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Practices and Barriers towards Pharmacovigilance and Adverse Drug Reporting among Intern Pharmacists in Nigeria

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Authors' contributions

This work was carried out in collaboration among all authors. Author SCE conceptualized the idea, designed the study tools and analyzed the results and wrote the results section of the manuscript. Author ECO wrote the introduction, methodology and designed the study tools. Author GOO was involved in the study design and analysis of the results. Author WEA wrote the discussion sections of the manuscript. Authors KCE, ULA, CEM, CCM, VCA, CJN and KOI were involved in the data collection. All authors read and approved the final manuscript.

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ABSTRACT

Background: The practice of Pharmacovigilance (PV) and Adverse Drug Reaction (ADR) reporting is very necessary to ensure adequate safety of all drugs in use and is an integral component of post marketing surveillance. Pharmacist, including interns are at a central position in carrying out this important function.
Objectives: This study sought to assess the practice of pharmacovigilance and adverse drug reaction reporting and the perceived barriers towards its implementation among pharmacist interns in Nigeria.
Methods: This was a cross-sectional study among pharmacist interns in Nigeria. The 18-item semi-structured questionnaires were administered online using simple random sampling with the snowballing technique to recruit the participants and the results were analyzed with IBM SPSS version 25. Descriptive statistics were used to summarize the data. The chi-square test was used to evaluate associations.
Results: A total of 450 pharmacist interns participated in this study. The practice of PV and ADR reporting is poor among the respondents, less than 40% of the participants have ever reported ADR before, while only 29.1% have reported ADR since starting their internship program. Only 35.8% said “yes” to documenting ADR. Verbal information (61.1%) is the most widely used method of reporting ADR. Lack of cohesion among healthcare professionals, unavailability of feedback from relevant authorities, and fear of being wrong are the most reported barriers towards PV and ADR reporting among the participants. This is a correlation between the number of months spent in internship program and the practice of PV by the participants. ‘Fear of being wrong’ is an essential barrier to PV and ADR reporting among participants in tertiary hospitals (86.0%).
Conclusion: The practice of pharmacovigilance is poor among the participants. Many barriers also affect ADR reporting among the interns. Measures should be taken to encourage ADR reporting and the reported barriers should be reviewed to improve pharmacovigilance activities.

Keywords: Pharmacovigilance; adverse drug reaction; practice; barriers; pharmacist interns; Nigeria.

1. INTRODUCTION

Worldwide, adverse drug reactions (ADRs) significantly affect morbidity and mortality [1]. An adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as any toxic, unexpected, and unwanted effect of a medicine that happens at dosages used in humans for prevention, diagnosis, or therapy [2]. The research and practices involved in identifying, evaluating, comprehending and preventing adverse effects or any other potential drug-related issue are referred to as pharmacovigilance (PV) [3,4]. PV is a global initiative spearheaded by the WHO that entails gathering ADRs into a single database to find previously unrecognized or poorly understood adverse drug reactions (ADRs) to medications [5,6]. An essential goal of PV is to support national drug regulatory agencies in their efforts to enhance medication safety profiles and stop further tragedies [7].

Drug use is characterized by weighing the safety of the drug, which is a significant component, against the risk that comes with it. Therefore, the propensity of a drug to produce no harm when used for the period and conditions suggested is what is meant by "drug safety" [8]. Pharmacists and many other healthcare professionals take the Hippocratic Oath, which expressly mandates them to protect patients from harm, emphasizes the necessity for safety, and further highlights the significance of safety. However, it is paradoxical

and widely acknowledged that no medicine is safe. Based on this, most nations have legalized practical drug usage [9]. The identification, documenting, and reporting of ADRs are the responsibility of healthcare professionals, and they play a crucial role in the early identification and reporting of an ADR [10]. Every nation must set up a national pharmacovigilance system since variations can influence data gathered from such reports in population, medication usage, and native remedies [11,12].

In pharmacovigilance, spontaneous (voluntary) reporting is the primary technique [13]. A spontaneous report (SR) is an unsolicited communication from a healthcare professional or a consumer describing one or more adverse drug reactions (ADRs) associated with one or more medications [7]. Given the numerous restrictions of pre-marketing clinical trials, an adequate spontaneous reporting system for adverse drug reactions (ADRs) is a fundamental element for thorough post-marketing monitoring of drug-induced risks and the research of drug safety [14,15].

Despite the benefits of SR of suspected ADRs, under-reporting remains a significant challenge globally [16]. According to one study, only 6 - 10% of all ADRs are reported. The reasons for under-reporting ADRs are multifaceted and may differ across countries [7]. The reporting of an ADR by a healthcare professional is influenced by a variety of factors, including ignorance, ambiguity regarding the ADR and its reporting system, and difficulties in understanding the reporting system [17,18].

The one-year mandatory internship program in Nigeria intends to inculcate the skills, functions, and disciplines of the pharmacy practice into young pharmacy graduates under the close supervision of fully licensed pharmacists [19]. An essential part of the learning for the intern pharmacist is identifying and reporting ADRs. Pharmacists, including interns, are easily accessible; they work long hours and come in contact with many patients, which places them in the hot spot of the practice of pharmacovigilance and ADR reporting [20]. The data (ADR reports) required for the quick recall of unsafe medicines depends on the active involvement of the reporters, including Intern Pharmacists [21]. Therefore, the active participation of Intern pharmacists in ADR reporting will greatly improve the efficiency of the pharmacovigilance system by significantly increasing the number of reports leading to more post-marketing withdrawals and safe use of medicines in the population. So many studies have assessed the knowledge and perception, practices and barriers towards pharmacovigilance among pharmacists; however, no study, to the best of our knowledge, involved the pharmacist interns [7]. This study aims to assess the level of practice of Pharmacovigilance among Pharmacist interns and their perceived barriers toward ADR reporting.

2. METHODOLOGY

2.1 Study Technique and Sampling Technique

This cross-sectional study was conducted among pharmacist interns undergoing their one-year mandatory internship program across Nigeria. Simple random sampling involving the snowballing technique was used to recruit the participants in the study.

2.2 Study Instrument and Administration

The study instrument was an 18-item semi-structured questionnaire designed to obtain information on the respondents' practice and perceived barriers towards pharmacovigilance and ADR reporting in Nigeria. The questionnaire consisted of three parts; the first included seven (7) questions on the Pharmacist Interns' sociodemographic (independent) variables, such as age, gender, place of internship, duration of the internship program, ethnicity, and religion. The practice of pharmacovigilance and ADRs reporting was measured in part two with six (6) questions, each bearing options 'yes,' and 'no,.' The final section was on the respondents' perceived barriers towards Pharmacovigilance and ADR reporting with five (5) questions, each bearing a 5-point Likert scale of 'strongly agree to strongly disagree.'

The questionnaire development first involved a thorough literature review, from which the study instrument was adapted and modified to suit our study context [22,23]. Face validity, content validity, and test-retest by experts in the field were further used to validate the questionnaire. The instrument's reliability was tested by conducting an alpha cronbach's test. The alpha Cronbach's value of the scales in the instrument was between the ranges of 0.70 – 0.82. The questionnaire was distributed online via WhatsApp, Telegram, and Facebook.

2.3 Duration of Study

This study's data was collected over two months from August 2022 to October 2022.

2.4 Inclusion/Exclusion Criteria

The questionnaire was shared only with fresh pharmacy graduates currently undergoing their one year mandatory internship programme across the country. Student pharmacists, post intern pharmacists and fully licensed pharmacists were all excluded.

2.5 Sample Size Determination

A minimum sample size of 430 was estimated using Fisher's formula [24]. The assumed working proportion of 50% from the previous study was used at a 95% confidence level, and the desired accuracy level (from the confidence interval) was set at 0.05.

$$\text{sample size} = \frac{z^2 p(1-p)}{d^2}$$

Where z = the z score from the distribution table with the confidence interval set at 95%; p= Knowledge level among youths from published literature; d= margin of error.

Then, using z= 1.96 and p= 0.5 (50%) and d= 0.05 (5%),

Sample size = $\frac{1.96 \times 1.96 \times 0.5 \times 0.78}{0.05 \times 0.05}$ = 384 participants

Accounting for non response rate of 10%, the minimum number of sample size= 384/(1-0.1)= 430 responses

2.6 Data Analysis

The questionnaire was assessed for completeness, and only questionnaires with complete responses were subjected to analyses. The data were analyzed with the aid of SPSS version 23. Descriptive statistics such as frequencies and percentages were used to summarize the data. The different modes used by the participants to report ADR and their perceived barriers were graphed using a bar chart. The association between the demographic variables of the respondents and their practice and barriers towards Pharmacovigilance and ADRs reporting were evaluated using the chi-squares test. The level of significance was set at $p < 0.05$.

3. RESULTS

The survey was sent out to 500 Pharmacist interns (Respondents), with 450 consenting to participate, giving a total response rate of 90%. Table 1 shows the sociodemographic representation of the participants. Nearly half (50%) of the respondents are between 26-30yrs. There were more males (58.2%) than females (41.8%), with nearly all possessing a pharm. B degree. More than half of the respondents (55.2%) have spent 7-9 months in their internship program, followed by a 27.7% who have done 4-6 months. Respondents undergoing their one-year mandatory internship program in a tertiary hospital account for bout 79.2% of all the respondents, followed by those in specialist and military hospitals. The Igbo ethnic group represents a whopping 75.6% of the participants, followed by the hausa (3.5%), while 95% of the respondents were christians.

3.1 Practice of PV and ADR Reporting among the Participants

The practice of PV and ADR reporting is deplorable among the respondents, as shown in Fig 1. Only on advising the patients to report ADR did more than 50% (53.6%) of the respondents say “yes.” The practice of documenting ADR is poor, as only 35.8% said “yes” to documenting ADR. Less than 40% of the participants have ever reported ADR before, while only 29.1% have reported ADR since starting their internship program. Participants aged between 26-30 years have the highest number who have ever reported ADR (42.3%) and those who have reported ADR since they started the internship program (33.1%) Table 2. Documenting ADR and counseling patients to report ADR (56.0%) is higher among those aged greater than 30 years. However, age and degree are not significantly correlated with the practice of PV and ADR reporting. Reporting ADR (43.9%) and counseling patients to report ADR (56.5%) are more common among males than females, even though the females documents ADR more than the male respondents (75.5%). Pharmacist interns with a Pharm D degree are better in all areas of practice of PV and ADR reporting assessed. A higher number of the participants who have spent over nine months in their internship program said ‘Yes’ to the questions on the practice of PV, as shown in Table 2. Specialist hospitals, followed by tertiary hospitals and then military hospitals, have the highest percentage response of ‘Yes’ to the practice questions.

3.2 Modes of Reporting ADR among the Participants

The various modes of reporting ADR used by the participants are shown in Fig 2. Reporting through verbal information (61.1%) is the most widely used method, followed by direct reporting to management (29.7%). The use of online forms for reporting is also common either by physical form (29.7%) or online forms (12.8%). Reporting directly to the manufacturers (9.2%) is the least common method used for ADR reporting among the participants. 11.3% of the respondents use other unspecified methods and tools for reporting ADR.

3.3 Barriers towards Pharmacovigilance and ADR Reporting among the Participants

Lack of cohesion among healthcare professionals (SA=22.4%; A=52.5%) and unavailability of feedback from relevant authorities (SA=16.9%; A=49.8%) are the most reported barriers towards PV and ADR reporting among the participants, as shown in Fig 3. 42.3% of the respondents agree that the "fear of being wrong" is a barrier to their practice of PV and ADR reporting. Poor knowledge of pharmacotherapy is also a perceived barrier (SA=16.5% A=44.4%). Finally, the unavailability of yellow forms is the least reported barrier (A=12.3% SA=31.8%). 'Fear of being wrong' is significantly associated with the age, gender, degree, and duration of the internship program but not with the place of internship of the participants, as shown in Table 3. Participants between 26-30 years (SA=55.8% A=49.5%), who are females (SA=62.8 A=44.1), those with B. Pharm. (SA=45.3% A=99.0%) and those who have gone 7-9 months into the internship program (SA=60.8% A=56.4%) all agree that 'fear of being wrong is an essential barrier to PV and ADR reporting. This is also a significant barrier for participants in tertiary hospitals (SA=86.0% A=79.2%). Lack of cohesion among healthcare professionals, poor pharmacotherapy knowledge, unavailability of yellow forms, and feedback from relevant authorities have similar trends for participants in tertiary hospitals. Participants aged 26-30 years, who are females, are Pharm. B. degree holders; who have gone 7-9 months into their internship program and tertiary hospitals all have higher numbers choosing Agree and Strongly Agree towards the barriers of PV and ADR reporting.

Table 1. Summary of the sociodemographic characteristics of study population

Sociodemographic variable	Frequency (n)	Percentages (%)
Age (yrs)		
21-25	214	44.8
26-30	236	50.0
>30	25	5.2
Gender		
Male	278	58.2
Female	200	41.8
Degree		
Pharm. B	474	99.2
Pharm. D	4	0.8
Duration into internship program		
<4 months	34	7.1
4-6 months	133	27.7
7-9months	265	55.2
>9months	46	9.6
Place of internship		
Tertiary Hospital	380	79.2
Specialist Hospital	39	8.1
Military Hospital	20	4.2
Community Pharmacy	15	3.1
Others	23	4.8
Ethnicity		
Igbo	363	75.6
Yoruba	14	2.9
Hausa	17	3.5
Others	84	17.5
Religion		
Islam	20	4.2
Christianity	456	95.0
Others	2	0.4

4. DISCUSSION

This study assessed the practices and barriers toward pharmacovigilance and ADR reporting among pharmacist interns across Nigeria. To the best of our knowledge, this study is the first of its kind among pharmacist interns in Nigeria. ADRs cause morbidity, mortality, and a financial burden (extended hospitalization) on our fragile healthcare system. Recently, spontaneous reporting of ADRs is imperative for every citizen of Nigeria under the National Pharmacovigilance Program (NPP), which involves all healthcare workers like doctors, nurses, pharmacists & all patients [25]. Our study was conducted among pharmacists interns undergoing their one-year mandatory internship program in various healthcare settings and facilities across the country (Nigeria). Interns are front-line health care-worker in pharmaceutical care and are

upcoming pharmacists in the community; it is, therefore, a core part of their responsibility to encounter various adverse effects of drugs and note them down to PV or ADR monitoring centers [26].

Most participants are between the ages of 21 and 25 (44.8%), which corresponds to the average age of graduates in Nigeria. Almost all of the participants have Pharm. B. degree since there are currently only two pharmacy schools in Nigeria that offer the Pharm. D. program [19]. Fresh pharmacy graduates begin their internship program immediately, as proven by the results, which show that 55.2% of respondents have already completed 7-9 months of their internship program. Over 79.0% of the participants are pharmacist interns in tertiary hospitals nationwide. This is easily explained by the fact that tertiary hospitals across the country have the highest intake of interns each year because they can train them in terms of human resources and finances. Tertiary hospitals in various countries receive the highest health funding from their respective federal governments. This observation is also consistent with studies in Saudi Arabia, where 51.4% of respondents work in Ministry of Health (MoH) hospitals, which are classified as tertiary hospitals [23]. The significant representation of the Igbo ethnic group (75.6%) and christianity (95.0%) among participants reflects the large number of pharmacy schools operating in the country's southern region, as opposed to northern Nigeria, which is predominantly hausa and islam [19].

The practice of Pharmacovigilance was poor among the participants. Less than 40% of the participants have ever reported ADR before. This can be explained by the fact that the participants are fresh pharmacy graduates and have not had many opportunities to work in the health system. A similar study conducted among final-year students on pharmacovigilance in Nigeria posits almost non-existent practice of ADR reporting among the participants [27]. Many low- and middle-income countries face the challenge of low ADR reporting, as low ADR reporting generates minimum signals and thus lacks pharmacovigilance data [28].

On "whether the participant has reported ADR since the start of the internship," only 29.1% responded positively. This reflects a deplorable practice among the intern pharmacists. Works by Adisa & Omitogun, in 2019, reported a high awareness and positive attitude towards PV and ADR reporting [21]. However, such knowledge has not translated into acceptable practices. Possible reasons could be poor attitude despite the excellent knowledge and barriers to reporting, which will be discussed shortly. In work done among intern doctors in Sangli, India, good knowledge of ADR reporting did not translate into a marked increase in the practice of reporting ADR [26,29]. Under-reporting ADR is a severe concern for young professionals like pharmacist interns [30]. This is because new drugs are emerging in the pharmaceutical markets with older ones which could lead to masking reactions, thus paving the way to increased morbidity and mortality among patients [31].

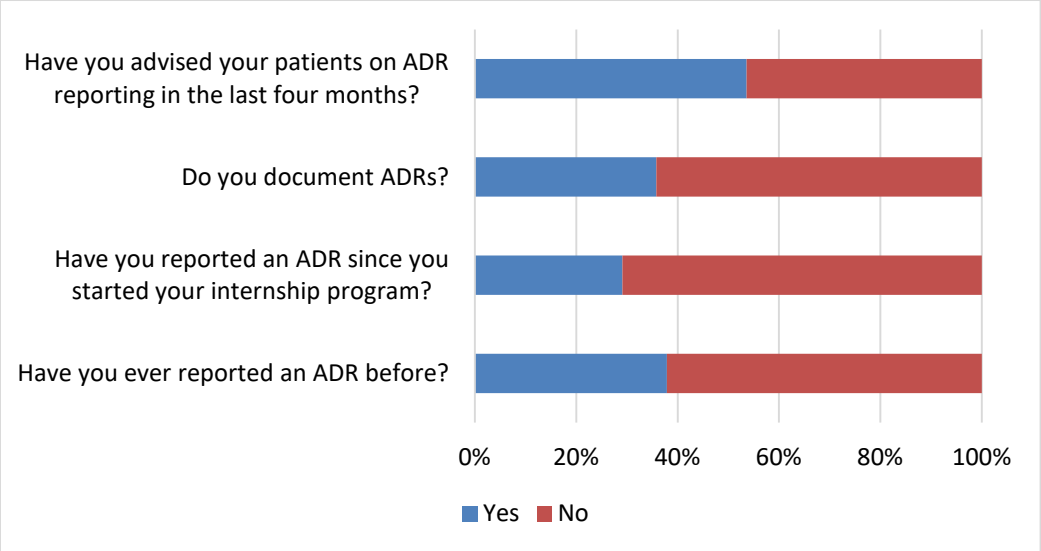

Fig. 1. Practice of pharmacovigilance and ADR reporting among the participants
ADR = Adverse Drug Reaction

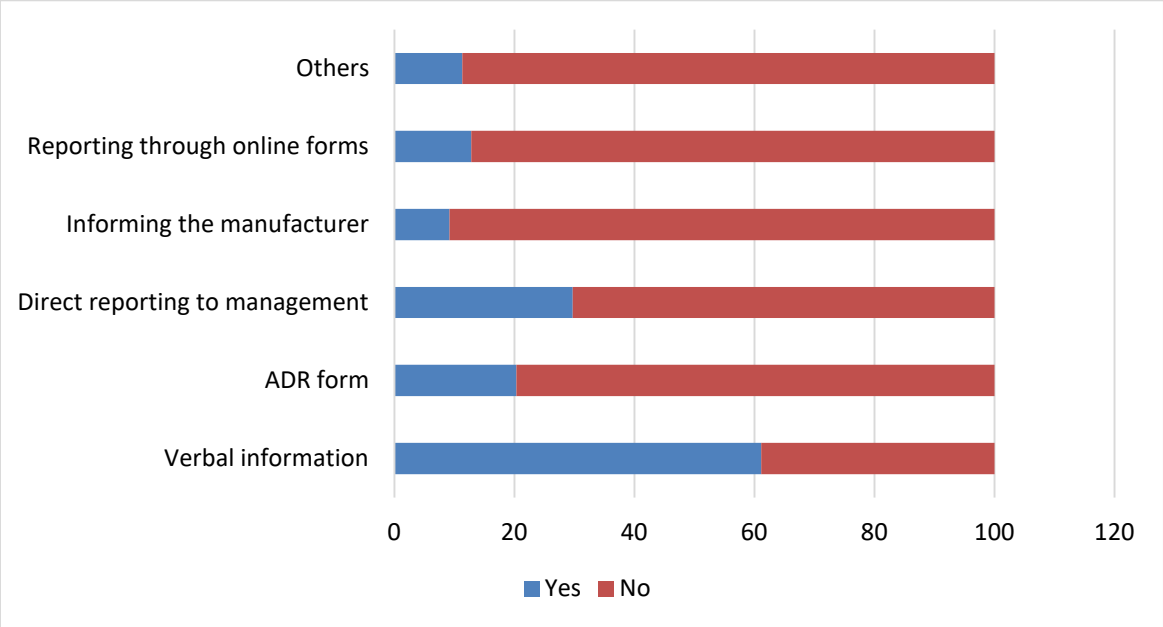

Fig. 2. Bar chart showing modes of reporting ADR used by the participants
ADR = Adverse Drug Reaction

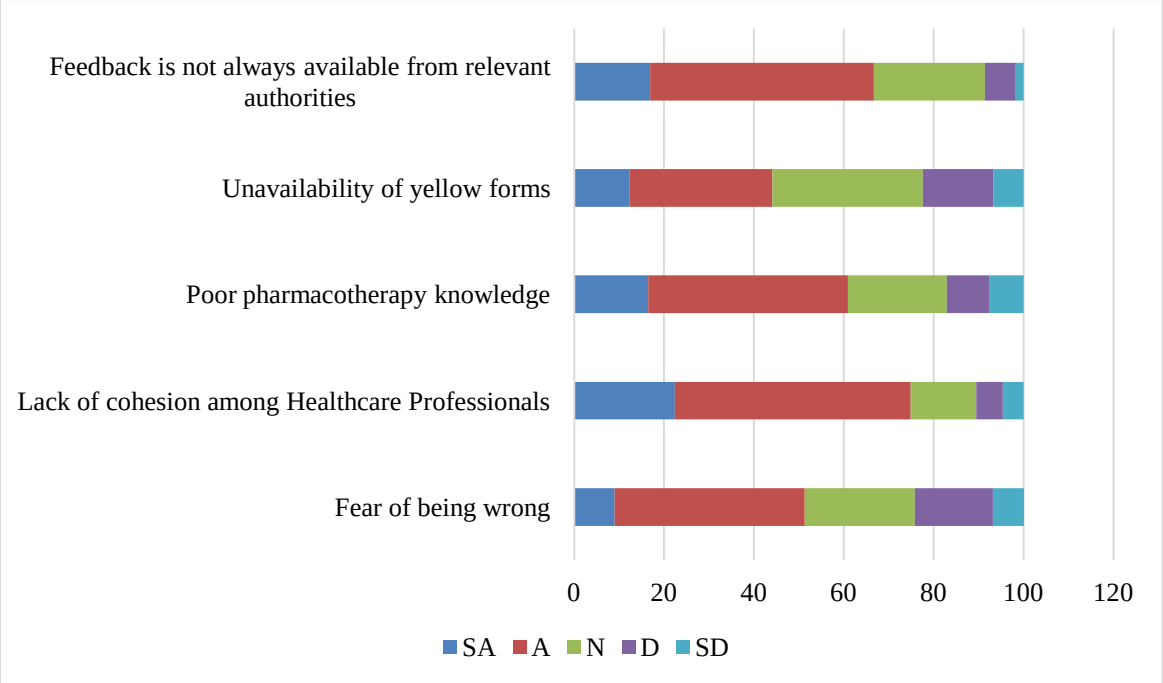

Fig. 3. Barriers towards pharmacovigilance and ADR reporting among the participants

A famous maxim in scientific circles says that "If it was not documented, then it was never done." Only 35.8% of the interns documented ADR. Not documenting ADR encounters poses a severe threat to drug and patient safety. Without such reports, further treatment cannot be guided, which could lead to drug safety problems [22,32]. Similar studies also reported low reporting among healthcare professionals despite encountering numerous ADRs during practice [33,34,35]. The participants used verbal information (61.1%) most of the time in reporting ADR. This finding correlates with the low level of documentation found among the interns who reported ADR in this study.

Table 2. Association between practice of pharmacovigilance and sociodemographic of participants

Socio-demographic Variable	Have you ever reported an ADR before?		Have you reported an ADR since you started your internship program?		Do you document ADRs?		Have you advised your patients on ADR reporting in the last four months?	
	Yes	No	Yes	No	Yes	No	Yes	No
Age (yrs)								
21-25	70 (32.7)	144 (67.3)	52 (24.3)	162 (75.7)	73 (34.1)	141 (65.9)	105 (49.1)	109 (50.9)
26-30	101 (42.3)	138 (57.7)	79 (33.1)	160 (66.9)	84 (35.1)	155 (64.9)	133 (55.6)	106 (44.4)
>30	10 (40.0)	15 (60.0)	8 (32.0)	17 (68.0)	14 (56.0)	11 (44.0)	18 (72.0)	7 (28.0)
X^2 (P value)	4.427 (0.11)		4.306 (0.12)		4.749 (0.09)*		5.257 (0.06)*	
Gender								
Male	122 (43.9)	156 (56.1)	90 (32.4)	188 (67.8)	103 (37.1)	175 (62.9)	157 (56.5)	121 (43.5)
Female	59 (29.5)	141 (70.5)	49 (24.5)	151 (75.5)	68 (34)	132 (66)	99 (49.5)	101 (50.5)
X^2 (P value)	10.230 (0.002)*		3.497 (0.04)*		0.471 (0.50)		2.275 (0.13)	
Degree								
Pharm. B	181 (38.2)	0	139 (29.3)	335 (70.7)	171 (36.1)	303 (63.9)	252 (53.2)	222 (46.2)
Pharm. D	293 (61.8)	4 (100)	0	4 (100)	0	4 (100)	4 (100)	0
X^2 (P value)	2.458 (0.12)		1.654 (0.25)		2.247 (0.30)		3.498 (0.06)*	
Duration into Internship Program								
<4 months	3 (8.8)	31 (91.2)	4 (11.8)	30 (88.2)	9 (26.5)	25 (73.5)	20 (58.8)	14 (41.2)
4-6 months	48 (36.1)	85 (63.9)	36 (27.1)	97 (72.9)	51 (38.3)	82 (61.7)	85 (63.9)	48 (36.1)
7-9months	104 (39.2)	161 (60.8)	74 (27.9)	191 (72.1)	86 (32.5)	179 (67.5)	134 (50.6)	131 (49.4)
>9months	26 (56.5)	20 (43.5)	25 (54.3)	21 (45.7)	25 (54.3)	21 (45.7)	17 (37.0)	29 (63.0)
X^2 (P value)	19.386 (<0.001)*		19.616 (<0.001)*		9.843 (0.02)*		12.160 (0.007)*	
Place of Internship								
Tertiary Hospital	134 (35.3)	246 (64.7)	105 (27.6)	275 (72.4)	120 (31.6)	260 (68.4)	191 (50.3)	189 (49.7)
Specialist Hospital	27 (69.2)	12 (63.9)	20 (51.3)	19 (48.7)	23 (59.0)	16 (41.0)	30 (76.9)	9 (23.1)
Military Hospital	9 (45)	11 (55.0)	7 (35)	13 (65.0)	17 (85.0)	3 (15.0)	20 (100)	0
Community Pharmacy	2 (13.3)	13 (86.7)	2 (13.3)	13 (86.7)	3 (20)	12 (80.0)	4 (26.7)	11 (73.3)
Others	9 (39.1)	14 (60.9)	5 (21.7)	18 (78.3)	8 (34.8)	15 (65.2)	11 (47.8)	12 (52.2)
X^2 (P value)	22.296 (<0.001)*		12.863 (0.025)*		35.331 (<0.001)*		33.379 (<0.001)*	

*ADR = Adverse Drug Reaction Chi square test of association (X2); *Significant difference exist between groups (p<0.01)*

Table 3. Association between barriers to pharmacovigilance and sociodemographic of participants

Sociodemographic Variable	Fear of being wrong		Lack of cohesion among Healthcare Professionals		Poor pharmacotherapy knowledge		Unavailability of yellow forms		Feedback is not always available from relevant authorities	
	SA	A	SA	A	SA	A	SA	A	SA	A
Age (yrs)										
21-25	19 (44.2)	93 (46.0)	36 (33.6)	121 (48.2)	32 (40.5)	101 (47.6)	28 (47.5)	65 (42.8)	36 (44.4)	99 (41.6)
26-30	24 (55.8)	100 (49.5)	63 (58.9)	120 (47.8)	43 (54.4)	103 (48.6)	30 (50.8)	78 (51.3)	42 (51.9)	125 (52.5)
>30	0	9 (4.5)	8 (7.5)	10 (4.0)	4 (5.1)	8 (3.8)	1 (1.7)	9 (5.9)	3 (3.7)	14 (5.9)
X^2 (P value)	26.0 (0.001)*		18.047 (0.02)*		18.150 (0.02)*		9.416 (0.31)		15.64 (0.48)	
Gender										
Male	16 (37.2)	113 (55.9)	50 (46.7)	150 (59.8)	35 (44.3)	135 (63.7)	34 (57.6)	97 (63.8)	34 (42.0)	153 (64.3)
Female	27 (62.8)	89 (44.1)	57 (53.3)	101 (40.2)	44 (55.7)	77 (36.3)	25 (42.4)	55 (36.2)	47 (58.0)	85 (35.7)
X^2 (P value)	11.481 (0.02)*		9.318 (0.05)*		43.21 (<0.001)*		13.077 (0.01)*		16.647 (0.02)*	
Degree										
Pharm. B	41 (45.3)	200 (99.0)	105 (98.1)	249 (99.2)	77 (97.5)	210 (99.1)	59 (100)	152 (100)	81 (100)	236 (99.2)
Pharm. D	2 (4.7)	2 (1.0)	2 (1.9)	2 (0.8)	2 (2.5)	2 (0.9)	0	0	0	2 (0.8)
X^2 (P value)	9.563 (0.048)*		2.392 (0.66)		4.342 (0.361)		8.017 (0.09)*		2.077 (0.72)	
Duration into Internship Program										
<4 months	2 (4.7)	16 (7.9)	5 (4.7)	21 (8.4)	1 (1.3)	19 (9.0)	2 (3.4)	9 (5.9)	0	21 (8.8)
4-6 months	12 (27.9)	61 (30.2)	35 (32.7)	59 (23.5)	16 (20.3)	62 (29.2)	12 (20.3)	36 (23.7)	21 (25.9)	69 (29.0)
7-9months	26 (60.8)	144 (56.4)	60 (56.1)	147 (58.6)	50 (63.3)	120 (5.2)	35 (59.3)	94 (61.8)	49 (60.5)	136 (57.1)
>9months	3 (7.0)	11 (5.4)	7 (6.5)	24 (9.6)	12 (15.2)	11 (5.2)	10 (16.9)	13 (8.6)	11 (13.6)	12 (5.0)
X^2 (P value)	21.118 (0.049)*		40.22 (<0.001)*		33.85 (0.001)*		26.04 (0.01)*		31.56 (0.002)*	
Place of Internship										
Tertiary Hospital	37 (86.0)	160 (79.2)	94 (87.9)	189 (75.3)	72 (91.1)	168 (79.2)	49 (83.1)	127 (83.6)	67 (82.7)	189 (79.4)
Specialist Hospital	3 (7.0)	14 (6.9)	6 (5.6)	24 (9.6)	2 (2.5)	20 (9.4)	6 (10.2)	17 (11.2)	5 (6.2)	24 (10.1)
Military Hospital	1 (2.3)	13 (6.4)	1 (0.9)	10 (4.0)	2 (2.5)	4 (1.9)	1 (1.7)	1 (0.7)	2 (2.5)	7 (2.9)
Community Pharmacy	1 (2.3)	7 (3.5)	1 (0.9)	13 (5.2)	1 (1.3)	7 (3.3)	1 (1.7)	2 (1.3)	1 (1.2)	5 (2.1)
Others	1 (2.3)	7 (3.5)	5 (4.7)	14 (5.6)	2 (2.5)	12 (5.7)	2 (3.4)	4 (2.6)	6 (7.4)	12 (5.0)
X^2 (P value)	28.45 (0.099)		25.80 (0.17)		28.60 (0.096)		48.42 (<0.001)*		38.80 (0.007)*	

*ADR = Adverse Drug Reaction Chi square test of association (X2); *Significant difference exist between groups (p<0.01)*

Healthcare professionals in work done by Hussain reported ADR verbally to management, while others reported on manual forms [22]. Another study in northern Nigeria described the same practices among healthcare professionals, including pharmacists [1]. Pharmacist interns with Pharm D degrees are better at ADR reporting than Pharm B degree holders. This is understandably clear as the core of the Pharm D program is pharmaceutical and patient care. Pharmacovigilance is taught and enforced through clinical clerkship in hospital settings [36,37,38]. The number of months participants have gone into the internship program is also associated with their practice of PV. Interns who have spent at least nine months had a high percentage of positive responses to practice questions. Professional experiences from the number of years of practice are a critical factor in reinforcing these measures. In many similar works across different professionals, those with many years of experience often outperform junior colleagues [33,39].

The practice of pharmacovigilance, however, is not without many challenges in Nigeria. Both professional, institutional, and government-engineered practices militate against ADR reporting in Nigeria [40]. Lack of cohesion among healthcare professionals and unavailability of feedback from relevant authorities are the two most important reported barriers to the practice of PV and ADR reporting among pharmacist interns in this study. Inter-professional cohesion is at the bedrock of clinical practice today. To deliver patient-centered care, a multidisciplinary team comprising pharmacists, doctors, and nurses must work together [41]. The World Health Professional Alliance (WHPA) has identified duplication, gaps, and discontinuity in services offered in healthcare systems (WHO, 2010). Collaboration in healthcare has been shown to improve patient outcomes by reducing preventable ADR and decreasing morbidity and mortality rates [42,43]. This, however, should be done with role clarity in mind and ultimate trust and confidence. Nurses and other healthcare professionals should report ADR to pharmacists and doctors for assessment before reporting to appropriate agencies.

The lack of feedback from relevant authorities is also a severe setback for ADR reporting in this study. In Nigeria, NAFDAC, through the NPC, must communicate and make recommendations and directives to appropriate organizations and individuals [25]. Such feedback is vital to support healthcare professionals in their decisions and reaffirm the relevance of reporting ADR [7]. Fear of being wrong reported by 42.3% of the respondents is also linked to poor inter-professional collaboration in ADR reporting. Poor access and nonavailability of the yellow form is a barriers to ADR reporting in this study. This was consistent with the findings of similar studies, in which access to ADR reporting yellow forms was challenging [16,17,44]. This could occur concurrently with the fundamental problems unique to low-income countries due to power supply and internet access challenges. Yellow forms are ideally issued by the National Pharmacovigilance Center (NPC), but copies can be obtained online or directly from any health institution. Therefore, improving access to ADR reporting forms may be possible by providing printed copies to hospitals and neighborhood pharmacies; this idea merits additional research.

As a drug expert, the pharmacist has a vital role in ensuring the safety of medicines through detecting and reporting ADRs [33]. Over the past few decades, the position of the pharmacist has changed globally based on the healthcare system, ranging from the dispenser to the guardian of medication safety.[27,33,45].

5. CONCLUSION

Based on this survey, the practice of Pharmacovigilance is poor among the participants. Many barriers also affect ADR reporting among the interns. Measures should be taken to encourage ADR reporting and the reported barriers should be reviewed to improve Pharmacovigilance activities. This needs a concerted effort involving both the government and pharmacist bodies to inculcate this discipline among intern pharmacists who are the future healthcare professionals.

6. LIMITATIONS

The major strength of this study is that it focused on an issue that has not been adequately studied, especially in Nigeria. The study also dug deep on the impact of duration of internship program and place of internship as independent variables. However, there are some limitations. The main limitation of this study that it is a cross-sectional study, so the causality could not be warranted. Secondly, the study was based on a self-reported questionnaire, so personal bias may have affected the results. Also, The sociodemographic of our participants is a bit

skewed as much data was not collected from the Northern part of the country which influenced the ethnicity and religion distribution of the participants. Also only about two Pharmacy Schools in Nigeria are currently running Pharm D. program which also affected the distribution of degrees held by the participants.

CONSENT

As per international standard or university standard, patient(s) written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX I: QUESTIONNAIRE

Sociodemographic of the Participants

1. Age (21-25yrs; 26-30yrs; >30yrs)
2. Gender (Male; Female)
3. Degree (Pharm. B; Pharm. D)
4. Duration into Internship Program (<4 months; 4-6 months; 7-9 months; > 9 months)
5. Place of Internship (Tertiary Hospital; Specialist Hospital; Military Hospital; Community Pharmacy; others)
6. Ethnicity (Igbo; Yoruba; Hausa; others)
7. Religion (Islam; Christianity; Others)

Different Types of ADR to be Reported (Yes, No, Don't know)

1. Suspected reactions
2. Reactions causing hospitalization
3. Reactions causing persistent disability
4. Minor reactions such as vomiting and diarrhea
5. Reactions to old drugs
6. Reactions to newly introduced drugs in the market

Practice of Pharmacovigilance and ADR Reporting (Yes, No)

1) Have you ever reported ADR before
2) Have you reported ADR since you started your internship program
3) Do you document ADRs
4) Have you advised your patients on ADR reporting in the last two months

Modes of Reporting ADR Used (Yes, No)

1. Verbal information
2. ADR form
3. Direct reporting to management
4. Informing the manufacturer
5. Reporting through online forms
6. Others

Barriers to Pharmacovigilance and ADR Reporting (Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree)

1) Fear of being wrong
2) Lack of cohesion among healthcare professionals
3) Poor pharmacotherapy knowledge
4) Unavailability of yellow forms
5) Unavailability of feedback from relevant authorities

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