

Awareness, Attitude, and Practice of Pharmacovigilance among Health Care Professionals in Nigeria: Survey in a Teaching Hospital

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Abstract

Background and Objectives: Pharmacovigilance is central to the control of the menace of adverse drugs reactions. Despite the fact that development of policy and practice framework to improve patients' safety partly rely on availability of authentic data on pharmacovigilance activities, knowledge about pharmacovigilance activities among healthcare professionals in Nigeria is limited. To help fill this gap, this study explored the awareness, attitude and practice of pharmacovigilance activities among the healthcare professionals in the Nigerian Nnamdi Azikiwe University Teaching Hospital.

Methods: A descriptive cross-sectional survey was carried out among healthcare professionals in the Nnamdi Azikiwe University Teaching Hospital, Nnewi. The participants were doctors, pharmacists, nurses and health records officers employed in the teaching hospital. The sample was selected using stratified random sampling. A structured, self-administered questionnaire was used as the survey instrument. Key informant interview was also conducted among hospital's administrative officers using standard interviewer guide. Descriptive statistics were calculated for the demographic variables. Quantitative data were compared using inferential statistics.

Findings: Low level of awareness among the healthcare professionals about pharmacovigilance activities was observed. About half of them, 130 (50.4%), stated that they were not aware of the Nigerian National Pharmacovigilance tool that is used for documenting and reporting of adverse drug reactions. Only about one tenth of the respondents, 35 (13.7%), mentioned that they use this tool for documenting and reporting of adverse drug reactions whereas the majority of them, 220 (86.3%), stated that they had not used the tool.

Conclusions: The study indicated that the healthcare professionals in Nnamdi Azikiwe University Teaching Hospital have a limited awareness about pharmacovigilance. There is also low frequency of utilization of the Nigeria NPV tool for documentation and reporting of adverse drug reactions. Our findings highlight the need for educational and managerial interventions to improve monitoring and reporting of adverse drug reactions within an all-inclusive pharmacovigilance system in this country.

Keywords: Pharmacovigilance, Hospital, Patient Safety, Adverse Drug Reactions, Healthcare Professionals

Background and Objectives

Adverse drug reactions (ADRs) continue to present as one of the greatest challenges towards the attainment of the gold standard of quality and safety in healthcare delivery worldwide [1, 2]. It has been shown that ADRs occur almost daily in medium-sized hospitals and outpatient departments [3] with overall incidence of 15.1 % [4]. Much of these ADRs (50%) were preventable [5]. Thus there is a dire

need to develop effective strategy for detecting and reporting ADRs within the framework of a functional and efficient pharmacovigilance system.

The negative effects of ADRs include high morbidity and mortality rates among patients as well as increase in legal, operational and patient care costs [6]. A study in the UK showed that 6.5% of people admitted to hospitals had experienced at least one ADR, and that in 80% of those cases, ADR was the direct cause of hospitalization. ADRs are also accounted for the projected annual cost of £466 million to the UK's National Health Services [7]. In the United States, it was reported that over two million ADRs occur annually resulting in more than 100,000

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deaths, making ADRs the fourth leading cause of death ahead of pneumonia, AIDS, automobile accidents and diabetes [8, 9]. The fiscal cost to the US health systems was estimated at \$136 billion per year [10, 11]. Data on the incidence and impact of ADRs and pharmacovigilance practices in emerging health systems in some countries such as Nigeria are yet scanty. There is, therefore, need to further study pharmacovigilance practices among the Nigerian healthcare professionals in order to align the Nigeria's pharmacovigilance system with global healthcare best practices.

The last decade has witnessed notably unprecedented international health initiatives from various international agencies: the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and the Global Fund to Fight AIDS, Tuberculosis (TB) and Malaria (Global Fund). These initiatives have provided treatments for HIV/AIDS, TB, and Malaria in resource-limited countries including Nigeria, resulting in significant increase in access to medicines for the management of these public health diseases [12]. In Sub-Saharan Africa (SSA) about 4 million people had access to Antiretroviral Therapy (ART) in 2009 compared to only 50,000 in 2002. The number of Artemisinin-based Combination Therapy (ACT) treatment courses procured has increased from 11.2 million in 2005 to 158 million in 2009 [13, 14, 15]. This increased access to newly introduced essential medicines at reduced or no cost to the patients has thrown up the need to increase safety monitoring through effective pharmacovigilance [16].

As a global response to the menace of ADRs and other healthcare negative outcomes, the World Health Organization (WHO) has set up an international pharmacovigilance system for collaborative monitoring and reporting of ADRs between the member states. Pharmacovigilance has been defined as: "the science and activities relating to detection, assessment, understanding and prevention of ADRs or any other drug related problem" [17]. Although Nigeria joined the WHO pharmacovigilance scheme in 2004 as the 74th member country, pharmacovigilance activities in this country had actually commenced in the 80's [18].

Most national pharmacovigilance systems rely on voluntary reporting of ADRs by healthcare professionals. In Nigeria, reporting of ADRs is based on the use of National Pharmacovigilance (NPV) tool developed by the National Pharmacovigilance Centre (NPC), which is a subsidiary of the National Agency for Food and Drug Administration and Con-

trol (NAFDAC). The NPC is responsible for providing the NPV reporting forms, collating, evaluating, and communicating the ADRs reports from Nigeria to the NAFDAC for onward transmission to the WHO drug monitoring centre in Uppsala, Sweden [19].

Despite the existence of a national pharmacovigilance system in Nigeria, available data shows that ADRs are grossly underreported in the country [20–24]. Poor understanding of the reporting system among Nigerian healthcare professionals has been documented as the major reason for underreporting of ADRs in this country [19]. Six years after the inception of the NPC in September 2004, only 10,000 (ADR) reports had been received from healthcare professionals across the country [17]. This translates to about 800 ADRs reports or eight (8) individual case safety reports (ICSRs) per million of the population per year. For over 160 million Nigerian population, this is far below the WHO recommended standard of over 250 ICSRs per million of the population per year. Recently the Federal Executive Council of Nigeria has set up a National Pharmacovigilance Policy for the country as part of efforts to properly monitor and control ADRs in this country. This initiative, which also seeks to ensure prompt reporting of ADRs to the appropriate authority, will be formally implemented by the Nigeria NPC.

A recent assessment of the Nigerian Pharmacovigilance System (PVS) as well as those of most of the Sub-Saharan countries showed that they did not meet their PVS' capacity and performance indicators [25, 26]. One of the cardinal objectives of the five year Pharmacovigilance Plan for Nigeria (2007 – 2011) is "To ensure that over 80% of healthcare providers are aware and have acceptable level of knowledge on the concept of ADRs and take appropriate measures to control them, notably their documentation and reporting" [27]. The success of a pharmacovigilance program depends on the involvement of the healthcare professionals and their willingness to report ADRs. Much of the research work on this topic focused on pharmacovigilance practices among the community pharmacists, resident doctors and patent medicine vendors [28]. It is necessary to study the pharmacovigilance practices among the institutional healthcare professionals in the teaching hospital settings in a systematic way as they are the apex and referral healthcare facilities in Nigeria. In this project, we studied the pharmacovigilance practices among the healthcare professionals in the Nnamdi Azikiwe University Teaching Hospital, Nnewi. This project was undertaken to provide research-based data that would help in the

development of institutional and national policies/practice guidelines towards effective pharmacovigilance systems and patients' safety.

Methods

A cross sectional study using a structured 43-item questionnaire instrument was designed to assess the awareness, attitude and practice among the healthcare professionals about pharmacovigilance practices in a Nigerian teaching hospital.

Study Setting

The study was carried out among the doctors, pharmacists, nurses and health records officers working in the Nnamdi Azikiwe University Teaching Hospital (NAUTH), located in Nnewi town in Anambra state, south-east of Nigeria. This hospital is one of the leading teaching hospitals in Nigeria designated as the centre of excellence in nephrology. The teaching hospital has full complements of all clinical departments and service units namely: surgery, medicine, paediatrics, obstetrics and gynaecology, pathology and radiology, HIV/AIDS and DOTS centre, nursing services, pharmacy, medical records, and other non-clinical departments. It has over seven wards with more than 1000 bed capacity and about 1200 healthcare professionals, who provide specialist healthcare in the hospital. It has over five outstations located in rural areas for providing community medicine services to the adjoining rural communities.

Sample size

Participants in the present survey were doctors, pharmacists, nurses and health records officers. The sample size for the participants in the questionnaire survey was derived from an approximate population size of 1200 eligible healthcare professionals in the teaching hospital using the formula $n = Z^2pq / d^2$ [29]. Twenty percent was added to the calculated sample size to adjust for probable attrition or withdrawals, which resulted in the final sample size of 350. A stratified random sampling technique in proportion to the respective size of each sampling frame was used to select the participants within each professional group using a ratio of 2:3:2:1 for doctors, nurses, pharmacists, and health records officers, respectively. Thus 88 doctors, 131 nurses, 88 pharmacists and 44 health records officers were selected to be included in the study. The structured questionnaire instrument

Table 1 Demographic characteristics of the survey respondents

Variable	Number	%
Profession (<i>n</i> = 258)		
Doctor	71	27.5
Pharmacist	39	15.1
Nurse	111	43
Health records officer	37	14.3
Age (<i>n</i> = 257)		
20 – 34 years	53	20.6
35 – 40 years	179	69.6
> 40 years	25	10
Gender (<i>n</i> = 258)		
Male	93	36
Female	165	64
Marital status (<i>n</i> = 249)		
Never married	55	22.1
Married	181	72.7
Divorced	9	3.6
Widowed	4	1.6
Length of service (<i>n</i> = 251)		
0 - 4 years	27	10.8
5 - 9 years	139	55.4
Over 10 years	85	33.9
Total	251	100

Table 2 Awareness of the respondents about the occurrence and reporting of ADRs

Variable:	Number	%
Seriousness of ADRs (<i>n</i> = 257)		
High	24	9.3
Moderate	204	79.4
Low	29	11.3
Frequency of ADRs (<i>n</i> = 245)		
Very often	2	0.8
Often	9	3.7
Occasionally	202	82.4
Never	32	13.1
Relevance of documenting ADRs (<i>n</i> = 258)		
Strongly agree	206	79.8
Agree	50	19.4
Strongly disagree	2	0.8

Table 3 Awareness and practices of survey respondents about pharmacovigilance and use of the NPV tool for reporting ADRs

Variables	Profession of the survey respondents				
	Doctors	Pharmacists	Nurses	Health records officer	N (%)
Knowledge of NAFDAC Yellow form (n = 258)					
Yes	56	39	33	0	128 (49.6)
No	15	0	78	37	130 (50.4)
Sub-total	71 (27.5%)	39 (15.1%)	111 (43.2%)	37 (14.3%)	258 (100.0)
Knowledge and skills on pharmacovigilance (n = 257)					
Excellent	0	0	0	1	1 (0.4)
High	14	0	0	0	14 (5.4)
Average	40	29	15	3	87 (33.9)
Poor	16	10	95	32	153 (59.5)
None	0	0	1	1	2 (0.8)
Total	70 (27.2%)	39 (15.2%)	111 (43.2%)	37 (14.4%)	257 (100.0)
Use of national ADRs reporting form (n = 255)					
Yes	11	23	1	0	35 (13.7)
No	58	16	109	37	220 (86.3)
Total	69 (27.1%)	39 (15.3%)	110 (43.1%)	37 (14.5%)	255 (100.0)
Use of ADRs reporting form (n = 257)					
Very often	0	0	0	0	0(0.0)
Often	0	0	0	0	0(0.0)
Occasionally	15	23	4	5	47(18.3)
Never	55	16	107	32	210(81.7)
Sub-total	70 (27.2%)	39 (15.2%)	111 (43.2%)	37 (14.4%)	257(100.0)
Receiving pharmacovigilance training (n = 241)					
Yes	1	0	0	0	1 (0.4)
No	70	39	95	37	241(99.6)
Sub-total	70 (29.0%)	39 (16.2%)	95 (39.4%)	37 (15.4%)	242 (100.0)

was self-administered to the selected participants. The questionnaire instrument was adapted from the tool used for a questionnaire-based analysis of pharmacovigilance activities in 55 low- and middle-income countries [29]. To further ensure its validity, the questionnaire instrument for this survey was pre-tested with some healthcare profession-

als, who were excluded from the study population. Phone calls and SMS were used to monitor the participants, who had completed their questionnaire for collection by the researcher. Key informant interview among the principal officers of the hospital was also done using appropriate facilitator's guide. The following key officers of the teach-

Table 4 Knowledge of survey respondents about key pharmacovigilance indicators

Variables	Professional category of the survey respondents				N (%)
	Doctors	Pharmacists	Nurses	Health records officer	
Presence of pharmacovigilance unit in hospital (n = 200)					
Yes	0	21	0	0	21 (10.5)
No	1	11	22	19	53 (26.5)
Not know	23	7	78	18	126 (63.0)
Sub-Total	24 (12.0%)	39 (19.5%)	110 (55.0%)	37 (18.5%)	200 (100)
Presence of pharmacovigilance committee in your hospital (n = 188)					
Yes	0	0	0	0	0 (0.0)
No	0	29	2	29	33 (17.6)
Not know	24	36	97	31	155 (82.4)
Sub-Total	24 (12.8%)	38 (20.2%)	97 (51.6%)	31 (16.5%)	188 (100)
Availability of pharmacovigilance guidelines on in the hospital (n = 196)					
Yes	0	0	0	0	0 (0.0)
No	0	23	9	4	36 (18.4)
Not know	24	14	91	31	160 (81.6)
Sub-Total	24 (12.2%)	37 (18.9%)	100 (51.0%)	35 (17.9%)	196 (100)
Presence of designated officer for pharmacovigilance services (n = 199)					
Yes	0	0	0	0	0 (0.0)
No	0	23	12	21	56 (28.1)
Not know	24	15	88	16	143 (71.9)
Sub-Total	24 (12.1%)	38 (19.1%)	100 (50.2%)	37 (18.6%)	199 (100)
Registers for pregnancy/pediatrics ADRs in pharmacovigilance (n = 247)					
Yes	0	0	0	0	0 (0.0)
No	57	23	38	15	133(53.8)
Not know	14	16	62	22	114(46.1)
Sub-total	71 (28.7%)	39 (15.8%)	100 (40.5%)	37 (6.1%)	247 (100)

ing hospital were interviewed: the chief medical director, the chairman of Medical Advisory Committee, the director of administration, the chief nursing officer and the responsible pharmacovigilance officer for the hospital.

Data analysis

All data from this study were collected, sorted and checked for quality and accuracy. They were then

entered into a database specially created for this project using the SPSS version 17 and analyzed. Descriptive statistics were computed for the demographic variables of the survey respondents. Quantitative data were analyzed by computing frequency tables, means, proportions, percentages and descriptive cross tabulations. Categorical variables were summarized using frequencies and percentages. Level of significance was set to 0.05 and data with p-values <0.05 were considered statistically

significant. Significant factors were summarized using odds ratios at 95% confidence intervals.

Ethical Issues

Full ethical approval was obtained from the Ethical Review Board of the Nnamdi Azikiwe University Teaching Hospital, Nnewi. Eligible participants for the study were contacted and given the informed consent forms for their consent.

Results

Of the 350 healthcare professionals involved in this study, 258 returned their completed questionnaire giving the response rate of 73.7%. Among these respondents, 71 (27.5%) were doctors, 39 (15.1%), pharmacists, 111 (43%) nurses, and 37 (14.3%) health records officers. About two thirds of the respondents, 165 (64%), were females and 93 (36%) were males, giving male to female ratio of 1: 1.8. The mean age of the respondents was 35.6 years \pm 6.0, with the median age (interquartile range) of 35-40 years. The respondents' median duration of service was 5-9 years. Demographic details of the respondents are summarized in Table 1.

In general, the respondents demonstrated high level of awareness about ADRs and the need to report them within a pharmacovigilance system. Majority of them (88.7%) stated that ADRs are either very serious or somewhat serious, while only 11.3% of them stated that ADRs are not a serious healthcare problem in their hospital. While most participants (82.4%) mentioned that they had encountered ADRs occasionally, only 4.5% had often encountered ADRs, and only about one tenth of them (13.1%) responded that they had never encountered ADRs in the course of their routine healthcare delivery to the patients. Virtually, all of the respondents, 256 (99.2%), agreed on the relevance of documenting ADRs. Of this proportion, while 79.8% strongly disagreed that ADRs should be documented, 19.4% just agreed, and 0.8% disagreed. The awareness and attitudes of the respondents about ADRs and their reporting are presented in Table 2.

About half of the respondents (49.6%) stated they knew about the Nigeria ADRs reporting tool, popularly called the NPV tool, also commonly referred to as the NAFDAC Yellow Form. Similar proportion of them (50.4%) stated that they did not know about this tool. Furthermore, only few of the respondents (5.8%) rated their knowledge and skills in pharmacovigilance to be high, while more than one third of them (33.9%) described their knowledge and skills

to be on the average. More than half of them (59.5%) rated their knowledge about this tool as poor. Only about one tenth of the respondents (13.7%) stated they use the NPV tool for documenting and reporting of ADRs, while most of them (86.3%) mentioned that they had never used the tool. Regarding the frequency of utilization of the NPV tool, only 18.3% of the respondents stated that they used the tool occasionally, while majority of them 81.7% had never used the tool for ADRs documentation and reporting; none (0%) of the respondents often used the tool for documenting of ADRs. Summary of the survey results on the attitudes and practices of the respondents towards pharmacovigilance practices and the actual use of the NPV tool (NAFDAC Yellow Form) for documentation of the ADRs is presented in Table 3.

There were 5 questions related to the awareness of important key indicators of pharmacovigilance, which were included in the survey tool. The responses of the healthcare professionals to these questions showed that they were generally not aware of pharmacovigilance activities in their hospital. Only one tenth of the respondents showed that they had pharmacovigilance unit in their hospital while the rest of them (89.5%) stated that either they did not have pharmacovigilance unit or they were not aware of the existence of such unit in their hospital. Details of the awareness of respondents about key pharmacovigilance indicators are presented in Table 4.

On the challenges to the effective use of the NPV tool to report ADRs, the respondents showed diverse responses. The major challenges towards the effective use of the NPV tool for reporting ADRs among the respondents were lack of awareness about the NPV tool (36.0%) as well as lack of the reporting forms 53.1% (Figure 1).

Discussion

The ultimate goal and targeted outcome of pharmacovigilance activities is to prevent the negative consequences of pharmacotherapy on the patients. To achieve this goal it is imperative that healthcare professionals have high level of awareness and skill in pharmacovigilance in the day-to-day patient care practices, especially in the teaching hospitals that should provide practice leadership in this regard. While spontaneous reporting remains as one of the most widely used approaches to pharmacovigilance, it is generally associated with relatively low levels of reporting. It has been documented that only 5 to 10%

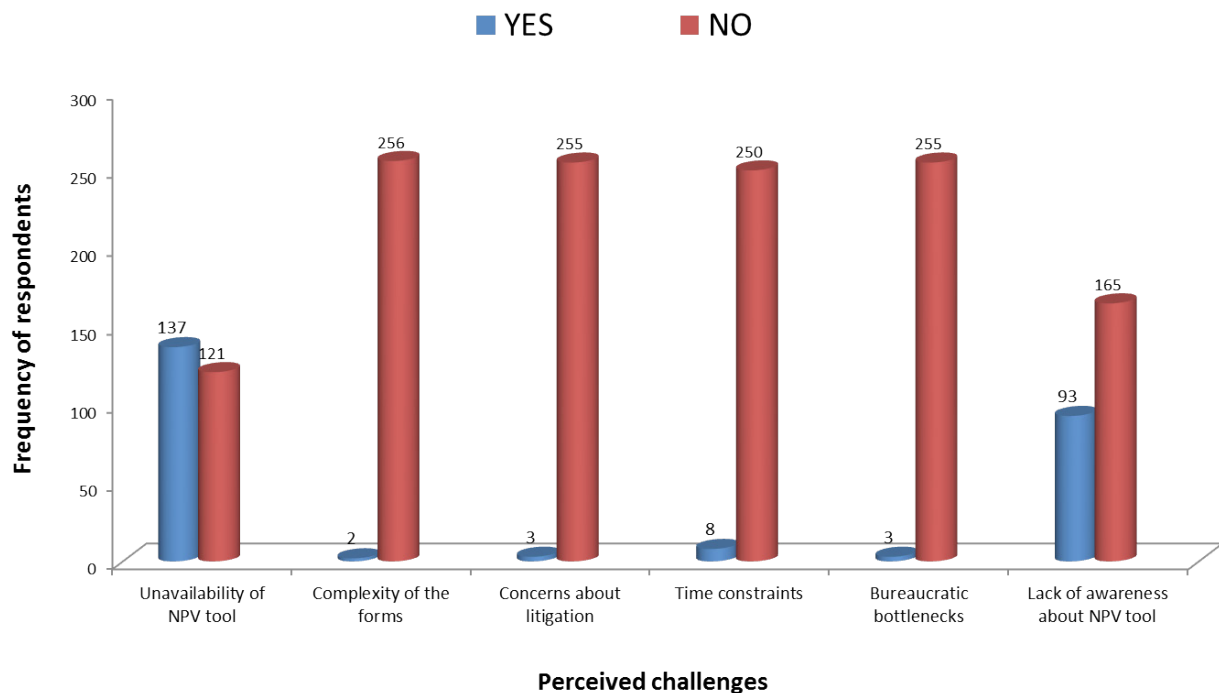


Figure 1 The perceived challenges toward use of NPV tool (n = 258)

of serious reactions are reported [30-33]. Even in countries with advanced pharmacovigilance, there is still high level of under-reporting of ADRs [34]. One of the widely acclaimed strategies to overcome ADRs under-reporting is to increase the awareness of the healthcare professionals about ADRs monitoring and other pharmacovigilance activities.

The healthcare professionals in this study demonstrated the importance of ADRs as majority of the respondents believed that ADRs are either very serious or somewhat serious healthcare problem. Most of them stated that they encounter ADRs occasionally in the course of healthcare delivery to the patients. They also showed strong positive attitude towards the need to document ADRs and report them when they occur. In addition, almost all of the respondents agreed that ADRs should be documented. This result is similar to those of other researchers in a Nepalese teaching hospital [35]. However, the results of this study showed low level of awareness among the respondents about pharmacovigilance and ADRs reporting using the Nigeria ADRs reporting form (the NAFDAC Yellow Form). Similar low level of awareness about pharmacovigilance has been documented in other countries, including Northern India [36, 37], France [38] and Italy [39]. Our study also found that more than half of the respondents were not aware of the NAFDAC Yellow Form. These results demonstrate the need for interventions

to improve the awareness of the healthcare professionals about pharmacovigilance system.

The low level of awareness of the respondents in this study may be due to the low level of training on pharmacovigilance in Nigeria. Only one respondent stated that he had received training on pharmacovigilance. Inadequate training programs and poor funding have been identified as the major challenges to the pharmacovigilance system in low- and medium-income countries such as Nigeria [40]. It stands to reason that there is low level of awareness among the respondents in this study as one can only give what one has. This low level of awareness about this NAFDAC Yellow Form among the respondents was also corroborated by the low level of utilization of this tool among the respondents. Only 18.3% of them stated that they had used the tool occasionally while most of them, 210 (81.7%), never used the tool to document and report ADRs. None of the respondents reported frequent use of the tool in documenting and reporting ADRs.

Half and one third of the respondents identified non-availability of the reporting forms and lack of awareness about the forms as the major challenges to the effective utilization of the NAFDAC Yellow Form for reporting ADRs, respectively. Very few respondents stated that they had concern for litigation or time constraint as their challenges to effective

utilization of the NAFDAC Yellow Form. Other researchers had documented time constraint and fear of litigation as major challenges to effective reporting of ADRs among the respondents in their study [21, 41,42].

There is no universally acceptable indicator for the evaluation of pharmacovigilance systems, [18]. However, some questions were included in the survey tool to assess the respondents' perception of some relevant pharmacovigilance indicators including, existence of pharmacovigilance unit, pharmacovigilance committee, policy guidelines on pharmacovigilance, and having designated pharmacovigilance officers in their hospital. The respondents showed low level of awareness about these key pharmacovigilance indicators in their hospital. Furthermore, almost all of them were not aware of the existence of pharmacovigilance committee or policy guidelines on pharmacovigilance activities in their hospital.

Conclusions

According to the results of this study, there is urgency for the development of strategies to create more awareness among the healthcare professionals on the pharmacovigilance system in Nigeria. This could be achieved through regular training and retraining of the healthcare professionals. In addition, the tools for reporting ADRs should be included in the patients' treatment charts to make them easily available to the healthcare professionals at the point of care of patients. Moreover, further research should also focus on the development of electronic reporting system and the use of trigger tool methodology for ADRs detection and reporting in Nigerian hospitals.

Abbreviation

(ADRs): Adverse drug reactions; (PEPFAR): President's Emergency Plan for AIDS Relief; (PMI): President's Malaria Initiative; (SSA): Sub-Saharan Africa; (ART): Anti-retroviral Therapy; (ACT): Artemisinin-based Combination Therapy; (WHO): World health Organization; (NPV): National Pharmacovigilance; (NPC): National Pharmacovigilance Center; (NAFDAC): National Agency for Food and Drug Administration and Control; (ICSRs): Individual Sase Safety Reports; (PVS): Nigerian Pharmacovigilance System; (NAUTH): Nnamdi Azikiwe University Teaching Hospital.

Competing Interest

The authors declare no competing interests.

Authors' Contributions

Dr. Raymond C. Okechukwu conceived the original concept of the study, designed the research, developed and adapted the research tools, administered the questionnaire/the key informant interview, entered the data into the project database, and also prepared the draft manuscript, Mr. Sunday O. Osinduka helped to prepare and review the manuscript, Mrs. Grace N. Ele contributed in data collection, and Prof. Matthew J. Okonta supervised the project work.

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