Knowledge and attitudes of health workers regarding adverse drug reactions monitoring and reporting in HIV treatment centers in Nigeria

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ABSTRACT

Background: Adverse drug reaction (ADR) monitoring and reporting is pivotal to the withdrawal of several approved and licensed drugs from the market because of drugs induced toxicities. However, under-reporting is a major problem and the underlying factors may vary between countries. The study evaluated knowledge and attitudes of health workers regarding adverse drug reactions (ADR) monitoring and reporting in Nigeria

Methods: This was a cross-sectional study. Out of 7126 health workers (doctors, pharmacists, nurses and laboratory scientists) in 51 secondary hospitals, a study-specific questionnaire was administered to 1160participants who were selected using stratified random sampling technique. A midpoint of the 5- point Likert-type attitude scale was determined by adding all scores and computing the average. Mean scale scores above midpoint were regarded as positive attitudes while below as negative attitudes. Chi-square was used for inferential statistics and $P<0.05$ indicated statistical significance.

Results: The mean questionnaire return rate was 60.1%. Data from 728(62.8%) participants were analyzed; and included 148(20.3%) doctors, 139(19.1%) pharmacists, 349(47.9%) nurses and 85(11.7%) laboratory scientists. Majority of the participants (35.6%) had >15years of professional experience. Twenty-nine percent and 59.1% participants defined pharmacovigilance and ADR correctly respectively. Of the participants, 23.4% and 85.8% reported good knowledge of WHO Causality Criteria and risk factors for ADRs respectively; and 59.8% were wrong about type-A ADR. Knowledge differences between groups was significant ($p<0.05$). 20.4% were aware of the yellow card scheme. The mean attitude scores by area of practice were 3.1(95%CI, 2.8–3.4) doctors, 3.1(95%CI, 2.8–3.5) pharmacists, 3.2(95%CI, 2.9–3.4) nurses and 3.0(95%CI, 2.7–3.3) laboratory scientists. The difference in attitudes between groups was not significant..

Conclusion: The knowledge and attitudes of doctors, pharmacists, nurses and laboratory scientists regarding ADR monitoring and reporting was somewhat poor in this study. Laboratory scientists were most affected. Re-orientation and capacity building of all relevant health workers on ADR monitoring and reporting is highly desirable.

Keywords: Pharmacovigilance, Knowledge, Attitudes, Health Workers, Patients, Nigeria.

INTRODUCTION

Pharmacovigilance is pivotal to the withdrawal of several approved and licensed drugs from the market because of drugs induced toxicities.[1,2] However, studies in the developed and developing countries reported poor knowledge and attitudes of health workers (mainly doctors and pharmacists) to adverse drug reactions (ADR) monitoring and reporting.[3-7] The lack of completeness of ADR reports is one of the identified problems of pharmacovigilance in France.[8] In Scotland, majority of healthcare professionals accepted responsibility for reporting suspected ADRs; however, <50% of them reported good knowledge about the Yellow Card reporting.[9] In Germany, about 20% of the physicians do not know the spontaneous reporting system and 30% do not know how to report ADR.[10] In India, 66% of doctors knew the definition of ADR, 38% defined pharmacovigilance correctly, 10% knew what should be reported and 30% knew whom to report to, while 47% knew the current status of the pharmacovigilance programme in their hospital.[11] In China, 70% of pharmacists defined ADR correctly and 78.0% knew how to report ADRs, however only one-third knew what should be reported.[12] In Nigeria, 78.1% of doctors were reported to have inadequate knowledge about pharmacovigilance; and 71.2% were unaware of the yellow forms for ADR reporting.[13] A study reported that *35.9 % of health workers have knowledge of the yellow form used for spontaneous reporting of ADR.*[14] Majority (89.9%) of medical doctors considered doctors as the most qualified health professionals to report ADRs, but only 32.3% of them ▸

were aware of the Yellow Card reporting scheme.[15] About 79.3% of doctors defined pharmacovigilance correctly, 56.2% did not know how to report ADRs and 71.7% did not know where to obtain the ADR forms.[16] Only 18% of the community pharmacists' defined pharmacovigilance correctly.[17]

ADR monitoring and reporting is the responsibility of all categories of health workers including nurses, laboratory scientists and the patients. Laboratory monitoring of patients on pharmacotherapy is very important for early detection and prevention of some ADRs as abnormal laboratory values may signal the occurrence of ADR. Nonetheless, laboratory scientists and nurses are often not included in studies evaluating pharmacovigilance program. We observed that most of the studies in Nigeria were conducted mainly among doctors and pharmacists, and none to our knowledge included laboratory scientists. In addition, sample sizes of the different categories of health workers were too small for reasonable comparison and inferences. Understanding the extent of knowledge and the attitudes of these health workers about ADR monitoring and reporting is important to inform interventions towards improving ADRs reporting rate. The study evaluated the knowledge and attitudes of health workers to ADRs monitoring and reporting in selected HIV treatment centers in Nigeria.

METHODS

Research Design

This was a cross-sectional study.

Setting

The study was conducted in 51 secondary hospitals in 25 states of Nigeria. These hospitals provide comprehensive HIV care and treatment services at no cost to the patients with support from Global HIV/AIDS Initiative Nigeria (GHAIN), a project funded by United States President Emergency Fund for AIDS Relief (PEPFAR) through United States Agency for International Development (USAID). All the healthcare professionals were eligible to participate in this study irrespective of whether they are involved in the management of HIV-infected patients or not.

Study Population

The population for the study sites included a total of 92 comprehensive HIV treatment centres supported by GHAIN in the 25 selected states of Nigeria. The study population for healthcare professionals included 7126 health workers comprising of 1523 medical doctors, 435 pharmacists, 347 laboratory scientists and 4821 nurses working in the 51 selected study sites.

Selection Criteria

All comprehensive antiretroviral treatment (ART) centres supported by GHAIN project in the 25 states of Nigeria were eligible to be included in the study. All healthcare professionals (doctors, pharmacists, nurses and laboratory scientists only) working in the selected study sites and consented to participate were eligible to be included in the study. All GHAIN-supported centres not providing comprehensive ART services, and those providing comprehensive antiretroviral treatment in the selected 25 states of Nigeria but not supported by GHAIN were excluded. All healthcare professionals from the selected hospitals who did not consent to participate in the study and those on leave or absence from duty during the study period were excluded. All other workers who were not doctors, pharmacists, nurses and laboratory scientists in the study sites were excluded.

Sample and Sampling Methods

The 25 states were selected as study states from the 37 states (plus Federal Capital Territory) of Nigeria. The sampling was purposively done to include at least 2 states from each of the 6 geopolitical zones of Nigeria. From the 92 comprehensive HIV treatment centres supported by GHAIN in the 25 selected states of Nigeria, 51 (55.4%) of the treatment centres were selected using purposive sampling technique. In this study, a total of 713 healthcare professionals (152 medical doctors, 44 pharmacists, 35 laboratory scientists and 482 nurses) were selected using stratified random sampling technique. The sample size was determined based on the 'rule of the thumb' proposed by Nunnaly, who suggested that the number of subjects should be at least 10 times the number of items.[18] However, the study instrument was distributed to 1160 healthcare professionals (300 medical doctors, 150 pharmacists, 110 laboratory scientists and 600 nurses) to accommodate for possible losses due to failure to return completed questionnaires and/or its non-completion..

Validity and Reliability of Instrument

The study instrument was circulated to the technical experts and a biostatistician; and was objectively discussed and modified based on their feedbacks for content validity. The study instrument was also pretested and it provided an opportunity to assess the feasibility and reliability of the study instrument. The site and participants involved in the pre-testing of the instrument were not included in the main study. The characteristics of the site and participants used in the pre-testing were similar to the study sites and participants to avoid bias.

Data collected from the pre-testing were analyzed and lessons learnt used in the modification of this study instrument.

Ethical Consideration

The ethical approval was obtained from National Health Research Ethics Committee (NHREC), Abuja Nigeria. Informed consents were also obtained from the study participants. They were assured of the confidentiality of the information.

Data Collection

The study-specific data collection tool had 3 sections namely: 4-items demographics which included sex, age groups, area of practice, and years of professional experience; 6-items knowledge and 28-items attitudes components. It employed mainly a 5-point Likert-type scale and was self-administered to participants by the researcher and 10 trained research assistants.

Data Analysis

The PASW statistics-18 software was used for data analysis. The responses were analyzed using descriptive statistics. Likert rating scale was anchored as follows: strongly agree = 5, agree = 4, neutral = 3, disagree = 2, and strongly disagree = 1; negatively worded items were reverse coded so that higher scores represent higher knowledge and attitudes. A Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was calculated to determine the extent to which the attitude variables belonged together and were appropriate for factor analysis. The sample is adequate if the value of KMO is >0.5;[19] values >0.90 are rated as "marvellous" for factor analysis.[20] Bartlett's test of sphericity was also used; and a value <0.05 of the significance level supports the usefulness of factor analysis with variables. Factor analysis was performed using principal components extraction and Varimax rotation with Kaiser Normalization. Listwise deletion was used for missing values. Factors selected for rotation had eigenvalues greater than 1. Items with factor loadings ≥ 0.40 were considered significant, and loadings of 0.50 or greater were considered "very significant".[21] Rated attitude scores were treated as interval data suited for quantitative analysis. Mean item scores were computed for the individual attitude items. One-Sample T-Test was used to compute the groups' rated attitude scores mean and test the association within groups. A midpoint of 3.6 was used for the 5-point scale which was determined by adding all the scores and computing the average. Mean scale scores above the midpoint were regarded as positive attitudes while below the mid-point were considered as negative attitudes. One-way Anova was used to test the association of the rated attitude scores mean between groups. The reliability analysis was determined using Cronbach's alpha. All reported P values were two-tailed and P<0.05 used to determine statistical significance, except where otherwise indicated.

RESULTS

Characteristics of Study Participants

From the 51(55.4%) selected HIV treatment centers, 728(10.2%) of the healthcare professionals participated in the study. Of these health workers, 349(47.9%) were nurses, 53.8% were females and 56.3% were aged 25-49 years old and 35.6% had >15 years of professional experience **(Table 1)**. The mean questionnaire return rate was

Table 1: Area of practice of HCWs segregated by sex, age and years of professional experience; Values in parenthesis are percentages; N = 728

Characteristics	Area of practice (%)					Total (%)
	Medical Doctor	Pharmacist	Nurse	Laboratory Scientist	Not indicated	
Sex						
Male	118 (79.7)	87 (62.6)	64 (18.3)	61 (71.8)	3 (42.9)	333 (45.7)
Female	30 (20.3)	52 (37.4)	285 (81.7)	24 (28.2)	1 (14.2)	392 (53.8)
Not indicated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (42.9)	3 (0.4)
Total	148 (20.3)	139 (19.1)	349 (47.9)	85 (11.7)	7 (1.0)	728 (100)
Age group (years)						
20-24	1 (7.7)	2 (15.4)	9 (69.2)	1 (7.7)	0 (0.0)	13 (1.8)
25-29	24 (31.6)	19 (25.0)	25 (32.9)	7 (9.2)	1 (1.3)	76 (10.4)
30-34	31 (36.0)	20 (23.3)	23 (26.7)	12 (14.0)	0 (0.0)	86 (11.8)
35-39	24 (31.6)	17 (22.4)	23 (30.3)	12 (15.8)	0 (0.0)	76 (10.4)
40-44	9 (10.0)	18 (20.0)	46 (51.1)	17 (18.9)	0 (0.0)	90 (12.4)
45-49	9 (11.0)	4 (4.9)	62 (75.6)	6 (7.3)	1 (1.2)	82 (11.3)
50-54	7 (11.3)	5 (8.1)	42 (67.7)	7 (11.3)	1 (1.6)	62 (8.5)
55-59	0 (0.0)	2 (16.7)	9 (75.0)	1 (8.3)	0 (0.0)	12 (1.6)
60+	0 (0.0)	1 (33.3)	1 (33.3)	1 (33.3)	0 (0.0)	3 (0.4)
Not indicated	43 (18.9)	51 (22.4)	109 (47.8)	21 (9.2)	4 (1.8)	228 (31.3)
Professional experience (years)						
< 1	9 (6.1)	6 (4.3)	13 (3.7)	4 (4.7)	0 (0.0)	32 (4.4)
	70 (47.3)	56 (40.3)	55 (15.8)	24 (28.2)	2 (28.6)	207 (28.4)
6 – 10	29 (19.6)	37 (26.6)	51 (14.6)	22 (25.9)	0 (0.0)	139 (19.1)
11 – 15	13 (8.8)	14 (10.1)	38 (10.9)	12 (14.1)	0 (0.0)	77 (10.6)
> 15	23 (15.5)	22 (15.8)	192 (55.0)	21 (24.7)	1 (14.3)	259 (35.6)
Not indicated	4 (2.7)	4 (2.9)	0 (0.0)	2 (2.4)	4 (57.1)	14 (1.9)

60.1% (95%CI, 60.1 ± 6.9).

Knowledge of Study Participants regarding ADRs Monitoring

The mean number of participants who reported been trained on pharmacovigilance was 18.8% (95%CI, 18.8% ±2.3). The proportion of these participants by area of practice included 9.9% medical doctors, 37.7% pharmacists, 18.0% nurses, 3.5% laboratory scientists and those whose profession were not indicated were 25.0%. The mean number of these trained participants who reported that the training adequately met their expectation in the least was 81.1% (95%CI, 81.1%± 3.8); and the proportion by area of practice included 64.3% medical doctors, 77.6% pharmacists, 63.8% nurses, 100.0% laboratory scientists and 100.0% of those whose area of practice were not indicated.

Of the participants, 42.2% defined pharmacovigilance incorrectly and included 52.4% nurses, 41.2% laboratory scientist, 33.8% medical doctors and 28.1% pharmacists. Contrary, 29.0% of the participants defined pharmacovigilance correctly and included 54.7% pharmacists, 37.2% medical doctors, 25.9% laboratory scientist, 16.0% nurses, and 28.6% of those whose area of practice were not indicated. However, 2.6% of the participants did not know the definition of pharmacovigilance and included 2.0% medical doctors, 3.5% laboratory scientist and 3.7% nurses. Only 26.2% of participants did not respond to the question item. When the participants' knowledge of ADR definition was assessed, 59.1% defined ADR correctly, 23.8% defined it incorrectly, 2.1% did not know while 15.1% did not respond. The proportion of those who defined ADR correctly included 72.3% medical doctors, 69.8% pharmacists, 53.3% nurses, 45.9% laboratory scientist, and 14.3% of those whose area of practice were not indicated. Those who defined it incorrectly included 18.2% medical doctors, 16.5% pharmacists, 24.6% nurses, 40.0% laboratory scientist, 42.9% of those whose area of practice were not indicated. Participants who did not know the definition of ADR included 1.4% medical doctors, 2.9% nurses, and 3.5% laboratory scientist. On assessment of knowledge of WHO Causality Criteria for ADR, an average of 23.4% (95%CI, 23.4% ±0.7) participants that responded were correct and included 25.7% medical doctors, 26.6% pharmacists, 24.4% nurses, 25.9% laboratory scientists and 14.3% of those whose area of practice were not indicated.

On assessment of knowledge of risk factors for ADRs, 85.8% of participants had a good knowledge of the subject; and the differences in knowledge by area of practice was statistically significant for dosage, duration of treatment and route of administration as risk factors ($p<0.05$) - Table 2. Of the participants, 59.8% reported wrongly that type-A adverse drug reactions are not related to the pharmacologic effect of the drug (Table 2). Only 20.4% participants were aware of the existence of national ADR reporting form or the yellow card scheme in the

Table 2: Frequency distribution of the participants who responded in affirmation to the risk factors for ADRs and the features of type-A ADR

The following is a risk factor for ADR	Profession (%)					Total, N (%)	P-Value
	Medical Doctor	Pharmacist	Nurse	Lab. Scientist	Not indicated		
Age	125 (88.7)	111 (86.7)	302 (92.4)	75 (91.5)	1 (50.0)	614 (90.3)	0.102
Genetic Constitution	124 (87.9)	116 (90.6)	290 (89.0)	77 (93.9)	2 (100.0)	609 (89.7)	0.631
Bathing with hot water	24 (17.0)	24 (18.8)	130 (39.8)	26 (31.7)	2 (100.0)	206 (30.3)	**0.000**
Sex	100 (71.4)	100 (78.1)	241 (74.4)	60 (73.2)	1 (50.0)	502 (74.3)	0.689
Dosage	127 (90.1)	117 (92.1)	315 (96.6)	77 (93.9)	1 (50.0)	637 (94.0)	**0.004**
Duration of treatment	133 (94.3)	117 (91.4)	321 (98.5)	79 (96.3)	2 (100.0)	652 (96.0)	**0.009**
Route of administration	134 (95.0)	122 (95.3)	314 (96.9)	76 (95.0)	1 (50.0)	647 (95.9)	**0.018**
Co-morbid conditions	132 (93.6)	120 (93.8)	314 (97.2)	78 (95.1)	1 (50.0)	645 (95.4)	0.064
Inappropriate Medication	138 (98.6)	122 (95.3)	310 (96.0)	78 (95.1)	2 (100.0)	650 (96.3)	0.750
Prescribing End-Organ dysfunction	137 (97.9)	126 (98.4)	307 (94.5)	79 (96.3)	2 (100.0)	651 (96.2)	0.057
Don't know	12 (8.5)	1 (0.8)	38 (11.7)	6 (7.4)	0 (0.0)	57 (8.4)	**0.006**
Characteristics of type-A ADR							
Not predictable or preventable	4 (3.5)	4 (3.9)	13 (4.7)	5 (7.1)	0 (0.0)	26 (4.6)	0.813
Related to the pharmacologic effect of the drug	59 (52.2)	63 (61.8)	86 (31.0)	16 (22.9)	3 (100.0)	227 (40.2)	**0.000**
Only a small fraction of all adverse reactions	8 (7.1)	10 (9.8)	33 (11.9)	4 (5.7)	0 (0.0)	55 (9.7)	0.404
All of the above	7 (6.2)	15 (14.9)	43 (15.6)	9 (12.9)	0 (0.0)	74 (13.2)	0.221
Don't know	40 (35.7)	19 (18.6)	100 (36.1)	36 (52.2)	0 (0.0)	195 (34.6)	**0.002**

ospitals.

ttitudes of Health Workers regarding DR Monitoring

DR monitoring was reported the esponsibility of all health workers 1.2% (of which 24.4% were medical octors, 22.9% were pharmacists, 9.3% were nurses, and 12.4% were aboratory scientists); pharmacists nly 22.2% (of which 38.5% and 42.7% f these respondents were harmacists and nurses respectively); nedical doctors only 12.4% (of which 3.8% and 37.5% of these respondents were medical doctors and nurses espectively); nurses only 5.0% (of which 84.4% and 6.3% of these espondents were nurses and aboratory scientist respectively); laboratory scientists only 9.6% (of which 72.6% and 21.0% of these respondents were nurses and laboratory scientists respectively); medical doctors and pharmacists only 5.6% (of which 41.7%, 16.7%, 30.6%, and 11.1% of these respondents were medical doctors, pharmacists, nurses and laboratory scientists respectively); medical doctor, pharmacists and nurses only 8.8% (of which 33.3%, 28.1% and 38.6% of these respondents were medical doctors, pharmacists and nurses respectively).

Table 3 shows the frequency distribution of participants' attitudes towards ADR monitoring and reporting in clinical practice. The overall rated scores mean of the participants' attitudes to ADR monitoring and reporting in clinical practice were 3.6 (95%CI, 3.4-3.8; p=0.000). The rated scores mean by area of practice were 3.1 (95%CI, 2.8-3.4; p=0.000) for medical doctors, 3.1 (95%CI, 2.8-3.5; p=0.000) for pharmacists, 3.2 (95%CI, 2.9–3.4; p=0.000) for nurses, 3.0 (95%CI, 2.7-3.3; p=0.000) for laboratory scientists and 3.1 (95%CI, 2.8–3.5; p=0.000) for health workers whose area of practice were not indicated (Table 4). The differences in the rated scores mean of the groups' attitudes towards ADR monitoring and reporting in clinical practice were not statistically significant (p>0.05).

able 3: Frequency distribution of participants' attitudes towards ADR monitoring and eporting in clinical practice; (Values in parenthesis are percentages)

Questionnaire items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Total # of respondents (%)
Mandatory ADR screening policy is justified	263 (38.1)	340 (49.3)	49 (7.1)	34 (4.9)	4 (0.6)	690 (94.8)
ADR screening form should be introduced into clinical practice for routine screening of patients for ADRs	326 (46.4)	334 (47.5)	17 (2.4)	21 (3.0)	5 (0.7)	703 (96.6)
ADRs screening for each and every patient (universal screening) is not justified because of low prevalence of ADRs?	52 (7.4)	143 (20.4)	70 (10.0)	350 (49.9)	86 (12.3)	701 (96.3)
Patients' follow-up visits provide a unique opportunity for screening all patients for ADRs (universal screening)?	224 (32.0)	390 (55.8)	37 (5.3)	44 (6.3)	4 (0.6)	699 (96.0)
ADR reporting form should be used for reporting ALL suspected ADRs	234 (33.9)	332 (48.0)	67 (9.7)	47 (6.8)	11 (1.6)	691 (94.9)
ADR reporting form should be used for reporting ONLY moderate to severe ADRs	50 (7.3)	134 (19.6)	98 (14.4)	299 (43.8)	101 (14.8)	682 (93.7)
I am prepared to screen patients for ADRs?	118 (20.2)	320 (54.9)	84 (14.4)	48 (8.2)	13 (2.2)	583 (80.1)
I am prepared to screen patients for ADRs for each and every patient (universal screening)?	99 (16.8)	260 (44.1)	91 (15.4)	119 (20.2)	20 (3.4)	589 (80.9)
I am prepared to screen patients for ADRs only in case of suspected ADRs (directed screening)?	71 (13.0)	206 (37.7)	54 (9.9)	174 (31.8)	42 (7.7)	547 (75.1)
ADR is the patients' problem for which they should worry about and take responsibility	49 (7.2)	76 (11.1)	23 (3.4)	254 (37.1)	283 (41.3)	685 (94.1)
ADR monitoring is a phenomenon that concerned only chronically ill patients on life-long medication and therefore its screening should be confined to them	22 (3.2)	54 (7.9)	23 (3.4)	330 (48.2)	256 (37.4)	685 (94.1)
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADR	209 (33.1)	318 (50.3)	50 (7.9)	47 (7.4)	8 (1.3)	632 (86.8)
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADRs for each and every patient (universal screening)	127 (19.9)	284 (44.6)	93 (14.6)	113 (17.7)	20 (3.1)	637 (87.5)
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADRs ONLY when ADR is suspected (directed screening)	80 (13.1)	204 (33.3)	77 (12.6)	191 (31.2)	61 (10.0)	613 (84.2)
I am very knowledgeable about ADRs to deal with it in clinical practice	47 (7.0)	241 (35.7)	146 (21.6)	192 (28.4)	49 (7.3)	675 (92.7)
I am sufficiently skilled to screen patients for ADRs	29 (4.3)	169 (24.8)	158 (23.2)	257 (37.7)	68 (10.0)	681 (93.5)
I am familiar with the signs and symptoms indicating possible ADR	72 (10.5)	399 (58.3)	98 (14.3)	89 (13.0)	26 (3.8)	684 (94.0)
I am familiar with the management of ADR or action to be taken when ADRs is identified in a patient	66 (9.7)	319 (46.8)	123 (18.0)	141 (20.7)	33 (4.8)	682 (93.7)
Overall, healthcare professions are insufficiently familiar with the monitoring of ADRs in order to adequately deal with it in clinical practice	101 (14.8)	262 (38.4)	115 (16.9)	170 (24.9)	34 (5.0)	682 (93.7)
ADR screening can prevent the undesirable effects of drugs to patients	292 (42.4)	329 (47.8)	29 (4.2)	35 (5.1)	3 (0.4)	688 (94.5)
It is of no use to screen for ADR because it is not preventable and will still occur anyway	18 (2.6)	32 (4.7)	49 (7.1)	395 (57.4)	194 (28.2)	688 (94.5)
It is of no use to screen for ADR because of a lack of skilled personnel or specialized facilities for ADR management	21 (3.1)	67 (9.9)	48 (7.1)	377 (55.4)	167 (24.6)	680 (93.4)
It is of no use to screen for adverse drug reaction because of a lack or unavailability of standardized ADR screening or reporting forms in the facility	31 (4.5)	95 (13.9)	79 (11.6)	349 (51.2)	128 (18.8)	682 (93.7)
Most patients will feel scared of taking the prescribed medications if I disclose to them the adverse effects of the drugs	59 (8.6)	260 (37.9)	86 (12.5)	245 (35.7)	36 (5.2)	686 (94.2)
Most patients will feel scared or worried if I ask them if they have experienced ADRs	25 (3.7)	168 (25.0)	83 (12.3)	347 (51.6)	50 (7.4)	673 (92.4)
Most patients will stop or feel scared to continue their medications if they know that the undesirable effects complained of are due to their medications. Hence, no need to disclose it to them	28 (4.1)	113 (16.5)	67 (9.8)	389 (56.9)	87 (12.7)	684 (94.0)
I don't have the time to thoroughly discuss adverse effects of drugs with the patient	27 (4.0)	159 (23.7)	71 (10.6)	320 (47.6)	95 (14.1)	672 (92.3)
I don't have the time to screen ALL patient for possible adverse reactions or side effects of drugs	42 (6.3)	236 (35.1)	72 (10.7)	258 (38.4)	64 (9.5)	672 (92.3)

Table 4: Distribution of participants' attitudes to ADR monitoring and reporting in clinical practice (segregated by area of practice)

Questionnaire items	Rated Score (values are mean at 95% Confidence Interval) Overall	Medical Doctor	Pharmacist	Nurse	Lab. Scientist	Not indicated	Total, N (%)	P-value
Mandatory ADR screening policy is justified	4.2 ± 0.1	4.2 ± 0.1	4.3 ± 0.1	4.1 ± 0.1	4.3 ± 0.2	4.3 ± 0.5	690 (94.8)	0.693
ADR screening form should be introduced into clinical practice for routine screening of patients for ADRs	4.4 ± 0.1	4.2 ± 0.1	4.5 ± 0.1	4.3 ± 0.1	4.4 ± 0.2	4.5 ± 0.6	703 (96.6)	0.455
ADRs screening for each and every patient (universal screening) is not justified because of low prevalence of ADRs	3.4 ± 0.1	3.4 ± 0.2	3.7 ± 0.2	3.3 ± 0.1	3.5 ± 0.2	4.0 ± 0.8	701 (96.3)	0.060
Patients' follow-up visits provide a unique opportunity for screening all patients for ADRs (universal screening)?	4.2 ± 0.1	4.1 ± 0.1	4.3 ± 0.1	4.0 ± 0.1	4.2 ± 0.2	4.0 ± 0.0	699 (96.0)	0.320
ADR reporting form should be used for reporting ALL ADRs	4.0 ± 0.1	3.9 ± 0.2	4.3 ± 0.1	4.1 ± 0.1	3.9 ± 0.2	4.3 ± 0.5	691 (94.9)	**0.000**
ADR reporting form should be used for reporting ONLY moderate to severe ADRs	3.4 ± 0.1	3.5 ± 0.2	3.6 ± 0.2	3.2 ± 0.1	3.4 ± 0.2	3.8 ± 0.5	682 (93.7)	0.115
I am prepared to screen patients for ADRs?	3.9 ± 0.1	3.7 ± 0.2	4.0 ± 0.2	3.8 ± 0.1	3.8 ± 0.2	4.0 ± 0.0	583 (80.1)	0.325
I am prepared to screen patients for ADRs for each and every patient (universal screening)?	3.5 ± 0.1	3.1 ± 0.2	3.7 ± 0.2	3.6 ± 0.1	3.6 ± 0.2	3.8 ± 1.2	589 (80.9)	**0.006**
I am prepared to screen patients for ADRs only in case of suspected ADRs (directed screening)?	2.9 ± 0.1	2.4 ± 0.2	2.7 ± 0.2	3.1 ± 0.2	3.0 ± 0.3	2.0 ± 0.0	547 (75.1)	**0.001**
ADR is the patients' problem for which they should worry about and take responsibility	4.1 ± 0.1	4.5 ± 0.1	4.2 ± 0.2	3.6 ± 0.1	4.0 ± 0.3	4.3 ± 0.0	685 (94.1)	**0.000**
ADR monitoring is a phenomenon that concerned only chronically ill patients on life-long medication and therefore its screening should be confined to them	4.1 ± 0.1	4.5 ± 0.1	4.3 ± 0.1	3.8 ± 0.1	4.1 ± 0.2	3.5 ± 1.7	685 (94.1)	**0.000**
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADR	4.1 ± 0.1	4.1 ± 0.2	4.3 ± 0.1	4.0 ± 0.1	3.7 ± 0.3	4.0 ± 1.4	632 (86.8)	**0.000**
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADRs for each and every patient (universal screening)	3.6 ± 0.1	3.3 ± 0.2	3.8 ± 0.2	3.7 ± 0.1	3.4 ± 0.2	3.5 ± 1.0	637 (87.5)	**0.001**
It is my professional responsibility to screen patients for signs and symptoms indicating possible ADRs ONLY when ADR is suspected (directed screening)	2.9 ± 0.1	2.6 ± 0.2	2.9 ± 0.2	3.0 ± 0.1	3.1 ± 0.3	3.7 ± 1.7	613 (84.2)	**0.006**
I am very knowledgeable about ADRs to deal with it in clinical practice	3.1 ± 0.2	3.1 ± 0.2	3.5 ± 0.2	3.0 ± 0.1	2.4 ± 0.2	2.5 ± 1.3	675 (92.7)	**0.000**
I am sufficiently skilled to screen patients for ADRs	2.9 ± 0.1	2.8 ± 0.2	3.2 ± 0.2	2.6 ± 0.1	2.3 ± 0.2	3.5 ± 1.0	681 (93.5)	**0.000**
I am familiar with the signs and symptoms indicating possible ADR	3.6 ± 0.1	3.8 ± 0.1	3.8 ± 0.1	3.6 ± 0.1	3.0 ± 0.2	3.5 ± 0.6	684 (94.0)	**0.000**
I am familiar with the management of ADR or action to be taken when ADRs is identified in a patient	3.4 ± 0.1	3.6 ± 0.2	3.6 ± 0.1	3.4 ± 0.1	2.5 ± 0.2	3.3 ± 0.9	682 (93.7)	**0.000**
Overall, healthcare professions are insufficiently familiar with the monitoring of ADRs in order to adequately deal with it in clinical practice	2.6 ± 0.1	2.7 ± 0.2	2.8 ± 0.2	2.7 ± 0.1	2.3 ± 0.2	3.0 ± 1.1	682 (93.7)	0.052
ADR screening can prevent the undesirable effects of drugs to patients	4.3 ± 0.1	4.3 ± 0.1	4.3 ± 0.1	4.2 ± 0.1	4.4 ± 0.2	4.5 ± 0.6	688 (94.5)	0.706
It is of no use to screen for ADR because it is not preventable and will still occur anyway	4.1 ± 0.1	4.2 ± 0.1	4.2 ± 0.1	3.9 ± 0.1	4.1 ± 0.2	4.0 ± 0.8	688 (94.5)	0.120
It is of no use to screen for ADR because of a lack of skilled personnel or specialized facilities for ADR management	4.0 ± 0.1	4.0 ± 0.1	4.0 ± 0.2	3.7 ± 0.1	4.0 ± 0.2	4.3 ± 0.9	680 (93.4)	0.186
It is of no use to screen for adverse drug reaction because of a lack or unavailability of standardized ADR screening or reporting forms in the facility	3.8 ± 0.1	3.8 ± 0.2	3.9 ± 0.2	3.5 ± 0.1	3.9 ± 0.2	3.8 ± 1.2	681 (93.5)	0.054
Most patients will feel scared of taking the prescribed medications if I disclose to them the adverse effects of drugs	2.9 ± 0.1	3.1 ± 0.2	3.3 ± 0.2	2.7 ± 0.1	2.8 ± 0.3	2.8 ± 1.5	686 (94.2)	**0.003**
Most patients will feel scared or worried if I ask them if they have experienced ADRs	3.3 ± 0.1	3.5 ± 0.1	3.6 ± 0.2	3.2 ± 0.1	3.2 ± 0.2	3.5 ± 1.3	673 (92.4)	**0.000**
Most patients will stop or feel scared to continue their medications if they know that the undesirable effects complained of are due to their medications. Hence, no need to disclose it to them	3.6 ± 0.1	3.7 ± 0.1	3.8 ± 0.2	3.4 ± 0.1	3.5 ± 0.2	4.3 ± 0.5	684 (94.0)	**0.014**
I don't have the time to thoroughly discuss adverse effects of drugs with the patient	3.4 ± 0.1	3.0 ± 0.2	3.5 ± 0.2	3.6 ± 0.1	3.4 ± 0.2	3.0 ± 1.1	672 (92.3)	**0.001**
I don't have the time to screen ALL patient for possible adverse reactions or side effects of drugs	3.2 ± 0.1	2.6 ± 0.2	3.2 ± 0.2	3.2 ± 0.1	3.4 ± 0.2	3.0 ± 1.1	672 (92.3)	**0.000**

ollowing the listwise deletion of issing values, 354 cases were left for actor analysis. The aiser–Meyer–Olkin measure of ampling adequacy for the factor nalysis was 0.72. The Bartlett's Test of phericity was statistically significant) = 0.000). The sample was found to e adequate for factor analysis as etermined by KMO value[19] which was onsistent with the result of Bartlett's est of Sphericity.The internal onsistency of the 28-items attitude cale based on standardized items as easured by Cronbach's alpha was .779. This is acceptable[18] and superior) 0.70 indicating that the items are ufficiently correlated to constitute a cale.[22] Using the criterion of an igenvalue >1.0, nine factors were xtracted (Table 5) which accounted or 61.8% of variance. Of the ommunalities, 92.9% were ≥ 0.40, 8.6% were ≥ 0.50 and 35.7% were ≥ .70. A large first factor accounted for 6.3% of the variance. The second to inth factors accounted for 9.2%, 7.7%, .9%, 5.0%, 4.8%, 4.2%, 2.1% and 3.6% f the variance, respectively. However, he scree plot indicated a break after he ninth factor (eigenvalue =0.931). ut of 28 items, 26 items had one actor loading of ≥ 0.40 which may ndicate that the extracted factors epresented the variables well.[21] We ecided to maintain all items because his was a first application and next tudies with this instrument could onsider the exclusion of the two items hich had insignificant factor loadings. he extracted factors reduced the omplexity of the dataset with a 38.2% ss of information.

ISCUSSION

he study reported poor knowledge nd negative attitudes to ADR onitoring and reporting among ealth workers. Less than one-fifth of the participants were trained on pharmacovigilance previously; and majority of them were pharmacists. About one-quarter of participants defined pharmacovigilance correctly and majority were pharmacists followed by medical doctors. This is not consistent with findings by Awodele *et al* [16] which reported that over three-quarter of doctors' defined pharmacovigilance correctly. This is similar to what Chopra *et al* [11] and Oreagba *et al* [17] reported among doctors and pharmacists respectively. Ohaju-Obodo *et al* reported that over three-quarter of doctors had inadequate knowledge about pharmacovigilance.[13] This may imply that less than one-quarter of the resident doctors had adequate knowledge about pharmacovigilance and this is somewhat similar to our study findings. This is generally very poor. On the contrary, knowledge about the ADR was somewhat different. About one-half of the participants defined ADR correctly and majority were doctors followed by pharmacists, nurses and then laboratory scientists, similar to previous research findings.[11, 12] The knowledge about WHO Causality Criteria for ADRs was poor among all categories of health workers. Majority of participants had good knowledge of the risk factors for ADRs. About one-fifth were aware of the existence of the yellow card scheme in their hospitals. This was far less than what both Pulford *et al* [9] and Hasford *et al* [10] reported previously respectively but somewhat consistent with what studies had reported in Nigeria.[13-15]

More than 50% of the participants reported that they were familiar with the signs and symptoms indicating possible ADR. This is not consistent with previous research findings which reported that 10%–33% of the participants knew what should be reported.[11, 12] Majority of health workers accepted responsibility for screening patients for ADRs in clinical practice similar to previous research finding.[9] About one-tenth of participants reported that ADR screening is the responsibility of only medical doctors; and this is less than the previous report in Nigeria.[15] The participants had negative attitudes towards ADR monitoring and reporting in clinical practice. This is consistent with previous research findings.[3-7]

The study identified knowledge and altitudinal gaps in pharmacovigilance program in Nigeria. There is need for a re-orientation of health workers through pharmacovigilance training in the hospitals. Multidisciplinary approach to pharmacovigilance should be promoted in hospitals. The study may be limited by response bias. Some participants may deliberate report good or poor knowledge and attitudes to ADR monitoring and reporting to portray them in a good or bad light. This may overestimate or underestimate the rated scores mean. There may also be selection bias committed by the researcher when selecting the study sites. Most of the sites selected were mainly in the urban communities where the healthcare professionals may have easy access to information on the subject than their counterparts in rural communities. This may affect the generalization of the study findings. There may be recall bias by some participants when responding to the questions in the instrument. This has the potential to either overestimate or underestimate the effects been measured. Non-probability sampling technique including the Nunnally's rule of thumb used may affect the generalization of the study findings.

CONCLUSION

The knowledge and attitudes of doctors, pharmacists, nurses and laboratory scientists regarding ADR monitoring and reporting was somewhat poor in this study. Laboratory scientists were most affected. Re-orientation and capacity building of all relevant health workers on ADR monitoring and reporting is highly desirable.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

All authors on this publication contributed to the study concept and data interpretation. KAA drafted the initial study concept including plan for data analysis which was circulated and critically revised by ACO and UMO. The data analysis was done by KAA and critically revised by ACO and UMO. KAA drafted the manuscript and circulated to ACO and UMO for critical revision. The study was coordinated by KAA. All authors read and approved the final manuscript.

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