

# Pharmacovigilance Reporting During Seasonal Malaria Chemoprevention in Nigeria: Findings From the 2020 Campaign

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## Research Article

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# Abstract

## Background

Seasonal malaria chemoprevention (SMC) campaign is known to reduce malaria-related morbidity and mortality among children aged 3 -59 months in the Sahel regions of Africa. However, the success of the intervention may be adversely affected by the absence of a robust pharmacovigilance system to monitor safety. This paper aims to describe our pharmacovigilance reporting experience during the campaigns conducted across seven states in Nigeria in 2020.

## Methods

The SMC campaigns were held from July to November 2020 over 4 cycles with about 12 million eligible children reached by trained community drug distributors. Suspected adverse drugs reactions were reported routinely through the national pharmacovigilance system. Completed PV forms submitted to the National Agency for Food, Drugs Administration And Control were retrieved and analyzed.

## Results

The ADR reporting across the seven states was low, with 5 states failing to report any incidence. Abdominal pain, weakness, diarrhea, fever, rash and vomiting were reported, with vomiting being the commonest. Children aged 12-59 months accounted for most (~86%, 49/57) of the reports, with over 70% (40/57) of these reports completed by Community Health Extension Workers. The System Organ Class showed the gastrointestinal system as the most affected (65%, 37/57).

## Conclusion

Our experience suggests potential ADR underreporting from the campaign. The quality and quantity of reports have been identified as a major concern, highlighting the need for active surveillance, strengthen health workers' capacity and the national pharmacovigilance system for optimum ADR reporting.

## 1.0 Background

Malaria is one of the leading causes of morbidity and mortality globally. In 2020, 241 million malaria cases in 85 malaria endemic countries (including the territory of French Guiana) were reported, increasing from 227 million in 2019, with most of this increase coming from countries in the WHO African Region [1]. It is implicated in millions of deaths over the last decades, with children under 5 years a major victim [2] African countries are disproportionately affected, with Nigeria and Congo accounting for 37.0% of cases and deaths globally have been implemented across the continent.

Seasonal Malaria Chemoprevention targeted at children under five years is one of such preventive interventions [3]. It involves the administration of a combination of sulphadoxine and pyrimethamine in

addition to amodiaquine (SPAQ) to health eligible children between the ages of 3 to 59 months during the peak of rainy season in the Sahel region of Africa [4,5]. Once administered, the therapeutic level attained can protect children against malaria throughout the peak of the rainy season [6]. Provided that the drug is administered according to the recommended guideline, WHO (2012) revealed that this intervention can reduce malaria cases by 75%, and by extension, malaria mortality.

The success of the intervention depends on the efficacy and safety of the SPAQ. While satisfactory efficacy and safety are preconditions for marketing authorization, post marketing surveillance is highly encouraged to identify safety issues that may arise during large scale use. To effectively identify and respond to safety issues post authorization, reliable pharmacovigilance system capable of detecting, monitoring and reporting adverse drug event associated with the drugs used for the SMC campaign must be in place. Countries and health programmes either adopt an active or passive pharmacovigilance strategy and, in some instances, a combination of both. The active pharmacovigilance system involves actively looking for cases of adverse drug reaction. On the other hand, the passive strategy relies on end-users to report suspected adverse drug reaction cases.

In Nigeria, ADR reporting is done in a passive form using the ADR forms, obtained from National Agency for Food and Drug Administration and Control (NAFDAC) state offices in the 36 states in the country, and the National Pharmacovigilance Centre (NPC) NAFDAC Headquarter ,or any of the pharmacovigilance centres across the country [7,8]. The form is expected to be filled and returned to any of the listed collection centers. More recently, an online reporting system was inaugurated [7]. In line with the national strategy, all suspected cases of ADR are expected to be reported using the ADR form and transmitted to the designated centers.

## **1.1 Aim and Objectives**

There are currently no systematically documented findings on the reporting of suspected adverse drug reaction during seasonal malaria chemoprevention campaigns in Nigeria. This paper aims to provide details on the reporting of suspected ADR from the seasonal malaria chemoprevention campaign across seven states in a bid to uncover gaps in pharmacovigilance. This article provides details of the number and type of ADRs associated with SPAQ while highlighting potential strategies for strengthening pharmacovigilance.

## **1.2 Ethical Approval**

Ethical approval for this study was received from the National Health Research Ethics Committee, Abuja , Nigeria. On the 8<sup>th</sup> of December 2020.

## **1.3 Nigeria National Pharmacovigilance Reporting System for Adverse Drug Reaction:**

The Nigeria National Pharmacovigilance system is coordinated by the National Pharmacovigilance center situated within the National Agency for Food and Drug Administration and Control (NAFDAC) Nigeria's drug regulatory agency [9]. The agency expects all suspected or actual adverse reactions to drugs and other related substances to be reported using the pharmacovigilance reporting form also known as yellow form [10]. A typical adverse drug reaction form (also known as yellow form or individual case safety report (ICSR) form) provides information on:

- a. Patient demographics (name, age, sex and weight)
- b. Adverse drug reaction (description, date reaction started and stopped and outcome– recovered fully, congenital abnormality, recovered with abnormality, life-threatening and death)
- c. Suspected drug (brand and generic names, batch number, NAFDAC number, expiry date)
- d. Concomitant medicines (all medicines taken in the last three months)
- e. Source of report

This form can be obtained from

- Any NAFDAC state office in the 36 states in the country.
- The National Pharmacovigilance Centre (NPC) NAFDAC Headquarters Wuse Zone 7 Abuja.
- Any of the Zonal Pharmacovigilance Centres (ABUTH, Shika, FMC, Owerri, LUTH, Lagos, UBTH, Benin, UITH, Ilorin and UMTH, Maiduguri)

Reports of adverse drug reaction are transmitted to the nearest pharmacovigilance centre. Recently, there is also an ADR reporting form online that can be used to report adverse drug reaction electronically [7].

In addition to healthcare providers (pharmacists, doctors and nurses), organizations or individuals holding a marketing authorization for medicinal products must report any suspected ADR to their products. Reporting is usually not mandatory; rather it is voluntary [11]. Overall, Nigeria's pharmacovigilance system is a passive surveillance system that involves the reporting of adverse drug reaction by health facilities across the country after observation of patients presenting such reactions

## 2.0 Methods

### 2.1 Design

This study extracted pharmacovigilance data from the End of Cycle reports of the SMC 2020 campaigns in States implemented by Malaria Consortium as submitted to the National Pharmacovigilance Centre through the National Agency for Food, Drugs Administration and Control (NAFDAC). The SMC campaign was implemented by Malaria Consortium in all the wards and Local Government Areas of Bauchi, Jigawa, Kano, Katsina, Kebbi, Sokoto and Yobe States. Prior to the campaign, health facility workers recruited for the campaign were trained on identifying and reporting adverse drug reactions using the national pharmacovigilance forms in line with the national pharmacovigilance system and provided with the pharmacovigilance form (NAFDAC Yellow Form). During each SMC cycle, households were visited by trained community drug distributors (CDDs) to administer SPAQ (see table 1 for brands and dosage used for the campaign) to eligible children within the target communities. The CDDs explained the reason for the visit to caregivers and the caregivers are encouraged to visit health facilities with their children in the event of any suspected adverse reaction to the drugs. This includes but not limited to vomiting, weakness, convulsion, among others.

### 2.2 Data Collection

At the end of the SMC round, the completed PV from the health facilities were picked up from the health facilities by the programme field officers. These completed reports were analyzed by the program team at the state level to identify trends in ADR reporting and then transmitted to the National Pharmacovigilance Center through the National Agency for Food and Drug Administration and Control (NAFDAC) offices in the respective states. For this study, the copies of the forms sent to NADFAC were analyzed. All the ADR forms analyzed were collated in December 2020.

### **2.3 Analysis of Adverse Drug Event Reports**

Completed Pharmacovigilance forms were retrieved during and after the seasonal malaria chemoprevention campaign that was held between July 2020 and November 2020 across the seven states Northern Nigeria states. The information listed below were extracted from the collected reports.

1. Adverse drug reaction reported
2. Age of the child
3. Profession of reporter
4. System Organ Class

Descriptive statistics showing the frequency of the various adverse drug reaction segregated by age group (3 - <12 months and 12-59 months) were presented. Frequency count and percentage on reporters' profession and the number of reports per 100,000 children was also presented. The WHO-ART for system organ class (SOC) classification was used to analyze the reports submitted.

## **3.0 Results**

SMC was administered to approximately 12,000,000 children aged 3–59 months across the targeted communities in seven Northern Nigeria states. High coverage of four courses of treatment was achieved across the communities where the intervention was implemented from July –November 2020.

### **Suspected Adverse Drug Reaction Reports**

In 2020, six types of adverse drug reaction to SPAQ were reported during the seasonal malaria chemoprevention campaign. Vomiting (persistent for more than 2 hours) was the most commonly reported adverse drug reaction during the campaign, accounting for almost half (28/57) of all reported suspected cases. Only two states (Bauchi and Jigawa) reported adverse drug reaction using the national pharmacovigilance reporting system. Bauchi and Jigawa States had a total of 42 and 15 pharmacovigilance reports, respectively. This translates to 1.5 reports per 100,000 children and 0.3 reports per 100,000 children in Bauchi and Jigawa States, respectively.

### **Type of Reporters**

Most (70%, 40/57) of the reporters are community health extension workers, while one of the reporters is a housewife. Seven of the reports (12.2%) did not capture information on the job title of the reporter. From the 57 suspected adverse drug reaction reports submitted, most (49/57) of the reactions were observed in children

aged 12 – 59 months as shown in Table 5. Gastrointestinal system disorders (persistent vomiting) accounted for 65% (37/57) of the reports with 86% found in children aged 12 – 59 months. Skin rashes and hyperthermia accounted for the second largest (24.5%, 14/57) of the reports submitted. Skin rashes associated with the drug of intervention was observed to have occurred in children aged 12 – 59 months and accounted for 10.5% (6/57) of the reports submitted, with all (100%, 6/6) of the reaction happening in the 12 – 59 months age group.

## 4.0 Discussion

In 2020, more than 12 million children under 5 were exposed to SPAQ to protect them from malaria morbidity and mortality. The low incidence seen in the two states (Bauchi 1.5/100,000 and Jigawa 0.3/100,000) does not necessarily translate to better safety profile of the SMC drug across the seven states. This further highlights the need poor pharmacovigilance reporting in Nigeria as indicated by zero reports from five of the seven states. The finding also shows that more than 85% of the ADRs (49/57) were reported by less skilled community health extension workers who are the classes of health professionals commonly found across primary health care centers in Northern Nigeria which were used as hub facilities for the implementation of the SMC campaign. This class of health workers is also consistent with the caliber of health workers working at these health facilities across the country. A total of 57 PV reports were submitted in 2020 with about 6 different types of suspected cases of ADR. The reported ADRs are abdominal pain, diarrhea, fever, weakness, rash, and vomiting which represent the most common reported suspected ADR. Approximately, 86% (49/57) of the reported ADRs are in children between the ages of 12-59 months. Also, vomiting represents the most commonly reported adverse drug reaction accounting for 49.1% (28/57) of the total reported ADR. This finding is in line with previous studies on the reported ADR during SMC implementation in Nigeria and other African countries within the Sahel belt of Africa.

However, the ADR reporting is abysmally low with five states reporting zero ADR reporting after the deployment of millions of doses for administration to target children despite training of health workers on pharmacovigilance reporting. Although training of health workers on pharmacovigilance reporting have been shown to increase ADR reporting in public health programs [11], the result of this study seems to have a divergent outcome with low ADR reporting at the end of the SMC round in 2020 despite the training of participating health workers by a team of state level trainers on pharmacovigilance prior to the commencement of the SMC round in the implementing states. Although the attitude of the health workers may be a major factor in the observed low ADR reporting. Also, studies have implicated poor knowledge as a major reason for pharmacovigilance underreporting [12]. This finding may point to the low quality of pharmacovigilance training delivered prior to the SMC round which may result in the poor knowledge on pharmacovigilance among health workers who are otherwise expected to acquired pharmacovigilance knowledge at the end of the training. Also, low ADR reporting is not strange within the Nigeria Pharmacovigilance systems as several studies has reporting similar findings [13 – 16]. Another reason for the low level of ADR reporting may be due to the passive nature of the ADR reporting. During the SMC campaign caregivers were instructed by community drug distributors to report to health facilities when their children who were previous administered SPAQ shown signs of adverse drug reactions, like vomiting, rash and other. This is a passive surveillance approach which largely relies on care givers reporting to the health facilities. When a caregiver seek care outside the target health facility for the observed ADR, the suspected ADR will be missed

and will not be reported. These concerns are vital because of the diverse health seeking behavior observed in Northern Nigeria during the most recent demographic and health survey [17]. Thus, the success of this approach depends on the health seeking behavior of the caregivers within the community. For this reason, an active surveillance system where caregivers are directly visited and asked about suspected ADRs observed in their children as a result of the administered SPAQ may help address the gaps from the passive surveillance ADR detection model used during the SMC campaign. Since studies with active surveillance ADR reporting systems shows higher ADR reporting.

Community health extension workers and community health officers represent the bulk of health care workers reporting ADRs as captured on the reporting forms. Community health extension workers (CHEWs) account for 70.2% (40/57) of the reporters while community health officers (CHO) accounts for 15.8% (9/57) (Table 3). This is because the CHEWs and CHOs are the cadres of staffs available in primary health centers [18] used during SMC implementation in Nigeria. Although studies have shown that workers in this setting have poor understanding of pharmacovigilance [19], they are still used to providing pharmacovigilance reports during the SMC campaign. To address these gaps, all health workers from these primary health centers were trained on pharmacovigilance. Despite the training on pharmacovigilance, capacity gaps still persist evidenced by the absence of name of the reporters in 12.2% (7/57) of the submitted pharmacovigilance forms (Table 2).

Patient reporting of ADR is desirable to be beneficial because it adds new information, and perspective about ADRs which may be missing from the reporting from health facility workers [20]. This new information may therefore help uncover potential safety measures to be implemented during the SMC campaign (Table 3). The analysis of pharmacovigilance report from the project shows the reporting of a suspected Adverse Drug Reaction by one of the caregivers whose child benefited from the SMC intervention. This possibility or parental reporting of ADR was also captured in a research in Lagos, Nigeria [21]. This is in line with recommendation by NAFDAC for patients to also report pharmacovigilance findings to the National Pharmacovigilance Centres (NPC) in addition to health care providers [22]. However low literacy level may be a challenge in ADR reporting by patients or caregivers in some part of Nigeria [23].

The system organ classes classification revealed that most of the suspected adverse drug reactions were gastrointestinal system and skin related which is seen in several studies on adverse drug reaction reporting in pediatrics [24 – 26].

#### **4.1 Limitation of the study**

The study acknowledges the possibility of some suspected ADRs either not reported to the health facility by the caregivers or the health facility workers not reporting to the higher level of reporting in accordance to the National Pharmacovigilance guidelines. The fact that the study results showed no suspected ADRs reports from five states of Kano, Katsina, Kebbi, Sokoto, and Yobe, does not necessarily mean no ADR occurred during the SMC drug distribution in those States. This limitation also highlights the need to strengthen ADR reporting in all HFs and States implementing SMC to ensure no case is missed. The fact that this study only attempted the explore only reporting rates, there is need for further research around causality assessment.

## **5.0 Conclusions**

Due to the abysmal low ADR reporting from the 2020 SMC campaign and observed quality issues with some of the completed reports, it is clear that capacity gaps exist among health workers across health facilities used as supervising health facilities during the SMC campaign in 2020. Also, the national pharmacovigilance system in its current states is not robust enough to ensure timely and accurate reporting of ADRs during the SMC campaign in Nigeria, despite the support provided by Malaria consortium in the form of availability of pharmacovigilance forms across all the target health facilities and training of staffs in these facilities. Implementers and National Pharmacovigilance centers should further collaborate and explore other options like active surveillance for ADRs, patient reporting, deployment of self-reporting applications and other technologies that can help achieve timely and accurate ADR reporting during the SMC campaign. Therefore, this study has shown an urgent need to strengthen the pharmacovigilance system during each round of SMC implementation to ensure adequate ADR reporting during the SMC campaign.

## List Of Abbreviations

ADR  
Adverse Drug Reaction  
CDD  
Community Drug Distributor  
CHEWs  
Community Health Extension Workers  
CHO  
Community Health Officer  
HF  
Health Facility  
ICSR  
Individual Case Safety Report  
NAFDAC  
National Agency for Food, Drug Administration and Control  
NPC  
National Pharmacovigilance Centre  
PV  
Pharmacovigilance  
SMC  
Seasonal Malaria Chemoprevention  
SPAQ  
Sulphadoxine Pyrimethamine + Amodiaquine  
WHO  
World Health Organization

## Declarations

**Ethics approval and consent to participate:** Ethical approval for this study was received from the National Health Research Ethics Committee, Abuja , Nigeria.

**Consent for publication:** Consent participation and publication was received from all participants whose data appears in this study, through the Publication Ethics Committee of the State Ministries of Health of the respective states.

**Availability of data and material:** Data sharing not applicable to this article as no datasets were generated or analysed during the current study. Copies of the pharmacovigilance forms generated from the campaign, collated and shared with the National Agency for Food, Drug Administration and Control are available from the corresponding author on reasonable request.

**Competing interests:** Kunle R., Jimmy A., Chrysanthus D., Kenneth M., Daniel O., Ademola, J.I. and Olusola O. declare that they have no conflict of interest.

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**Authors' Contribution:** K.R conceptualized the study protocol, K.R and A.J.I wrote the first draft of the manuscript, J.A proofread and formatted the final manuscript, the other authors read and approved the manuscript.

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## Tables

**Table 1:** Showing details of the drugs used to implement the campaign

Dispersible tablet of SPAQ 1 and SPAQ 2 were sourced from Guillin Pharmaceuticals in China who is the only source of WHO prequalified SPAQ dispersible tablet at the time of program implementation.

| Brand Name | Manufacturer                     | Packaging                | Generic Name   | Dosage  |
|------------|----------------------------------|--------------------------|--|---|
| SPAQ-CO    | Guillin Pharmaceuticals in China | Co-blister 50 x 3+1 Tabs | Amodiaquine 76.5mg + Sulphadoxine/Pyrimethamine 250/12.5mg dispersible tablets | <i>Children 3 month to less than 12 month</i><br><br>Day 1: Amodiaquine 76.5mg plus 1 tablet of Sulphadoxine/Pyrimethamine 250/12.5mg<br><br>Day 2: Amodiaquine 76.5mg<br><br>Day 3: Amodiaquine 76.5mg   |
| SPAQ-CO    | Guillin Pharmaceuticals in China | Co-blister 50 x 3+1 Tabs | Amodiaquine 153mg + Sulphadoxine/Pyrimethamine 500/25mg dispersible tablets    | <i>Children 3 month to less than 12 month</i><br><br>Day 1: Amodiaquine 153mg plus<br><br>1 tablet of Sulphadoxine/Pyrimethamine 500/25mg<br><br>Day 2: Amodiaquine 153mg<br><br>Day 3: Amodiaquine 153mg |

**Table 2:** Number and the type of suspected adverse drug reaction reported

| Age Group      | Presentation and number of reported ADR |           |          |          |          |           |           |
|----------------|---|-----------|----------|----------|----------|-----------|-----------|
|                | Abdominal Pain                          | Weakness  | Diarrhea | Fever    | Rash     | Vomiting  | Total     |
| 3 - <12 months | 0                                       | 3         | 1        | 0        | 0        | 4         | 8         |
| 12 – 59 months | 4                                       | 10        | 4        | 1        | 6        | 24        | 49        |
| <b>Total</b>   | <b>4</b>                                | <b>13</b> | <b>5</b> | <b>1</b> | <b>6</b> | <b>28</b> | <b>57</b> |

**Table 3:** Number of Adverse Drug Reaction reports per 100,000 children across implementing states

| State   | Number of Treatments (Cycle 1 - 4) | Number of PV Reports | Number of reports /100,000 children |
|---------|------------------------------------|----------------------|-------------------------------------|
| Bauchi  | 2,876,436                          | 42                   | 1.5                                 |
| Jigawa  | 5,650,589                          | 15                   | 0.3                                 |
| Kano    | 12,347,805                         | 0                    | -                                   |
| Katsina | 7,359,312                          | 0                    | -                                   |
| Kebbi   | 4,541,495                          | 0                    | -                                   |
| Sokoto  | 4,725,111                          | 0                    | -                                   |
| Yobe    | 3,127,059                          | 0                    | -                                   |

**Table 4:** Profession of pharmacovigilance reporter

| Profession of PV Reporter         | Number (%) |
|-----------------------------------|------------|
| Community Health Extension Worker | 40 (70.2)  |
| Community Health Officer          | 9 (15.8)   |
| Housewife                         | 1 (1.8)    |
| Not stated                        | 7 (12.2)   |

**Table 5:** System Organ Class of Suspected Adverse Drug Reaction submitted according to age groups

| System Organ Class (SOC)          | Age            |                |           |
|-----------------------------------|----------------|----------------|-----------|
|                                   | 3 - <12 months | 12 - 59 months | Total     |
| Gastrointestinal System Disorders | 5              | 32             | 37        |
| Skin and Appendages Disorders     | 0              | 6              | 6         |
| Body as a whole General Disorders | 3              | 11             | 14        |
| <b>Total</b>                      | <b>8</b>       | <b>49</b>      | <b>57</b> |