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RESEARCH

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Spontaneous adverse drug reaction reporting during the seasonal malaria chemoprevention campaign in 2022

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Abstract

Background Seasonal administration of antimalaria drug, sulphadoxine/pyrimethamine plus amodiaquine to children 3–59 months is a malaria preventive intervention used for the reduction of childhood malaria morbidity and mortality in area with highly seasonal malaria transmission like sub-Saharan Africa. This intervention has been deployed in Nigeria and other sub-Saharan African countries for years and may continue for more years to come either alone or combination with other novel interventions. Despite the importance of pharmacovigilance, there is currently a dearth of pharmacovigilance data in most African countries, especially in public health interventions like seasonal malaria chemoprevention campaigns. The availability of quality safety data is likely to improve the acceptability of this preventive intervention.

Results The study identified vomiting as the most reported adverse drug reaction. Other reported reactions include weakness, fever, abdominal pain, convulsion, redness of the eyes, swollen hand/face, rash, itching, cough, headache, and excessive salivation. Using Naranjo scale, 69.2% of the reported reactions can be classified as possible; while 29.5% can be classified as probable, only 1.3% is classified as definite. 92.3% of reported adverse drug reactions were from children 12–59 months and 7.7% were from those 3–11 months. The proportion of ADRs classified according to the affected organ/system is as follows: central nervous system (10.26%), gastrointestinal (60.26%), ocular (10.26%), musculoskeletal (7.69%), and dermatological (11.53%). The study also suggests better tolerability to the seasonal malaria chemoprevention medicines with more implementation experience, as states with more implementation experiences reported fewer suspected adverse drug reactions.

Conclusions The findings from this study provide additional information on possible adverse drug reactions during seasonal malaria chemoprevention campaigns. This additional information should be communicated to caregivers during the seasonal malaria chemoprevention campaigns as a way of building trust and improving acceptability of the intervention. Also, strengthening of the national pharmacovigilance system is vital to ensure improved timeliness, quality, and quantity of pharmacovigilance reporting on SMC intervention in Africa, as results from the study show low levels of pharmacovigilance reporting across the states.

Keywords Pharmacovigilance, Medicine safety, Adverse drug reaction, Seasonal malaria chemoprevention, Malaria, Under 5 population

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Background:

Adverse drug reaction (ADR) is a major public health problem across the globe (Coleman and Pontefract 2016; Elzagallaai et al. 2017). Severe ADRs are one of the leading causes of death in developed countries and are documented to occur in 6.7% of hospitalized patients (Elzagallaai et al. 2017). Additionally, 100,000 and 197,000 mortalities are associated with serious ADRs in the USA and Europe, respectively (Lazarou et al. 1998; Elzagallaai et al. 2017). These data may be lower in developing countries mainly due to little data availability in low- and middle-income countries (Angamo et al. 2016). Medicines safety problem is of more concern in children and infants who are prone to adverse reactions compared to non-elderly adults (Smyth et al. 2012) due to age-related development of the structure and function of biological systems and how this affects absorption, distribution, metabolism, elimination, and response to drugs (Elzagallaai et al. 2017). Undoubtedly, these concerns are pronounced in public health interventions like the seasonal malaria chemoprevention campaigns where infants and children are exposed to malaria medicines monthly for a period of 4 or 5 months.

Seasonal administration of antimalaria drug, sulphadoxine/pyrimethamine plus amodiaquine (SPAQ) to children 3–59 months is a tool in the reduction of childhood malaria morbidity and mortality in area with highly seasonal malaria transmission like sub-Saharan Africa (World Health Organization 2013; NDiaye et al. 2016; Nikiema et al. 2022), although updated recommendation for the strategy now allows a broader application of the strategy (World Health Organization 2022a, b). Since all medicines can be linked to one or more risk of adverse drug reactions ranging from minor reactions to severe reactions, pharmacovigilance (PV) is required in the use of SPAQ to ensure safety among the target children exposed to the medicines (Curtin and Schulz 2011; Khan et al. 2016). Due to the exposure of millions of children to the intervention over a period of 4–5 months, it became necessary to ensure the timely identification, reporting and understanding of the possible adverse reactions associated with the medicine.

Adverse drug reactions following public health interventions like the seasonal malaria chemoprevention campaigns should be rapidly identified and effectively dealt with during the campaign (World Health Organization 2013). These reactions should be promptly identified to allow additional research and appropriate action to take place. If not addressed, it can undermine confidence in the intervention and ultimately have dramatic consequences for future seasonal malaria chemoprevention coverage which may negatively impact malaria incidence among the under 5 populations who benefits from the intervention. This is concerning due to the increased exposure of a large proportion of the public to medicines during public health interventions.

The World Health Organization (WHO) is currently advocating for the wide use of malaria chemo-preventive strategies as a tool for the prevention of malaria morbidity and mortality, which involves the mass administration of preventive chemotherapeutic agents such as sulphadoxine/pyrimethamine and amodiaquine (SPAQ) (World Health Organization 2011, 2013, 2020) and also the use of newer preventive RTS,S vaccines, recently recommended for use in malaria endemic regions in Africa (World Health Organization 2022c). The use of these chemotherapeutic strategies is currently being promoted as a therapeutic tools to help in reducing malaria morbidity and mortalities in sub-Saharan Africa (World Health Organization 2020, 2022c).

While SMC drugs are known to be effective and safe (World Health Organization 2013), their safety under large-scale operational use has not been fully assessed and documented (Amouh et al. 2021) in addition to the potential of development of resistance by plasmodium against the chemotherapeutic agents used for this intervention (Amouh et al. 2021; Plowe 2022). Also, the frequency and severity of side effects may be very different when a medicine is used for longer period of time in a heterogeneous patient population with a range of comorbidities and concomitant medication and for off-label indications (Mehta et al. 2017) in addition to the potential for misuse.

In Nigeria, the seasonal malaria chemoprevention have been utilized for the prevention of malaria in the country for several years (Ward et al. 2019, 2022; Cola et al. 2022; Rotimi et al. 2022). The combination of sulphadoxine/pyrimethamine + Amodiaquine (SPAQ) has been the mainstay for the implementation of the seasonal malaria chemoprevention (SMC) projects. The safety of these medicines is well documented in scientific literature. In contrast, the safety and potential long-term effect on resistance when use on a large scale for preventive purpose in a population has not been fully documented. Also, concerns have been raised on the use of these malaria drugs for malaria prevention related to adherence, delayed acquisition of immunity, and resistance and medication misuse by care giver in terms of child/infants overdosage which may have serious adverse consequences. This study will attempt to explore the adverse reactions to these medications in regions of Nigeria where they were deployed in 2022 for seasonal malaria chemoprevention campaign. The study will utilize the national passive pharmacovigilance system where health workers are only encouraged to report adverse drug reactions (Federal Ministry of Health 2020) during the SMC campaigns

across the implementing states. The identified ADRs from this study may be included in the database of potential ADRs that will be communicated to caregivers during the seasonal malaria chemoprevention campaigns.

Methods

The study is a descriptive cross-sectional assessment of records of pharmacovigilance reports collected during the 2022 seasonal malaria chemoprevention round in Nigeria. We cross-sectionally analysed pharmacovigilance data from the SMC campaigns implemented by the National Malaria Elimination Programme (NMEP) from July 2022 to November 2022 across nine areas in Nigeria. The study focuses on the SMC campaigns implemented in eight states: Bauchi, Oyo, Kebbi, Borno, Kogi, Nasarawa, Sokoto, Plateau States, and the federal capital territory (FCT). Before the campaigns, health facility workers recruited for the campaigns were trained on identifying and reporting adverse drug reactions using the national pharmacovigilance forms in line with the national pharmacovigilance system. They were also provided with the revised pharmacovigilance form which now captures key information for causality assessment. Each health facility was provided with one booklets of the revised national pharmacovigilance reporting forms. All the reported adverse drug reactions with filled pharmacovigilance forms were considered for this study, and it serves as the sample size. Study variables are types of adverse drug reactions, reporting rate, states, age group (3–11 months and 12–59 months), and sex. Naranjo adverse drug reaction probability scale (Naranjo et al. 1981) was used to assess the reported adverse drug reactions and classified them into probable, possible, definite, and doubtful. The modified World Health Organization Adverse Reactions Terminology (WHO-ART) system organ class (SOC) classification of the ADRs previously used by a study in similar environment was used to classify the reported ADRs (Kushwaha et al. 2020).

Data collection

The national spontaneous pharmacovigilance reporting systems and tools were used for the collection of PV reports during the campaign (Appendix). At the end of the SMC round, the completed PV forms from the health facilities filled by facility-based health workers were picked up by the programme field officers. The program team analysed these completed reports at the state level to identify trends in ADR reporting and then transmitted them to the National Pharmacovigilance Centre 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 analysed. All the ADR forms analysed were collated from June to October during the seasonal malaria chemoprevention campaign in 2022.

Analysis of adverse drug reaction reports

The information listed below was extracted from the submitted ADR forms.

1. Adverse drug reactions reported
2. Age of the child
3. Concomitant medicines used
4. Relevant medical history
5. Reaction stopped or reduced after drug withdrawal?
6. Reaction reappeared after drug reintroduction?

We used descriptive statistics for all analysis. Specifically, we estimated the number of ADR reports per 100,000 children for each of the eight states and FCT, the number of reported adverse drug reactions segregated by age (3–< 12 months and 12–59 months) and the Naranjo causality assessment scale was used to classify the reported ADR into possible, probable, doubtful, and definite based on the information available on the PV reporting forms. The assessment was carried out by KR, who is an experienced pharmacist with training on causality assessment.

Data analysis

Data analysis was carried out using Microsoft excel 2016. The frequency, distribution of the cases, and ADR reporting rates were analysed using descriptive statistics. Adverse drug reaction incidence rates were calculated using the number of reported ADRs as the numerator and total administered treatments from states as the denominator for the period. The ADR reporting rate for the various implementing states per 100,000 treatment courses was estimated. Graphs and bar charts were also used to present the frequency of reported ADRs and the distribution and system organ classification of the reported ADRs.

Ethics: Ethical approval was obtained from the various implementing states for the publication of the findings.

Results

The SMC campaign for this study took place in 8 states in Nigeria and the federal capital territory (FCT) which translates into 9 implementation regions across the country. The SMC drug of choice, SPAQ was administered to

Table 1 Cummulative distribution of reported ADR by sex. The distribution of reported ADR between male and females was similar between both sexes with males representing the highest percentage of reported ADRs

Sex	Number of PV reports	Proportion (%)
Male	42	54
Female	36	46
Total	78	100

Table 2 Cumulative distribution of reported ADR by age group. More reported ADRs were reported for children 12–59 months (92.3%) compared to infants (7.7%)

Age	Number of reported ADR	Percentage (%)
3–11 months	6	7.7
12–59 months	72	92.3
Total	78	100

47,502,443 children aged 3–59 months across the targeted communities in the 9 implementing regions/states. Five courses of SMC treatments were implemented in Plateau, Nasarawa, FCT, Oyo, Kogi, and some local government areas (LGAs) in Bauchi states, while 4 courses were administered in Borno, Sokoto, Kebbi, and some LGAs in Bauchi states. There was high coverage of 4 and 5 courses of treatments across the communities where the intervention was implemented from June to October 2022.

The distribution of reported ADRs varies by age and sex (Tables 1 and 2). The study identified vomiting as the most reported adverse drug reaction. Other reported reactions include weakness, fever, abdominal pain, convulsion, weakness, redness of the eyes, swollen, rash, itching, cough, headache, and excessive salivation (Figs. 1 and 2). Using Naranjo scales, 69.2% of the reported reactions can be classified as possible; while 29.5% can be classified as

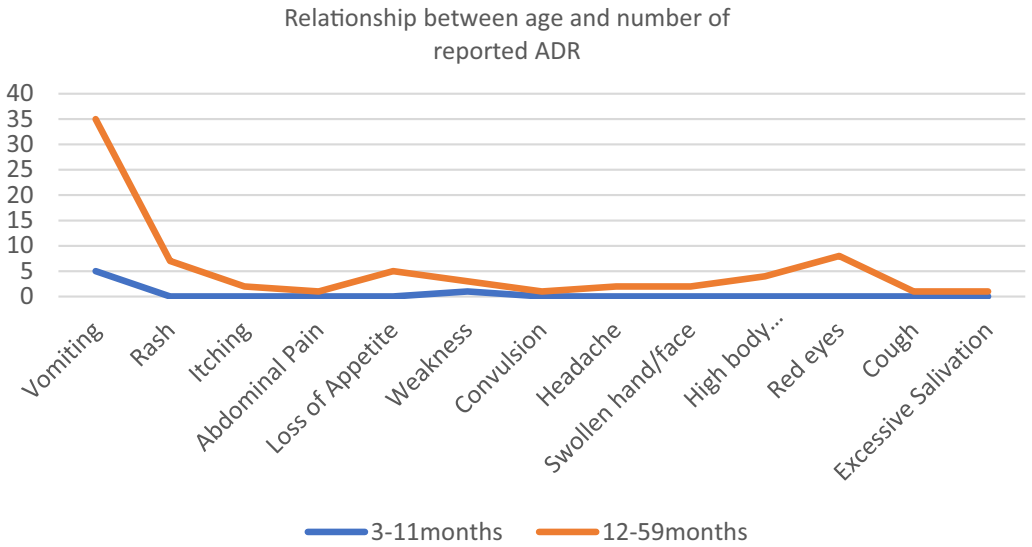

Fig. 1 Distribution of suspected ADR by age. Most of the reported ADRs were in children aged 12–59 months, while only 6 cases were reported in younger children. Vomiting represents the most common reported ADR across both age groups

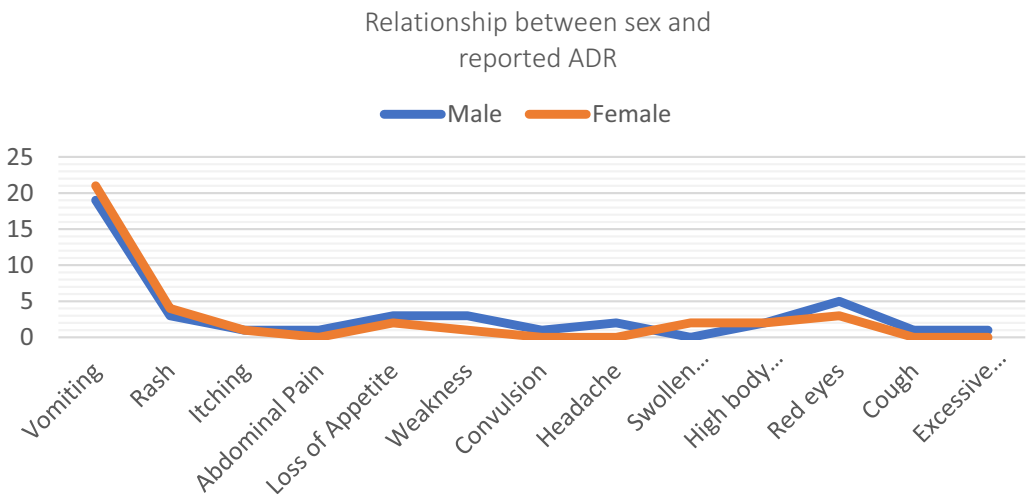

Fig. 2 Distribution of suspected ADR by sex. The distribution of ADRs appears similar between male and female with only few variations in few ADRs like weakness, red eyes, loss of appetites, and others

Table 3 Causality assessment of ADR using Naranjo causality assessment scale. An assessment of the reported ADR shows 69.2% of the reported ADR classified as possible, while only 1 of the reported ADR is ranked as definite. None of the reported ADR is doubtful

Interpretation of ADR	Number	Percentage (%)
Doubtful	0	0.0
Possible	54	69.2
Probable	23	29.5
Definite	1	1.3
Total	78	100.0

Table 4 Reporting rates for adverse drug reactions per 100,000 children across implementing states. Two of the nine states (Borno and Sokoto) reported no adverse drug reaction using the national pharmacovigilance reporting system. Oyo and Nasarawa States had a total of 30 and 18 pharmacovigilance reports, respectively. This translates to 2.04 reports per 100,000 children and 0.42 reports per 100,000 children in Oyo and Nasarawa States, respectively

S. no.	State	Number of Treatments	Number of PV Reports	Number of ADR/100,000	Number of SMC Round
1	Bauchi	9,137,312	3	0.03	3
2	Borno	8,301,865	0	–	3
3	FCT	3,456,187	6	0.17	1
4	Nasarawa	4,259,260	18	0.42	2
5	Kebbi	5,319,687	6	0.11	3
6	Kogi	5,661,171	1	0.02	2
7	Oyo	1,468,807	30	2.04	1
8	Plateau	4,659,207	14	0.30	2
9	Sokoto	5,238,947	0	–	5

probable, only 1.3% is classified as definite (Table 3). 92.3% of reported adverse drug reactions were from children 12–59 months, and 7.7% were from those 3–11 months. ADR reporting rates varies across the states where SMC campaign was implemented in 2022 (Table 4). The proportion of ADRs classified according to the affected organ/system is as follows: central nervous system (10.26%), gastrointestinal (60.26%), ocular (10.26%), musculoskeletal (7.69%), and dermatological (11.53%) (Fig. 3). The study also suggests better tolerability to the seasonal malaria chemoprevention medicines with more implementation experience, as states with more implementation experiences reported fewer suspected adverse drug reactions.

Discussion

The study identified suspected adverse reactions among infants and children during the 2022 SMC round in Nigeria. These reactions includes weakness, fever, abdominal pain, convulsion, weakness, redness of the eyes, swollen, rash, itching, cough, headache, and excessive salivation. The distribution of ADR by sex shows 54% of suspected ADRs occurs in males while females experience 46% of the suspected ADRs (Table 1), whereas distribution of the suspected ADRs based on sex shows that 92.3% of the suspected ADR occurs in children 12-59months and 7.7% in infants (Table 2). Causality assessment of the suspected reactions using Naranjo scale classified most of the reported reactions as possible, while only one of the suspected reaction can be classified as definite.

There were no ADRs with a doubtful causality by Naranjo's Algorithm Scoring system ,since almost all

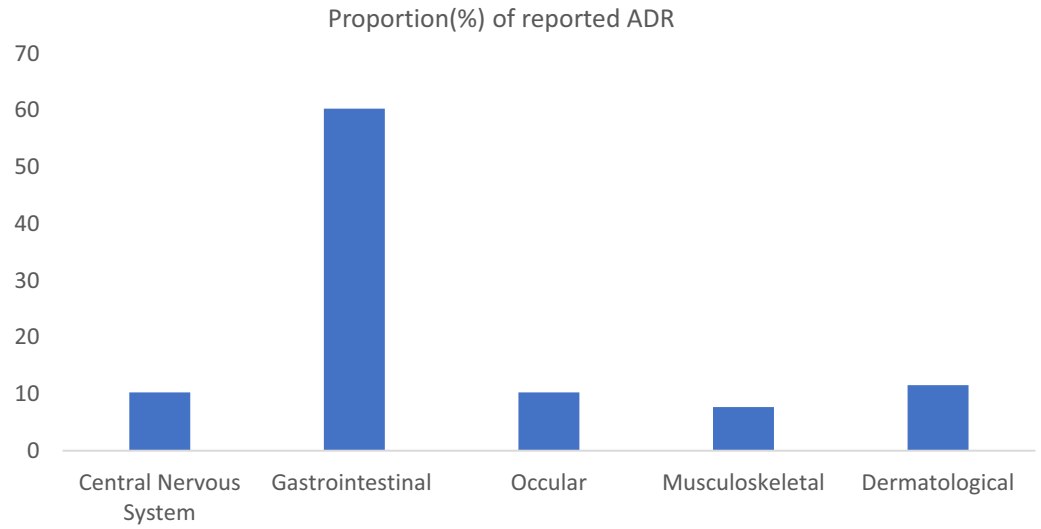

Fig. 3 Systems/organ classification of suspected ADRs. The suspected ADRs can be linked to 5 body organ/systems. The proportion of ADRs classified according to the affected organ/system is as follows: central nervous system (10.26%), gastrointestinal (60.26%), ocular (10.26%), musculoskeletal (7.69%), and dermatological (11.53%)

the reported reactions occur after exposure to the SMC medicines. Most of the reactions had a possible causality score (69.2%) followed by probable causality score (29.5%) and definite causality score represent 1.3% of all reported reaction (Table 3). There were no serious reactions requiring hospitalization in our study. There was also no case of death reported in our study period.

More ADR reports were in males (54%) compared to females (46%) (Table 1). This indicates that there are some differences in the occurrence of ADR between male and female children between the ages of 3- 59 months during SMC campaign. In a similar study, a total of 48 (37.79%) ADRs & 79 (62.20%) ADRs were reported for male and female pediatric patients respectively (Dash et al.), this shows more females experiencing ADR than males. However, other studies aligns well with findings from our study indicating more males experiencing ADR compared to females (Gallo et al. 2012; Li et al. 2014).

Overall, more children experienced an ADR (92.3%) compared to infants (7.7%) (Table 2). This findings may be due to the fact that ADRs varies according to age (Montastruc et al. 2021). Similarly, the study suggested that infants were less likely to react to SPAQ compared to children between the ages of 12 month to 59 month. In contrast, studies have shown a higher incidence of ADR among infants compared to older children (Priyadharsini et al. 2011; Nasso et al. 2020). However, in this study more older children were exposed to the SMC medication than infants. Alternatively, the higher number of older children experiencing vomiting may be linked to higher number exposure in this age group. Nevertheless, the finding point to the need to consider vomiting as a common reaction to SPAQ during SMC campaigns due to numerous publications suggesting vomiting as a widely reported ADRs to SMC medications (NDiaye et al. 2016; Baba et al. 2020; Chotsiri et al. 2022; Rotimi et al. 2022).

The findings indicate a significant high proportion of vomiting reaction to the SMC medications (Fig. 1). This aligns with reports from similar study in Nigeria (Rotimi et al. 2022) and other sub-Saharan countries where SMC campaigns has been implemented (NDiaye et al. 2016). Although, in addition to adverse drug reaction vomiting may also results from acute gastroenteritis, acute infection, and food poisoning (Allen 2007; Kendrick et al. 2012). The distribution of vomiting appears similar between male and female children (Fig. 2). A total of 40 children experienced vomiting during the SMC campaign with only 5 of the cases in children ages 3–11 months, indicating 87.5% of the reported cases of vomiting in the older children.

Like vomiting, abdominal pain and loss of appetite were also reported in the study. All three reactions are related to the gastrointestinal tract according to system organ classification of ADRs, which represent 60.26% of reported ADR (Fig. 3). This system represents the highest proportion of reported ADRs. Rashes, and itching classified as affecting the dermatological body system were also identified in the study which represent 11.53% of reported ADRs (Fig. 3). These two reactions are the most common ADRs in pediatric patients (Priyadharsini et al. 2011) and have been reported in other safety studies during SMC campaigns (NDiaye et al. 2016; Ambe et al. 2020; Baba et al. 2020; Rotimi et al. 2022). Rashes and itching may be linked to the SP component of the SMC medications since they are both common with sulphonamide antimicrobial agents (Giles et al. 2019). Even though, this reaction is well documented, they are rare compared to the number of patients exposed to sulphonamides (Giles et al. 2019; Asyraf et al. 2022). Additionally, genetic influences has a role to play in this reaction (Asyraf et al. 2022) which indicate the feasibility of preventing this reaction by excluding children with history or family history of reacting to sulfa drugs from the SMC interventions. As a more severe rash, Stevens-Johnson syndrome / Toxic epidermal necrolysis may occur which can be fatal (Harr and French 2010; Benedetti 2022). Likewise, rashes and itching have also been linked to amodiaquine, suggesting that amodiaquine may also be a culprit for this reaction (Swana et al. 2017).

Ocular reactions were also reported among children exposed to SPAQ during the campaign. Eight children between the ages of 12 and 59 months representing more than 10% of the reported ADRs were reported to have reddish eyes after taking SPAQ (Fig. 1). This reaction was minor and appears to resolve with time and does not require any medical intervention. The reaction may be associated with amodiaquine, since it has been linked to ocular damage (Maguire and Kolb 1964; Wittes 1987). However, 4-amino quinolines-based antimalaria like amodiaquine has only been linked to retinopathy with long-term use (Adjei et al. 2012) and overdose (Fitsum et al. 2019), so within the context of SMC it may not be responsible for the reddish eyes observed in this study, since SPAQ was administered at the appropriate dose over a short period. Nevertheless, ocular reactions should always be monitored during SMC interventions.

Central nervous systems and musculoskeletal systems were also identified as organ systems affected by the suspected ADRs. These reactions includes dizziness, weakness, swellings, headaches, convulsion, and high body temperature/fever. Some of these reactions have also been identified in other studies and may be linked to either SP or Amodiaquine (NDiaye et al. 2016; Ndiaye et al. 2018; Baba et al. 2020; Rotimi et al. 2022).

The study indicates difference in the incidence rate of vomiting among children 12–59 months compared

to infants. This finding suggests a higher probability of vomiting with the higher dose tablets used for the 12-59 months age group. The frequency of vomiting in this age group is concerning because poor acceptability may affect compliance with the regimen (Nunn and Williams 2005) and may also increase wastage during SMC campaign since a re-dose is usually required when an administered dose is vomited by the child (World Health Organization 2013). Additionally, increased frequency of vomiting among the older children suggests lower tolerability among this group of children (Kurth et al. 2010). Consequently, there may be a need to examine the formulation used among the older children. This is because the tolerability of an administered drug can be improved with an advancement or modification in a paediatric formulation to a more acceptable forms (Kurth et al. 2010).

The pharmacovigilance reporting rates varies across the states with Oyo state having the highest rate (2.04 per 100,000 treated children) among the study state (Table 4). Similar study in one of the state shows more reporting in 2020 (Rotimi et al. 2022) compared to finding from this study in 2022, despite repeatedtraining of health workers in 2022 before the commencement of the SMC round. Overall, the reporting rate is generally low across the states with some states reporting no adverse drug reactions throughout the SMC campaign. This findings is similar to reports of poor ADR reporting among health workers in Nigeria (Oshikoya and Awobusuyi 2009; Fadare et al. 2011; Rotimi et al. 2022), thus suggesting the persistence of poor PV reporting across the country. In contrast to the low reporting rates observed in this study in some states, the PV reporting rates in Oyo state is higher compared to the other states. This finding from Oyo state may be related to the high willingness to report ADR observed in a study in the state, where 98.8% of health workers indicated willingness to actively participate in ADR reporting (Adisa and Omitogun 2019).

From the table on reporting rate of suspected ADRs (Table 4), it can be deduced that the suspected incidence of ADR is higher in states with less experience with the implementation of the campaign. More reports came from states with one round of SMC implementation, while highly experienced states tend to have very low suspected ADR reports. For example, Sokoto with five rounds of SMC campaigns reported zero suspected ADR (Table 4). This finding suggest better tolerability to the SMC medicines with more implementation experience, as states with more implementation experiences reported fewer suspected ADRs.

In general, from the study the pharmacovigilance reporting rate is abysmally low across the state (Table 4). Due to the fact that among the general population approximately 3–8% of patients are reported to experience a sulfonamide allergy (Giles et al. 2019). Another study suggests 0.09% of people experience hypersensitivity reactions to sulphonamides (Slatore and Tilles 2004). Since sulphadoxine/pyrimethamine (SP) a common sulphonamide is a significant component of the SMC medication, proportion of ADR from the study suggest an extremely low ADR reporting during the campaign. Similarly in one of the study environment, the prevalence of sulphonamide hypersensitivity among study subjects was 15.5% (Mary et al. 2015), which therefore reinforced the possibility of PV under reporting during the campaign in 2022. This finding points to the need for more training and capacity building on pharmacovigilance among health workers to promote increased awareness and positive attitude in pharmacovigilance reporting. While trainings and capacity building have been shown to improve knowledge of PV among health workers, it seems to have a modest effect on the overall systems in Nigeria (Osakwe et al. 2013). Thus, a more comprehensive, coordinated, collaborative, and innovative approach should be deployed to ensure a more reliable national PV system capable of producing quality PV reporting, especially during public health programmes like the SMC campaigns. This may include patients ADR reporting which may be beneficial and should be encouraged (Inácio et al. 2017).

Conclusions

Due to safety concerns, some public health interventions have not been widely accepted especially in low- and middle-income countries . The availability of quality safety data on these interventions is likely to improve the acceptability and consequently ensuring a broader access and reach of these public health interventions which will subsequently help in reducing morbidities and deaths among children and infants.

Generally, ADRs reported in this study have mild presentations; however, some of the possible reactions may be severe and sometimes fatal, especially if not treated urgently. The consequences of some of these ADRs may be profound resulting in the lack of trust in SMC intervention, thereby leading to low coverage. Thus, an evidence base of pharmacovigilance will provide a reliable information source on all possible ADRs associated with SMC medicines to serve as a guide for the successful implementation of SMC campaigns in sub-Saharan Africa. This evidence base will also serve as safety information for use by local regulatory authorities on SMC medications. Consequently, future research should focus on building safety database on seasonal malaria chemoprevention using data from this study and other similar studies which will ultimately help to strengthened

communication on the safety of the SMC interventions in Africa. Strengthening of the national pharmacovigilance will also be vital to ensure improved timeliness, quality, and quantity of pharmacovigilance reporting on SMC interventions in Africa.

Appendix

The Nigeria national spontaneous pharmacovigilance (PV) reporting 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. In line with the national pharmacovigilance policy in Nigeria, all suspected or actual adverse reactions to drugs and other related substances should be reported using the pharmacovigilance reporting form which is in paper form (National Agency for Food and Drug Administration and Control 2017). More recently an e reporting form is also available for pharmacovigilance reporting directly to NAFDAC which is also available as a phone App.

The hard copies of the ADR forms are obtained through the following means:

- 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 suspected adverse drug reaction in the PV form are transmitted to the nearest pharmacovigilance centre (National Agency for Food and Drug Administration and Control 2017). The PV reporting is spontaneously in nature with health workers in service delivery points filling the forms appropriately when presented with a suspected ADR to medicines and other related products.

Abbreviations

ADR	Adverse Drug Reaction
FCT	Federal Capital Territory
NAFDAC	National Agency for Food, Drug Administration and Control
NMEP	National Malaria Elimination Programme
PV	Pharmacovigilance
SMC	Seasonal Malaria Chemoprevention
SP	Sulphadoxine/Pyrimethamine
SPAQ	Sulphadoxine Pyrimethamine + Amodiaquine
SOC	System Organ Classification
WHO	World Health Organization
WHO-ART	World Health Organization Adverse Reactions Terminology

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Author contributions

The input of the contributors is as follows: KR, BF, and OO conceptualized the study protocol, KR wrote the first draft of the manuscript, proofread, and formatted the final manuscript, JA, CD, TI, AA, VG, OO, and DO participated in data collation and analysis, KR, JA, CD,OO, TK, KM, DO, AO, AB, BF read and approved the manuscript. All authors have read and approved the manuscript.

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Availability of data and materials

Data sharing is 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.

Declarations

Ethics approval and consent to participate

Approval for this project was received from the designated authorities at the state ministry of health and state malaria elimination programme of the respective as part of the approval for the implementation of the seasonal malaria chemoprevention campaigns. In line with the national guidelines for public health projects in Nigeria, there is no need for consent to participate.

Consent for publication

Consent publication was received from all participants whose data appear in this study, through the State Ministries of Health of the respective states.

Competing interests

The authors declare that they have no competing interests.

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