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A study evaluating the impact of the corona virus vaccine amongst pregnant women attending antenatal clinic at 3 primary healthcare clinics in plateau state, Nigeria: A qualitative analysis

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Abstract

The aim of this study was to evaluate the impact of the corona virus vaccine amongst pregnant women attending antenatal clinic at 3 primary healthcare clinics in plateau state; Nigeria this was done utilizing a cross-sectional study that utilized a validated data tool with over 250 participants. Systemic side effects noticed were Headaches (47.6%), catarrh (28.6%), injection site swelling (22.2%), fever (20.5%) and fatigue (16.0%) where the most common systemic side effects experienced by those who had taken the vaccine. While the common pregnancy related side effects were Abdominal pain, preterm contractions and per vagina bleeding.

Keywords: Side effects, pregnancy, COVID-19, vaccine, antenatal-care, PHCs

Introduction

As of Thursday the 17th of March, 2022, there were 500,186,525 confirmed cases of COVID-19, and 6,190,349 confirmed deaths [1]. While As of the 14th day of April, 2022, Europe with about 202,822,518 confirmed cases has the highest about of cases in the world, about 11,551,403 cases of the global cases defined are from Africa. The least of the continents, only second to Oceania. The top 5 countries in Africa with most cases are South Africa, Morocco, Tunisia, Egypt and Libya [2].

The low case prevalence in Africa amidst a rapid rising and highly virulent case prevalence and incidence in the western regions created room for a lot of misinterpretations as it posed a scientific mystery. Although, theories such as hygiene hypothesis were proposed amongst others, no singular explanation has been proposed and accepted yet [3]. Hence, this has also translated to problems with acceptance of the vaccines when they were brought into Africa. Although the initial aim was to vaccinate at least 20% of the African population by the end of 2021, with problems arising from both vaccine inequity and vaccine hesitancy, only 16% have been fully vaccinated [4]. This is amid multiple international donations from all over the world, such as the United Arab Emirate, India, China and Russia, amongst others [5].

The COVAX Vaccines arrived Africa in 2021 and the first doses were administered in Africa on the 1st of March, 2021 at the Treichville Vaccination Centre, in Abidjan, Core d'Ivoire [6]. By the next day, the first batch of the Vaccines were shipped into Nigeria. They contained 3.94 million doses of the AstraZeneca/Oxford vaccines. The nation promptly began distribution on voluntary grounds [7]. It commenced this with a plan to have vaccinated over 40% of her populace by the end of 2021 [8]. However, as at April 14th of 2022, only 14.85% of Nigerians had been vaccinated [5].

Furthermore, there were a lot of side effects that were being noticed, ranging from non-fatal to fatal events. The safety levels of the corona vaccine were constantly reviewed and adjustments were subjectively and objectively made. This however, was not yet defined as completely safe for pregnant women, and in Nigeria, they were not yet "officially" cleared to receive the corona vaccines. However, as a result of changes in maternal physiology and immune function during pregnancy, pregnant women may be at risk of infection with SARS-COV-2 and developing more adverse events that non-pregnant women [9]. This created a health paradox.

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In a cross-sectional study conducted in Qatar amongst pregnant and breastfeeding women, it revealed that about 25% of the participants showed hesitancy towards the vaccination due to safety reasons [10]. While a similar study at the Ankara Hospital in Turkey revealed that over 37% of women were willing to accept the vaccination if it was declared safe for pregnant women (37%). Furthermore, a 7-day post-vaccination observational case-control study of pregnant and non-pregnant women who were vaccinated with two-dose regimen of the BNT162b2 vaccine at the same time period at the Sheba Medical Center in Israel showed that, aside the general symptoms similarly experienced by the non-pregnant women, pregnant women experienced no additional adverse effects. The rates of obstetric complications were very low following vaccination [11].

Notwithstanding, a clear-cut list of possible adverse effects to be experienced by pregnant women who take the vaccine is yet to be published. Also, the teratogenic side effects, as well as the pregnancy subjective effects are yet to fully be established. Although the Nigerian government only recently cleared pregnant women to receive the vaccine, some centres have been giving pregnant women before the clearance.

Hence, the aim of this study is to evaluate the impact of the corona virus vaccine amongst pregnant women attending antenatal clinic at 3 primary healthcare clinics in plateau state; Nigeria.

Methodology

Study area

Plateau is the twelfth-largest state in Nigeria. Approximately at the center of the country. It is geographically unique in Nigeria due to its boundaries of elevated hills surrounding the Jos plateau its capital, and the entire plateau itself. Plateau state is celebrated as "The Home of Peace and Tourism". With natural formations of rocks, hills and waterfalls, it drives its name from the Jos plateau and Jos a population of around 4.2 million people.

Bukuru is a city located on the Jos Plateau in Nigeria. It was previously considered separate city from the city of Jos close by, but like every other form of urbanization, the city of Jos merged with the town of Bukuru to form the Jos-Bukuru metropolis. It is the headquarters of Jos South LGA. The major forms of transportation connecting in and out of Bukuru is by road and rail. The rail ways connect Bukuru with Bauchi, Zaria, Lago and Port Harcourt. Mainly used for business, import and export of natural minerals [12].

Although it has a mix of Christians and Muslims, there is a Christian majority. There is also a central mosque in Bukuru [13].

Study site

The study sites are three (3) Primary HealthCare Centres (PHCs) in Bukuru. According to data obtained from the Ministry of Health and utilization of scientific tools of remote sensing GPS and GIS for a better update, there are about twenty-one (21) health facilities in Bukuru. Of these, one (1) is a tertiary facility, four (4) are PHCs and the others are health center levels [14].

Of these 4 Primary healthcare centres, we conducted our study amongst three (3). They are, Bukuru Express Primary Healthcare Centre, Bukuru Central Primary Healthcare Centre and Ecwa Comprehensive Healthcare Centre. Both Bukuru Express and Bukuru central are Government owned

primary healthcare facilities that are equipped with about 8 and 6 bed spaces, respectively. Their healthcare team comprises of a public health nurse, a Midwife and a Community Health Worker (CHEW). However, the ECWA comprehensive Healthcare Centre has 14 bed spaces and a larger facility. They have doctors (consultants) who come to run clinics on some days. It is a privately owned facility, charges more, better kept environment and has less patients visiting. They are all located within a 3-5 minutes Motorcycle or Tricycle ride away from each other, and costs about N50. Bukuru Express is located about 5 minutes from the tertiary facility, Bukuru Specialist Hospital. While Bukuru central and ECWA comprehensive Healthcare Centre is located about 15 minutes from the specialist hospital. Hence, have a longer time to patient transfer in emergency referrals.

Study population

The study population are the pregnant women currently attending Antenatal. These facilities are PHC Bukuru Central (BC), PHC Bukuru Express (BE), ECWA Comprehensive Health Centre (EHC).

Table 1: A table showing the total number of women registered and attending the ANC at the PHCs in Bukuru being used for this study

	BC	BE	EHC	TOTAL
No currently registered for ANC	56	58	46	160
No of Registered women in ANC this year	376	397	116	889

Inclusion criteria

1. A Pregnant woman who is registered at a Primary Healthcare facility in Bukuru for her Antenatal care

Exclusion criteria

1. Any man.
2. Any woman who does not fall within the inclusion criteria.
3. Any woman who did not consent to participating in the study.

Sample size determination

Total number of women currently attending ANC in these facilities = 160

Total Number of women who have registered and attended this year = 889

Sample size determination

Calculation of sample size [15]

$$n = Z^2 pq / d^2$$

Where n= Minimum sample size

Z = Standard normal deviation set at 1.96 (Confidence interval 95%)

P = Proportion of women currently attending ANC clinic amongst those registered this year (18.14%)

q = Complementary probability (1-p)

d = Degree of precision (0.05)

Sample Size = n + (10% of n)

$$\text{Where; } n = 1.96^2 (0.18)(1-0.18) / (0.05)^2$$

n= 227 (Minimum Sample size)

Sample Size; 227 + (10% of 227) = 250.

Sampling technique: Sampling technique was done using a multistage sampling technique.

Stage 1: Using simple random technique, we balloted for 1 Local Government Area, amongst 17 in Plateau state and got Bukuru Jos South Local Government Area. (Speak about how many towns are in jos south and how you got Bukuru).

Stage 2: Using simple random technique, we balloted for 3 primary health care centers amongst 4 that were in the Bukuru Local Government Area. From this we got, Ecwa Comprehensive Health Care, Bukuru Express and Bukuru Central Primary Healthcare Centres.

Stage 3: Using stratified technique we calculated for the respondents under the ANCs in each of the facilities.

S/N	PHC Facility	ANC
1	Bukuru express PHC	100
2	Bukuru Central PHC	100
3	Ecwa CHC	50

Stage 4: Using simple random sampling we distributed the questionnaires amongst the women attending the ANCs at the PHCs.

Study design

It is a cross-sectional randomized study design.

Preparation for Data Collection

Prior to data collection, permission was sought and obtained from the ethical committee Bingham University Teaching Hospital. Further consent was verbally sought from heads of each of the Primary Health Care Centers. Informed verbal consent was sought and obtained from each of the respondents after the purpose of the study was clearly explained to them. They were also informed that participation in the study was voluntary and that they could decide to withdraw their participation at any point in the interview. In order to ensure confidentiality, serial numbers instead of names were used to identify respondents.

Data Collection

A pre-tested structured self-administered questionnaire and a focused group discussion was used to obtain the relevant information. Questionnaires were administered to pregnant women at the PHCs until the required sample size was obtained.

Data analysis

Data will be entered Microsoft Excel package and cleaned. Analysis will be carried out using SPSS (Statistical Package for the Social Sciences) version 20. Socio-demographic variables will be presented on tables using frequencies and proportions. Knowledge, attitude and perception will be scored and graded appropriately. Bivariate analysis will be used to test association between Socio-demographic factors, knowledge and attitude, and perception. Multivariate logistic regression analysis will be done to determine predictors of good knowledge, attitude, perception, as well as acceptance of the COVID-19 vaccine. The level of significance will be set at a p-value ≤ 0.05.

Ethical consideration

Ethical clearance was obtained from the Bingham University ethical committee before the commencement of the study. In addition, informed consent was taken from each study participant after purpose of the study has been clearly explained. Data collected from the study was also kept confidential.

Limitations to study and how they were overcome

1. Language barriers

▪ We utilized the aid of the public health Nurses, Community Health Workers (CHEWs) and Community Health Officers (CHOs) who were present to help us interpret the questions were asked them. They also helped us with interpretation of the responses the respondents gave. However, some of the women understood some level of English, though mostly vernacular.

2. Financial constraints

▪ To cut down on transportation costs, we travelled together to the study site. To overcome cost or questionnaire printing, we printed the questions on both pages of an A4 sheet. Data organization and analysis were self-done, to cut down on cost of a statistician. However, these and other cost demanding activities were catered for by in-pocket funding.

Result

Section 1: Sociodemographic

Table 1: Showing sociodemographic n=250

Variable	Frequency	Percent (%)
Age group		
15-19	29	11.6
20-24	94	37.6
25-29	56	22.4
30-34	37	14.8
35-39	19	7.6
40-44	5	2.0
Religion		
Christian	141	56.4
Islam	109	43.6
Wife's occupation		
None	124	49.6
Self employed	85	34.0
Civil servant	29	11.6
Private sector	12	4.8
Wife's education		
None	33	13.2
Primary	16	6.4
Secondary	144	57.6
Post-secondary	57	22.8
Husband's occupation		
None	63	25.2
Self employed	117	46.8
Civil servant	36	14.4
Private sector	34	13.6
Husband's education		
None	77	30.8
Primary	10	4.0
Secondary	102	40.8
Post-secondary	61	24.4
Total	250	100

Two hundred and fifty questionnaires were administered. The highest number of respondents were from the age group 20-24(37.6%). Most of the respondents were Christians (56.4%) while the rest were Muslim (43.6%) The majority of the population were unemployed (49.6%), followed by self-employed (34.0%) and the least was the private sector employee (4.8%). Most of the respondents

had attained secondary school (57.6%) level of education while about 22.8% of the respondents had post-secondary level of education, 13.2% of the respondents had no level of education.

Section 2: Prevalence of acceptance

Table 2: Showing acceptance n = 250

Questions	Frequency	Percentage (%)
Have you received the vaccine before		
Yes	96	38.4
No	154	61.6
Total	250	100
When did you take it?		
Before pregnancy	46	18.4
In pregnancy: you knew you were pregnant	14	5.6
After pregnancy	36	14.4
I have not taken it	154	61.6
Total	250	100

From 250 respondents 61.6% had not received the vaccine at all while 38.4% had. Of these, 18.4% percent received it before they got pregnant, 5.6% received it while pregnant,

and 1.2% after they had delivered.

Section 3: Prevalence of side effects of the COVID-19 vaccine.

Table 3: Showing risk factors for allergic reaction to the corona vaccine and prevalence of gravid recipients; n = 96

Variables	Prevalence	Frequency	Percentage (%)
Are you allergic to any drugs, injections or vaccines	Yes	40	41.6
	No	56	58.3
Did you experience any allergic symptoms when you took the corona vaccine (s)	Yes	23	24
	No	73	76
Did you take the vaccine during pregnancy	Yes	14	14.6
	No	82	85.4
If you took the vaccine in pregnancy, did you experience any side effects	Yes	14	25
	No	72	75

This showed that less than half (41.6%) of those who had received the vaccine had known history of orthodox medication allergies. With an even lesser percentage (24%)

of these experiencing any side effects when they took the corona vaccination. While 25% of the vaccine recipients received it in pregnancy.

Table 4: Showing the prevalence of allergies experienced by those who had received the corona virus vaccine. n = 96

Symptoms experienced	Frequency	Percentage (%)
Headache	46	47.6
Catarrh	27	28.6
Swelling At Injection Site	21	22.2
Fever	20	20.5
Fatigue	15	16.0
Pain At Injection Site	14	14.1
Arthralgia	14	14.1
Chills	12	12.8
Insomnia	10	10.3
Dizziness	9	9.5
Chest Pain	5	4.8
Stomach Pain	5	4.8
Loss Of Consciousness	5	4.8

Headaches (47.6%), catarrh (28.6%), injection site swelling (22.2%), fever (20.5%) and fatigue (16.0%) where the most

common systemic side effects experienced by those who had taken the vaccine.

Table 5: Showing pregnancy related side effect symptoms experienced by respondents who took the vaccine while they were pregnant. n = 14

Symptoms/side effects	Frequency	Percentage (%)
Abdominal pains	3	18.8
Preterm contraction	2	15.6
Bleeding per vaginam	2	15.6
Miscarriage	1	9.4
Reduced or poor fetal kicks	1	9.4
Others	4	28.1

This shows that majority of the women who had pregnancy related side effects after receiving the vaccines had abdominal pain, preterm contractions and bleeding per vaginam. However, this goes to point the low prevalence of side effects amongst those who took the vaccine in pregnancy.

Discussion

This study sought to evaluate the impact of the corona virus vaccine amongst pregnant women attending antenatal clinic at 3 primary healthcare clinics in plateau state; Nigeria. The area chosen for the study was Bukuru LGA, Jos sought; Plateau state in Nigeria.

From the study we found that almost half of the women attending antenatal care clinics in this region were 24 years and younger, with the youngest being 15 years of age and the oldest being 44 years of age. The religion practiced amongst the respondents was Christianity and Islam, approximately 6 in 10 of the respondents were Christians. As regards the occupation of the women, although majority of them were unemployed, most of those who were gainfully working were self-employed. With attainment of varying educational levels, 6 in 10 of them had secondary school education, while approximately 1 in 10 had attained no form of formal education.

Of the 250 respondents, about 96 participants had either experienced or noticed some form of side or adverse effects on receiving of the vaccine. Of these group, four in ten already had a history of known allergy to an orthodox medication. Only two in ten of these had any form of allergic or adverse reactions following their vaccination. One in ten of these women received the vaccine in pregnancy, with the same prevalence experiencing systemic or pregnancy related adverse/side effects on receiving it. Of the side effects experienced, Headaches (five in ten), catarrh (three in ten), injection site swelling (two in ten), fever (two in ten) and fatigue (two in ten) where the most common systemic side effects experienced by those who had taken the vaccine. While specific pregnancy related symptoms experienced were mainly abdominal pains, followed by preterm contractions and bleeding per vaginam. These could lead to an increased risk of spontaneous abortion, which is a globally identified risk of immunization in pregnancy [16]. Furthermore, our study identifying these symptoms and risk of spontaneous abortion were in keeping with another study conducted amongst 92, 286 pregnant women who had received the COVID-19 vaccines. This identified a prevalence of 14.26% associated spontaneous abortion. Mostly amongst those who received the mRNA-1273 and BNT162b2 RNA vaccines [17].

These does not totally rule out the possibility of pregnant women receiving the Corona virus vaccination. As pregnant

and nursing mothers have been recognized as being at high risk of exposure to the virus. However, it is important to determine the safety profile of these vaccinations in real time [18]. Although the Johns Hopkins hospital in a Q and A session on the corona vaccine in February 2021 stated that people who were pregnant could receive the vaccine, this was based on the fact that the CDC had included pregnant women in the list of high-risk groups, not based on available safety studies at the time. Furthermore, they highlighted the fact that available data from CDC had shown that completion of the mRNA vaccines in pregnancy may help in prevention of hospitalization due to COVID-19 in infants born to these mothers, up to 6 months of age or younger [19]. After so much debate, the CDC as at August of 2021 finally released a statement stating that the COVID-19 vaccine was safe for pregnant and breastfeeding women [20].

Now, after all said and done, as regards the pregnant women, the decision to vaccinate or not should be informed based, as clinicians are availed with limited data on evidence-based decisions in trying to evaluate the potential risks whether real or theoretical as regards the potential effects of the vaccine on pregnancy and pregnancy on the vaccine [18].

The limitation of this study was the limited number of pregnant participants who had actually received the vaccine, as a wedge-stick to proposing with some certainty the percentage risk per pregnancy-related side effect the vaccine does carry.

Conclusion

The most common systemic side effects that were experienced by those who had received the vaccine were Headaches (47.6%), catarrh (28.6%), injection site swelling (22.2%), fever (20.5%) and fatigue (16.0%). While amongst those who received the vaccine in pregnancy mainly experienced abdominal pains (18.8%), bleeding per vaginam (15.6%) and preterm contractions (15.6%).

The percentage of pregnancy related side effects are relatively very low and most are non-fatal. Hence, the corona vaccine is relatively safe for women in pregnancy with no known history to hypersensitivity to vaccines.

Recommendations

Based on our findings, we have the following recommendations;

To the Government and PHC – Board

1. The government and the PHC board should as matter of urgency intensify sensitization of communities and patients about the covid vaccine. Paying attention to;
 - a. Hosting community seminars and workshops to make the community aware of the corona virus vaccination scheme, of the objectives and distribution.
 - b. To use the media such as television and radio which seems to be a significant means of awareness amongst the respondents in this study.
 - c. Mobilize the health workers to enlighten the persons who come for Ante Natal Care (ANC) through posters and oral awareness.
 - d. Make available the vaccine to the various PHCs and notify the women so that they can have access to it.
2. Make policy statements to enable pregnant women get the COVID vaccine

To the Healthcare workers

1. To update their knowledge on the virus and the vaccines regularly.
2. Healthcare workers should encourage willingness to accepting the COVID vaccine, through health education, workshops and clinical counseling.
3. Should promote informal conversations on the importance of the vaccines at their social gatherings.

To prospective researchers

1. More randomized Case-control trials should be done to better ascertain the impact of the vaccine on pregnancy and pregnancy on the vaccine
2. To conduct systematically reviewed studies to create a general stratification of safety criteria for acceptance of the vaccines in pregnancy and prenatal period, especially amongst nursing mothers.
3. To better make available regional data acquired through quantitative and qualitative studies, information on the safety and possible adverse effects of the vaccine amongst pregnant women.

To the Pharmaceutical industries

1. To release accompanying data on contraindications that possibly permit or forbid specific risk group of individuals from receiving the vaccines.

To step up and make available their analysis of data gotten from reliable large group pharmacovigilance reports on the vaccines.

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Authors Contribution

Conceptualization, Data collection and Writing = OTOBO Daniel David

Data analysis and Final editing = OKORO Ngozi Ijeoma

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