astrazeneca	85	12.9
Moderna	66	10.0
Pfizer	145	22.1
Cannot remember	361	54.9
Received First Dose in Enugu State		
No	8	1.2
Yes	649	98.8
Side Effect		
No	464	70.6
Yes	193	29.4
Which of the doses did you experience side effects?		
Both	4	2.1
First dose	186	96.3
Second dose	3	1.5
Second Dose Status		
Yes	167	25.4
No	303	46.1
Not due for 2nd dose	187	28.5

Table 2: Vaccination characteristics of respondents

ISSN No:-2456-2165

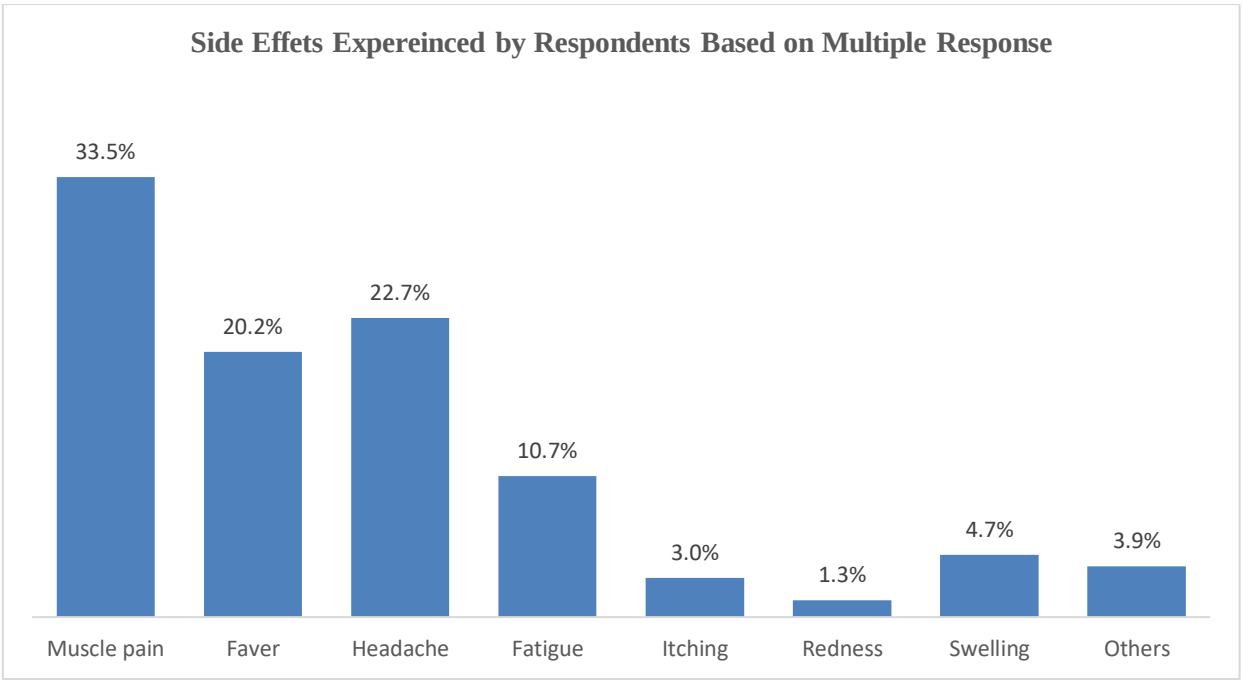

Fig. 1: Side Effects Experienced by Respondents Based on Multiple Response

From the result, muscle pain and headache, and fever were, respectively, the most frequently-reported AEFI (33.5%, 22.7%, and 20.2%), while redness and itching were the least reported at 1.3% and 3.0%, respectively (figure 1). Actions taken by the respondents after experiencing side effects include taking paracetamol (36.5%), drinking plenty of water (13.5%), and application of wet cloth over the area (6.5%) (figure 2). In addition, 3.0% responded to having exercised their arm and dressed lightly at the injection site, whereas 37.5% others either had enough rest or did nothing.

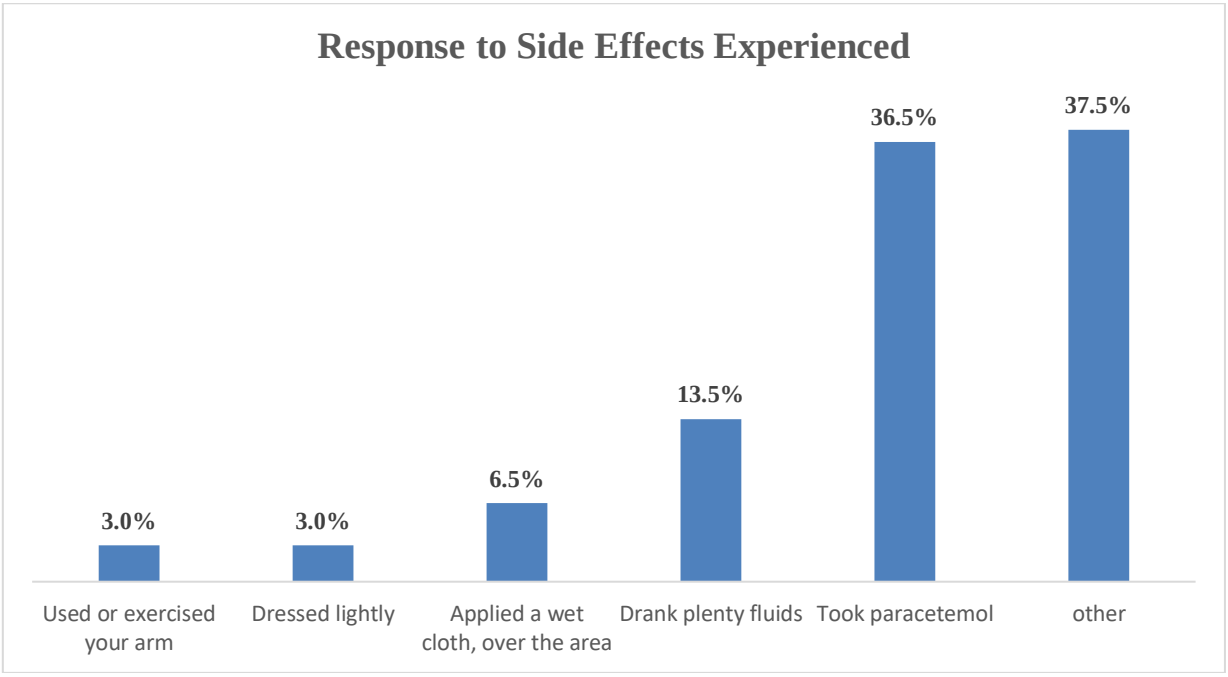

Fig. 2: Response to Side Effects Experienced by Respondents

ISSN No:-2456-2165

Variables	Side Effect		Total	p-value
	No (%)	Yes (%)		
Age Group				
18-49	391(69.6)	171(30.4)	562	0.013
50 and above	77(81.1)	18(18.9)	95	
Education Status				
Post graduate	146(65.5)	77(34.5)	223	0.023
Post-secondary	172(71.7)	68(28.3)	240	
Secondary	116(74.8)	39(25.2)	155	
Primary	34(87.2)	5(12.8)	39	
Employment Status				
Artisan	21(84.0)	4(16.0)	25	0.245
Business	154(75.5)	52(24.5)	204	
Employed	122(68.5)	56(31.5)	178	
Retired	12(70.6)	5(29.4)	17	
Unemployed	159(68.2)	74(31.8)	233	
Type of Vaccine				
Astrazeneca	50(58.8)	35(41.2)	85	0.205
Moderna	39(59.1)	27(40.9)	66	
Pfizer	100(69.0	45(31.0)	145	

Table 3: Prevalence and characteristics of Adverse Events Following COVID-19 vaccination

A cross-tabulation analysis showed that reported AEFI were significantly associated with age and education of the respondents, with P-values of 0.013 and 0.020, respectively (Table 3). No significant association was established between the type of vaccine received or employment status. Further binary logistics regression analysis showed that respondents between the age of 18 and 49 were 1.871 more likely to admit to have experienced AEFI than aged 50 years and above (95% CI: 1.086 – 3.222) (Table 4). Also, respondents with post graduate and post secondary education were 3.568 (95% CI: 1.348 – 9.541) and 2.688 (95% CI: 1.009 – 7.162) times more likely to admit that they have experienced AEFI.

	Exp (B)	95% C.I. for EXP (B)		*P*-value
		Lower	Upper	
Age group				
Age group (18 – 49 years)*	1.871	1.086	3.222	0.024
Age group 50 years and above	0			
Education				
Post graduate*	3.586	1.348	9.541	0.011
Post secondary*	2.688	1.009	7.162	0.048
Secondary	2.286	0.836	6.255	0.107
Primary	0			

Table 4: Logistics regression analysis of the relationship between respondents' admittance to AEFI and age and education

V. DISCUSSION

This is a report of adverse events following COVID-19 vaccination among people vaccinated with COVID-19 vaccines available in Enugu State, Nigeria. It also detailed how adverse events were treated by the study participants(Figure 1). The major strengths of this research include the fact that it examined the surveillance for adverse events following vaccination that is crucial to ensure safety, maintain trust, and guide policy-makers.

Different demographic profiles of respondents vaccinated against COVID-19 were investigated classified in two major agae groups; 18-49 years and 50years and above (Table 1). We observed a decrease in the vaccinated population as age increases. The number of population vaccinate are more between ages 18-4 years. This trend agreed with previous work reported that more vaccinated population were between ages 18 to 49 years [6,13]. Further, respondents between the ages 18 and 49 were willing to discuss the adverse events following vaccination of COVID-19 (Table 4).

The data from this study show that most AEFI reported from the respondents were minor cases following COVID-19 vaccination (Fig. 1). Although, muscle pain was reported as one of the events, it may be classified as serious events because according to WHO definition that an adverse events following vaccination is considered serious if it is life-threatening, results in hospitalisation or disability/incapacity, or leads to fatality. All of the events were reported to go away after self cares (Fig. 2).

Further, we evaluated the data based on vaccine types. Result indicates that a higher number of respondents that reported events took Astrazeneca, followed by Moderna, and the least from Pfizer. Our study is subjected to some limitations. For one,the perceived misconception of COVID-19 vaccination among the populace[2]caused unwillingness of the respondents to complete the questionnaire resulted in low participation.

VI. CONCLUSION

The focus of vaccine safety surveillance is to facilitate early detection, investigation and analysis of adverse events following immunization (AEFIs) and to ensure an appropriate and rapid response. We hereby report adverse events following COVID-19 vaccination in Enugu, Nigeria. The most reported AEFI was muscle pain. Other events reported are headache,fever, and itching. The least event reported was redness.

Perhaps, strategies that will improve frequency and timely reporting of advance event following COVID-19 vaccination on the existing AEFI reporting platform would improve active surveillance of incidence, thus would make an effective public health preparedness and rapid response for COVID-19 pandemic.

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