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Adverse Events Following COVID-19 Vaccination in Anambra State, South East Nigeria

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Authors' contributions

This work was carried out in collaboration among all authors. Authors ALO and ECE conceptualized and designed the study. Author NBO reviewed the framework of the study. Authors ECE, ESI, UCM and OID were involved in data collection and analysis. All authors were involved in the writing and revision of the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

The use of safe and effective vaccination is critical to control of pandemics. Vaccines remain the bedrock in management of infectious diseases outbreaks. There has always been hesitancy to vaccination due to the fear of adverse events. It is therefore necessary that post vaccination adverse events be studied for effective enlightenment of the general populace.

Objective: We aimed to investigate the adverse reactions following COVID-19 vaccination in Anambra state, South East Nigeria.

Methods: Using a cross-sectional study design, 433 subjects aged 18years or older who had received any dose of the four COVID-19 vaccines (Moderna, Astra Zeneca, Pfizer and J&J (Janssen) were selected using a multi-stage sampling technique. The subjects were interviewed about COVID-19 vaccine related adverse reactions using self-administered questionnaire. Descriptive statistics (mean, standard deviation) and analytical statistics were performed and level of significance set at < 0.5 using SPSS V24.

Results: Of the 433 subjects finally studied, 62.8% were females and 22.4% were married. About 69% of them had tertiary education. Those who received the second dose of their respective vaccines were 44.8% while 11.5% had received a booster dose. Approximately half (50.3%) of the COVID-19 vaccines had adverse events. The most common types of adverse events (AEs) were local pain at injection site (62.1%) followed by headache (54.3%) and then fatigue (50.1%). Majority of the adverse events were mild to moderate in severity. Those who had only local adverse events were 70.2% while 45% had systemic adverse events.

Conclusion: In this study, severe adverse events were rare, even after the second dose. Most of the adverse events were mild to moderate in severity and therefore awareness campaign should be created to enlighten the community about the adverse effects of COVID-19 vaccines.

Keywords: COVID-19; vaccination; adverse events; local; systemic; severity.

1. INTRODUCTION

Increasing citizens' access to COVID-19 vaccines is key to the World Health Organization (WHO) goals of getting 40% of the world's population vaccinated by the end of 2021 as well as 70% vaccinated by the end of 2022 [1]. Vaccine hesitancy studies in Nigeria revealed that 56% of the populace are still not vaccinated with only about 10% of them being willing to become vaccinated [1]. The fact remains that vaccine acceptance among a large population of people to a large extent determines the success of COVID-19 pandemic control. The episode of SARS-CoV-2 (being referred to as COVID-19) which was first reported in Wuhan province of China had spread rapidly across the globe and was therefore declared by WHO as a global pandemic. There has been 266,675 confirmed cases with 3,155 deaths in Nigeria [2]. However, many Nigerians are yet to come to terms with the reality of the COVID-19 virus [3]. Many do not believe in the existence of the virus while some others believe there are conspiracy theories around the COVID-19 virus [4]. The fact that in some parts of the world, people who were fully vaccinated died of COVID-19 associated symptoms rather deepened the uncertainty about the safety and effectiveness of the vaccines [4,5]. A lot of measures have been put in place to help curb the spread of the virus. These measures which include extensive testing, restriction of movement, social distancing, use of face masks, and isolation of infected patients have been difficult to enforce among the general populace and as such are not enough to curb the spread of the virus. This further strengthens the fact that vaccination remains the most cost effective life-saving strategy for infection control and hence the need for safe and effective vaccination of the general populace as a key measure to containing the spread of the virus. Vaccines boost resistance to specific disease agents by strengthening the immune system [6]. They act by activating the body's inherent defense mechanisms against disease agents [6]. The COVID-19 pandemic is currently the greatest challenge globally. Despite lots of vaccines against COVID-19 being rolled out, there is still a high rate of vaccine hesitancy prevalent in many communities [7-12]. The uptake of the vaccine had remained low globally and worse in Africa especially Nigeria. When the majority of the population gets vaccinated, a sufficient percentage of the population becomes immune to the infection thereby reducing the likelihood of infection for vulnerable individuals who cannot get vaccinated due to health conditions. This

'herd immunity' can only be achieved with 70% population vaccination [13,14].

For the global eradication of COVID-19, 70% of all humans must receive the COVID-19 vaccines. The 70% vaccination threshold for eliminating COVID-19 before the end of 2022 eluded Nigeria as only 30.5% of the Nigerian population had full COVID-19 vaccination status as of February 2023 [7,15-17]. Although COVID-19 vaccines are available in Nigeria, the vaccine uptake is still poor. Many people have attributed their unwillingness to be vaccinated due to adverse events of the COVID-19 vaccines [18-20].

According to the CDC in 2021, any local or systemic health problem or side effect that occurs after vaccination is an adverse event (AE). Global adverse events resulting from COVID-19 vaccination varies according to the type of vaccine and include fatigue, headache, muscle and joint pain, low-grade fever and pain or redness at injection site [21-25].

This study was designed to investigate the adverse events associated with COVID-19 vaccination in a Nigerian population as well as determine whether these adverse events are severe enough to prevent/discourage the vaccine uptake.

2. MATERIALS AND METHODS

2.1 Study Site

This study was conducted among COVID-19 vaccinees at the three major vaccine centres (Nnamdi Azikiwe University Teaching Hospital, Nnewi, Chukwuemeka Odumegwu Ojukwu Teaching Hospital Awka and General Hospital , Onitsha). All three hospitals are tertiary health facilities, the first owned by Federal Government and the other two owned by the State Government. All three health facilities are located in the three major cities of the state. They are major vaccination centres in the state as they also serve as both treatment and referral centre for management of COVID-19 cases.

2.2 Study Design

This was an institution based cross-sectional descriptive study.

2.3 Study Population

The study population consisted of all individuals who had taken at least a dose of any of the COVID-19 vaccines, resident in Anambra state and are 18years and above.

2.4 Inclusion Criteria

All COVID-19 vaccinees who voluntarily gave their consent to participate in the study.

2.5 Exclusion Criteria

All COVID-19 vaccinees who were acutely ill.

2.6 Sample Size Determination

The study derived its sample size using Cochrane's formula for population size [26] where $n = Z^2pq/d^2$ with a p value of 0.506 derived from previous study [27]. With an attrition rate of 10%, final sample size was 450.

2.7 Sampling Technique

A multistage sampling technique was used. In the first stage, the state was divided into the 3 senatorial zones. In the second stage, three hospitals were conveniently selected, one from each of the three zones. The third stage involved proportionate allocation of numbers of respondents from each hospital according to their numbers relative (ratio) to the entire population of each hospital: The fourth stage involved the systematic sampling of respondents from the COVID-19 Vaccination register. Those selected were then contacted and administered with questionnaires.

2.8 Data Collection Method

A well-adapted, pretested, semi-structured and self-administered questionnaire was used to collect data.

2.9 Statistical Analysis

The data was cleaned and collated. SPSS V24 was used to analyze the data. Sample summary statistics such as arithmetic mean, standard deviation and percentages were used to describe the key data. Bivariate analysis was used to investigate the association between the dependent and independent variables using Chi-Square analysis. Statistical significance was set at a $P < 0.05$.

3. RESULTS

433 questionnaires were finally retrieved, giving a response rate of 96.2%.

Table 1. Socio-demographic characteristics of the respondents

		Frequency	Percent
Sex	Male	161	37.2
	Female	272	62.8
Age range	< 25 years	243	56.1
	26-50 years	169	39
	51-75 years	20	4.6
	>75 years	1	0.2
	Mean ± STD	27.52 ±12.5	
Marital status	Single	322	74.4
	Married	97	22.4
	Widowed	9	2.1
	Separated	3	0.7
	Divorced	2	0.4
Educational status	No formal	2	0.5
	Primary	15	3.5
	Secondary	101	23.3
	Tertiary	300	69.3
	Informal Education	15	3.5
Religion	Christianity	419	96.8
	Islam	7	1.6
	Traditional religion	2	0.5
	Judaism	5	1.2
Occupation	Health-care worker	88	20.3
	Student	245	56.6
	Civil servant	54	12.5
	Trader	35	8.1
	Others	11	2.5

Table 2. Type of vaccines received and the occurrence of adverse reactions

		Frequency	Percent
Vaccine type received	Pfizer	102	23.6
	Mordena	112	25.9
	Astrazeneca	133	30.7
	J & J	86	19.9
No of dose	1	239	55.2
	2	144	33.3
	Booster	50	11.5
Occurrence of any adverse reaction	Yes	218	50.3
	No	211	48.7
	Not sure	4	0.9

Table 3. Association of adverse events with types of Covid-19 vaccines

Vaccine type received		Yes	Percent	RR(C.I)	p-value
Pfizer	n=102	44	43.1%	1.02(0.81-1.27)	0.85
Mordena	n=112	74	66.1%	1.47(1.23-1.76)	<0.01
AstraZeneca	n=133	78	58.6%	1.25(1.04-1.51)	0.02
J&J	N= 86	22	25.6%	0.45(0.31-0.65)	<0.01
Total	n=218	218	50.3%		

Table 4. Adverse events from Covid-19 vaccination

Adverse events*	Frequency	Percent
Pain at injection site	269	62.1
Fatigue	217	50.1
Headache	235	54.3
Malaise	166	38.3
Swelling or redness at injection site	142	32.8
Chills	91	21
Fever	195	45
Nausea and vomiting	57	13.2
Insomnia	52	12
Adenopathy	50	11.5
Hives and rashes	37	8.5

**Responses consists of multiple answers*

Table 5. Adverse events to first and second dose of Covid-19 vaccination

	Yes	
	n	%
First Dose*		
Local adverse event	157	70.2
Systemic adverse event	100	45.0
Potential life-threatening event	8	1.8
Need for drug(antipyretic/analgesics)	23	10.3
Second Dose*		
Local adverse event	32	16.5
Systemic adverse event	34	17.5
Potential life-threatening event	2	1.0
Need for drug(antipyretic/analgesics)	17	8.7

**Responses consists of multiple answers*

Table 6. Severity of adverse event experienced after first or second dose vaccination

		Frequency	Percentage
First dose (n=433)			
Severity	Mild	120	27.8
	Moderate	90	20.8
	Severe	8	1.8
	None	211	48.7
Second dose (n=194)			
Severity	Mild	80	41.2
	Moderate	40	20.6
	Severe	2	1.0
	None	72	37.1

Table 7. Shows the Risk Benefits of different covid-19 vaccines

Vaccine type received	Yes	Percent	RR(C.I)	Benefit (Harm-benefit)	p-value
Pfizer	44	43.1%	0.82(0.64-1.04)	10.45b (61.39h-4.84b)	0.85
Mordena	74	66.1%	1.47(1.23-1.76)	4.67h (9.28h-3.12h)	<0.01
Astra Zeneca	78	58.6%	1.25(1.04-1.51)	8.38h (56.64h-4.51h)	0.02
J&J	22	25.6%	0.45(0.31-0.65)	3.3b (2.34b-5.10b)	<0.01
Total	218	50.3%			

Table 8. Association between socio-demographic variable, medical history and prevalence of self- reported adverse reaction

Variable	Occurrence of any adverse reaction	
	Chi square	p-value
Age	4.71	0.96
Sex	3.23	0.17
Tribe	20.20	0.25
Religion	12.34	0.11
Marital status	8.25	0.83
Educational status	12.86	0.14
Occupation	13.33	0.07
History of allergy	22.29	0.00*
History of chronic diseases	15.31	0.38
History of severe acute respiratory syndrome (SARS) infection	11.50	0.02*

4. DISCUSSION

In this study, the male constitutes 32.7% of the respondents. The mean age group was 27.5±12.5. Majority of them had tertiary education (69.3%) and 74.4% of them were single. About 20% of them were health workers while 56.6% were students. It is not surprising that many of the respondents are students. This is because two of the tertiary facilities were teaching hospitals which had medical and allied health students undergoing training. It also explains why many of the respondents are single. Many of the respondents having tertiary education is supported by the finding by Olu-Abiodun et al that respondents with primary, secondary and tertiary education were more likely to be vaccinated compared to their counterparts with no formal education [4]. One would have also expected a lower rate of vaccine uptake by the students in view of the fact that COVID-19 is assumed to run a mild course in younger individuals. However, the knowledge the students have on the nature, course and possible complications may have motivated them to take the vaccine.

Approximately half (50.3%) of the vaccinees reported adverse events while 48.7% had no adverse events. This is similar to the finding by Harry et al in Rivers State of Nigeria where 50.5% of the respondents reported post vaccination adverse events [27]. Osibogun et al also reported a 52.6% incidence of adverse events which is similar to our finding in this study [28]. This is similar to the finding in Iran where 55.56% reported adverse events after first dose [29]. Higher values appear to have been recorded outside of Africa. A similar study in a developed country Poland revealed that 96.5% of the people reported at least one side effect after receiving one dose of the vaccine [30]. Similar studies also recorded adverse event incidence of 93.5%, 90.9% and 79.4% in Afghanistan, Korea and Nepal respectively [31-33]. This difference could be attributed to the poor reporting attitude and beliefs obtainable in the Nigerian environment [34,35].

A study consisting of many African countries as well as Africans living in diaspora had 80.8% of vaccinees reporting adverse events [36]. A similar study in the South-South region of Nigeria found an incidence rate of 90.1% which is also as high as that seen in other studies outside Africa [37].The commonest adverse events recorded in this study were local pain at injection site (62.1%), headache (54.3%) and fatigue (50.1%). These were followed by fever (45%) and malaise (38.3%). Other AEs reported were chills, insomnia, adenopathy, hives and rashes as well as redness at injection sites. The study done in Yenogoa, South-South Nigeria revealed pain at injection site as the commonest symptom followed by headache and fatigue [35]. Previous studies also have similar findings [31-33,38-40]. A similar study in Ghana had reported commonest adverse events to be general body weakness (fatigue) (32%), headache (27.3%) and fever (19.1%) [41]. This is similar to the findings by Odeigah et al in Kwara State where headache was the commonest with 51.6% of the respondents presenting with headache as the commonest symptom.

The incidence of adverse events was more with the first dose than the subsequent dose. The symptoms that make up the local AEs include

swelling and/or pain at injection sites, itching of injection site and redness at the injection site. Our study revealed 70.2% incidence of local reactions and 45.0% of systemic reactions to the first dose of vaccine which is more than that reported after the second dose (16.5% and 17.5%respectively). This is contrary to the 54.8% increase recorded in Poland [30]. The incidence of life-threatening reaction in our study was 1.8%. This is much lower than the finding by Anjorin et al in which the incidence of near fatal cases was 5.3% [36]. About 10.3% of respondents needed a form of drug (analgesics/antipyretics) treatment for their adverse events. Most of the adverse events recorded in this study were mild or moderate in severity. Only 1.8% of the adverse events were severe after the first dose and 1.0% after the second dose of the vaccine. Two hundred and thirty nine (55.2%) vaccinees had received only one dose, while 33.3% had received 2 doses. Only 11.5% had received a booster dose of the COVID-19 vaccine. Thirty percent (30.7%) of the vaccinees had received AstraZeneca vaccine while 25.9% had received Moderna. Twenty-three percent (23.6%) received Pfizer while only 19.9% received J & J vaccine. The occurrence of adverse events also varied with the type of vaccine. Moderna vaccine was associated with the highest incidence of AEs (66.1%, RR-1.47) while the Janseen vaccine had the least incidence of AEs(25.6%,RR- 0.45). The association was significant for both vaccines. Cheon et al had also a similar finding in their study where the Moderna vaccine had the highest incidence rate of AEs when compared with Pfizer and Janssen [42].

Furthermore, our study revealed that there was a significant association between occurrence of adverse events and history of allergy as well as previous history of SARS 2 COVID infection. No significant relationship was observed between age and gender and occurrence of AEs. This is similar to the finding by Odeigah et al. [38] Osibogun et al in their study however observed that the older age group(>60 years) had a lower likelihood for COVID-19 Vaccine AEs compared with the 18-24 years age group [28]. In this study, there was also no significant association between the occurrence of AEs and the sociodemographic variables of respondents. This is similar to the finding by Ademola et al that no significant association exists between sociodemographic factors and AEs [43]. The occurrence of AEs therefore appears unpredictable. This calls for need for further studies on the predictors of severity of AEs.

5. STRENGTH AND LIMITATION

The strength of this study lies in the fact that the participants are educated and could provide necessary details required of them. There could also be misreporting and recall bias on the part of the respondents. The study has demonstrated that further work will be needed to establish the direction of associations.

6. CONCLUSION

Adverse events are not rare with COVID-19 vaccination. The fear of these adverse events can lead to COVID-19 vaccine uptake hesitancy. It is therefore necessary to educate the general populace that most of these adverse events if they occur, are relatively mild to moderate in severity and are often self-limiting. Continuous health education and promotion is required in our communities with regards to the importance of vaccination in COVID-19 pandemic control.

ETHICAL APPROVAL AND CONSENT

Research ethics approval was obtained from the Ethics and Research Committee of Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State. (NAUTH/CS/66/Vol.16/ver.3/269/2022/086).

Informed oral consent was obtained from each respondent after thoroughly debriefing them on what the study is all about.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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