

Research Article

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Adverse Events Following Immunization with Covid-19 Vaccines: Results from the State Registry and Surveillance System in Rivers State, Nigeria

Chidinma N Eze-Emiri^{1,2*}, Golden C Owghonda¹, Foster A Patrick^{1,2}, Victor Abiikor¹ and Ifeoma Nwadiuto¹

¹Department of Public Health & Disease Control, Rivers State Ministry of Health, Port Harcourt, Rivers State, Nigeria

²Department of Epidemiology, School of Public Health, University of Port Harcourt, Rivers State, Nigeria

ABSTRACT

Introduction: The manufacture of COVID-19 vaccines was a response to the COVID-19 public health emergency. Four of the WHO approved COVID-19 vaccines were available and administered in Nigeria. Side effects may manifest physically post-vaccination and are part of a normal immune response; they are usually mild and fleeting. Common side effects of the COVID-19 vaccines include fever, pain at the injection site, headache, and fatigue; allergic reactions may also occur. Some severe side effects also reported include myocarditis and Bell's palsy. This study aimed to describe the adverse events occurring after COVID-19 vaccination, as reported by the Adverse Event Following Immunization (AEFI) surveillance system in Rivers State.

Methods: A retrospective study describing all reported cases of adverse events post-COVID-19 vaccination in Rivers State. Data were collated from the Rivers State registry and AEFI surveillance system between March 18, 2021, and January 31, 2022. AEFI severity was classified as mild, moderate, and serious. The outcomes of interest were categorised as recovered, death, and disability.

Results: The total number vaccinated in Rivers State as of 31 January 2022, was 548,383 and total persons reporting an AEFI was 1042. There were ten hospitalisations, and zero deaths recorded. Fever was the most reported adverse event – 57% of the cohort; and the Oxford-AstraZeneca vaccine was administered to 78.3% of the reporting population. The reporting rate for total doses received was nineteen cases per 10,000 doses administered; and the reporting rate for serious reactions was 18 cases per 1,000,000 doses administered. The proportion between males and females reporting an AEFI was significantly different.

Conclusion: The COVID-19 vaccines were safe in the study population as there were no major safety concerns identified and the benefits inherently outweighed the risk.

*Corresponding author

Chidinma N Eze-Emiri, Department of Public Health & Disease Control, Rivers State Ministry of Health, Port Harcourt, Rivers State, Nigeria.

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Introduction

Vaccination is one of the most successful public health interventions and constitute a cost-effective strategy to reduce both the morbidity and mortality associated with infectious diseases [1]. The severity of the COVID-19 disease and its resultant public health emergency pre-empted the urgency for COVID-19 vaccine production. Although there are currently over 30 COVID-19 vaccines manufactured and authorized for use globally, only ten are authorized by the and four out of the ten – the Oxford–AstraZeneca, Moderna, Johnson & Johnson's Janssen, and Pfizer-BioNTech COVID-19 vaccines-are currently available in Nigeria [2-4].

The Pfizer-BioNTech and Moderna COVID-19 vaccines are messenger RNA (mRNA) vaccines that initiates the production

of a spike protein when introduced into the body cells. The presence of the spike protein on the cells' surface triggers an immune response; thereby, building an immune memory against the virus. Oxford-AstraZeneca and Johnson & Johnson's Janssen are viral vector vaccines that contain a safe, modified version of the virus – known as 'the viral vector' – to deliver genetic code for the antigen. When administered, our cells use the genetic material to produce a specific viral protein, which is recognised by our immune system and triggers an immune response [5].

Vaccines help the body build immunity by imitating an infection; thereby, causing the immune system to produce T-lymphocytes and antibodies. By reason of a host's immune response to vaccine antigens, vaccines may cause side effects as with all medications and may manifest physically as symptoms such as fever or pain or redness at the injection site; these symptoms are usually mild and short-termed [6]. Side effects typically associated with COVID-19 vaccines are mild to moderate in

severity and usually resolved within a few days of vaccination. Common reported side effects included pain at the injection site, fever, fatigue, headache, muscle pain, chills and diarrhoea; other less common side effects included severe allergic reactions such as anaphylaxis [7,8]. Other rare adverse health outcome have been reported; some are Thrombosis with Thrombocytopenia Syndrome and Bell's Palsy, Myocarditis, and Guillain-Barré Syndrome [9-11]. Although there have also been reports of deaths following COVID-19 vaccination, there is no current evidence supporting a causal link [7,12,13].

Nigeria received its first shipment of COVID-19 vaccine -the Oxford–AstraZeneca- on the 2nd of March 2020; likewise, also made available later in the year were doses of the Moderna, Janssen and Pfizer-BioNTech COVID-19 vaccines. By the end of January 2022, 20.4 million vaccine doses had been administered in Nigeria; indicating that 6% of the target population had been fully vaccinated [14]. The COVID-19 vaccination campaign program in Nigeria began on 5 March 2021; and it was rolled out in four phases: Phase 1: Health workers and supporting staff, frontline workers, and first responders; Phase 2: Priority persons 1 and 2: Persons aged 60 years and above, and Persons aged 50-59 years respectively; Phase 3: Persons aged 18-49 years with co-morbidities; Phase 4: The rest of the eligible population aged 18-49 years [15]. The flag-off ceremony to roll-out COVID-19 vaccination program in Rivers State was held on 18 March 2020.

The aim of this study was to provide an update on the adverse events occurring after COVID-19 vaccination, as reported by the Adverse Event Following Immunization (AEFI) surveillance system in Rivers State.

Methods

Study Design and Population

This is a population-level retrospective study describing all reported cases of adverse events post-COVID-19 vaccination in Rivers State. Data were obtained from the Rivers State registry and AEFI surveillance system between March 18, 2021, and January 31, 2022. In accordance with the vaccination program, persons eligible to receive a COVID-19 vaccine in Nigeria were adults aged 18 years and above.

Assessment of Severity and Reactions

AEFIs are classified depending on their severity as proposed by the guidelines for surveillance of adverse events following immunization [16]. Severity is used to describe the intensity of a specific event and is categorised as mild, moderate, or severe: mild severity were non-serious events with no intervention necessary; moderate severity were non-serious events with medication given or physician visits; and severe were serious events with any untoward medical occurrence that resulted in either death, hospitalization, persistent or significant disability/incapacity, or a life-threatening event. AEFI reactions were grouped into two types –local and systemic reactions. Local reactions were reactions that occurred around the point of vaccination; systemic reactions were reactions that occurred in any other organs of the body, they were further classified to four types –neurologic, allergic, gastrointestinal, and non-specific [16,17].

Outcome

Serious AEFIs were the outcome of interest; they were noted and categorized as 'recovered', 'disability,' and 'death.'

Data Analysis

Microsoft Excel 365 was used for data collation and visualization [18]. Analysis was conducted using SPSS program for descriptive statistics and reporting rates. Data summaries were reported using both measures of central tendencies and dispersion for continuous variables; categorical variables were expressed as counts and percentages [19]. Reaction types were categorised for each brand of COVID-19 vaccine by age and sex. Reporting rates of AEFI were per 10,000 doses administered; they were analysed by both number of doses received and reaction severity categories.

Results

Patient Characteristics

The total number of persons vaccinated in Rivers State was 548,383 on the 31st of January 2022, and 1042 persons reported at least one AEFI; [Figure 1] shows a detailed summary of vaccination doses received.

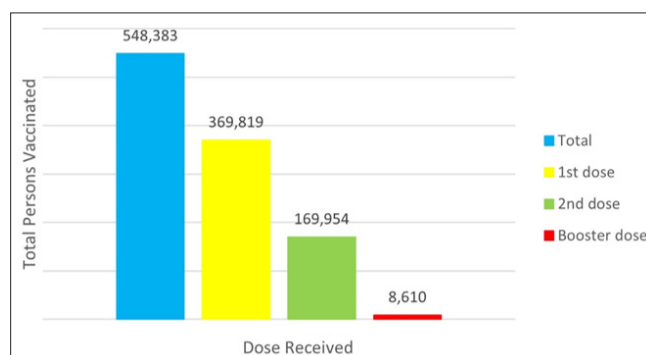


Figure 1: Rivers State Vaccination Summary -January 31, 2020

The average age of AEFI cases was 41.51 ± 13.0 years with a range of 18 to 92 years.

The age distribution of AEFI cases was depicted using a histogram in [Figure 2].

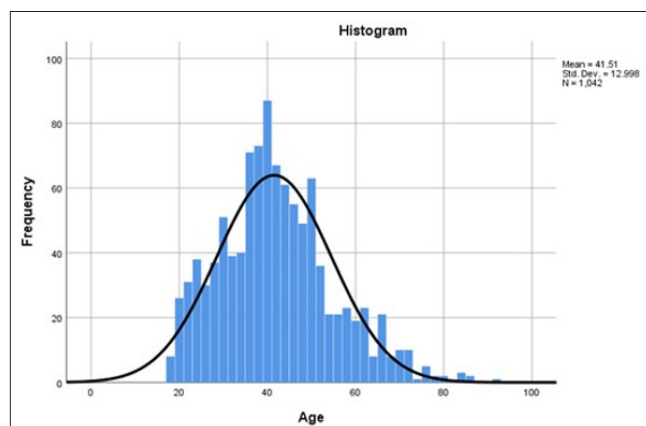


Figure 2: Age Distribution of AEFI Cases

The proportion of males among reported AEFI cases was 57%; 80.9% of reported AEFIs were among recipients of their first dose, and 65.5% of reported AEFIs were categorized as moderate. The average time between vaccination and onset of AEFI was 12.6 hours. Ten persons (1%) were hospitalized, an indication of a serious AEFI; but no deaths were recorded. Three cases (0.3%) reported having a history of allergies. [Table 1] summarizes the characteristics of cases reporting an AEFI.

Table 1: Summary of Patient Characteristics of AEFI cases

Variable	n (%)		
	Total	Male	Female
Sex	1042 (100)	594 (57.0)	448 (43.0)
Age			
Mean $\pm$ SD	41.51 $\pm$ 13.0	42.18 $\pm$ 13.31	40.63 $\pm$ 12.54
Median (IQR)	40 (18 - 92)	40 (18 - 86)	40 (18 - 92)
COVID-19 Vaccine			
Oxford AstraZeneca	816 (78.3)	466 (78.5)	350 (78.1)
Moderna	219 (21.0)	127 (21.4)	92 (20.5)
Pfizer	1 (0.1)	0 (0.0)	1 (0.2)
Unspecified (Incomplete Data)	6 (0.6)	1 (0.2)	5 (1.1)
Dose Received			
First	843 (80.9)	476 (80.1)	367 (81.9)
Second	178 (17.1)	109 (18.4)	69 (15.4)
Booster	1 (0.1)	0 (0.0)	1 (0.2)
Missing Data	20 (1.9)	9 (1.5)	11 (2.5)
Reaction severity			
Mild	345 (33.1)	196 (33.0)	149 (33.3)
Moderate	683 (65.5)	392 (66.0)	291 (65.0)
Severe Cases	10 (1)	4 (0.7)	6 (1.3)
Life threatening	0 (0.0)	0 (0.0)	0 (0.0)
Disability	0 (0.0)	0 (0.0)	0 (0.0)
Hospitalization	10 (1)	4 (0.7)	6 (1.3)
Congenital anomaly	0 (0.0)	0 (0.0)	0 (0.0)
Unspecified (Incomplete Data)	4 (0.4)	2 (0.3)	2 (0.4)
Medical History (Allergy Presentation)			
Yes	3 (0.3)	2 (0.3)	1(0.2)
Mean Interval between Vaccination and Onset of Adverse Event (Hours)*	12.6	12.9	12.2
Outcome			
Recovered	1042 (100)	594 (100.0)	448 (100.0)
Disability	0 (0.0)	0 (0.0)	0 (0.0)
Death	0 (0.0)	0 (0.0)	0 (0.0)

*Total (n) = 887, Male (n) = 511, Female (n) = 376

The results of significance testing for differences in proportions among sexes are detailed in [Table 2].

Table 2: Test for Difference in Proportions between Males and Females

n	Male	Female	p-value, 95% CI
1042	594	448	<0.00000; 0.0966 - 0.1836

The classification of the adverse events according to reaction type and their respective proportions are described in [Table 3]. Fever was the most reported adverse event, occurring in 53% of the population; other frequently reported adverse events were headache, body pain and pain at the injection site. Non-specific systemic reactions were the most reported reaction type; the proportions among persons who received the Oxford-AstraZeneca and Moderna vaccine were 89.7% and 84.5% respectively.

Table 3: Adverse events following immunization of COVID-19

Reaction Type	n (%)		
	Total	Male	Female
Local reactions			
Pain at Injection Site	142 (13.5)	87 (14.4)	55 (12.2)
Undefined Local Reaction	15 (1.4)	8 (1.3)	7 (1.6)
Site Induration	10 (0.9)	5 (0.8)	5 (1.1)
Abscess at Injection Site	17 (1.6)	9 (1.5)	8 (1.8)
Numbness of arm	3 (0.3)	2 (0.3)	1 (0.2)
Heaviness of arm	9 (0.9)	2 (0.3)	7 (1.6)
Systemic reactions			
Neurologic	0 (0.0)	0 (0.0)	0 (0.0)
Allergic			
Rash/Urticaria	7 (0.7)	5 (0.8)	2 (0.4)
Itching	2 (0.2)	2 (0.3)	0 (0.0)
Low Blood Pressure	1 (0.1)	0 (0.0)	1 (0.2)
Difficulty breathing	4 (0.4)	2 (0.3)	2 (0.4)
Chest Pain	3 (0.3)	2 (0.3)	1 (0.2)
Catarrh	1 (0.1)	1 (0.2)	0 (0.0)
Cough	3 (0.3)	2 (0.3)	1 (0.2)
Gastrointestinal			
Abdominal Cramps	7 (0.7)	3 (0.5)	4 (0.9)
Vomiting	2 (0.2)	1 (0.2)	1 (0.2)
Diarrhoea	2 (0.2)	1 (0.2)	1 (0.2)
Hunger	3 (0.3)	1 (0.2)	2 (0.4)
Nausea	1 (0.1)	0 (0.0)	1 (0.2)
Non-Specific			
Dizziness	32 (3.0)	18 (3.0)	14 (3.1)
Headache	278 (26.4)	160 (26.5)	118 (26.3)
Weakness	40 (3.8)	19 (3.1)	21 (4.7)
Fainting/Syncope	3 (0.3)	1 (0.2)	2 (0.4)
Loss of vision	1 (0.1)	1 (0.2)	0 (0.0)
Lymph Node Enlargement	1 (0.1)	1 (0.2)	0 (0.0)
Body Pain	158 (15)	86 (14.2)	72 (16.0)
Muscle Pain	98 (9.3)	56 (9.3)	42 (9.4)
Joint Pain	43 (4.1)	28 (4.6)	15 (3.3)
Fever	559 (53.1)	305 (50.5)	254 (56.6)
Chills	23 (2.2)	16 (2.7)	7 (1.6)
Insomnia	3 (0.3)	1 (0.2)	2 (0.4)
Malaise	1 (0.1)	0 (0.0)	1 (0.2)
Discomfort / Restlessness	3 (0.3)	1 (0.2)	2 (0.4)
Unconsciousness	1 (0.1)	1 (0.2)	0 (0.0)

[Table 4] categorises reaction type by sex and age for all vaccine brands; with the Oxford-AstraZeneca having the largest proportion of AEFI reported. The reporting rate for AEFIs among all COVID-19 doses administered is 19 cases per 10,000 doses administered and 18 cases per 1,000,000 doses administered for serious cases of AEFI.

Table 4: Reaction Type Among Recipients of the Vaccine

Variables	Local reactions	Systemic reactions			Total
		Allergic	Gastrointestinal	Non-specific	
Oxford-AstraZeneca Vaccine					
Age	44 ± 14.50	44.11 ± 16.95	43.00 ± 10.71	41.21 ± 12.65	41.58 ± 12.86
	(20 -86)	(24 -76)	(33 - 63)	(18 - 84)	(18 -86)
Sex					
Male	78 (16.7)	8 (1.7)	5 (1.1)	408 (87.6)	466 (57.1)
Female	52 (14.9)	1 (0.3)	6 (1.7)	324 (92.6)	350 (42.9)
Total	130 (15.9)	9 (1.1)	11 (1.3)	732 (89.7)	816 (100)
Moderna Vaccine					
Age	42.84 ± 14.08	37.29 ± 13.50	47.00 ± 10.74	40.64 ± 13.52	41.32 ± 13.8
	(19 - 92)	(23 - 56)	(34 - 60)	(18 - 92)	(18-92)
Sex					
Male	28 (22)	3 (2.4)	2 (1.6)	105 (82.7)	127 (58)
Female	27 (29.3)	4 (2.4)	2 (2.2)	80 (87)	92 (42)
Total	55 (25.1)	7 (3.2)	4 (1.8)	185 (84.5)	219 (100)
Pfizer-BioNTech Vaccine					
Age	22	-	-	-	22
Sex					
Male	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Female	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
Total	1 (100)	0 (0)	0 (0)	0 (0)	1 (100)
Unspecified COVID-19 Vaccine					
Age	33	-	-	42 ± 10.46 (32 – 53)	42 ± 10.46 (32 - 53)
Sex					
Male	1 (100)	0 (0)	0 (0)	1 (100)	1 (16.7)
Female	0 (0)	0 (0)	0 (0)	5 (100)	5 (83.3)
Total	1 (100)	0 (0)	0 (0)	6 (100)	6(100)

The highest reports of AEFIs occurred in the first dose with 19 cases reported per 10,000 doses administered; the reporting rates for all vaccination dose scenarios and reaction severity are presented in [Tables 5] respectively.

Table 5: Reporting Rates of Adverse Events

By Number of Doses Received				
Dose received	Total Administered	AEFI Reported	Proportion	Reporting Rate
Total	548,383	1042	0.19%	19 cases per 10,000 doses administered
First	369,819	843	0.23%	23 cases per 10,000 doses administered
Second	169,954	178	0.10%	10 cases per 10,000 doses administered
Booster	8,610	1	0.01%	1 case per 10,000 doses administered
By Reaction Severity				
Reaction Severity	Total Administered	AEFI Reported	Proportion	Reporting Rate
Mild	548,383	345	0.06%	6 cases per 10,000 doses administered
Moderate	548,383	683	0.12%	12 cases per 10,000 doses administered
Serious	548,383	10	0.002%	18 cases per 1,000,000 doses administered

Discussion

This study reported on the surveillance of adverse events following COVID-19 immunization. COVID-19 vaccines were available for only adults in our study setting; adverse events were reported mostly among males and the middle aged -roughly between 35 years and 55 years old. Males reporting more AEFIs may be suggestive of more vaccine uptake among males as various studies inherently associated the male sex with an increased willingness for COVID-19 vaccine uptake; there was also a significant difference in proportions between males and females reporting an AEFI in our study, ($p < 0.0000$) [20-22]. The Oxford-AstraZeneca was the frequently reported vaccine; reason may be because for a period of about six months, it was the only available vaccine in the State and country at large [23,24]. Majority of AEFI cases were classed as moderate –65% because some form of treatment was administered after diagnosis of event. There were only ten cases (1%) that met the serious AEFI definition and required hospitalisation; also, no deaths were recorded. Evidence demonstrated that fever, headache, and pain at injection site are among the most reported symptoms, and results from this study coincides with this evidence [24,26]. Non-specific systemic reactions were the most reported reaction types, followed by local reactions; there was also no report of any neurologic reactions. Most adverse events reported were in persons who received the first dose. The reporting rates reduced drastically in subsequent doses; from twenty-three reports to one report per 10,000 doses administered for the first dose to booster dose, respectively; it aligns with evidence from the vaccine safety reports stating a reduction in post-vaccination reactions following succeeding doses of the COVID-19 vaccines [27]. The reporting rate of eighteen serious cases per one million doses administered, in addition to a 100% recovery and no recorded death, also emphasises the safety of the vaccines; this rate was similar to reports from other nations [28,29].

The use of register-based data obtained over an extended period is a strength for this epidemiologic study, as it reduces the chance of bias. The availability of administered doses and standardised reporting using the WHO surveillance guidelines also improved the data utilised in this study. As a limitation to the study, information on both prior COVID-19 infection and pre-existing co-morbidities were not available; these may have been potential confounders. A test for association with these variables would have better informed the study. It was also not feasible to determine causal relationship between AEFIs and vaccines in individual reports. Although inconsistencies in data entry made it impossible to give timing of event onset in all participants, the utilisation of population data in this study serves as an advantage as it is representative of study population.

The findings of this study is added evidence to the safety of the COVID-19 vaccines and an informative tool to increase willingness for COVID-19 vaccine uptake in the region and country at large. This study serves as a baseline for further analyses of this ongoing surveillance in the future; and its limitations provide focus areas for improvement of the surveillance and reporting tools. The collection of more detailed individual clinical data would also improve the quality of the current surveillance data and provide needed information to assess causal associations.

An in-depth investigation into serious AEFIs and its clinical management are areas to be explored in future research; active case findings and potential research of possible neurological

reactions that may have been not reported would also be beneficial.

Conclusion

The study identified no serious AEFIs; therefore, it highlights the safety of the COVID-19 vaccines. This supports existing evidence indicating that the benefits of COVID-19 vaccines continue to outweigh the risks of the disease.

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Conflict of Interest

The authors have declared no competing interest.

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Data Availability Statement

Data are available upon reasonable request from the Rivers State Ministry of Health.

Authors' Contributions

EEC: Conceptualization, Methodology, Data Collation and Analysis, Writing—Original Draft Preparation and Review. OGC: Writing—Review and Editing, Supervision. PFA: Writing— Review and Editing. NI: Writing— Original Draft Preparation and Review, Data Collation, Supervision. All authors read and gave final approval of the manuscript version submitted for publication.

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