Side Effect Profile of COVID-19 Vaccine among Health Workers in a Tertiary Health Institution in South-South Nigeria

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ABSTRACT

Background: Side effect following vaccination usually ranges from mild to moderate and occasionally severe in a small proportion of people. Covid-19 vaccine is no exception as side effects have been reported which are mostly mild to moderate and transient. The chances of any of these side effect following vaccination differ according to the specific COVID-19 vaccine.

Objective: To determine the side effect profile of the Health workers that received the COVID-19 vaccination in the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria.

Materials and Method: This study was a descriptive cross-sectional study. It was carried out between 15th and 30th April 2021 among 151 health workers that received COVID-19 vaccination in the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria. The data were collected with a predesigned questionnaire and were analysed using IBM SPSS 23.0 version.

Results: About 52.3% were female health workers, 49.0% were aged between 36–45 years. Side effects were reported in 9 of every 10 health workers who received the vaccine. Most side effects (53.0%) started on the day of vaccination. The most common side effect was pain at the injection site, and it was reported by 104 recipients of the vaccine (68.9%). Fever, headache, tiredness and chills were reported in 57.0%, 49.0%, 47.7% and 43.7%, respectively.

Conclusion: As with medications and other vaccines, COVID-19 vaccines have side effects. Protective immunity against COVID-19 is developed following vaccination. In the face of a still rapidly evolving situation, what seems obvious is that vaccination currently remains the best route to achieving herd immunity.

Keywords: COVID-19, Wuhan, COVID-19 vaccination, Health workers, Side effects, Yenagoa.

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I. INTRODUCTION

The coronavirus disease 2019 (COVID-19) was identified for the first time in December 2019 as it was said to have emerged from a livestock market in Wuhan, the capital of Hubei province in the People's Republic of China [1]. It is a respiratory disease that is caused by Severe Acute Respiratory Syndrome Corona Virus-2 (SARS-CoV-2). The disease is a significant cause of morbidity and mortality worldwide. Therefore, the need for global vaccination and subsequent development of herd immunity.

Some vaccines are presently available and approved for public use. These vaccines include Oxford/AstraZeneca viral vector vaccine, Pfizer/BioNTech mRNA vaccine, Moderna mRNA vaccine, Janssen/Johnson and Johnson viral vector vaccine, Sinopharm inactivated viral vaccine, Sinovac inactivated viral vaccine and Gamaleya viral vector vaccine, Bharat Biotech Inactivated viral vaccine and Novavax Protein subunit vaccine [2].

However, news of untoward side effects of some of the vaccines like the rare blood clot formation with the use of Oxford/AstraZeneca vaccine has made some countries of the

world to temporarily suspend its use. Another vaccine that has been associated with rare blood clot formation is Janssen/Johnson and Johnson vaccine. It may be possible that the antibodies that these vaccines produce trigger the coagulation and platelet activation, and subsequently blood clot formation. More researches need to be painstakingly carried out to determine how these rare blood clots are formed, and how to tackle them. The characteristics of selected COVID-19 vaccines have been summarized in Table I.

AstraZeneca has stated that advanced trial data (from a study in the USA) on its COVID-19 vaccine revealed 79% effectiveness, and there was little or no risk of formation of blood clots [3]. AstraZeneca, on the 14th of March, 2021 has reassured of the safety of its vaccine as none of the 17 million people that were vaccinated in Europe and United Kingdom with its COVID-19 vaccine presented with any evidence of an increased risk of deep vein thrombosis, pulmonary embolism or thrombocytopenia, in any country, gender, age group or batch of the vaccine [4]. The study revealed that the vaccine was 100% effective in preventing severe disease and hospital admission.

The risk of blood clot formation with Oxford/AstraZeneca COVID-19 vaccination is 0.0004% (4 cases in 1,000,000 vaccines), which is comparable to the risk of blood clot formation in the general population [5]. The risks of blood clot formation in women on oral contraceptives, smokers and those with COVID-19 are 0.05-0.12% (500 – 1,200 cases in 1,000,000 women), 0.18% (1,763 cases in 1,000,000 smokers) and 16.5% (165,000 cases in 1,000,000 cases) respectively [5]. The risk of blood clot formation with the Oxford/AstraZeneca COVID-19 vaccine is by far lower than

the risk of blood clot formation in those with COVID-19, women on oral contraceptives and smokers. This risk of the vaccine appears even more rare with the second dose [6]. In other words, the benefits of taking the vaccine by far outweighs the risk of blood clot formation associated with the disease. Fear of side effects is one of the reasons many people hesitate to take the COVID-19 vaccines as was revealed in two previous studies carried out in our Centre [7], [8].

The mRNA vaccines like Pfizer/BioNTech and Moderna are reactogenic. When they are received by some individuals, brisk immune response is generated, which may cause some adverse reactions in them. The commonest side effects of vaccines are pain at the site of injection [9]. Other common side effects are fever, malaise, fatigue, chills, headache, muscle pain, joint pain, chest pain, dizziness [10], and swelling of the axillary breast of females at the side of the injection site. These side effects may start within the first 24 hours and resolve within a few days. Side effects of vaccines occur more in younger people and those that receive the second dose of COVID-19 vaccine [10]. Women are more likely to develop side effects when they receive Oxford/AstraZeneca vaccine than those who receive the Pfizer/BioNTech vaccine [11].

It has been noted that people who have been previously infected with COVID-19 present with more severe side effects when they receive COVID-19 vaccine compared to those that have never been infected by it [12]. The reason is that the immune system has already been primed following the previous infection or previous COVID-19 vaccination to respond to the virus any other time it enters the body. This includes the harmless viral vector or inactivated viral fragments that are contained in vaccines.

TABLE I: CHARACTERISTICS OF SELECTED COVID-19 VACCINES*

Manufacturer	Platform	Status	Doses and Interval	Phase 3 Sample Size	Efficacy Against Symptomatic Disease (95%CI)	Efficacy Against Severe Disease†	Reactogenicity	Storage and Temperature
Pfizer/BioNTech	mRNA	EUA	2 at 3 weeks apart	43 661	95.0% (90.3%-97.6%)	9 vs. 1	Fatigue, muscle aches, chills, fever, local reactions	—70 °C for 6 months 2-8 °C for 5 days
Moderna	mRNA	EUA	2 at 4 weeks apart	30 351	94.1% (89.3%-96.8%)	30 vs. 0	Local pain, fatigue, headache, myalgia, arthralgia, chills, fever	—20 °C for 6 months 2-8 °C for 30 days RT for 12 hours
AstraZeneca	Recombinant chimpanzee adenovirus (nonreplicating)	Enrolling phase 3	2 at 4 weeks apart	~30 000	NA	NA	Local pain, fatigue, headache, fever, Myalgia	2-8 °C for 6 months
Johnson & Johnson/Janssen	Recombinant human adenovirus 26 (nonreplicating)	Completed phase 3 enrollment	1	~45 000	NA	NA	Local pain, fatigue, headache, myalgia	2-8 °C
Novavax	Recombinant Protein	Enrolling phase 3	2 at 3 weeks apart	~30 000	NA	NA	Local pain, fatigue, headache, myalgia	2-8 °C
Sanofi/GlaxoSmith Kline	Recombinant Protein	Phase 2	1 or 2 at 3 weeks apart	NA	NA	NA	NA	2-8 °C
Merck	Recombinant vesicular stomatitis virus (replicating)	Phase 1	1	NA	NA	NA	NA	—70 °C

EUA = emergency use authorization; NA = not available; RT = room temperature.

* All vaccines are directed toward the spike protein of SARS-CoV-2.

† Number of severe cases of COVID-19 (placebo vs. vaccine group).

Reference: Connors M, Graham BS, Lane HC, Fauci AS. SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn. *Ann Intern Med.* 2021; M21-0111. doi:10.7326/M21-0111.

The benefits of COVID-19 vaccination by far outweighs the risk of not receiving the vaccine as far as the significant morbidity and mortality associated with COVID-19 are concerned. The presence of conspiracy theories impacts negatively on the success of COVID-19 vaccination worldwide. Some conspiracy theories making the rounds include vaccines are riskier than they are thought, vaccine is related to poisoning, loss of libido, infertility, etc. For COVID-19 vaccination to be globally successful, the conspiracy theories have to be debunked completely, the issue of the rare COVID-19 vaccine side effect of blood clot formation laid to rest, and more research with assurances of what is likely and what is unlikely.

Vaccination of health workers with the Oxford/AstraZeneca COVID-19 vaccine commenced at the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria on March 15, 2021. Therefore, the objective of this study was to determine the side effect profile of the health workers that received the COVID-19 vaccination at the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria.

II. MATERIALS AND METHODS

This survey was carried out among health workers in all the departments of the Federal Medical Centre, Yenagoa, Bayelsa State, South-South, Nigeria between 15th and 30th April 2021. It was a descriptive cross-sectional study. There are 2,408 health workers in this health facility.

The participants were counselled and enrolled in the study after giving a written informed consent. An explanation of the nature of the study and the likely benefits preceded the administration of written consent. All health workers (including doctors) who took the vaccine when it was brought to the hospital were included in the study. Health workers that declined consent/incompletely filled the consent form were excluded from the study.

A. Data Analysis

The information in the filled questionnaire were entered into the IBM SPSS 23.0 version, which was also used for data analysis. Categorical variables are expressed in frequencies and percentages while continuous variables are summarized in mean and standard deviation. Results are presented in figures and tables as appropriate.

III. RESULTS

A. Sociodemographic Characteristics of Recipients of COVID-19 Vaccine

The side effect profile of 151 health workers that took the COVID-19 vaccine in the hospital was explored. About 52.3% were female health workers, 49.0% were aged between 36–45 years, 62.3% were married and 66.9% were medical doctors (Table II). Almost all respondents were Christians (99.3%).

TABLE II: SOCIODEMOGRAPHIC CHARACTERISTICS OF RECIPIENTS OF COVID-19 VACCINE

Characteristics	Frequency N = 151	Percent (%)
Sex		
Male	72	47.7
Female	79	52.3
Age group		
≤ 35years	66	43.7
36 – 45years	74	49.0
>45years	11	7.3
Marital status		
Single	49	32.5
Married	94	62.3
Separated/Divorced/Widowed	8	5.2
Religion		
Christian	150	99.3
Islam	1	0.7
Occupation		
Doctor	101	66.9
Nurses	27	17.9
Pharmacists	5	3.3
Medical Laboratory Scientist	12	7.9
Administration officers	6	4.0

B. Chronic Illnesses and COVID-19 Related Features among Recipients of COVID-19 Vaccine

Table III showed that almost a tenth of respondents were hypertensive (9.9%), and less than 1 in every 20 respondents was either a Diabetic (3.3%) or an asthmatic (2.6%). Twenty-seven respondents (17.9%) have tested positive to COVID-19 in the past, and about half (45.7%) have had contact with someone diagnosed with COVID-19.

TABLE III: CHRONIC ILLNESSES AND COVID-19 RELATED FEATURES AMONG HEALTH WORKERS

Characteristics*	Frequency N = 151	Percent (%)
Chronic Illnesses		
Hypertension	15	9.9
Diabetes mellitus	5	3.3
Bronchial Asthma	4	2.6
COVID-19 related features		
Respondents have tested positive for COVID-19	27	17.9
Possibly infected with COVID 19 without testing	40	26.5
History of Loss of taste and smell	48	31.8
History of contact with someone diagnosed of COVID-19	69	45.7
Has lost someone due to COVID-19 infection	18	11.9

*More than one option is applicable.

C. Reported Side Effects of COVID-19 Vaccine among Health Workers

As shown in Table IV, the most common reported side effect is pain at the injection site. This was reported by 104 (68.9%) recipients of the vaccine. Fever, headache, tiredness, and chills were reported in 57.0%, 49.0%, 47.7% and 43.7% respectively. Difficulty in breathing and severe chest pain following vaccination was reported in 0.7% of recipients.

D. Side Effect Features among Recipients of COVID-19 Vaccine

Of the 151 health workers who received the vaccine, a tenth reported no side effects (9.9%). Side effects were reported in 9 of every 10 health workers who received the vaccine. Most side effects (58.8%) started on the day of

vaccination (Table V). While about a fifth of the recipients of the vaccine reported only 1 side effect (19.9%), a tenth of these health workers reported 8–10 side effects following COVID-19 vaccination (Table V). All the side effects resolved within one week.

TABLE IV: REPORTED SIDE EFFECTS OF COVID-19 VACCINE AMONG HEALTH WORKERS

Side Effect*	Frequency N = 151	Percent (%)
Pain at injection site	104	68.9
Fever	86	57.0
Headache	74	49.0
Tiredness	72	47.7
Chills	66	43.7
Muscle Pains	60	39.7
Joint pain	47	31.1
Painful nodes	22	11.6
Nausea	13	8.6
Vomiting	11	7.3
Dizziness	2	1.3
Restless	2	1.3
Light head	1	0.7
Eye pain	1	0.7
Abdominal pain	1	0.7

*More than one option is applicable.

TABLE V: SIDE EFFECT FEATURES AMONG RECIPIENTS OF COVID-19 VACCINE

Characteristics	Frequency N = 151	Percent (%)
Occurrence of Side effect		
No side effect	15	9.9
Side effect present	136	90.1
Onset of Side effect	N = 136	%
Day 1	80	58.8
Day 2	51	37.5
Day 3 – 7	5	3.7
Number of Side effect	N = 136	%
1 side effect	27	19.9
2 side effects	21	15.4
3 side effects	13	9.6
4 side effects	18	13.2
5 side effects	10	7.4
6 side effects	18	13.2
7 side effects	15	11.0
8–10 side effects	14	10.3

IV. DISCUSSION

This study reveals that most of the respondents who received the Oxford/AstraZeneca COVID-19 vaccine (56.3%) were above 35 years of age with slightly more women (52.3%) than men. It means that more women had so far received the vaccine in our facility. This is similar to some reports that more women have been vaccinated, and thus may present more with any side effects associated with the vaccines, especially the viral vector vaccines [11], [13], [14]. These findings are however not in consonance with some other studies on vaccination intention which had suggested that men were more willing to receive the COVID-19 vaccines [7], [15]–[18].

Most of the vaccine recipients were frontline health workers – doctors (66.9%) followed by nurses (17.9%), who are more likely to have a general knowledge about vaccines or a previous history of vaccination and perceive the severity of COVID-19. These factors have severally been reported to enhance vaccine uptake [14]–[18]. In our study, doctors received the vaccine more than the other health workers. This may be because they are more at risk (compared to other health workers) of being infected with COVID-19. It may also be because they probably have better knowledge about

the pathogenesis of the disease and mechanism of action of the vaccine, and the significant COVID-19 associated morbidity and mortality.

A large population of the study participants reported having had at least one COVID-19 related feature such as testing positive for COVID-19 (17.9%), possibly infected with COVID-19 without testing or contact with a confirmed positive case, history of loss of taste and smell or having lost someone due to COVID-19. These reasons may have influenced some of the participants positively to accept the COVID-19 vaccine as was previously reported [7], [19], [20]. This may also reflect a high prevalence of COVID-19 among the studied health workers as reported in other studies [21], [22].

In the face of vaccine hesitancy of varied proportion in different countries of the world, due partly to concerns about early- and late-onset side effects of a vaccine whose production was sped up due to emergency needs, the initial recipients are watched by others as validators for acceptance or rejection of the COVID-19 vaccine [7], [8], [23], [24]. In two previous studies in this Centre by Oriji et al. [19] and Allagoa et al. [20], 48.1% and 70.5% of the participants declined COVID-19 vaccination because they wanted to wait to see what happens to those that received the vaccine.

As with medications and other vaccines, COVID-19 vaccines have side effects. Protective immunity against COVID-19 is developed following vaccination. The spike protein is a viral protein present on the surface of the virus. Vaccines contain this spike protein which in turn mimics the natural process of viral infection, and then commences an immune response. Innate immune response to the viral protein is almost immediate. Inflammatory response is initiated with fever and pain at injection site. Therefore, it is this innate immune response that causes the initial common side effects of COVID-19 vaccination. Adaptive immunity is the main aim of vaccination which generates T cells and antibodies, and in turn protect against infection or its severe forms on subsequent exposure to the virus. Both the innate and adaptive immune systems respond in form of side effects.

The side effects witnessed by the participants in this study were mild. Out of the 151 health workers who received the vaccine, 136 (90.1%) had side effects. More than half (58.8%) of the side effects started on the day of vaccination. A few participants (9.9%) did not report any side effect. This does not mean that the vaccine did not work. After a vaccine clinical trial, it was reported by Pfizer that despite the fact that half (50%) of the studied participants had mild/no side-effects, 90% of the participants had immunity against COVID-19 [25]. Moderna reported that only 10% of those that took its COVID-19 vaccine had common side-effects, yet 95% of those that took the vaccine were protected against the virus [25].

The immune system of every individual reacts differently to vaccines, with some having more physical response to vaccine than others. Some reasons for this difference are: gender, age, individual's health status, immunocompromise, genetic make-up, previous infection with COVID-19, previous COVID-19 vaccination, use of anti-inflammatory agents, time of the day that vaccine was received, individual's nutrition and environment. As an individual ages, immune activity gradually declines due to lower antibody levels. This

difference can also be explained with the role of testosterone. Testosterone reduces inflammatory response, and subsequently the side-effects associated with vaccines. Men have more testosterone compared to women. This may explain why men have fewer side effects. Individuals with inflammatory conditions like inflammatory bowel disease, multiple sclerosis and rheumatoid arthritis, and people on immunosuppressive medications usually have fewer/no side effects to vaccination.

Most of the side effects which range from mild to moderate are normal and not a cause for alarm as they mostly resolve spontaneously [26], [27], just as they occurred in our study. The commonest side effect in this study was pain at the injection site (68.9%), followed by fever (57%). These have also been reported as the most common side effects in previous studies [9], [10], [14]. The other side effects reported in the studied participants include headache, fatigue, chills, muscle pains, and joint pains. This report is similar to findings from some other studies [9], [10], [14], [26].

Other less common mild to moderate side effects reported by the studied participants were painful nodes, nausea, vomiting, dizziness, restlessness, light head, eye pain, and abdominal pain. These side effects which resolved spontaneously after a few days are regarded as normal signs, indicating that the body is mounting an immune response against the COVID-19. In this study, there were no cases of rare/severe side effects such as anaphylaxis or blood clot formation. No participant in this study presented with features of pulmonary embolism, deep vein thrombosis or thrombocytopenia. This severe but rare side effect of blood clot formation could be fatal, prompting policy changes on vaccine rollout globally.

V. CONCLUSION

In the face of a still rapidly evolving situation, what seems obvious is that vaccination currently remains the best route to achieving herd immunity. This is especially very important for developing countries such as Nigeria with about 206.14 million citizens. As of May 14, 2021, only 0.8% of Nigeria's population have received a dose of the Oxford/AstraZeneca vaccine [28]. This is grossly low. Efforts to allay the fears and concerns about side effects of the vaccines should be continuous through health education and health promotion. Efforts to also develop our own vaccine production capability should be explored and invested in.

VI. LIMITATION

The results obtained from this hospital-based study may not reflect what is obtainable in other health institutions in the West-African sub-region and around the globe.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

AUTHORS' CONTRIBUTIONS

PCO conceptualised and designed the study, managed literature searches, collated data and wrote the first draft of the manuscript. DOA wrote the protocol of the study. LO wrote the results. OO participated in literature searches, and data collation. OSO wrote the discussion and participated in literature searches. EST participated in writing the results and discussion. SEO and GA supervised data collection. All authors read and approved the final manuscript.

CONSENT

Written informed consent was obtained from every health worker that participated in this study.

ETHICAL APPROVAL

The research work was examined and approved by the hospital research and ethics committee.

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