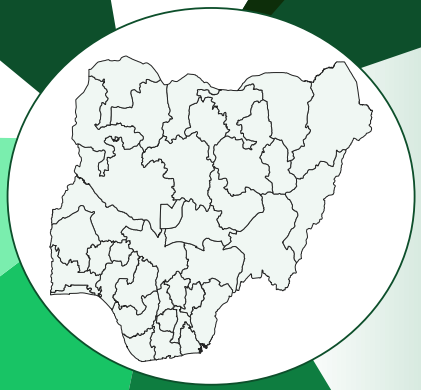
Cohort Event Monitoring

CEM



Safety Signal Detection After Vaccination with COVID-19 Vaccines And Post Market Monitoring in Nigeria

REPORT

November 2022

NAFDAC

CDC Centers for Disease Control and Prevention

University of Maryland Baltimore

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The Task Force for Global Health

COHORT EVENT MONITORING SAFETY SIGNAL DETECTION AFTER VACCINATION WITH COVID-19 VACCINES AND POST MARKET MONITORING IN NIGERIA REPORT

Cohort Event Monitoring Collaborating Institutions

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Centers for Disease Control and Prevention (CDC)
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The Task Force for Global Health

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LIST OF ABBREVIATIONS

AESI	Adverse Event of Special Interest
CDC	Centers for Disease Control and Prevention
CEM	Cohort Event Monitoring
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Corona Virus Disease 2019
DMP	Data Management Plan
EMA	European Medicines Agency
GEP	Good Epidemiological Practice
ICF	Informed Consent Form
IEC	Independent Ethics Committee
MAE	Medically Attended Event
IRB	Institutional Review Board
MEDDRA	Medical Dictionary for Regulatory Activities
NAFDAC	National Agency for Food and Drug Administration and Control
NIP	National Immunization Programme
PT	Preferred Term
SAE	Serious Adverse Event
SARS-COV-2	Severe Acute Respiratory Syndrome CoronaVirus 2
SAP	Statistical Analysis Plan
SCRI	Self-Controlled Risk Intervals
SIR	Standardized Incidence Ratio
SPEAC	Safety Platform for Emergency Vaccines
VAED	Vaccine-Associated Enhanced Disease
WHO	World Health Organization

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EXECUTIVE SUMMARY

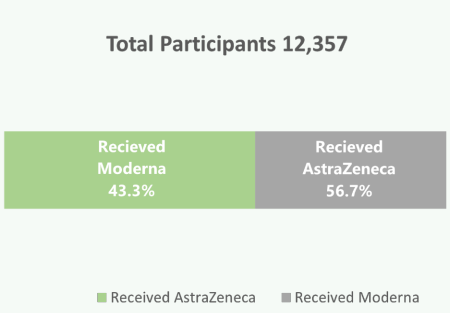
Purpose of Report

This report is a documentation of the results of the **Cohort Event Monitoring (CEM) For Safety Signal Detection, After Vaccination with COVID-19 Vaccines and Post Market Monitoring in Nigeria**. Cohort Event Monitoring (CEM) is an evaluation program proposed by the World Health Organization (WHO) which seeks to fill the safety data gap between phase 3 clinical trials and routine passive surveillance. This evaluation provides a quick and easy way to actively follow up on adverse events in persons exposed to the COVID-19 vaccines and the data generated will provide reassurance of safety for regulators, immunization programs, and the public.

The report describes the adverse events occurring in a cohort of enrolled individuals vaccinated with AstraZeneca and Moderna COVID-19 vaccines which were available in Nigeria during the period of data collection. It also captures the demonstrated outcomes of CEM that were designed for an intensive follow-up period of three-to-six months following the first and second doses, as applicable, of the COVID-19 vaccines.

The report describes the adverse events occurring in a cohort of enrolled individuals vaccinated with COVID-19 vaccines which were available in Nigeria during the period of data collection

Key Findings



- 12,357 participants who received first dose of vaccine were approached to be part of the CEM, 12,317 (99.7%) consented to participate; 6,990 (56.7%) of the enrollees received the AstraZeneca vaccine and 5,327 (43.3%) received Moderna.

- 11,911 (96.7%) participants were followed up with 11,046 (92.7%) reached within day 0 – 7 post first dose vaccination and accessed for reactogenicity. 56.3% experienced at least one local reactogenicity symptom and 41.1% reported systemic symptoms after first dose of vaccination.

- For the AstraZeneca vaccine, pain at injection site (95.8%) was the highest reported local reactogenicity while 0.6% reported redness at injection site. Pain at injection site (97.2%) was also commonly reported among those who received Moderna vaccine while 0.1% reported bruise around injection site.

- Fever was the most reported systematic reactogenicity after first dose vaccination among those who received AstraZeneca (57.4%) and Moderna vaccine (52.9%) while dizziness, cold and cough were the least.

- 66.1% (7,869) of those followed up (11,911) received second dose vaccine and accessed for reactogenicity within day 0 – 7 days after vaccination.
- Pain at injection site was the highest reported local reactogenicity after second dose vaccination among those who had AstraZeneca (98.0%) and Moderna (98.5%) vaccine while redness and bruise around injection site were least reported.
- Fever was the most commonly reported systematic reaction among those who received AstraZeneca (47.7%) and Moderna (69.6%) vaccine while shortness of breathe and palpitation were the least.
- Out of 11,911 participants that were followed up, 6.6% (786) reported that they sought medical care at least once post vaccination. The incidence of Medically Attended Events (MAES) among those who received Moderna was 1.38 times that of those on AstraZeneca.
- Of the 11,911 participants, 75 (0.6%) were hospitalized – 32 (0.6%) among those on Moderna and 43 (0.6%) on AstraZeneca.
- Out of all the participants followed up, 25 (0.2%) reported testing positive for SARS-CoV-2 following vaccination and 2 (0.02%) cases resulted in intensive care. Reporting of positive SARS-CoV-2 result were 0.2% (11) among those who received AstraZeneca and 0.3% (14) Moderna vaccine.

Conclusions and Recommendations

Among the 11,911 participants who consented and reached for follow up, no vaccine related mortality was recorded during the follow-up period

The AstraZeneca and Moderna COVID-19 vaccines are relatively safe as the adverse events recorded were not severe among most of the participants

A longer follow-up period is recommended to evaluate adverse events that may occur after 6 months of vaccination

Introduction

1.1 Background

Since December 2019, the world has been experiencing an outbreak of a respiratory disease caused by a novel coronavirus strain reported first in Wuhan City, China [1]. This strain of coronavirus known as "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) is responsible for the 2019 coronavirus disease (COVID-19). The virus spread massively from China to an increasing number of countries worldwide causing the World Health Organization (WHO) to declare the outbreak a pandemic on 12 March 2020 [1,2].

One of the main recommendations to curtail the spread of the SARS-CoV-2 pandemic was the introduction of safe and effective vaccines, with fair access to the vaccines worldwide. The development of safe and effective vaccines became one of the key recommendations for containing the SARS-CoV-2 pandemic alongside equitable access to the vaccines across the globe [3]. The WHO has supported vaccine research and is leading the COVAX initiative to reduce the negative fiscal and public health effects induced by the pandemic [3]. The safety and effectiveness of vaccines used in national immunization programs (NIPs) have been established through randomized controlled clinical trials [3,4,5].

However, despite rigorous safety evaluations during clinical development, the COVID-19 vaccines may not be completely free of risks. Occasionally, adverse events may inevitably occur following COVID-19 vaccination at the population level [6]. In Nigeria, as well as other countries, given that vaccines are often strongly recommended for all exposed individuals in the population including healthy persons, the key to success of NIPs on approved vaccines is gaining public trust of vaccine safety [7].

Thus, systematic vaccine safety surveillance and dissemination of key findings is critical for ensuring safety of vaccines and mobilizing public trust through informed processes. In any country, once a plan for immunization with COVID-19 vaccines is set up, pharmacovigilance efforts should start simultaneously, as conceptualized in the WHO Smart Safety Surveillance (3S) principles [8]. Furthermore, specific COVID-19 vaccine safety surveillance should be implemented as described in the WHO safety surveillance manual [9].

In Nigeria, COVID-19 vaccination started in March 2021 with the CoviShield vaccine from AstraZeneca – a viral vector vaccine, manufactured by the Serum Institute of India Pvt. Ltd as the only brand in-country. Since then, Nigeria has received COVID-19 vaccines from other manufacturers/developers, including Pfizer-BioNTech, Moderna, and Johnson and Johnson's Janssen. As of October 2022, out of 10.9 billion doses of COVID-19 vaccines administered globally, Nigeria has successfully given out 27.6 million doses, fully vaccinating [10, 11] about 4.1% of the population. Vaccination began with health care workers and frontline workers as a priority and later was extended to the entire adult population. In Nigeria, adult individuals ages 18 years and above are being primarily vaccinated at designated sentinel sites following the WHO's SAGE (Safe, Active, Green, and Easy) recommendations [12].

1.2 Overview of CEM

Cohort event monitoring (CEM) is an evaluation program proposed by the WHO and adopted by many developing countries which seeks to fill the safety data gap between phase 3 clinical trials and routine passive surveillance. CEM evaluation activities provide a quick and easy way to actively follow up on adverse events in persons exposed to new drugs and/or vaccines. Data generated from CEM activities provide reassurance of safety for regulators, Expanded Program on Immunization (EPI), and the public.

This report outlines the methodology, process and evaluation of the safety of COVID-19 vaccines using a CEM protocol to record adverse events observed in enrolled persons who received the COVID-19 vaccine Covishield or any other brand made available in Nigeria from September 9th, 2021, to March 31st, 2022. It also captures the demonstrated outcomes of CEM that were designed for an intensive follow-up period of three-to-six months following the first and second doses, as applicable, of COVID-19 vaccines.

1.3 Specific Objectives

The overall goal of this evaluation activity was to monitor the safety of enrolled individuals who have received any authorized COVID-19 vaccines in Nigeria. The specific objectives were to:

1. Characterize the adverse event following immunization (AEFI) profile among persons receiving COVID-19 vaccines, including medically attended events (MAEs), serious adverse events (SAEs), and adverse events of special interest (AESIs).

2. Estimate the incidence of SAEs in all enrolled vaccinated participants after each COVID-19 vaccine dose, or after the combined two doses, by COVID-19 vaccine brand.

3. Estimate the incidence of AESIs in all enrolled vaccinated participants after each COVID-19 vaccine dose or after the combined two doses, by COVID-19 vaccine brand.

4. Estimate the incidence of reactogenicity within seven days after each COVID-19 vaccine dose, by COVID-19 vaccine brand.

5. Estimate the incidence of COVID-19 for the possibility of vaccine-associated enhanced disease (VAED).

CEM Design and Methodology

2.1 Study Area

The CEM Phase I evaluation was conducted in six states. These include the Federal Capital Territory (FCT), Bauchi, Benin, Edo, Enugu, and Kaduna. Participants were recruited from six tertiary and at least five associated health facilities in the six geopolitical zones of the country used as vaccination centers for administration of COVID-19 vaccines. The associated health facilities were termed the "spokes" and were also the high-volume COVID-19 vaccination facilities where outreach was conducted. Only enrollment of the participants was conducted at the spokes, follow-up was from the tertiary facilities which served as the "hubs".

Study sites were selected based on the availability of sufficient and trained human resources, access by target population, geopolitical location, size of population covered, vaccination coverage, and access to a computer for data collection at the site level.

2.2 Sampling Methods

2.2.1 Sample size for overall cohort

For Phase I of the CEM evaluation, a total of 12,317 participants across the six participating tertiary hospitals were enrolled for follow-up. In the sample size calculation, 12,000 participants were used to exclude occurrences with a rate of one per 3,333 with 95% confidence if an event was not detected (WHO COVID-19 CEM protocol) [13] as shown in Table 1 below.

Table 1. Sample size required to rule out events with the indicated frequency if no event was observed with 95% confidence.

Sample size	Event Frequency
10,000	1 per 3,333
20,000	1 per 6,666
30,000	1 per 10,000
40,000	1 per 12,500
50,000	1 per 16,666
60,000	1 per 20,000
80,000	1 per 25,000
100,000	1 per 33,333
150,000	1 per 50,000
500,000	1 per 100,000

The participants included all consenting persons 18 years and above with significant comorbidities and other priority groups according to the National Deployment and Vaccination Plan [14].

2.3 Recruitment, Eligibility Criteria, and Consent Procedures

2.3.1 Recruitment

The aim of the CEM evaluation was to check for AEFIs following COVID-19 vaccination. Participants were recruited among individuals vaccinated at selected sites that participated in this CEM evaluation. Participation was strictly voluntary.

The CEM enrollment and follow-up process was done by two categories of people: the data entrants and the follow-up clinicians. The data entrants entered the participants' data and then the follow-up clinicians called the participants on Day 0, Day 3, and Day 7, checking for any AEFIs that may have occurred. The implementation design followed a series of processes, such as advertisement and recruitment of research assistants, advocacy campaign by the study principal officers, and training of the recruited research assistants.

The role of data entrants was to collect and enter participants' data (electronically, with the use of a tablet), complete the participants' baseline information (demographic and medical) and contact information (of participant and participant's next of kin), and record details of vaccination. A unique participant number was generated for each participant who gave consent to be followed up.

The follow-up clinicians contacted the participants thereafter via phone calls on Day 0, Day 3, and Day 7, respectively, after their vaccinations and once weekly thereafter. This was done to record any occurrence of AEFIs. They also monitored the participants after they had taken their second dose of the vaccine.

2.3.2 Eligibility/Inclusion Criteria

- Individuals who had received the COVID-19 vaccine and were 18 years and above.
- Ability and willingness to give informed consent in English, Pidgin English, Yoruba, Hausa, or Igbo.
- First dose of a COVID-19 vaccine already received at a vaccination centre participating in the surveillance activity.
- Individuals with a history of hypersensitive reactions/allergy to vaccines, immunosuppression, pregnant/breastfeeding women.

2.3.3 Exclusion Criteria

- Participants already vaccinated with any other COVID-19 vaccine before enrollment, irrespective of the brand.
- Participants unable to comply with study procedures (e.g., illiterate, cognitively impaired, etc.)
- Individuals with current or history of substance addiction.
- Individuals who refused to consent at enrollment or those who withdrew consent at any time following enrollment.

2.3.4 Withdrawal and loss to follow-up

- A participant had the right to withdraw from surveillance at any time and for any reason.
- A participant was considered lost to follow-up after five unsuccessful attempts within one week to contact the participant by phone, followed by five unsuccessful attempts within a week to contact participants' next of kin. All contact attempts were documented.
- Attempts were made to determine the underlying reason(s) for the withdrawal and, where possible, the primary underlying reason was recorded.
- Withdrawn participants and participants lost to follow-up were not replaced after the enrollment period had ended.
- For a participant who decided to withdraw, data collected up until time of withdrawal were included in the analysis except if the participant requested that the data should not be used.

2.3.5 CEM Implementation

CEM implementation teams received training on all contents of data collection instruments, tablet use, standard operating procedures (SOPs), and manuals. The training curriculum included:

- Overview of COVID-19
- Overview of COVID-19 vaccine globally and in Nigeria
- Overview of CEM
- Study organization, reporting structure, and documentation
- Team building and preparing for data collection through tracking.
- CEM study team, roles, and responsibilities.
- General techniques in Interview
- Communication skills and time management
- Research ethics and confidentiality
- Informed consent and consent taking

- Use of tablets for data collection
- Data capture and transmission
- Overview of study tools (enrollment questionnaire)
- Infection prevention and control (IPC) in the health facility

2.4 Ethical Approval

2.4.1 Supporting Principles

This study was carried out in accordance with the Good Epidemiological Practice (GEP) recommendations, the International Ethical Guidelines for Health-Related Research Involving Humans published by the Council for International Organizations of Medical Sciences (CIOMS, 2016), as well as other applicable national laws, regulations, and guidelines.

This evaluation was primarily observation-based with no medical intervention or alteration to the clinical and investigative competence of the vaccines, thereby rendering no immediate benefit to the enrollees. However, there are important potential societal benefits derived from this vaccine safety evaluation.

2.4.2 Respecting Participant Autonomy

Participants were informed about the evaluation through the health facilities offering immunization and had the opportunity to ask questions from the CEM staff. The informed consent form (ICF) was signed electronically before participant enrollment **(APPENDIX 1)**. By signing the ICF, participants agreed to have the data collection team contact designated hospital(s) at which they sought care during the evaluation period for confirmation of the details of the reaction that led to the occurrence

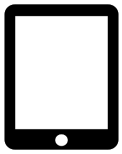
The ICF outlined the rationale and potential use of data to be collected, the reason behind the use, period of accessibility of the data and the methods by which participants can obtain information on the use of their data.

2.4.3 Participant Confidentiality

All parties involved ensured the protection of participants' personal data collected during the research. As a result, participant names were not included in any publication, or in any form of disclosure except where required by law. Local data protection and privacy regulations were observed in capturing, forwarding, processing, and storing participant data

2.4.4 Independent Ethics Committee/Institutional Review Board

Participating sites submitted National Health Research Ethics Committee (NHREC) approval to the site-specific Institutional Ethics Committee(s)/Institutional Review Board(s) (IRB) for documentation, following local regulations and compliance with any national ethics committee requirements. The protocol was also submitted to the United States Centers for Disease Control and Prevention (CDC) for approval of a determination of non-human subjects' research, as well as to the University of Maryland, Baltimore (UMB) IRB for approval. Therefore, informed consent was required from all participants or legal tutors.



2.5 Data Collection and Management

Data was collected at the time of enrollment and during follow-up by data entrants who were part of the study evaluation staff. Data collection at enrollment and vaccination was done on tablets using an electronic data collection tool – census and survey processing system (CSPro, version 7.4) [15]. Participation in the evaluation was voluntary with no form of incentive, compensation, or payment from the organization. Data was collected during the three-month follow-up period by telephone interviews. Responses from participants were documented in the electronic data collection tool in real time.

Enrollment activities took place within a month across all 36 study sites in the six states. Participants aged 18 years and above who consented to take part in the study were enrolled and followed up for three months if they only received one dose of vaccine and for six months for those who received the first and second dose of AstraZeneca or Moderna vaccine.

Completed questionnaires and hospital/laboratory data were stored on the data collection devices and sent daily directly to the central server through a secured connection. Data transmission was monitored centrally, and support was provided to the data collection teams for timely synchronization.

Reports with an adverse event were routed to the country's VigiFlow system using an E2B file, while other reports were exported as a CSV file for further analysis.

2.6 Definitions and Classifications of Events

2.6.1 Reactogenicity

Reactogenicity was categorized as either local or systemic reactogenicity. Local reactogenicity was defined as the presence of pain, redness, warmth, swelling, hardening/ induration, hematoma, or itching at or near the injection site. Systemic reactogenicity was characterized as the presence of fever, chills, headache, nausea, muscle or joint discomfort, or feeling unwell (3). Both categories of reactogenicity were recorded within the first eight days of the first dose at Day 3 and Day 7 post-vaccination, respectively, where the first day was recorded as Day 0. Participants were retrospectively asked about any new medical events including systemic symptoms in the three days prior to enrollment (excluding the day of enrollment).

2.6.2 Medically Attended Events

Medically Attended Events (MAES) were defined as adverse reactions that led to seeking medical care from a health practitioner or pharmacist, or health facility during any period of follow-up.

2.6.3 Serious Adverse Events

Events that resulted in death, were life-threatening, necessitated inpatient hospitalization or prolongation of an existing hospitalization, caused persistent or significant disability/ incapacity, or constituted congenital birth defects were referred to as serious adverse events (SAEs). SAEs associated with hospitalization were reported by the participant or next of kin while those resulting in death were reported by the next of kin.

2.6.4 Identification of MAEs and SAEs

The diagnoses reported by the participants during follow-up were coded using Medical Dictionary for Regulatory Activities (MedDRA) [16] by data managers. MAEs, and SAEs were identified by the MedDRA coding trained data managers. Reported MAE, or SAE were followed up for investigation using the already documented in-country approach for investigation of serious AEFIs. The State Epidemiologist and Disease Surveillance and Notification Officers (DSNOs) for that State where the cases occurred was involved in the investigation of the cases. All necessary medical reports related to each case were obtained for appropriate documentation by data managers.

2.6.5 Data Analysis

Participation rate over time was described, and demographic characteristics at enrollment were summarized using frequencies and percentages. Analysis of reactogenicity was conducted on participants with follow-up information between zero and seven days of receiving a vaccine, while MAEs and SAEs included all participants with at least one follow-up. Completion of the follow-up interviews by participants with no disclosure of an event was reported as the absence of an event. Missing values were not inputed.

Frequencies and percentages of MAEs and SAEs were provided for all reported cases. Length of time from first vaccination (reported in weeks) was considered in calculations of the likelihood of occurrence of identified SAEs among participants. Determination of diagnoses was carried out using Preferred Terms (PTs) assigned by MedDRA while 95% confidence intervals for proportions were determined precisely.

The frequency of participants reporting reactogenicity, MAEs, and SAEs were assessed and reported as percentages and grouped by age group, sex, vaccine brand, and risk group. Furthermore, incidence of MAEs and SAEs was calculated for the overall population and by age group, sex, vaccine brand, risk group, and pregnancy using the number of person-years contributed by each participant with the associated confidence interval.

Person-years of follow-up contributed by the cohort were accumulated for each client from the date of first vaccination (enrollment date) until the date of last contact or first diagnosis of any MAEs or SAEs. The 95% confidence intervals of the incidence rate were calculated using an exact method.

A multivariate Poisson regression was used to estimate the incidence rate ratios of reactogenicity, MAEs, and SAEs reporting by age group, sex, vaccine brand, and risk group with 95% confidence intervals. The incidence of COVID-19 disease ascertained by laboratory testing, diagnosis by a health professional, admission to a hospital or intensive care unit, or related death, was calculated by dose classification and by the interval between doses. The appearance of COVID-19 symptoms within one-to-two days after vaccination was a basis for exclusion of participants from the study.

2.6.6 Data Management

A data management plan (DMP) describing all related data activities and processes and outlining critical steps to ensure data collection and validation, including roles and responsibilities of staff, was developed prior to the onset of data collection.

The data collection staff were responsible for the entry of the data into the tablets. The evaluation staff were responsible for ensuring completion of the ICF and collection of other pertinent information such as participants demographic information, enrollment date, details about the vaccine, relevant information from interviews and medical charts, where applicable, and any data obtained in the event of additional follow-up after initial non-response.

Data collected was stored on UMB in-county servers with a backup database restored at the National Agency for Food and Drug Administration (NAFDAC) office.

2.6.7 Data Security

Participants were assigned a unique identification number for identifying their responses. The link to participants' personal information was maintained by authorized members of the evaluation team. All electronic databases were encrypted, and password protected to ensure confidentiality. Access to electronic data was restricted to authorized evaluation staff, such as the data managers and investigators. For events that required prompt identification and response by EPI and NAFDAC, patient identification details were made available to the relevant persons via Nextcloud, a client-server software for creating and using file hosting services which supports all technical safeguard requirements and is in full compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

2.6.8 Data Transfer

Data uploaded by the data entrants were transmitted to the central evaluation server over the internet using secured https protocol. Data was only accessed for follow-up over the internet using secure https protocol. Hence, data was handled with high confidentiality and security checks.

Response Rate

3.1 Background

This section presents a description of state-level enrollment and follow-up of participants. Participants followed-up are those whose phone numbers were reachable after enrolling into the study.

3.2 Results

The description of participant enrollment and follow-up by states are detailed in Table 3-1.

3.3 Key Findings

- Of 12,357 participants that were approached about the study, 12,317 (99.7%) gave their consent for participation in the study; 6,990 (56.7%) of the enrollees received the AstraZeneca vaccine and 5,327 (43.3%) received Moderna.
- Out of the enrolled participants (12,317), about 3.3% (406) were not reachable for follow-up due to inaccurate capture of participant phone numbers during enrollment.
- Of the 11,911 participants that were followed up, 66.1% (7,869) had a second dose of the vaccination- 49.5% (3,891) among AstraZeneca and 50.5% (3,978) among Moderna vaccinees.
- FCT had the highest proportion (82.4%) of participants receiving the second dose of vaccine, while Bauchi (46.8%) had the lowest rate. About 10.9% (1,293/11,911) of the participants followed up were lost to follow-up, with Kaduna having the highest rate (19.0%) and Enugu (2.1%) having the lowest.
- A total of 10,618 (89.1%) participants completed the follow-up schedule among 11,911 that were followed up.
- 72.0% (2,912/4,042) of those who received only the first dose of a vaccine completed the three-month follow-up, while 97.9% (7,706/7,869) had complete follow-up among those who received first and second doses of a vaccine (Figure 1).

States with the highest enrollment rates due to the high volume of persons receiving a COVID-19 vaccine.

Table 3-1: Description of enrollment and follow-up by state

State	# Enrolled (n)	# Followed up		# Received 2nd dose		# Lost to follow-up	
		n_0	$\%(n_0/n)$	n_1 %	(n_1/n_0)	n_2	$\%(n_2/n_0)$
Bauchi	2,024	2,001	98.9	936	46.8	47	2.3
Edo	2,063	1,936	93.8	925	47.8	268	13.8
Enugu	2,043	2,027	99.2	1,574	77.7	41	2.0
FCT	2,078	2,056	98.9	1,695	82.4	235	11.4
Kaduna	2,034	1,914	94.1	1,183	61.8	365	19.1
Lagos	2,075	1,977	95.3	1,556	78.7	337	17.0
Total	12,317	11,911	96.7	7,869	66.1	1,293	10.9

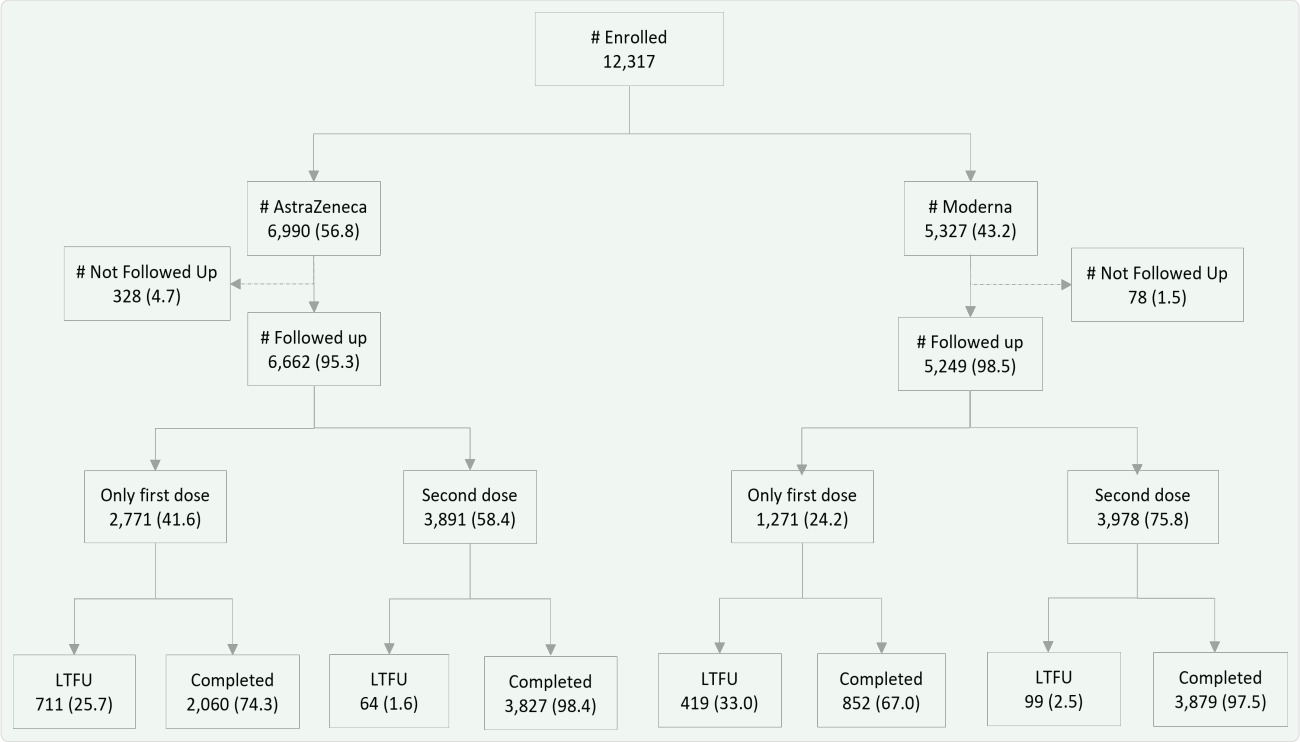


Figure 3-1: Description of enrollment and follow-up

Participants Characteristics at Enrollment

4.1 Background

This session summarizes the socio-demographic characteristics, and background information of participants at enrollment.

4.2 Results

Table 4-1 presents the distribution of participants characteristics at enrollment.

4.3 Key Findings

- More females (57.1%) were enrolled and about one-fourth were 35-44 years (25.7%) while only 13.9% were less than 25 years old.
- About 4,470 (36.3%) of enrolled participants experienced at least one of the following symptoms within three days prior to vaccination: fever, nauseous, malaise, chills, headache, joint pain, muscle aches, and tiredness.
- Of the vaccine brands, 6,990 (56.7%) received AstraZeneca while 5,327 (43.3%) of the participants were vaccinated with the Moderna vaccine.
- Only 1.7% (205) were reportedly diagnosed with COVID-19 based on laboratory confirmation prior to vaccination.

Table 4-1: Distribution of participants' characteristics at enrollment

Variables	Frequency	Percent (%)
Age group		
18 - 24 years	1,709	13.9
25 - 34 years	3,147	25.5
35 – 44 years	3,165	25.7
45 – 54 years	2,131	17.3
55+ years	2,165	17.6
Gender		
Male	5,282	42.9
Female	7,035	57.1
History of Chronic Diseases		
None	9,426	76.7
Yes	2,866	23.3
History of reaction to vaccination		
Yes	445	3.6
No	11,872	96.4
Pre-vaccination (3 days prior) symptoms		
Yes	4,470	36.3
No	7,847	63.7
Vaccination Brand		
AstraZeneca	6,990	56.7
Moderna	5,327	43.3
Previous COVID-19 diagnosis		
No	11,724	95.2
Yes, Not laboratory confirmed	388	3.1
Yes, Laboratory confirmed	205	1.7

Local and Systemic Reactogenicity within 7 days of first dose

5.1 Background

This section focused on the bi-variate distribution of the cumulative incidence of local and systemic reactogenicity by vaccine brand and overall, within 7 days of first dose. It also includes the pattern of specific reactogenicity reported by vaccine brand.

5.2 Results

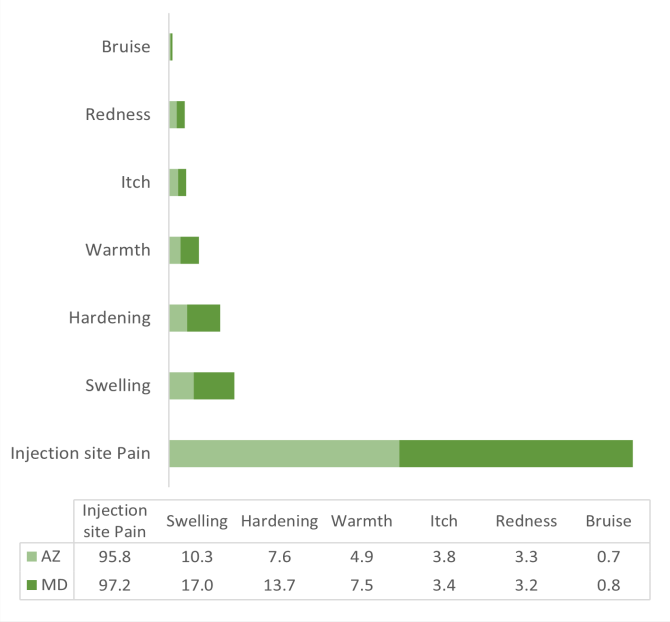
The distribution and cumulative incidence of local and systematic reactogenicity are presented in Table 5 1 while Figure 5-1(A) and Figure 5-2(B) shows the pattern of specific reactogenicity reported.

5.3 Key Findings

- Out of 11,911 participants that were followed up, only 11,046 (92.7%) were reachable for reactogenicity assessment within 0 – 7 days after the first dose.
- Of the 11,046, a little over half (56.3%) experienced at least one local reactogenicity symptom and 41.1% reported systemic reactogenicity symptoms.
- There was a difference in the experience of local reactogenicity by vaccine brand; those who received the Moderna vaccine (72.4%) reported more local symptoms than those with AstraZeneca vaccines (43.5%). However, the distribution of reported symptoms was similar across the vaccine brand – pain at the injection site was most commonly reported, while bruise around the injection site was least experienced.
- Similarly, the occurrence of systemic reactogenicity symptoms among those who received Moderna (42.8%) was different from those who had AstraZeneca (39.8%). Also, the pattern of symptoms experienced were similar across the brands – fever and headache were among the most common while dizziness and cold were least reported.

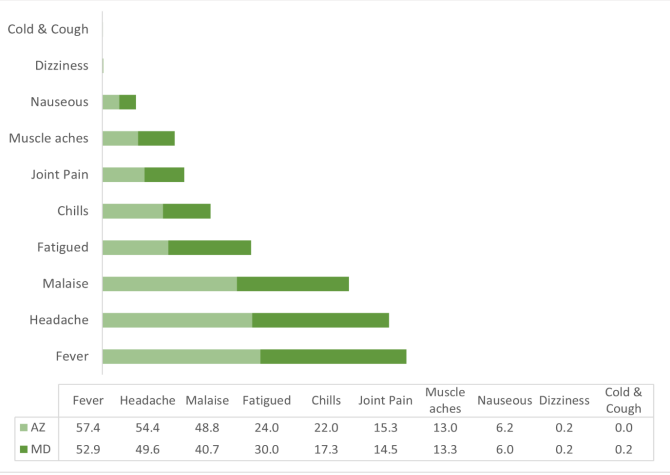
Table 5-1: Distribution and cumulative incidence of local and systemic reactogenicity within 7 days of first dose

Variable	Frequency N = 11,046	Vaccine brand; n (%)		p-value
	n (%)	AstraZeneca (N = 6,167)	Moderna (N = 4,879)	
Local	6,218 (56.3)	2,685 (43.5)	3,533 (72.4)	<0.001
Systemic	4,543 (41.1)	2,456 (39.8)	2,087 (42.8)	<0.001



AZ= AztraZeneca, MD= Moderna

Figure 5-1(A): Distribution of specific local reactions within day 0-7 of first dose



AZ= AztraZeneca, MD= Moderna

Figure 5-2(B): Distribution of specific systemic reactions within day 0-7 of first dose

Local and Systemic Reactogenicity within 7 days of second dose

6.1 Background

This section focused on the bi-variate distribution of the cumulative incidence of local and systemic reactogenicity by vaccine brand and overall within 7 days of second dose. It also includes the pattern of specific reactogenicity reported by vaccine brand.

6.2 Results

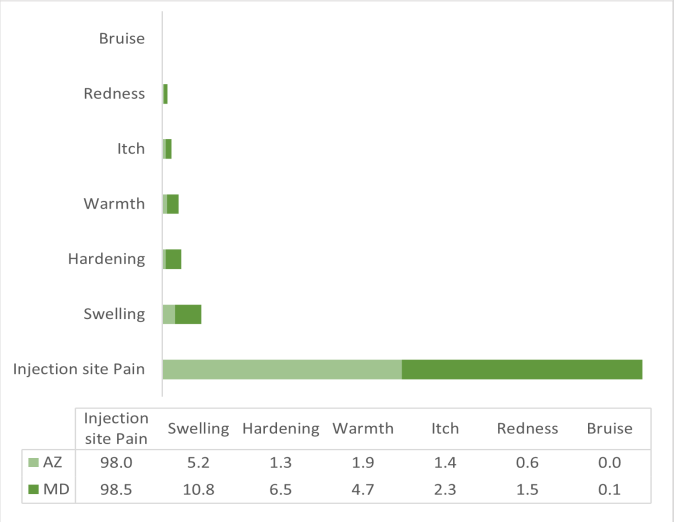
The distribution and cumulative incidence of local and systematic reactogenicity are presented in Table 6-1 while Figure 6-1(A) and Figure 6-2(B) shows the pattern of specific reactogenicity reported after second dose of vaccination.

6.3 Key Findings

- From the overall incidence of reactogenicity within the first seven days among participants, 49.5% of reports were from those that received the AstraZeneca vaccine and 50.5% were from those that received the Moderna vaccine.
- The incidence of Local reactogenicity was 36.5% while that of systemic reactogenicity was 30.6%.
- For the AstraZeneca vaccine, the highest percentage of local reactogenicity reported was pain at injection site which was 98% of reporters, while the lowest percentage was redness at the injection site for 0.6% of reporters.
- For the Moderna vaccine, the highest percentage of local reactogenicity reported was pain at injection site which was 98.5%, while the lowest percentage was bruise around the injection site at 0.1%.
- For the AstraZeneca vaccine, the highest percentage of systemic reactogenicity reported was fever which was 47.7%, while the lowest percentage was shortness of breath at 0.3%.
- For the Moderna vaccine, the highest percentage of systemic reactogenicity reported was fever which was 69.6%, while the lowest percentage was shortness of breath and palpitation at 0.2%.

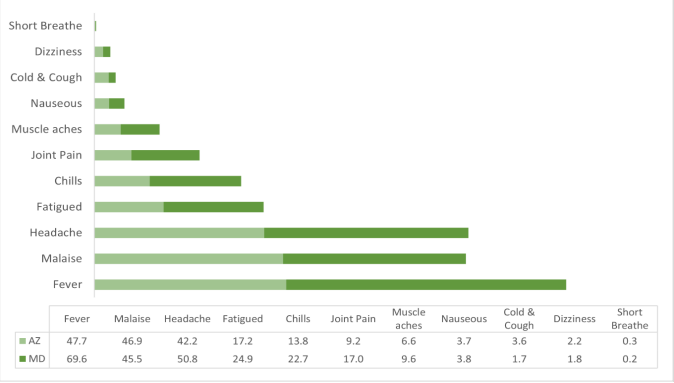
Table 6-1: Distribution and cumulative incidence of local and systemic reactogenicity within 7 days of second dose

Variable	Frequency N = 7,869	Vaccine time; n (%)		p-value
	n (%)	AstraZeneca (N = 3,891)	Moderna (N = 3,978)	
Local	2,876 (36.5)	897 (23.0)	1,979 (49.7)	<0.001
Systemic	2,407 (30.6)	727 (18.7)	1,680 (42.2)	<0.001



AZ= AztraZeneca, MD= Moderna

Figure 6-1(A): Distribution of specific local reactions within day 0-7 of first dose



AZ= AztraZeneca, MD= Moderna

Figure 6-2(B): Distribution of specific systemic reactions within day 0-7 of second dose

Occurrence of reactogenicity by participants' characteristics

7.1 Background

This section compares the occurrence of any reactogenicity within 0 – 7 days by participants characteristics at enrollment and dose classification.

7.2 Results

Table 7-1 shows the distribution and incidence rate ratio of occurrence of any reactogenicity.

7.3 Key Findings

- Out of 11,911 participants followed up, 11,590 (97.3%) had follow-up information at 0 – 7 days after the first or second dose of vaccination.
- Overall, 70.2% of the 11,590 experienced at least one reactogenicity symptom within 0 – 7 days regardless of vaccine dose. The overall incidence of reactogenicity was 82.5% among Moderna vaccine and 60.5% among those who received AstraZeneca.
- The incidence rate of any reactogenicity symptoms among those who received Moderna were 1.46 times (95% C.I: 1.43-1.50) higher than those who received AstraZeneca.
- Also, the occurrence of any symptoms was more likely (IRR: 1.49, 95% C.I: 1.44 – 1.53) among those who received both vaccine doses (76.3%) compared to those who only received the first dose (57.5%).
- Similarly, those who experienced at least one symptom within three days prior to vaccination were 1.14 (95% C.I: 1.11-1.17) more likely to have the occurrence of any reactogenicity compared to those who had no prior experience.
- Furthermore, symptoms were less likely among males (IRR: 0.84, 95% C.I: 0.82-0.86) and across age groups, while more likely among those who had history of at least one chronic disease (IRR: 1.14, 95% C.I: 1.11-1.18) and history of reaction to vaccination (IRR: 1.11, 95% C.I: 1.04-1.17) .

Table 7-1: Distribution and incidence rate ratio of reactogenicity occurrence by participant characteristics

Variable	N	Reported Reactogenicity n(%)	Incidence Rate Ratio (adjusted)	95% Confidence Interval
Age group				
<25 years	1,591	1,138(71.5)	1.00	-
25 - 34 years	2,973	2,242 (75.4)	1.06*	1.01 - 1.10
35 – 44 years	2,974	2,147 (72.2)	0.92*	0.89 - 0.96
45 – 54 years	2,000	1,346 (67.3)	0.81*	0.77 - 0.85
55+ years	2,052	1,269 (61.8)	0.64*	0.61 - 0.67
Gender				
Female	4,924	3,674 (74.6)	1.00	-
Male	6,666	4,468 (67.0)	0.84*	0.82 - 0.86
History of Chronic Diseases				
None	8,853	6,163 (69.6)	1.00	-
Yes	2,713	1,965 (72.4)	1.14*	1.11 - 1.18
History of reaction to vaccination				
No	11,160	7,810 (70.0)	1.00	-
Yes	430	332 (77.2)	1.11*	1.04 - 1.17
Pre-vaccination (3days prior) symptoms				
No	7,393	5,055 (68.4)	1.00	-
Yes	4,197	3,087 (73.5)	1.14*	1.11 - 1.17
Vaccination Brand				
AstraZeneca	6,439	3,894 (60.5)	1.00	-
Moderna	5,151	4,248 (82.5)	1.46*	1.43 - 1.50
Vaccine Dose				
Only first dose	3,721	2,141 (57.5)	1.00	-
Second	7,869	6,001 (76.3)	1.49*	1.44 - 1.53

**significant at p<0.05*

Occurrence of MAE's by participants' characteristics

8.1 Background

This section present findings on the distribution of cumulative incidence of MAEs by vaccine brands and the pattern of specific symptoms by brand. All reported cases of MAEs were reported regardless of its causal relationship with the vaccine.

8.2 Results

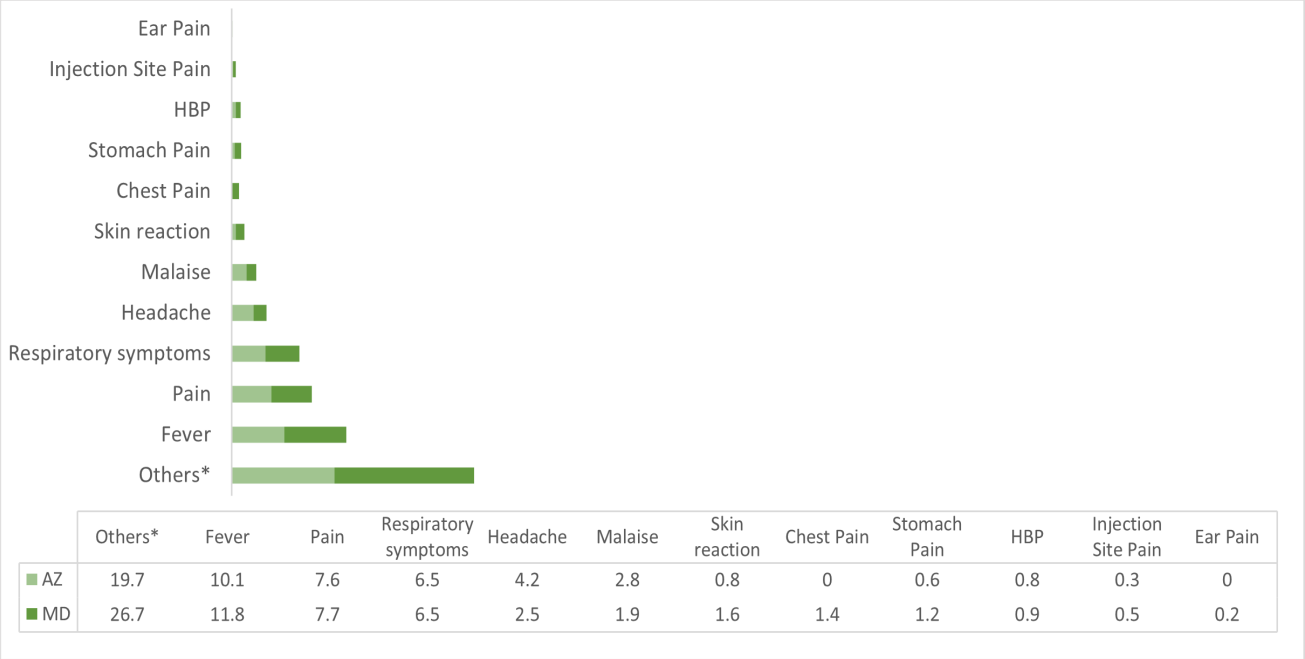
The distribution of MAEs cumulative incidence and pattern of specific MAEs are presented in Table 8-1 and Figure 8-1 respectively. Table 8-2 shows the incidence rate ratio of occurrence of MAEs by study variables.

8.3 Key Findings

- Out of 11,911 participants that were followed up, 6.6% (786) reported that they sought medical care at least once post vaccination.
- There was a statistically significant difference in the proportion of participants who reported MAEs by vaccine brand – 8.2% among Moderna vaccine vs 5.3% AstraZeneca (Table 6).
- The distribution of specific symptoms or reaction for medical care were similar across vaccine brand – Fever and body pain were commonly reported while less than 1% of MAEs was due to pain at injection site and ear pain. Almost one-fourth (23.5%) of the reasons for seeking medical care included general medical consultation, routine and follow-up visits, surgical procedures, and treatment of malaria and typhoid.
- The incidence of MAEs among those who received Moderna was 1.38 times (95% C.I: 1.25-1.53) that of those on AstraZeneca.
- Participants who received both a first and second dose of vaccine (7.3%) had an higher rate (IRR: 1.30, 95% C.I: 1.15 – 1.46) of MAE occurrence compared to those who only received the first dose (5.2%).
- The rate of MAEs were higher among those who had at least one chronic disease (IRR: 1.27, 95% C.I: 1.13 – 1.43), and experienced symptoms within three days prior to vaccination (IRR: 1.24, 95% C.I: 1.11 – 1.37) compared to those without history of chronic disease and no pre-vaccine symptoms, respectively.
- However, those who had an history of reaction to vaccination had a lower rate (IRR: 0.70, 95% C.I: 0.62 – 0.96) of MAEs compared to those without reaction history.

Table 8 1: Distribution and cumulative incidence of medically attended events (MAEs)

Variable	Overall	Vaccine brand; n (%)		p-value
	n (%)	AstraZeneca	Moderna	
N	11,911	6,662	5,249	<0.001
MAEs; n(%)	786 (6.6)	355 (5.3)	431 (8.2)	



	Others*	Fever	Pain	Respiratory symptoms	Headache	Malaise	Skin reaction	Chest Pain	Stomach Pain	HBP	Injection Site Pain	Ear Pain
AZ	19.7	10.1	7.6	6.5	4.2	2.8	0.8	0	0.6	0.8	0.3	0
MD	26.7	11.8	7.7	6.5	2.5	1.9	1.6	1.4	1.2	0.9	0.5	0.2

**others; routine check up and follow up, medical consultation, surgery, malaria, typhoid, accident, ulcer, blood sugar, and antibiotics.*
**AZ= AztraZeneca, MD= Moderna*

Figure 8-1: Distributions of reported MAEs by vaccine brand

Table 8-2: Distribution, person-days incidence rate, and incidence rate ratio of occurrence of MAEs by study variables

Indicators	N	Reported MAEs n (%)	IR[α] per 10,000 person-days (95% C.I)	Incidence Rate Ratio	95% C.I
Age group					
<25 years	1,644	90 (5.5)	4.1 (3.9 - 5.9)	1.00	-
25 - 34 years	3,044	229 (7.5)	6.7 (5.8 - 7.5)	1.29*	1.07 - 1.54
35 – 44 years	3,065	208 (6.8)	6.0 (5.2 - 6.8)	1.19	0.99 - 1.43
45 – 54 years	2,059	115 (5.6)	4.7 (3.9 - 5.6)	1.00	0.82 - 1.23
55+ years	2,099	144 (6.9)	5.7 (4.8 - 6.6)	1.19	0.97 - 1.45
Gender					
Female	5,080	330 (6.5)	5.7 (5.1 - 6.4)	1.00	-
Male	6,831	456 (6.7)	5.7 (5.2 - 6.3)	1.07	0.96 - 1.20
History of Chronic Diseases					
None	9,105	570 (6.3)	5.5 (5.0 - 5.9)	1.00	-
Yes	2,781	214 (7.7)	6.6 (5.7 - 7.5)	1.27*	1.13 - 1.43
History of reaction to vaccination					
No	11,475	763 (6.7)	5.8 (5.4 - 6.2)	1.00	-
Yes	436	23 (5.3)	4.4 (2.6 - 6.2)	0.70*	0.52 - 0.96
Pre-vaccination (3 days prior) symptoms					
No	7,597	459 (6.0)	5.2 (4.8 - 5.7)	1.00	-
Yes	4,314	327 (7.6)	6.7 (5.9 - 7.4)	1.24*	1.11 - 1.37
Vaccination Brand					
AstraZeneca	6,662	355 (5.3)	4.5 (4.1 - 5.1)	1.00	-
Moderna	5,249	431 (8.2)	7.3 (6.6 - 8.0)	1.38*	1.25 - 1.53
Vaccine dose					
Only first dose	4,042	211 (5.2)	6.9 (6.0 - 7.8)	1.00	-
Second	7,869	575 (7.3)	5.4 (5.0 - 6.0)	1.30*	1.15 - 1.46

**significant at p<0.05*

[α]IR=Incidence Rate

Occurrence of SAE's by participants' characteristics

9.1 Background

Findings on the distribution of cumulative incidence of hospitalization and deaths including reported serious events by vaccine brand are documented in this section. Also, all reported cases of SAEs were reported regardless of its casual relationship with the vaccine.

9.2 Results

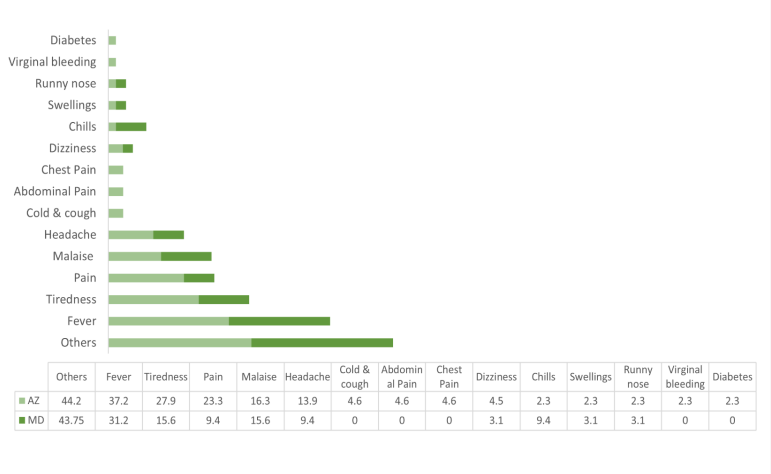
Table 9-1 and Figure 9-1(A) and Figure 9-2(B) shows the distribution of SAEs cumulative incidence and pattern of specific SAEs respectively while the incidence rate ratio of SAEs occurrence are presented in Table 9-2.

9.3 Key Findings

- Of the 11,911 participants, 75 (0.6%) were hospitalized – 32 (0.6%) among those on Moderna and 43 (0.6%) on AstraZeneca.
- The pattern of reported symptoms leading to hospitalization were similar by vaccine brand – fever and tiredness were commonly reported, while diabetic was reported by one participant.
- Overall, 11 (0.1%) deaths were reported next of kin – 4 (0.1%) among Moderna vaccinees and 7 (0.1%) of those who received AstraZeneca. Verbal autopsy reports indicated some causes of death including illness, cancer, and accident.
- Those who received Moderna had no significant difference in the incidence of SAEs (IRR: 0.97, 95% C.I: 0.63 – 1.51) compared with those on AstraZeneca. Also, there was no significant difference in the occurrence of SAEs by gender, age group, doses, history of reaction to vaccine, and experience of pre-vaccination symptoms.
- However, those who had history of chronic disease had 1.73 times (95% C.I: 1.06-2.84) the incidence of SAEs than those with no history.

Table 9-1: Distribution and cumulative incidence of serious adverse reactions.

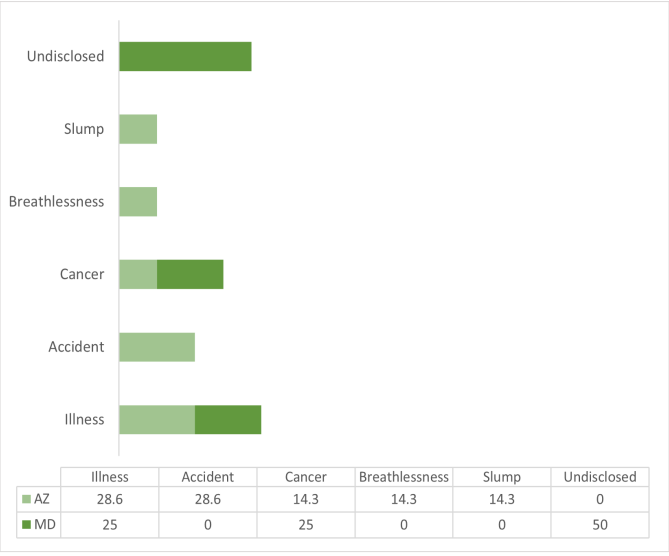
Variable	Frequency N = 11,911	Vaccine brand; n (%)		p-value
	n (%)	AstraZeneca (N = 6,662)	Moderna (N = 5,249)	
# hospitalized	75 (0.6)	43 (0.6)	32 (0.6)	0.81
# of deaths	11 (0.1)	7 (0.1)	4 (0.1)	0.77



	Others	Fever	Tiredness	Pain	Malaise	Headache	Cold & cough	Abdominal Pain	Chest Pain	Dizziness	Chills	Swellings	Runny nose	Virginal bleeding	Diabetes
AZ	44.2	37.2	27.9	23.3	16.3	13.9	4.6	4.6	4.6	4.5	2.3	2.3	2.3	2.3	2.3
MD	43.75	31.2	15.6	9.4	15.6	9.4	0	0	0	3.1	9.4	3.1	3.1	0	0

**Others; surgery, cataract, malaria, stooling, mouth sore, cancer, food poising, high blood pressure, low blood pressure, dysuria and constipation*
**AZ= AstraZeneca, MD= Moderna*

Figure 9-1 (A): Distributions of specific events leading to hospitalization



	Illness	Accident	Cancer	Breathlessness	Slump	Undisclosed
AZ	28.6	28.6	14.3	14.3	14.3	0
MD	25	0	25	0	0	50

**AZ= AztraZeneca, MD= Moderna*

Figure 9-1 (B): Distributions of reported causes of death

Table 9-2: Distribution, person-days incidence rate, and incidence rate ratio of occurrence of SAEs within important study variables

Indicators	N	Reported SAEs n (%)	IR[α] per 10,000 person-days (95% C.I)	Incidence rate ratio	95% C.I
Age group					
<25 years	1,644	4 (0.2)	0.2 (0.1 - 0.4)	1.00	-
25 - 34 years	3,044	32 (1.1)	0.9 (0.6 - 1.2)	4.32*	1.52-12.23
35 – 44 years	3,065	14 (0.5)	0.4 (0.2 - 0.6)	1.79	0.59-5.45
45 – 54 years	2,059	9 (0.4)	0.4 (0.1 - 0.6)	1.60	0.05-5.26
>55 years	2,099	25 (1.2)	1.0 (0.6 - 1.3)	3.99*	1.35 - 11.80
Gender					
Female	5,080	34 (0.7)	0.6 (0.4 - 0.8)	1.00	-
Male	6,831	50 (0.7)	0.6 (0.4 - 0.8)	1.12	0.72 - 1.74
History of Chronic Diseases					
None	9,105	54 (0.6)	0.5 (0.4 - 0.6)	1.00	-
Yes	2,781	30 (1.1)	0.9 (0.6 - 1.2)	1.73*	1.06 - 2.84
History of reaction to vaccination					
No	11,475	80 (0.7)	0.6 (0.5 - 0.7)	1.00	-
Yes	436	4 (0.9)	0.7 (0.1 – 1.5)	1.25	0.46 - 3.43
Pre-vaccination (3 days prior) symptoms					
No	7,597	51 (0.7)	0.6 (0.4 - 0.7)	1.00	-
Yes	4,314	33 (0.8)	0.6 (0.4 – 0.9)	1.05	0.67 - 1.64
Vaccination Brand					
AstraZeneca	6,662	48 (0.7)	0.6 (0.4 - 0.8)	1.00	-
Moderna	5,249	36 (0.7)	0.6 (0.4 - 0.8)	0.97	0.63 - 1.51
Vaccine dose					
First	4,042	32 (0.8)	1.0 (0.7 - 1.4)	1.00	-
First and Second	7,869	52 (0.7)	0.5 (0.3 - 0.6)	0.77	0.49 - 1.21

**significant at p<0.05*
[α]IR=Incidence Rate

Serious adverse events by duration of follow-up from first vaccination

10.1 Background

This section presents the incidence of hospitalization and deaths by post first dose interval. The Incidence ratio was estimated for cohort of participants at less than 4 weeks, 4 to 7 weeks, 8 to 11 weeks, 12 to 15 weeks and at least 16 weeks.

10.2 Results

Table 10-1 present the incidence of serious adverse events by duration of follow-up from first vaccination.

10.3 Key Findings

- The incidence of hospitalization decreased over the study period among those who received AstraZeneca; 24 (0.4%) were reported in the first one month, 5 (0.1%) between 8 – 11 weeks, while only 1 case was reported after 16 weeks of follow up.
- The rate of hospitalization among Moderna vaccinee was steady over the first 3 months – 10 (0.2%) cases monthly before declining to 2 cases.
- The overall incidence of death reporting was 0.1% (4) in the first one month of follow-up, and 3 (0.1%) cases were reported in both 4 – 7 weeks and 12 – 15 weeks of follow-up.

Table 10-1: Incidence of serious adverse events by duration of follow up from first vaccination

Follow-up duration	AstraZeneca		Moderna		Total	
	N	n (%)	N	n (%)	N	n (%)
Hospitalization						
<4 weeks	6,662	24 (0.4)	5,249	10 (0.2)	11,911	34 (0.3)
4-7 weeks	6,298	11 (0.2)	4,979	10 (0.2)	11,277	21 (0.2)
8-11 weeks	6,173	5 (0.1)	4,876	10 (0.2)	11,049	15 (0.1)
12-15 weeks	6,114	2 (0.0)	4,814	2 (0.0)	10,928	4 (0.1)
6+ weeks	3,971	1 (0.0)	3,912	-	7,883	1 (0.0)
Death						
<4 weeks	6,662	3 (0.1)	5,249	1 (0.0)	11,911	4 (0.1)
4-7 weeks	6,298	2 (0.0)	4,979	1 (0.0)	11,277	3 (0.1)
8-11 weeks	6,173	1 (0.0)	4,876	0 (0.0)	11,049	1 (0.0)
12-15 weeks	6,114	1 (0.0)	4,814	2 (0.1)	10,928	3 (0.1)
16+ weeks	3,971	-	3,912	-	7,883	-

Incidence of COVID-19

11.1 Background

Incidence of COVID-19 post-vaccination was tracked among study participants, including information on date of symptom onset and need for intensive care.

11.2 Results

Incidence of COVID-19 by vaccine brand and timing between first and second dose are presented in Table 11-1.

11.3 Key Findings

- Of the 11,911 participants followed up, 25 (0.2%) reported testing positive for SARS-CoV-2 following vaccination and 2 (0.02%) cases resulted in intensive care.
- Out of those who received the AstraZeneca vaccine, 11 (0.2%) were diagnosed positive, while among those who had Moderna, 14 (0.3%) were positive (Table 9).
- None of those who received AstraZeneca reported intensive care, while 2 (14.3%) of the Moderna vaccinees diagnosed positive with SARS-CoV-2 reportedly receivied intensive care.

Table 11-1: Incidence of COVID-19

Variables	N	n (%)
Vaccine Brand		
AstraZeneca	6,662	11 (0.2)
Moderna	5,249	14 (0.3)
Timing between doses		
No second dose	4,042	4 (0.1)
<6 weeks	2,718	10 (0.4)
6 - 8 weeks	2,725	7 (0.3)
9 - 11 weeks	1,571	3 (0.2)
12+ weeks	855	1 (0.1)

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Appendices

13.1 Appendix 1: Consent Form

13.1.1 English

Protocol Title: Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria

Principal Investigator: Manhattan Charurat, PhD

Sponsor: US CDC

Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria Adult Interview and follow-up

(Age 18–99 years and emancipated minors 15–17 years)

Interviewer reads: What language do you prefer for our discussion today?

☐ English

☐ Hausa

☐ Igbo

☐ Yoruba

Hello. My name is_____ ___. I would like to invite you to take part in this study on COVID-19 vaccination in Nigeria. The National Agency for Food and Drug Administration and Control (NAFDAC) is leading this study. Taking part in this study is your choice.

Purpose of study

This study is about COVID-19 vaccination in Nigeria. The purpose of this study is to help the Government of Nigeria better understand the effect of COVID-19 vaccination and the side effects. The study will help the government know how the vaccine affects people, immediately after it is given and over a period which may be up to 3 years.

We plan to invite about 12,000 persons to take part in this study. If you take part, you will help the Government of Nigeria respond quickly and protect the lives of people in Nigeria.

GO TO STUDY PROCEDURES

Study Procedures

If you take part in this study, we will ask you some interview questions about yourself, your recent travels, disease history and side effects you may experience after the vaccination. This interview will take about 10 minutes. After the interview today, our team will call again on days 3 and 7 following the vaccination and subsequently weekly for 3 months. There may also be a monthly follow-up for another 3 years. We will give you prior notice on the 3-year follow-up.

We will collect your study information on this tablet. The information will be stored securely. Only select study staff will be able to access this information. The interview will take place

in private here in the hospital/clinic. Everything you tell us is strictly confidential. Your name or other identifying information will never be used in any reports. The information we report from this study will contain no link to your identity.

Potential Risks

There is a very small risk that personal information we collect from you may not be kept private. We will do everything we can to protect the privacy of your information. We will store information in a secure place. We will use passwords to protect electronic information. We will also label your study information with a code number instead of your name.

Potential Benefits

You may or may not benefit by taking part in this study. If you take part in this study, you may help others in the future. We hope this study will help us understand the following:

- The side effects people who receive the COVID-19 vaccine experience.
- How best to improve on the quality of the vaccine.

Alternative to Taking Part in the Study

Your alternative is not to take part. If you choose not to take part, the services you or any member of your family receive in this hospital/clinic will not be affected.

Costs to Person Taking Part in the Study

It will not cost you anything to take part in this study.

Payment to Person Taking Part in the Study

You will not receive any payment for taking part in this study.

Confidentiality and Access to your Health Information

Only people involved with this study will have access to the information you give for this study. Efforts will be made to protect your information, including your study answers and your test results. All electronic information will be protected with passwords. We will use a code number instead of your name to identify your personal information and study answers. Only study staff can use this number to link your responses to you. The final report of the study will not include your name or personal information.

Your permission to allow us to use and share your name and contact information with the National Health Research Ethics Committee will expire two years after the end of the study. If you have questions about your rights as someone taking part in research, or if you feel these rights have been violated, you should contact NHREC at:

Address:
Federal Ministry of Health,
Federal Secretariat Complex Shehu Shagari Way,
Garki, Abuja P.M.B. 083, Garki-Abuja
Tel: 234-803-586-8293
E-mail: info@nhrec.net:

Refusal to Take Part and Right to Withdraw

Taking part in this study is voluntary. You are free to withdraw the permission to use your information at any time. If you refuse to take part, or if you withdraw from the study, the health services you or any member of your family receive will not be affected. If you decide to refuse or withdraw, information you gave will not be included in the study results. If you decide to stop taking part, there will be no harmful consequences of any kind. Please contact the Pharmacist in charge of the study, Pharm. Uchenna Elemuwa (contact information below), if any of the following occur:

- You have questions, concerns, or complaints about the study.
- You decide to withdraw from the study.

Pharm. Uchenna Elemuwa

Address:
The National Agency for Food and Drug Administration and
Control (NAFDAC), Abuja FCT
Phone: 08034099032
Email: uche2nice2000@yahoo.co.uk

Do you want to ask me anything about the study?

Consent Statement

I have read this form, or someone has read it to me. I was encouraged to ask questions. I had enough time to ask questions, and I am satisfied with the answers I received. I know that if I choose to take part, I may withdraw at any time. My taking part is voluntary. I have been offered a copy of this consent form.

1. Do you agree to do the individual interview and follow-up? 'YES' means that you agree to do the interview and follow-up. 'NO' means that you will NOT do the interview and follow-up

_____Yes _____No

2. Do you agree to be contacted if these future studies find information that could be important for your health care? We will only do this within a three-year period after this study. After this period, we will remove information that can be used to identify or contact you from questionnaire. 'YES' means that you agree to be contacted within this three-year period. 'NO' means that you do not agree to be contacted.

_____Yes _____No

Participant signature or mark_____ Date: ___/___/___

Printed name of participant_____

Participant ID number _____

[For illiterate participants]

Signature of witness_____ Date: ___/___/___

Printed name of witness_____

Signature of person obtaining consent_____ Date: ___/___/___

Printed name of person obtaining consent_____

Study staff ID number _____

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

13.1.2 Yoruba

FỌỌMU IFOHUNSI TI IWADI

Akọle Ilana: Ẹgbẹ ti o n topinpin Iṣẹlẹ (CEM)fun awari Ifihan Aabo, lẹhin abeere ajesara pẹlu awọn ajẹsara ti aisan Akoran Kofidi-19 ati Abajade Iwadi awon ontopinpin ni Orile Ede Naijiria.

Nomba Iwadi.: [Jọwọ ṣafikun nọmba Ilana UMB nikan]

Oludari Agba: [jọwọ pese orukọ, awọn iwe ti o ka, & nọmba foonu re]

Onigbowo: [Jowo paare ti ko ba je mo o]

Ẹgbẹ ti o n topinpin Iṣẹlẹ (CEM)fun awari Ifihan Aabo, lẹhin abeere ajesara pẹlu awọn ajẹsara ti aisan Akoran Kofidi-19 ati Abajade Iwadi awon ontopinpin ni Orile Ede Naijiria - ifọrọwanilenuwo fun agbalagba ati abewo siwaju si

(Ojo Ori mejidinlogun si mọkandinlọgọrun-un ati Omode ti o le se ipinnu ti o wa lojo ori mẹdogun si mẹtadilogun)

Aforowanilenuwo yi o ka: Ede wo ni o fẹ fun ijiroro wa loni?

☐ Ede Gẹẹsi

☐ Awusa

☐ Ibo

☐ Yoruba

Ẹ pẹlẹ o. Orukọ mi ni_____. N o fẹ lati pe yin lati kopa ninu iwadi yii lori abeere ajesara ti aranmo Kofidi-19 ni Orile ede Naijiria. Ile-isẹ ti o n risi Ounjẹ ati lilo Oògùn ati Iṣakoso re (NAFDAC) ni o n se agbateru iwadii yii. Kikopa ninu iwadi yii je ohun ti o yan.

Eredi ti iwadi

Iwadi yii wa fun abeere ajesara fun aisan aranmo Kofidi-19 ni orile ede Naijiria. Eredi iwadiyii ni lati se iranlowo fun ijoba Naijiria lati le ni oye ti o dara julọ ti ipa ti abeere ajesara aisan aranmo kofidi-19 ni. Iwadi yii ni yio ṣe iranlọwọ fun ijọba lati mọ bi abeere ajesara ṣe ni ipa lori eniyan, lẹsẹkẹsẹ lẹhin ti a ti fun ni ati ni akoko kan eyiti o le to ọdun mẹta.

A gbero lati pe awon eniyan ti o to ẹgbẹrun mejila lati kopa ninu iwadi yii. Ti e ba kopa, eyin yio ṣe iranlọwọ fun Ijọba Naijiria lati dahun ni kiakia ati daabobo awọn ẹmi eniyan ni orile ede Naijiria

LO SI ILANA IWADI

Ilana Iwadi

Ti e ba kopa ninu iwadi yii, a o beere awọn ibeere diẹ lọwọ yin nipa arayin, ibi ti e rin irin ajo lo, awon akosile aisan ati awon ipa ti ko dara ti e le ni iriri re ni kete ti e ti gba abeee ajesara. Iforowanilenuwo yii yio gba iseju mewa. Leyin iforowanilenuwo ti oni, awon igbimo wa yio kan si yin leyin ọjọ keta ati ikeje ni kete ti e ba ti gba abẹrẹ ajẹsara ati ni awon osẹ miran leralera fun osu meta, Abewo osoosu le waye fun odidi odun meta gbako. A o fi to yin leti awon abewo ti odun meta naa.

A o gba agbasile alaye ti e ba se fun wa lori iwadi yii sori tabulẹti yii. Alaye naa ni yio wa ni ipamọ fun idabobo. Oṣiṣẹ ti o wa fun iwadi yii nikan ni yio ni anfani lati wọle si alaye yii. Ifọrọwanilẹnuwo naa yoo waye ni ikọkọ nibi ile -iwosan/ile -iwosan. Ohun gbogbo ti e sọ fun wa jẹ mosinumosikun. Orukọ rẹ tabi alaye idanimọ miiran ni a kii yoo lo ninu awọn ijabọ eyikeyi. Alaye ti a jabo lati inu iwadi yii ko ni ọna asopọ si idanimọ rẹ rara.

Ewu ti o Fojuhan

Ewu kekere kan wa ti alaye ti ara ẹni ti a gba lati ọdọ rẹ le ma wa ni ipamọ. A o ṣe ohun gbogbo ti a le ṣe lati daabobo aṣiri ti alaye ti e sẹ fun wa. A o ṣafipamọ alaye ni aaye to ni aabo. A o lo awọn ọrọ igbaniwọle lati daabobo alaye ti e sẹ fun wa. A o tun ṣe aami alaye idanilẹkọ yin pẹlu nọmba koodu dipo orukọ rẹ.

Anfaani ti o fojuhan

O le tabi le ma ni anfani nipa kikopa ninu iwadi yii. Ti o ba kopa ninu iwadi yii, o le ṣe iranlọwọ fun awọn miiran ni ọjọ iwaju. A nireti pe iwadii yii yoo ran wa lọwọ lati loye awon atẹle wonyi:

λ Awọn ipa ti o buru ti awọn eniyan ti o iriri nigba ti won gba abeere ajesara aranmo Kodifi-19

λ Bawo ni o ṣe dara julọ lati ni ilọsiwaju lori sise amudara ajesara naa.

Yiyan lati kopa ninu Iwadii naa

Aṣayan rẹ kii ṣe lati kopa. Ti ẹ ba yan lati ma kopa, awọn itoju ti iwọ tabi eyikeyi mọlẹbi re n gba ni ile -iwosan/ile -iwosan yii ni ko ni ni idena kankan.

Awọn idiyele fun Eniyan ti o kopa ninu Iwadi naa

Ko ni na yin ni ohunkohun lati kopa ninu iwadi yii.

Sisanwo fun Eniyan ti o n kopa ninu Iwadii

Iwọ kii yio gba owo fun kikopa ninu iwadi yii.

Mosinumosikun ati nini anfaani si alaye lori Ilera rẹ

Awọn eniyan ti iwadi yi kan pẹlu nikan ni yo ni anfaani si awon alaye ti e fun wan fun iwadi yii. A o gbiyanju lati ri daju wipe a daabobo alaye yin, pẹlu awọn idahun ti e so fun iwadi yii ati awọn abajade ayewo yin. Gbogbo alaye ti a fi pamo si inu ero ayarabiasa ni a o se aabo fun pẹlu awọn ọrọ igbaniwọle. A o lo nọmba koodu dipo orukọ rẹ lati ṣe idanimọ alaye ti ara ẹni ati awọn idahun si iwadi. Oṣiṣẹ ti o wa fun idanileko yii nikan le lo nọmba yii lati se asopọ awọn idahun rẹ si ọ. Ijabọ ikẹhin fun iwadii yii ni kii yoo ni orukọ rẹ tabi alaye ti ara ẹni.

Iyọọda ara rẹ lati gba wa laaye lati lo ati pin orukọ rẹ ati alaye olubasọrọ pẹlu Igbimọ Ihuwasi Iwadi Ilera ti Orilẹ -ede yoo pari ni ọdun meji lẹyin ipari iwadi naa. Ti o ba ni awọn ibeere nipa awọn ẹtọ rẹ bi ẹnikan ti n kopa ninu iwadii, tabi ti o ba lero pe a ti ru awọn ẹtọ wọnyi, o yẹ ki o kan si NHREC ni:

Adiresi: Ajo Eleto Ilera ti Ijoba Apapo, Ile Ise ti Ijoba Apapo,
Ona ti o lo si Shehu Shagari, Garki, Abuja P.M.B. 083, Garki-Abuja
Ero Ibanisorol: 234-803-586-8293
E-mail: info@nhrec.net:

Kiko lati Gba lati Kopa ati Eto lati yọ kuro

Kikopa ninu iwadi yii jẹ atinuwa. O ni ominira lati jawo lai gbanilaaye lati lo alaye rẹ nigbakugba. Ti o ba kọ lati kopa, tabi ti o ba kuro ninu iwadi naa, awọn iṣẹ ilera ti iwọ tabi eyikeyi ọmọ ẹgbẹ ti idile rẹ ko ni kan. Ti o ba pinnu lati kọ tabi kuro, alaye ti e so fun wa ni a ki yio dapo mo awọn esi abajade iwadi. Ti o ba pinnu lati dawọ duro, ko si awọn abajade ipalara ti eyikeyi iru. Jọwọ kan si Apogun po ti o n bojuto iwadii naa, Pharm. Uchenna Elemuwa (alaye lori eniti a le basọrọ ni o wa ni isalẹ yii), ti eyikeyi ninu awon nkan ti a ko silẹ wonyi ba waye:

- Ti e ba ni awọn ibeere, awọn ifiyesi, tabi awọn awawi nipa iwadi naa.
- Ti e ba pinnu lati jawo ninu iwadi yii.

Pharm. Uchenna Elemuwa
Address: The National Agency for Food and Drug Administration
and Control (NAFDAC), Abuja FCT
Phone: 08034099032
Email: uche2nice2000@yahoo.co.uk

Ṣe o fẹ lati beere ohunkohun lọwọ mi nipa iwadi naa?

Gbólóhùn Igbanilaaye

Mo ti ka fọọmu yii, tabi ẹnikan ti ka fun mi. Won gba mi niyanju lati beere awọn ibeere. Mo ni akoko ti o to lati beere awọn ibeere, ati pe inu mi dun pẹlu awọn idahun ti Mo gba. Mo mọ pe ti mo ba yan lati kopa, mo le kuro nigbakugba. Ikopa mi jẹ atinuwa. A ti fun mi ni ẹda fọọmu ifohunsi yii.

Mo ti ka fọọmu yii, tabi ẹnikan ti ka fun mi. A gba mi ni imoran lati beere awọn ibeere. Eyikeyi awọn ibeere ti mo beere ni won idahun ni kikun. Mo loye pe Mo ni ominira lati yan boya lati kopa ninu iwadi naa. O ye mi pe mo le da ikopa mi duro nigbakugba.

1. Ṣe o gba lati darapo mo ifọrọwanilẹnuwo ẹni kọọkan ati abewo ti yio tele?

'BẸẸNI' tumọ si pe o gba lati darapo mo ifọrọwanilẹnuwo ati abewo ti o tẹle. 'BEEKO' tumọ si pe iwọ kii yio darapo mo ifọrọwanilẹnuwo ati awon abewo to yio tẹle

_____Beeni _____Beeko

2. Ṣe o gba lati je ki a kan si o ti o ba je wipe awọn iwadii ọjọ iwaju wọnyi ti o le ṣe pataki fun itọju ilera rẹ? A o ṣe eyi nikan laarin akoko ọdun mẹta lẹhin iwadi yii. Lẹhin asiko yii, a o yọ alaye ti won le lo lati ṣe idanimọ tabi kan si ọ lati inu iwe ibeere. 'BẸẸNI' tumọ si pe o gba lati je ki won kan si o laarin akoko ọdun mẹta yii. 'BEEKO' tumọ si pe o ko gba lati je ki won kan si O.

_____Beeni _____Beeko

Ibuwọlu Akopa tabi aami_____ Ojo: ___/___/___

Te oruko Akopa_____

Nomba Idanimo Akopa_____

[Fun Akopa ti ko le kawe]

Ibuwọlu Eleri_____Ojo: ___/___/___

Te oruko Eleri_____

Ibuwọlu eniti o n gba ifohunsokan_____ Ojo: ___/___/___

Te Oruko eniti o n gba ifohunsokan_____

Nomba idanimo osise fun iwadi_____ _____

GBÓLÓHÙN/ALAYE ILE-ẸKỌ GIGA TI YUNIFÁSÍTÌ NIPA EEWU IWADI

Ile-ẹkọ giga ti yunifásítì ti pinnu lati pese awọn olukopa ninu iwadii rẹ gbogbo awọn ẹtọ nitori wọn labẹ ofin Ipinle ati Apapo. Iwọ ko fi eyikeyi awọn ẹtọ ofin rẹ silẹ nipa fifi owo si fọọmu ifohunsi yii tabi nipa kikopa ninu iṣẹ iwadi. A ti ṣe atunyẹwo iwadi yii ati fọwọsi nipasẹ Igbimọ Atunwo Ile -iṣẹ (IRB). Jọwọ pe Igbimọ Atunwo Ile -iṣẹ (IRB) ti o ba ni awọn ibeere nipa awọn ẹtọ rẹ gegebi akopa ninu iwadi.

Iwadi yi ti a ṣapejuwe re ninu fọọmu ifohunsi yii ni a ti pin si bi eewu kekere nipasẹ IRB ti yunifásítì ti Maryland, Baltimore (UMB). IRB jẹ ẹgbẹ awọn onimọ -jinlẹ, awọn dokita, awọn amoye, ati awọn eniyan miiran. Ẹgbẹ IRB pẹlu awọn eniyan ti ko ni ajọṣepọ pẹlu UMB ati awọn eniyan ti ko ṣe awọn iṣẹ iwadi. Ipinnu awon Ẹgbẹ IRB pe iwadii jẹ eewu ti o kere ju ko tumọ si pe iwadii ko ni eewu. O n ro awọn ewu ti ipalara nitori abajade ikopa iwadi, bi a ti jiroro ninu fọọmu ifohunsi naa

Ti e ba ni ipalara nitori aibikita ti oluwadi, e le ṣe ibeere fun isanpada. Ti e ba ni awọn ibeere, awọn ifiyesi, awọn ẹdun ọkan, tabi gbagbọ pe e ti ni ipalara nipasẹ ikopa ninu iwadii yii nitori aifiyesi oluwadi, e le kan si awọn ọmọ ẹgbẹ ti IRB tabi oṣiṣẹ ti Ọfiisi Idaabobo Iwadi Eniyan (HRPO) lati beere awọn ibeere, jiroro awọn iṣoro tabi awọn ifiyesi re, gba alaye, tabi funni ni igbewọle nipa awọn ẹtọ rẹ gẹgẹbi olukopafun iwadii. Alaye lori bi a se le kan si olubasọrọ fun IRB ati HRPO ni:

Yunifásítì ti Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

13.1.3 Hausa

TAKARDAR BADA IZINI A YI AIKIN BINCIKE

Sunan Binciken: Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria

Lambar Binciken: [Please include the UMB protocol number only]

Mai Gudanar da Binciken: [please provide name, degrees, & phone number]

Mai Bada Tallafi: [delete if not applicable]

Tattaunawa da bin-mai-shiga a Binciken "Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria" na Manya

(Shekaru 18–99 da 'yantattun yara masu shekaru 15–17)

Mai tambaya ya karanta: A wane harshe ne ka/kika fi son mu tattauna yau?

☐ English

☐ Hausa

☐ Igbo

☐ Yoruba

Barka. Suna na _____ ___. Ina son in gayyace ka/ki shiga wannan bincike akan riga-kafin cutar COVID-19 a Najeriya. Hukumar "National Agency for Food and Drug Administration and Control" wato (NAFDAC) ne take jagorar binciken. Shiga wannan binciken zabinka/ki ne.

Dalilin binciken

Wannan bincike akan alurar riga-kafin cutar COVID-19 a Najeriya ne. Dalilin binciken shine a taimaki Gwamnatin Najeriya kara fahimtar yadda riga-kafin cutar COVID-19 yake shafan mutane da kuma sakamakonsa. Binciken zai taimaki gwamnati sanin yadda riga-kafin yake shafan mutane, da zarar an bayar, da kuma bayan wasu lokuta, wanda zai iya kaiwa shekaru 3.

Mun yi niyyar gayyatan kamar mutane 12,000 su shiga wannan binciken. Idan ka/kin shiga, zaka/zaki taimaki Gwamnatin Najeriya amsawa akan lokaci, da kuma kare rayukan mutane a Najeriya.

◊ JE ZUWA TSARIN BINCIKEN

Tsarin Binciken

Idan ka/kin shiga wannan binciken, zamu yi maka/maki wasu tambayoyi game da kai/ke, ko ka/kin yi tafiya cikin kwanankin nan, tarihin rashin-lafiya, da ko akwai wasu sakamakon alurar riga-kafin da ka/kika fuskanta.

Wannan tattaunawar zai dauki kamar minti 10. Bayan tattaunawar yau, jami'en zasu kara neman ka/ki a kwana na 3 da 7 bayan alurar riga-kafin, sai kuma a kowanne sati ma tsawon watanni 3. Kuma yana iya yuwa a bi-da-kai/ke ma shekaru 3 kuma. Zamu sanar da kai/ke kafin bi-da-kai/ke na shekaru 3 din.

Zamu saka bayanen binciken da ka/kika bayar cikin wannan allon. Za'a addana bayanen asirrance. Sai Jami'en da aka zaba ne zasu iya ganin wannan bayanen. Za'a gudanar da tattaunawar asirrance cikin wannan asibitin. Duka abun da ka/kika gaya mana na asirrance. Ba za'a yi amfani da suna ko wani abu da zai yi nuni da kai/ke ba a cikin wani rehotu. Bayani da zamu bayar cikin rehotunmu ba zai dauki wani abu da zai yi nuni da kai/ke ba.

Hadura da za'a iya Fuskanta

Akwai dan kalilan hadari na bayanai game da kai/ke wanda muka dauka na iya zama ba assirrance ba. Zamu yi iya kokarinmu mu kare sirrin bayanenka/ki. Zamu addana bayanai a wuri mai tsaro. Zamu yi amfani da faswod mu kare bayanen dake cikin na'ura. Kuma zamu rubuta lamba ne akan bayanenka/ki na binciken maimakon sunanka/ki.

Amfanin da za'a iya samu

Yana iya yu wa zaka/zaki samu, ko baza ka/ki samu wani amfanin shiga binciken ba. Idan ka/kin shiga wannan binciken, kana/kina iya taimaka ma wasu nan-gaba. Muna fatan wannan binciken zai taimaka mu fahimci wadannan abubuwan:

- Irin sakamakon da mutane ke ji bayan daukan alurar riga-kafin COVID-19
- Yadda zai fi dacewa a inganta riga-kafin.

Wata Hanya banda Shiga Binciken

Zabin da kake/kike da shi shine baza ka/ki shiga ba. Idan ka/kin zaba cewa ba zaka/zaki shiga ba, ba zai shafi ayyukan da kai/ke ko wani daga iyalinka/ki ke samu a wannan asibitin ba.

Abun da Mai-Shiga zai Biya

Ba zaka/zaki biya wani abu domin shiga wannan binciken ba.

Abun da za'a biya Mai-shiga wannan Binciken

Ba za'a ba ka/ki wani abu domin ka/kin shiga wannan binciken ba.

Sirri da Ganin Bayanen Kiwon Lafiyarka/ki

Sai mutanen dake cikin wannan binciken ne zasu samu su ga bayanen da ka/kika bayar a wannan binciken. Za'a yi kokarin kare bayanenka/ki, tare da amsoshin da ka/kika bayar a binciken, da sakamakon gwajinka/ki. Za'a tsare duk bayanen dake cikin na'ura da faswod. Zamu yi amfani da lamba maimakon sunanka/ki a matasayin alamar bayanenka/ki da amsoshin da ka/kika bayar a binciken. Sai jami'en binciken ne zasu iya amfani da wannan lambar su jona amsoshin da kai/ke. Rehotun karshe da za'a hada ba zai dauki sunana/ki ko wani bayani akan ka/ki ba. Izinin da zai bari mu yi amfani, da bayar da sunanka/ki da adireshinka/ki tare da Kwamitin "National Health Research Ethics Committee" zai kare shekarun biyu bayan karshen binciken. Idan kana/kina da tambayoyi game da 'yancinka/ki a matsayin mai-shiga bincike, ko kuma idan kana/kina ganin kamar an keta hakkinka/ki, ka/ki tuntubi NHREC a:

Adireshi: Federal Ministry of Health, Federal Secretariat Complex
Shehu Shagari Way,
Garki, Abuja P.M.B. 083, Garki-Abuja
Lambar waya: 234-803-586-8293
E-mail: info@nhrec.net:

Rashin Shiga da Yancin Fita

Shiga wannan binciken na sa-kai ne. kana/kina iya soke izinin a yi amfani da bayanenka/ki a kowanne lokaci. Idan ka/kin ki shiga, ko kuma idan ka/kin fita daga binciken, ba zai shafi ayyukan kiwon lafiya da kai/ke ko wani dan-uwanka/ki ke samu ba. Idan ka/kin yanke shawarar baza ka/ki shiga ba ko ka/ki fita, ba za'a saka bayanen da ka/kika bayar a sakamakon binciken ba. Idan ka/kin yanke shawarar fita, babu wani sakamako marasa kyau da zai auku. Tuntubi Jami'in bada magani wanda ke lura da binciken, Pharm. Uchenna Elemuwa (adireshin na kasa), idan wani daga cikin wannan ya auku:

- Kana/kina da tambayoyi, damuwa, ko kai-kuka game da binciken.
- Ka/kin yanke shawarar fita daga binciken.

Pharm. Uchenna Elemuwa
Adireshi: The National Agency for Food and Drug Administration
and Control (NAFDAC), Abuja FCT
Lambar waya: 08034099032
Email: uche2nice2000@yahoo.co.uk

Kana/kina son ka/ki tambaye ni wani abu game da binciken?

Jawabin bada Yarda

Na karanta wannan takardar/ko wani ya karanta mun shi. An nemi in yi tambayoyi. An bani isasshen lokaci na yi tambayoyi, kuma na gamsu da amsoshin da aka bani. Na san cewa idan na zabi in shiga, zan iya fita a kowanne lokaci. Shiga na binciken na sa-kai ne. An bani kwafin wannan takardar bada izini.

1. Ka/kin yarda a yi zaman tattaunawa tare da kai/ke, da kuma bi-da-kai/ke? 'EH' na nufin ka/kin yarda a yi zaman tattaunawa tare da kai/ke, da kuma bi-da-kai/ke. 'A'A' na nufin BA ZA'A yi zaman tattaunawa da bi-da-kai/ke ba

_____Eh _____A'a

2. Ka/kin yarda a tuntube ka/ki idan wadannan bincike na nan-gaba sun gano wani bayani wanda yake iya zama da muhimmanci ga kiwon lafiyarka/ki? Zamu yi wannan ma tsawon shekaru uku ne kawai bayan wannan binciken. Bayan wannan lokaci, zamu cire bayanen da zai iya yin nuni da kai/ke, ko ya sa a neme ka/ki daga takardun. 'EH' na nufin ka/kin yarda a neme ka/ki cikin wadannan shekaru uku. 'A'A' na nufin ba ka/ki yarda a neme ka/ki ba.

_____Eh _____ A'a

Sa hannu ko alamar Mai-Shiga_____ Kwanar wata: ___/___/___

Sunan Mai-Shiga a babban harufa _____

Lambar ID na mai-shiga _____

[Ma mai-shiga wanda bai iya karatu ko rubutu ba]

Sa hannun shaida _____ Kwanar wata: ___/___/___

Sunan shaida a babban harufa _____

Sa hannun mai neman izini _____ Kwanar wata: ___/___/___

Sunan mai neman izini a babbar harufa _____

Lambar ID na Jami'in bincike _____

JAWABIN JAMI'A AKAN HADURAN BINCIKE

Jami'ar ta dau alkawarin ba wa wanda suke cikin aikin bincikensu duk hakkinsu kamar yadda dokar Kasa da na tarraya ta tanadar. Baka/baki hana kanka/ki wani 'yanci ba domin ka/kin sa hannu a wannan takardar bada izini, ko don ka/kin shiga shirin binciken ba. Hukumar sa ido a Harkokin Kungiyoyi wato "Institutional Review Board" (IRB) sun duba kuma sun amince da wannan binciken. Tuntubi Hukumar "Institutional Review Board" (IRB) idan kana/kina da tambayoyi game da hakkinka/ki a matsayin mai shiga binciken.

Hukumar IRB na Jami'ar Maryland, Baltimore (UMB) ta kasa binciken da aka yi bayani akai a wannan takardar bada izini a matsayin wanda bai da hadari sosai. IRB kungiya ce na masanin kimiyya, likitoci, kwararru, da wasu mutane. 'Yan IRB sun kunsa mutane da basu cikin UMB da mutanen da basu gudanar da aikin bincike. Shawarar IRB cewa binciken bai da hadari sosai baya nufin cewa babu hadari gabaki-daya. Ka/kin kaddara cewa ana iya samun hadarin rauni sakamakon shiga binciken, kamar yadda aka bayyana a takardar bada izini.

Idan an ji maka/miki rauni sakamakon gangancin wani jami'in bincike, kana/kina iya neman diyya. Idan kana/kina da tambayoyi, damuwa, kuka, ko kana/kina ganin an ji maka/miki domin shiga wannan binciken sakamakon gangancin wani jami'in binciken, kana/kina iya tuntuban 'yan IRB ko ma'aikatan Ofishin masu Kare Dan Adam a Ayyukan Bincike, wato "Human Research Protections Office" (HRPO) don yin tambayoyi, tattauna matsaloli ko damuwa, samun bayani, ko bada bayani game da hakkinka/ki a matsayin mai shiga bincike. Adireshin offishin IRB da na HRPO shine:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

13.1.4 Igbo

RESEARCH CONSENT FORM

Protocol Title: Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria

Study No.: [Please include the UMB protocol number only]

Principal Investigator: [please provide name, degrees, & phone number]

Sponsor: [delete if not applicable]

Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring in Nigeria Adult Interview and follow-up

(Age 18–99 years and emancipated minors 15–17 years)

Ndeewo. Aha m bụ _____. A chọrọ m ịgwa gị ka i sonye na nchọcha a gbasara ọgwụ mgbochi COVID-19 na Naijiria. Ụlọ ọrụ na-ahụ maka igbochi ọgwụ na nri adịgboroja a kpọrọ National Agency for Food and Drug Administration and Control (NAFDAC) na Bekee bụ isi sekpụ nti na nchọcha a. Ọ bụghị iwu na ị ga-esonye na nchọcha a.

Ebumnuche nchọcha

Nchọcha a bụ maka ọgwụ mgbochi COVID-19 na Naijiria. Ebumnuche ya bụ inyere Gọvmenti Naijiria aka iji were ghọtawanye ihe ọgwụ mgbochi COVID-19 na-arụ nakwa ihe ọ na-eme n'ahụ ma a gbachaa ya. Nchọcha a ga-enyere gọvmenti aka ịmata ka ọgwụ mgbochi a si emetụta ndị mmadụ ozigbo a gbachara ya na ka ọ nọrọla ọbere oge a gbachara ya nke nwere ike iru afọ atọ.

Anyi bu n'uche ịkpọ mmadụ 12,000 ka ha sonye na nchọcha a. I sonye, ị ga-enyere Gọvmenti Naijiria aka ime ihe e kwesịrị ime ọsịịsọ ma chekwaa ndụ ndị Naijiria.

GAA N'USORO NCHỌCHA

Usoro nchọcha

I soro na nchọcha a, anyị ga-agba gị ajụjụ ọnụ ụfọdụ banyere onwe gị, njem i mere nsonso a, ọrịa ịrịagoro na mbụ nakwa ka ọgwụ mgbochi siri me gị n'ahụ mgbe ị gbachara ya. Ajụjụ ọnụ a ga-ewe ihe dịka nkeji 10. Agbachaa ajụjụ ọnụ taata, ndị ọrụ anyị ga-bịa ọzọ ma abalị 3 ma ọ bụ 7 e ji gbacha ọgwụ mgbochi. Nke a gachaa, ha ga-emekwa ya kwa izu ụka were ruo ọnwa 3. E nwekwara ike inwe isochi anya kwa ọnwa were ruo afọ 3.

Anyị ga-eji tablet anyị were ihe anyị chọrọ banyere gị na nchọcha a. A ga-echekwa ya nke ọma. Naanị ndị ọrụ a họtara ga-enwe ike ịhụ ya. A ga-agba gị ajụjụ ọnụ ebe naanị gị nọ n'ụlọ ọgwụ ebe a. A ga-ezochi ihe niile ị gwara anyị nke ọma. Agaghị eji aha gị ma ọ bụ akara ọzọ e ji mara gị na ndepụta mpụtara ọbụla. Ihe anyị ga-ekwu banyere nchọcha a agaghị enwe ka o ga-esi metụta onye ị bụ.

Nsogbu nwé ré ike ịdapụta

E nwere ike nwee ọbere nsogbu si n'amaghị chekwa ihe banyere gị ị nyere anyị. Anyị ga-agba mbọ nke ọma iji hụ na e chekwara ya nke ọma. Anyị ga-echekwa ya ebe enweghị ihe ga-eme ya. Anyị ga-eji akara nzochi were chekwaa ihe ndị dị n'igwe eletronik. Anyị ga-eji akara kod were mara ihe i nyere anyị kama aha gị.

Uru e nwere ike irite

I nwere ike rite uru ma ọ bụ hapụ irite uru site n'isonye na nchọcha a. I sonye na nchọcha a, i nwere ike inyere ndị ọzọ aka n'ọdịnihu. Anyị tụrụ anya na nchọcha a ga-enyere anyi aka ịghọta ihe ndị a:

- Ihe na-eme ndị mmadụ mgbe ha gbachara ọgwụ mgbochi COVID-19
- Ụzọ ka mma a ga-esi were kwalite ike ọgwụ mgbochi.

Ohere ọzọ i nwere ma isonyeghị na nchọcha a

Ohere ọzọ i nwere bụ ịjụ isonye na nchọcha a. I chọọ isonye, ọgaghị emetụta uru gị ma ọ bụ onye ezinụlọ gị na-erite n'ụlọ ọgwụ a.

Ihe ọ ga-ewe onye so eme nchọcha

Onye so eme nchọcha a agaghị akwụ ụgwọ ọbụla

Ihe a ga-akwụ onye so eme nchọcha

Agaghị akwụ gị ụgwọ ọbụla maka iso me nchọcha a.

Izochi na ịhụ ihe banyere ahụike gị

Naanị ndị so eme nchọcha a ga-ahụ ihe ndị ị gwara anyị maka nchọcha a. A ga-agba mbọ hụ na-e zochiri ihe banyere gị, tinyere ọsịsa i nyere nakwa mpụtara test gị. A ga-eji akara nzochi were kpuchi ihe niile dị n'igwe eletronik. Anyị ga-eji akara kod kama aha gị were mara ihe niile anyị ji banyere gị nakwa ọsịsa i nyere na nchọcha. Naanị ndị ọrụ so eme nchọcha a ga-enwe ike iji akara a mara ọsịsa gị. Mpụtara ikpeazụ banyere nchọcha a agaghị ebu aha gị nakwa ihe banyere gị.

Ikike i nyere anyị ka anyị nye Komitii nke Neshọnal Helt Risach Etiks aha gị nakwa ebe a ga-esi were chọta gị bụ nke agaghịzi adị ire ma afọ abụọ gachaa e ji mecha nchọcha a. I nwee ajụjụ banyere ikike gị dịka onye so eme nchọcha a ma ọ bụ ọ dị gị ka e mekpara gị ahụ, kpọtụrụ NHREC na:

Adres: Federal Ministry of Health,
Federal Secretariat Complex Shehu Shagari Way,
Garki,
Abuja P.M.B. 083,
Garki-Abuja
Akara ekwentị: 234-803-586-8293
E-mel: info@nhrec.net:

Ịjụ isonye na nchọcha na ikike i nwere ịkwụsị isonye

Isonye na nchọcha a abụghị iwu. I nwere ike ịnapụ ikike i nyere iji ihe banyere gị rụọ ọrụ mgbe ị chọrọ. Ịjụ isonye na nchọcha, ma ọ bụ pụọ mgbe masịrị gị agaghị emetụta uru nleta ahụike gị ma ọ bụ onye ọbụla bụ onye ezinụlọ gị. Ị jụ ma ọ bụ chọọ ịpụ, ihe ndị ị gwara anyị agaghị adị na mpụtara nchọcha. I kpebie na ịgaghịzi esonye, nsogbu ọbụla adịghị. Biko kpọtụrụ onye Famasist na-ahụ maka nchọcha a, Famasist Uchenna Elemuwa (ebe a ga-akpọtụrụ dị n'okpuru), ma otu n'ime ihe ndị a dapụta:

- I nwee ajụjụ, ihe edoghị gị anya, ma ọ bụ mkpesa banyere nchọcha a.
- I kpebie ịkwụsị isonye na nchọcha.

Pharm. Uchenna Elemuwa
Adres: The National Agency for Food and Drug Administration and
Control (NAFDAC), Abuja FCT
Akara ekwentị: 08034099032
E-mel: uche2nice2000@yahoo.co.uk

Ị chọrọ ị jụ m ihe ọbụla banyere nchọcha a?

Okwu inye ikike

Agụọla m akwụkwọ a, ma ọ bụ mmadụ agụọrọla m ya. E nyere m nkwado ịjụ ajụjụ. E nwekwara m ezigbo ohere maka ajụjụ. E nwere m afọ ojuju n'ọsịsa e nyere . Ama m na m sonye, e nwere m ike ịpụ oge ọbụla m chọrọ. Emeghị m mmanye isonye. E nyere m otu kọpị akwụkwọ a.

1. I kwere ka a gbaa gị ajụjụ ọnụ nakwa isochi gị azụ? 'EE' pụtara na i kwere ka a gbaa gị ajụjụ ọnụ nakwa ka e sochie gị azụ. 'MBA' pụtara na ịchọghị ka a gbaa gị ajụjụ ọnụ ma sochikwaa gị azụ.

_____Ee _____Mba

2. I kwere ka a kpọtụrụ gị ma ọ bụrụ na nchọcha a ga-eme n'ọdịnihu chọpụta ihe nwere ike ịdị mkpa maka ahụike gị? Anyị nwere ike ime nke a naanị n'afọ atọ e mechara nchọcha a. Oge a gachaa, anyị ga-ewepụ ihe niile a ga-eji were mara gị ma ọ bụ kpọtụrụ gị dị n'akwụkwọ ajụjụ a jụrụ gị. 'EE' pụtara na ị kwere ka a kpọtụrụ gị n'ime afọ atọ a. 'MBA' pụtara na ị kweghị ka a kpọtụrụ gị.

_____Ee _____Mba

Participant signature or mark_____ Date: ___/___/___

Printed name of participant_____

Participant ID number _____

[For illiterate participants]

Signature of witness_____ Date: ___/___/___

Printed name of witness_____

Signature of person obtaining consent_____ Date: ___/___/___

Printed name of person obtaining consent_____

Study staff ID number _____

IHE MAHADUM KWURU BANYERE NSOGBU NWERE IKE ỊPỤTA NA NCHỌCHA

Mahadum na-agba mbọ ịhụ na e nyere ndị niile na-esonye na nchọcha ya ikike niile ha kwesịrị ịnwe n'okpuru iwu steti na fedral. Ịgaghị ahapụ ikike ọbụla ị nwere site na ibinye aka n'akwụkwọ ikike a ma ọ bụ site na isonye na nchọcha a. Institushọnal Reviu Bọd (IRB)

enyochaala nchọcha a ma nye nkwado ya Biko kpọọ Institushọnal Reviu Bọd (IRB) ma ị nwee ajụjụ banyere ikike ị nwere dịka onye so eme nchọcha. Nchọcha a kọwara n'akwụkwọ ikike a bụ nke Univasiti nke Maryland, Baltimore (UMB) hụrụ dịka nke obere nsogbu nwere ike isi na ya pụta. IRB bụ otu ndị sayensị, ndị nlekọta ahụike na ndị ọkacha mara dị iche iche. Ndị so na IRB gụnyere ndị enweghị ihe jikọrọ ha na UMB na ndị anaghị eme nchọcha. Ihe IRB kpebiri na nsogbu nwere ike ịpụta pere mpe apụtaghị na nchọcha a enweghị nsogbu na ọghọm dị na ya. I na-abagide nsogbu nwere ike ịdapụta maka i so eme chọcha, dịka e si were kwuo n'akwụkwọ inye ikike.

Ọ bụrụ na ị merụọ ahụ maka nleghara anya nke onye na-eme nchọcha, i nwere ikwu ka a kwụọ gị ụgwọ were tie gị aka n'obi. I nwee ajụjụ, ihe na-echu gị ụra, mkpesa, ma ọ bụ na e merụrụ gị ahụ maka isonye na nchọcha a, i nwere ike ịkpọtụrụ ndị IRB ma ọ bụ ndị ọrụ Human Rịsach Protekshọn Ofis (HRPO) maka ị jụ ajụjụ, kpaa banyere ihe na-echu gị ụra, nweta ozi ma ọ bụ kwuo banyere ikike i nwere dịka onye so eme nchọcha. Ebe a ga-enweta ndị IRB na ndị HRPO bụ:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

13.1.5 Pidgin

RESEARCH CONSENT FORM

Protocol Title: Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring for Naija

Study No.: [Abeg, make you include only the UMB protocol number]

Principal Investigator: [Abeg give name, degrees, & phone number]

Sponsor: [delete if e no dey applicable]

Cohort Event Monitoring (CEM) for Safety Signal Detection, after Vaccination With COVID-19 Vaccines and Post Market Monitoring for Naija Adult Interview and follow-up

(Age 18–99 years and emancipated minors 15–17 years)

Interviewer reads: na which language you want make we take talk this mata today?

☐ English

☐ Hausa

☐ Igbo

☐ Yoruba

Hello. My name na_____ ___. I go like make you shook mouth for this mata wey dey ground on COVID-19 vaccination for Naija. The National Agency for Food and Drug Administration and Control (NAFDAC) nai dey lead this mata. Na your choice if u won join for this mata.

Koko wey dey the mata

This mata na on COVID-19 vaccination for Naija. The koko of this mata na to helep the Government wey dey for Naija better understand the effect wey COVID-19 vaccination get and the side effects wey e carry. The mata go helep the government know how the vaccine take dey affect pipo, once dem don take am finish and the time e go last and e fit reach like 3yrs.

Our plan na to call like 12,000 pipo make dem come join for this mata wey dey ground. If you gree join, you go helep the Government wey dey Naija make dem for sharp sharp answer and sharperly protect naija pipo.

make you go where dem dey call STUDY PROCEDURES

Study Procedures

If you gree join this study, we go like ask you some questions wey concern your pesin, where you been travel go like now, the history wey the disease carry and the side effectswey you fit feel afta you don take the vaccination. The questions wey we go ask you go take like 10mins. Afta you don answer all the questions finish, our pipo go call you afta 3-7 days to know how the vaccination kon be and dem go still call every week for 3 months. We go still dey check you for like every month inside 3 yrs. We go first let you know say we won dey call

you to check how you dey for like 3 yrs.

Na for inside dis tablet we go take all your info. We go make sure say we keep ur mata gidigba for one side wey nobody go see am. Na only those pipo wey dey inside the mata go fit see am. Na for one corner for the hospito abi na klinic wey pipo no go see us nai we go take ask you questions. Dey sure say anytin you tell us we go keep am gidigba and tight for you. Another ear no go hear am at all. We no go use your name abi anytin wey pipo fit take know you take save any reports. All the mata wey we go collect from this study, dey sure say e no go get anytin wey pesin go fit take know say na you.

Potential Risks

Make you no too fear say the mata wey we go collect from you we go keep am gidigba make another ear no hear am. Na everytin wey we fit do nai we go do make another ear for no hear the mata at all. Na for where another eye nor go see the mata nai we go keep am put. We go use passwords take keep your electronic mata. Na code numba we go take keep your info. Dey sure say we no go use your name at all o.

Potential Benefits

You fit or you fit no gain anytin if you gree join dis mata. If you gree join dis study, you go fit even helep other pipo tomorrow. We pray say make dis study help us understand all these mata wey we won mention naw:

- The side effects wey pipo wey take the COVID-19 vaccine go get
- The sure way wey we go take dey the best for the quality of the vaccine.

Alternative wey dey if you won join for the Study

You fit say you no won join for the mata. If you say you no won join, nothing go worry all the beta beta things wey you and your family don enjoy for dis hospito abi na klinic

Costs to Pesin wey Take Part for the Study

You no go pay anytin if you gree say you won join for this mata wey dey ground.

Payment to Pesin wey Take Part for the Study

We no go pay you anytin if you gree join for this mata wey dey ground.

Confidentiality and Access to your Health Information Na only pipo wey follow for dis study go fit know about the info wey you give us. We go make sure say we do everytin wey we fit do to make sure say another ear no go hear about the info wey you give us. Even your answers and your test results, another eye no go see am at all. Na passwords we go take save all your electronic info. Na code numba we go use instead of your name to take know your info and the answers wey we won study. Na only pipo wey join for this study go fit use your numba take know the answers wey you give us. Your name abi your personal info no go join for our final report.

Na afta two years the permission wey you give us to use and share your name and contact info with the National Health Research Ethics Committee go expire.

If you get any question wey you won ask about your rights as pesin wey join for dis research or you feel say this your rights, dem don abuse am, abeg make you sharp sharp call NHREC

Address: Federal Ministry of Health,
Federal Secretariat Complex Shehu Shagari Way, Garki,
Abuja P.M.B. 083,
Garki-Abuja
Tel: 234-803-586-8293
E-mail: info@nhrec.net:

Refusal to Take Part and Right to Withdraw

Na your choice if you join for this study. You dey free anytime wey you like to withdraw the permission wey you give us to use your info. If you no gree join abi you won comot from the study, dey sure say all the beta beta tins wey you and your family don enjoy, nothing go do am at all. If you say you no won join again, we no go join the info wey you give us for our study results. If you still say you no won join again, nothing wey anybody go do you. Abeg make you call the Pharmacist wey dey in charge of the study, Pharm. Uchenna Elemuwa (contact information below), if any of the following kon happen:

- You get questions, abi sometin wey dey worry you for the study.
- You won comot from the study

Pharm. Uchenna Elemuwa

Address: The National Agency for Food and Drug Administration and Control (NAFDAC), Abuja FCT

Phone: 08034099032

Email: uche2nice2000@yahoo.co.uk

You get anytin wey you won ask me about the study?

Consent Statement

I don read this form abi pesin don read am for me. I kom get mora to take ask questions. Dem give me plenty time make I for ask questions. Dem answer all the questions wey I ask wella and my belle sweet me well well with the way wey dem take answer the questions. E sure for me say if I say I won join for this mata wey dey ground, I fit still comot anytime wey I like if my mind kon change. Na me e concern if I won shook mouth for the mata. Dem don give me one copy of this consent form.

1. You gree say make we ask you questions kon still follow you up for the mata? 'YES' mean say you don gree say make we ask you question kon still follow you up join. 'NO' mean say you no gree make we ask you questions kon still follow you up join.

_____Yes _____No

2. Hope say you no mind if we call you for future if dis study kon get beta mata wey fit helep your health? Na within 3 yrs wey we go do am once we finish dis study. Afta dat time, we go remove any info wey pesin fit use know you or even call you kon dey ask you questions on the mata. 'YES' mean say you gree make we call you within dis 3 yrs. 'NO' mean say you no gree make we call you at all.

_____Yes _____No

Participant signature or mark_____ Date: ___/___/___

Printed name of participant_____

Participant ID number _____

[For pipo wey no go school]

Signature of witness_____ Date: ___/___/___

Printed name of witness_____

Signature of pesin wey obtain consent_____ Date: ___/___/___

Printed name of pesin wey obtain consent_____

Study staff ID number _____

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

I want make you know say na the university nai go provide everybody wey join for dis mata all the right wey concern State and Federal law. You no go loose any of your legal right if u sign dis consent form or even join for the research project. Dis research wey you dey see so, na Institutional Review Board (IRB) nai approve am o. if u get any question at all abi sometin wey dey spoil your belle or you dey fear say sometin fit happen to you if you join for dis mata, abeg make u halla the Institutional Review Board (IRB) o.

IRB wey dey inside the University of Maryland, Baltimore (UMB) don talk say make you no fear too much as you don agree to fill dis consent form. The IRB na pipo wey oyibo dey call scientists, physicians, experts, and other pipo. Pipo wey dey inside dis IRB na pipo wey no join with UMB and pipo wey no dey do research projects. As IRB say make you no fear too much no mean say you no go fear at all o. Anytin still fit do you as you don gree say you go join fill the consent form.

If anytin do you becos say the researcher do mistake, you fit tell us say make we give you sometin make your belle for sweet you. If you get any question abi some tin wey dey worry u abi sometin wey u won tell us abi you dey feel like say as you don join this research, sometin don wound you becos of the mistake wey the researcher do, you fit halla d pipo wey dey for IRB abi the staff wey dey for Human Research Protections Office (HRPO) to ask dem any question, abi sometin wey dey worry you, abi you won complain any gbege abi na becos say you join dis research nai you come wound becos say the researcher do mistake, you fit halla pipo wey dey inside the IRB abi the staff wey dey for the Human Research Protections Office (HRPO) to ask dem plenty questions, abi you won tell dem wetin dey worry you abi you won take some gists abi u won give input about your rights becos say you join for the research.

The contact information for the IRB and the HRPO na:

University of Maryland Baltimore

Human Research Protections Office

620 W. Lexington Street, Second Floor

Baltimore, MD 21201

410-706-5037

Appendix 2: Evaluation Questionnaire/Data Dictionary

Variable name	Type	Values and Coding	Definition	
Table 1: Participant information				
Form E1: Participant registration, informed consent, contact, and covariates				
siteID	Type of variable at discretion of site	[needs to be unique]	Unique and persistent identifier for each site	
participantID	Type of variable at discretion of site	[needs to be unique]	Unique and persistent identifier for each participant	
subjName	Text		Name of participant	
consent	Numeric (binary)	0 = No 1 = Yes	Provides informed consent	
Participant contact details				
subjPhone	Numeric		Participant's phone number	
NOKname	Text		Name of next of kin	
NOKphone	Numeric		Phone number of next of kin	
Participant covariates				
subjDoB	Date	dd/mm/yyyy	Date of birth of participant	
subjSex	Numeric (multinomial)	0 = Male 1 = Female	Sex of participant	
subjPreg	Numeric (multinomial)	0 = No 1 = Yes	Is the participant pregnant If subjSex = 1	
subjLact	Numeric (multinomial)	0 = No 1 = Yes	Is the participant breastfeeding? If subjSex = 1	
subjMedHist	Numeric (multinomial)	0 = No medical history 1 = Chronic respiratory disease or asthma 2 = Chronic heart disease 3 = Chronic liver disease 4 = Chronic renal disease 5 = Diabetes 6 = Immunocompromised / immunosuppressed 7 = Obesity 8 = Allergy	Medical history, presence of diseases?	

subjPriorCovid	Numeric (multinomial)	0 = No 1 = Yes, laboratory confirmed 2 = Probable but not laboratory-confirmed	Previous COVID-19 disease	
subjPriorRxn	Numeric (multinomial)	0 = No 1 = Yes 2 = Do not know	History of reaction to vaccination	
subjPriorRxnVac	Text		Indicate which vaccine (Only filled in if subjPriorRxn = 1)	
subjPriorRxnDes	Text	Describe reaction to vaccine (Only filled in if subjPriorRxn = 1)		
subjSocioE	Numeric (multinomial)	(classes to be defined locally)	Socioeconomic class	
subjHlthWkr	Numeric (multinomial)	0 = No 1 = Yes	Is the participant a healthcare worker?	
Table 2: Vaccine exposure information Table 2 can be linked to Table 1 by participantID				
Form E2: Participant exposure dose 1 & 2				
doseID	Numeric	1 = 1st vaccination 2 = 2nd vaccination	If the dose is the 1st or 2nd dose of vaccination?	
vaccDate	Date	dd/mm/yyyy	Date of vaccination	
vaccTime	Time	HH:MM	Time of vaccination	
vaccBrand	Numeric (multinomial)	1 – Oxford/ 2 – Johnson & Johnson 3 – Pfizer (to list all brand/ manufacturers available in the country)	Vaccine brand and manufacturer	
vaccBatch	Text		Vaccine Batch number	
vaccDiluent	Numeric (binary)	0 = No 1 = Yes	Was a separate diluent required?	

vaccDiluentBrand	Numeric (multinomial)	1 – Oxford/ 2 – Johnson & Johnson (to list all brand/ manufacturers available in the country)	Diluent brand and manufacturer (Only filled in if vaccDiluent = 1)	
vaccDiluentBatch	Text		Diluent Batch number (Only filled in if vaccDiluent =1)	
vaccOther	Numeric (binary)	0 = No 1 = Yes	Co-administration of vaccine against any disease other than COVID	
vaccOtherDis	Text		Specify which disease was vaccinated against (Only filled in if vaccOther = 1)	
Table 3: Pre-vaccination reactogenicity Table 3 can be linked to Table 1 by participantID Trigged only if prevaccFU = 1				
Form A1: reactogenicity (pre-vaccination)				
preLogID	Alphanumeric		Unique ID for the record of pre-vaccination reactogenicity	
preLogDate	Date	dd/mm/yyyy	Date of record	
preFebrile	Numeric (binary)	0 = No 1 = Yes	Did you feel fever in the past 3 days?	
preTempY	Numeric (binary)	0 = No 1 = Yes	Did you measure your temperature in the past 3 days?	
preTemp	Numeric (multinomial)	1 = Below 38.0°C (below 100,4 °F) 2 = 38.0°C to 38.4°C (100,4 to 101,12 °F) 3 = 38.5°C to 38.9°C (101,3 to 102,02 °F) 4 = Higher than 39.0 °C (higher than 102,2 °F)	What was your temperature? (Only filled in if preTempY = 1)	
preTempWhere	Numeric (multinomial)	1 = External(using digital thermometer on head, hand etc) 2 = Armpit 3 = Other	Where did you measure the temperature? (Only filled in if preTempY = 1)	

preNausea	Numeric (binary)	0 = No 1 = Yes	Did you feel nauseous in the past 3 days, or did you vomit?	
preNauseaSev	Numeric (multinomial)	1 = The nausea/ vomiting did not interfere with my activities 2 = The nausea/ vomiting somewhat interfered with my activities 3 = The nausea/ vomiting was considerable and prevented my daily activities	How severe was the nausea/vomitting? (Only filled in if preNausea = 1)	
preMalaise	Numeric (binary)	0 = No 1 = Yes	Did you experience general malaise in the past 3 days (feeling of weakness, not feeling well)?	
preMalaiseSev	Numeric (multinomial)	1 = The malaise did not interfere with my activities 2 = The malaise somewhat interfered with my activities 3 = The malaise was considerable and prevented my daily activities	How severe was the general malaise? (Only filled in if preMalaise = 1)	
preChill	Numeric (binary)	0 = No 1 = Yes	Did you have chills in the past 3 days?	
preChillSev	Numeric (binary)	1 = The chills did not interfere with my activities 2 = The chills somewhat interfered with my activities 3 = The chills were considerable and prevented my daily activities	How severe were the chills? (Only filled in if preChill = 1)	
preHeadache	Numeric (binary)	0 = No 1 = Yes	Did you have a headache in the past 3 days?	

preHeadacheSev	Numeric (multinomial)	1 = = The headache did not interfere with my activities 2 = The headache somewhat interfered with my activities 3 = The headache was considerable and prevented my daily activities	How bad was the headache (Only filled in if preHeadache = 1)	
prePain	Numeric (binary)	0 = No 1 = Yes	Did you have joint pain in the past 3 days?	
prePainSev	Numeric (multinomial)	1 = The joint pain did not interfere with my activities 2 = The joint pain somewhat interfered with my activities 3 = The joint pain was considerable and prevented my daily activities	How bad was the joint pain? (Only filled in if prePain = 1)	
preMuscle	Numeric (binary)	0 = No 1 = Yes	Did you have muscle aches in the past 3 days?	
preMuscleSev	Numeric (multinomial)	1 = The muscle aches did not interfere with my activities 2 = The muscle aches somewhat interfered with my activities 3 = The muscle aches were considerable and prevented my daily activities	How bad were the muscle aches? (Only filled in if preMuscle = 1)	
preTired	Numeric (binary)	0 = No 1 = Yes	Did you feel tired (fatigued) in the past 3 days?	
preTiredSev	Numeric (multinomial)	1 = The tiredness did not interfere with my activities 2 = The tiredness somewhat interfered with my activities 3 = The tiredness was considerable and prevented my daily activities	How bad was the tiredness?	

Table 4: Post-vacc dose ID				
posDoseID	Numeric (binary)	1 = 1st vaccine dose 2 = 2nd vaccine dose [unique per each participant]	Identifier if the subsequent record is for reactogenicity after the 1st or 2nd vaccine dose	
Table 5: Post-vaccination reactogenicity Table 5 can be linked to Table 4 by posDoseID				
Form A2: reactogenicity (post-vaccination)				
posLogID	Numeric	Numbers from 1 to 8 [unique per each posDoseID per each participantID]	ID for the record of pre-vaccination reactogenicity corresponding to each date	
posLogDate	Date	dd/mm/yyyy	Date of record	
posInjectPain	Numeric (binary)	0 = No 1 = Yes	Did you have pain at the injection site today?	
posPainSev	Numeric (multinomial)	1 = The pain did not interfere with my activities 2 = The pain somewhat interfered with my activities 3 = The pain was considerable and prevented my daily activities	How much pain did you have? (Only filled in if posInjectPain = 1)	
posRedness	Numeric (binary)	0 = No 1 = Yes	Did you have redness of the skin around the injection site today?	
posRedBig	Numeric (multinomial)	1 = Less than 2,5 cm 2 = 2,5 to 5,0 cm 3 = 5,1 to 10 cm 4 = More than 10 cm 5 = Unknown/not measured	How big was the red spot? (Only filled in if posRedness = 1)	
posSwell	Numeric (binary)	0 = No 1 = Yes	Did you have swelling of the skin around the injection site on today?	
posSwellBig	Numeric (multinomial)	1 = Less than 2,5 cm 2 = 2,5 to 5,0 cm 3 = 5,1 to 10 cm 4 = More than 10 cm 5 = Unknown/not measured	How big was the swelling? (Only filled in if posSwell = 1)	

posHard	Numeric (multinomial)	0 = No 1 = Yes	Did you have hardening (induration) around the injection site today?	
posHardBig	Numeric (multinomial)	1 = Less than 2,5 cm 2 = 2,5 to 5,0 cm 3 = 5,1 to 10 cm 4 = More than 10 cm 5 = Unknown/not measured	How big was the hardened spot? (Only filled in if posHard = 1)	
posBruise	Numeric (binary)	0 = No 1 = Yes	Did you have a bruise (haemotoma) around the injection site today?	
posBruiseBig	Numeric (multinomial)	1 = Less than 2,5 cm 2 = 2,5 to 5,0 cm 3 = 5,1 to 10 cm 4 = More than 10 cm 5 = Unknown/not measured	How big was the bruise? (Only filled in if posBruise = 1)	
posWarm	Numeric (binary)	0 = No 1 = Yes	Did you feel warmth around the injection site today?	
posWarmSev	Numeric (multinomial)	1 = The warmth did not interfere with my activities 2 = The warmth somewhat interfered with my activities 3 = The warmth was considerable and prevented my daily activities	How severe was the warmth? (Only filled in if posWarm = 1)	
posItch	Numeric (binary)	0 = No 1 = Yes	Did you have an itch around the injection site today?	
posItchSev	Numeric (multinomial)	1 = The itch did not interfere with my activities 2 = The itch somewhat interfered with my activities 3 = The itch was considerable and prevented my daily activities	How severe was the itch? (Only filled in if posItch = 1)	
posFebrile	Numeric (binary)	0 = No 1 = Yes	Did you feel feverish today?	
posTempY	Numeric (binary)	0 = No 1 = Yes	Did you measure your temperature today?	

posTemp	Numeric (multinomial)	1 = Below 38.0°C (below 100,4 °F) 2 = 38.0°C to 38.4°C (100,4 to 101,12 °F) 3 = 38.5°C to 38.9°C (101,3 to 102,02 °F) 4 = Higher than 39.0 °C (higher than 102,2 °F)	What was your temperature? (Only filled in if posTempY = 1)	
posTempWhere	Numeric (multinomial)	1 = External(using digital thermometer on head, hand etc) 2 = Armpit 3 = Other	Where did you measure the temperature? (Only filled in if posTempY = 1)	
posNausea	Numeric (binary)	0 = No 1 = Yes	Did you feel nauseous today, or did you vomit?	
posNauseaSev	Numeric (multinomial)	1 = The nausea/ vomiting did not interfere with my activities 2 = The nausea/ vomiting somewhat interfered with my activities 3 = The nausea/ vomiting was considerable and prevented my daily activities	How severe was the nausea/vomitting? (Only filled in if posNausea = 1)	
posMalaise	Numeric (binary)	0 = No 1 = Yes	Did you experience general malaise today (feeling of weakness, not feeling well)?	
posMalaiseSev	Numeric (multinomial)	1 = The malaise did not interfere with my activities 2 = The malaise somewhat interfered with my activities 3 = The malaise was considerable and prevented my daily activities	How severe was the general malaise? (Only filled in if posMalaise = 1)	
posChill	Numeric (binary)	0 = No 1 = Yes	Did you have chills today?	

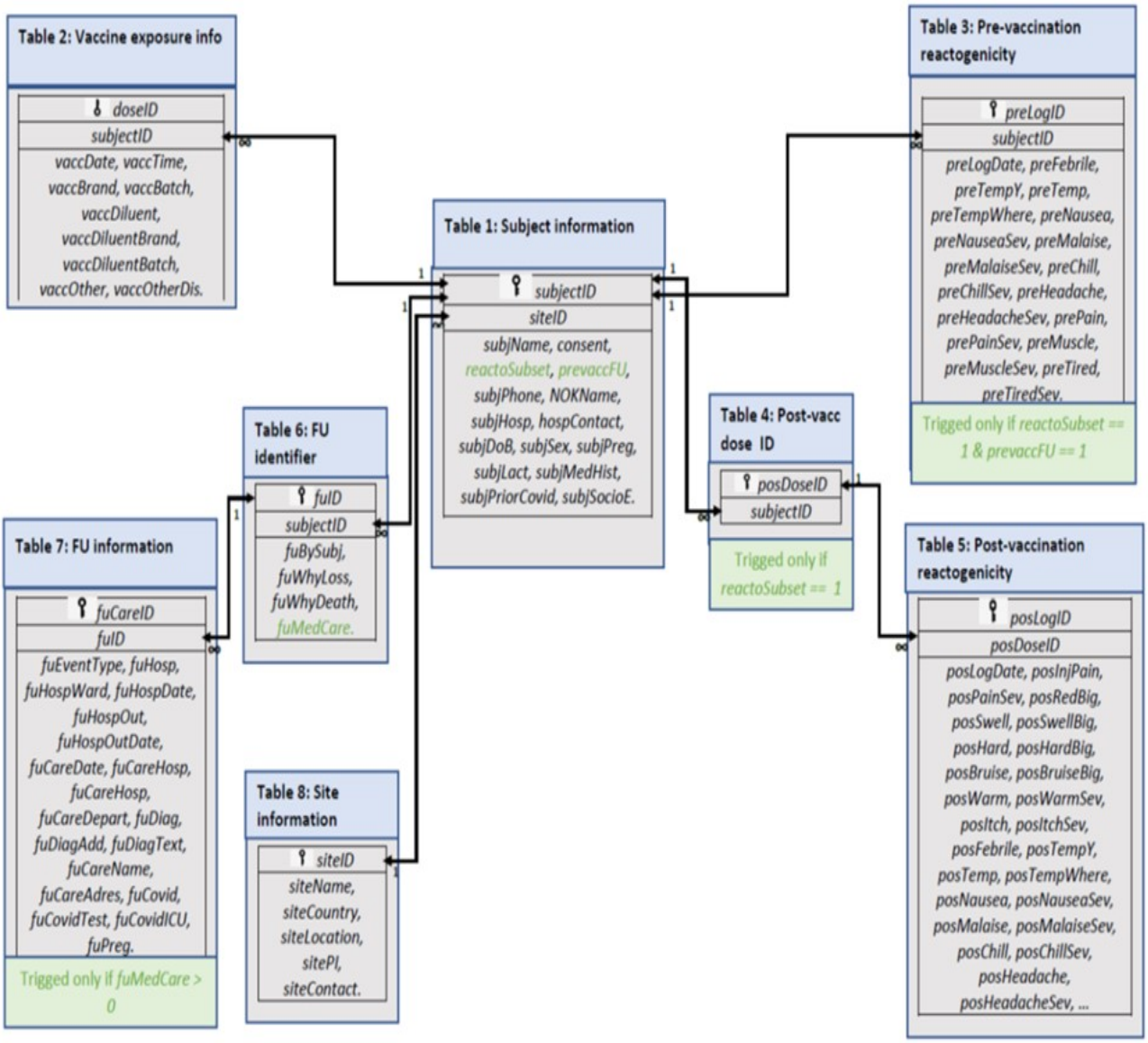
posChillSev	Numeric (binary)	1 = The chills did not interfere with my activities 2 = The chills somewhat interfered with my activities 3 = The chills were considerable and prevented my daily activities	How severe were the chills? (Only filled in if posChill = 1)	
posHeadache	Numeric (binary)	0 = No 1 = Yes	Did you have a headache today?	
posHeadacheSev	Numeric (multinomial)	1 = The headache did not interfere with my activities 2 = The headache somewhat interfered with my activities 3 = The headache was considerable and prevented my daily activities	How bad was the headache (Only filled in if posHeadache = 1)	
posPain	Numeric (binary)	0 = No 1 = Yes	Did you have joint pain today?	
posPainSev	Numeric (multinomial)	1 = The joint pain did not interfere with my activities 2 = The joint pain somewhat interfered with my activities 3 = The joint pain was considerable and prevented my daily activities	How bad was the joint pain? (Only filled in if posPain = 1)	
posMuscle	Numeric (binary)	0 = No 1 = Yes	Did you have muscle aches today?	
posMuscleSev	Numeric (multiniomial)	1 = The muscle aches did not interfere with my activities 2 = The muscle aches somewhat interfered with my activities 3 = The muscle aches were considerable and prevented my daily activities	How bad were the muscle aches? (Only filled in if posMuscle = 1)	
posTired	Numeric (binary)	0 = No 1 = Yes	Did you feel tired (fatigued) today?	

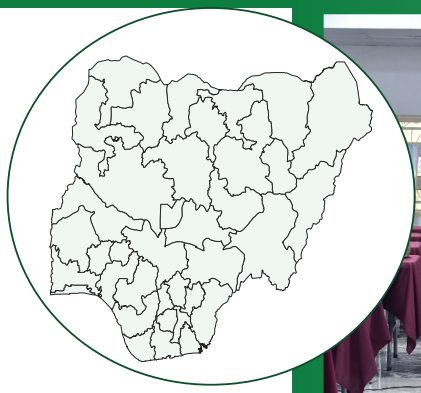
posTiredSev	Numeric (multiniomial)	1 = The tiredness did not interfere with my activities 2 = The tiredness somewhat interfered with my activities 3 = The tiredness was considerable and prevented my daily activities	How bad was the tiredness? (Only filled in if posTired = 1)	
Table 6: FU identifier (FU is follow up) Table 6 can be linked to Table 1 by participantID				
Form A3: Follow-up questionnaire				
fuID	Numeric	1 = FU one week after 1st dose 2 = FU one week after 2nd dose 3 = FU one month after 2nd FU 4 = FU one month after 3rd FU --- [needs to be unique per each participantID]	Identifier of the follow-up questionnaire	
fuBySujb	Numeric (binary)	0 = No 1 = Yes	Indicate if the form was completed by site staff (via the electronic tool)	
fuWhyLoss	Numeric (multinomial)	0 = No reason given 1 = The study takes too much time 2 = Not interested anymore 4 = Death 5 = Others	The reason for loss to follow-up. (Only if fuBySujb = 1)	
fuWhyDeath	Text		Reason for death (Only if fuWhyLoss = 4)	
fuMedCare	Numeric (multinomial)	0 = No 1 = 1 times 2 = 2 times etc	How many times did the participant seek medical care between [date X and date Y]? (e.g. at a local health center, at a hospital)	

Table 7: FU information Table 7 can be linked to Table 6 by fuID Triggered by fuMedCare > 0				
Form A3: Follow-up questionaire				
fuHosp	Numeric (binary)	0 = No 1 = Yes	Were you hospitalized since [date of last contact]? (Only if fuEventType = 3)	
fuHospDate	Date	mm/dd/yyyy	What was the date of admission to the hospital? (Only if fuHosp = 1)	
fuHospOut	Numeric (binary)	0 = No 1 = Yes	Are you already discharged? (Only if fuHosp = 1)	
fuHospOutDate	Date	dd/mm/yyyy	What was the date of discharge from the hospital (Only if fuHosp = 1 and fuHospOut = 1)	
fuReason	Text		Indicate reason for your hospitalization (Only if fuHosp = 1)	
fuDiag	Text		Indicate diagnosis by health care provider, if available (Only if fuHosp = 1)	
fuReport	Picture/ Attachment		Take a picture/attach your discharge report, if available	
fuHospID	Text		Name and place of hospital (Only if fuHosp = 1)	
fuCovid	Numeric (binary)	0 = No 1 = Yes	Were you diagnosed with COVID-19 disease by a healthcare professional?	
fuCovidTest	Numeric (multinomial)	0 = No 1 = Yes 2 = I don't know	Was the diagnosis based on a laboratory test (for the virus causing COVID-19 disease or antibodies against COVID-19 disease) (Only if fuCovid =1)	
fuCovidSympOnset	Date	dd/mm/yyyy	What was the date of symptom onset? (Only if fuCovid = 1)	

fuCovidICU	Numeric (binary)	0 = No 1 = Yes	Was admission to the intensive care unit necessary? (Only if fuCovid = 1)	
fuPreg	Numeric (multinomial)	0 = No 1 = Yes 2 = Not applicable	Are you pregnant? (Only if subjSex = 1 or 2)	
Data from electronic tool **Table 8: Site information** Table 8 can be linked to Table 1 by siteID				
siteName	Text		Name of the site	
siteCountry	Text		Site country	
siteLocation	Text		Location of the site	
sitePI	Text		Site principal investigator	
SiteContact	Text		Contact information of the site	

Appendix 3: Evaluation Questionnaire/Data Dictionary





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