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Original Work

The concept of adverse drug reaction reporting: awareness among pharmacy students in a Nigerian university

Johnson Segun Showande[Ψ] M Pharm and Fakeye Titilayo Oyelola PhD

Department of Clinical Pharmacy and Pharmacy Administration, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria

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ABSTRACT: Adverse drug reaction (ADR) is poorly reported globally but more in developing countries with poor participation by health professionals. Currently, there is no known literature on the Nigerian pharmacy students' knowledge on ADR reporting. Hence the purpose of this study was to find out the level of knowledge of pharmacy students on the concept of pharmacovigilance and adverse drug reaction reporting and also to evaluate their opinions on the National Pharmacovigilance Centre guidelines on adverse drug reaction reporting. A pretested 34-item semi-structured questionnaire was administered among 69 pharmacy undergraduate students in their penultimate and final years that consented to take part in the study, in one of the universities in Nigeria. The study was carried out strictly adhering to the principles outlined in the Helsinki declaration of 1964, which was revised in 1975. The questionnaire used had four sections which included a section on biographical data, a section which evaluated the students knowledge on the concept of pharmacovigilance and adverse drug reaction reporting, a section on students personal experiences of adverse drug reactions and modes of reporting them and the final section of the questionnaire evaluated the students' opinions on the National Pharmacovigilance Centre guidelines for reporting adverse drug reactions. Descriptive statistics, Mann-Whitney U and Kruskal Wallis statistical tests were used to analyze the data obtained. None of the participants knew the sequence of reporting ADR. More than half, 40(58.0%) had heard about pharmacovigilance at symposiums, 7(10.1%) during clinical clerkship program and 18(26.1%) from media jingles. Twenty nine (42.0%) agreed that pharmacovigilance was in their curriculum, however only 16(23.2%) could define the term correctly. None of the participants had seen or used an ADR form prior to the study, but the students could easily identify and describe the type of ADR they had personally experienced in detail, however, they did not know the channel of reporting it. Only 3% reported incidences of personal experience of ADR to the physician while another 3% reported cases of such to the pharmacist. There was a significant difference comparing students' year of study in the pharmacy program with their opinion scores on the National Pharmacovigilance Centre (NPC) guidelines on ADR reporting ($p < 0.05$). The lack of pharmacovigilance and adverse drug reaction reporting courses in the pharmacy school curriculum result in the poor knowledge of the students on the concept of adverse drug reaction reporting, nonetheless the view and knowledge they had garnered from different sources helped the students in identifying and describing ADR but this is not enough in properly documenting cases of ADRs. Thus, the poor knowledge on ADR reporting among the students requires speedy implementation of new curriculum incorporating pharmacovigilance to enhance the involvement of pharmacists in ADR reporting in Nigeria.

KEY WORDS: ***Students, Pharmacovigilance, Adverse drug reaction reporting, Nigeria***

[Ψ]**Correspondence at:** Department of Clinical Pharmacy and Pharmacy Administration, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria; Mobile: +2348027887608; Email: sj.showande@mail.ui.edu.ng

INTRODUCTION

Adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function[1]. It may result from the irrational use of medications[2-5] leading to hospitalization and increased economic burden to individuals and nations[6]. Adverse drug reaction has been shown to be the fourth to sixth principal cause of mortality in industrialized nations[7]. Despite this, about 95% incidences of ADR go undocumented worldwide[8,9]. However there is a dearth of information on ADR burden in developing countries like Nigeria[10].

For the proper monitoring and reporting of ADR, various countries have set up pharmacovigilance centres responsible for the monitoring of ADRs. The Nigeria National Pharmacovigilance Centre (NPC) established in 2004, is affiliated to the WHO international drug monitoring collaborating centre, Uppsala. One of the objectives of the centre includes creating awareness among health workers of the need to consider ADR reporting as one of their responsibilities[10,11].

Though, the Nigerian NPC guideline requires all health care workers including traditional medicine practitioners to report all suspected ADR, the few studies carried out in Nigeria showed that health professionals were less involved in the reporting of ADR[10,12,13]. In other studies, pharmacists have been shown to play important part in ADR reporting and other pharmacovigilance activities and were more likely to identify ADRs than other health care workers in various practice settings[14-16].

Oreagba et al[12] reported lack of training or inadequate training as one of the reasons adduced for poor knowledge on ADR reporting among community pharmacists in Nigeria. Another study in Malaysia showed that majority of final year pharmacy students had insufficient knowledge about pharmacovigilance and ADR reporting[17]. However, the involvements of pharmacy students in ADR reporting in some cases have contributed to increase in the number of documented ADRs[18].

As intending practitioners, pharmacy students need to be well grounded in pharmacovigilance activity, ADR reporting[15,18,19] and be familiar with their national pharmacovigilance centre guidelines[20,21]. Of the few studies conducted to evaluate students' knowledge and attitude on ADR reporting, none, to the best of our knowledge was available on Nigeria. The aim of this study was therefore to evaluate pharmacy students' knowledge of pharmacovigilance and ADR reporting and to assess their opinions on the NPC guidelines on ADR reporting.

METHODOLOGY

The study was carried out in September 2011 among pharmacy students in one of the Nigerian Federal Universities, University of Ibadan. Participants were drawn from the penultimate and the final year classes. The study was conducted at the end of the second semester examinations to ensure that all the students in their penultimate and final years had had all their lectures for the session signifying that the 400 level students (students in their penultimate year) were potential final year students while the final year students (500 level students) would soon graduate to be pharmacists. The study was carried out strictly adhering to the principles outlined in the Helsinki declaration of 1964, which was revised in 1975.

The questionnaire, which was the data collection instrument, was pre-tested among lower level pharmacy students and questions like religious affiliations and other professional qualifications were removed as suggested by the pharmacists in academia (lecturers) who reviewed the questionnaire. The results of the pre-test were not included in this study since the participants were not the primary targets of the study.

The questionnaire had four sections which included sections on demographic data, open and close ended questions to assess the level of knowledge of the student on pharmacovigilance and ADR reporting; a section on the personal experiences of the student with ADR and how it was reported while the last section was on ascertaining the participants' opinions on the guidelines for reporting ADRs by the NPC using a Likert scale with five graded responses ranging from strongly disagreed to strongly agreed. The reliability and internal consistency of the scales based on Cronbach alpha coefficient was between 0.7 and 0.8

The 87 students in the two classes were addressed separately on the study date and told the essence of the study and participation was made voluntary. Only 69 students who consented to take part in the study were given the questionnaires to fill.

The data collected were summarized with descriptive statistics: frequency and percentages, to evaluate participants' responses while Mann Whitney U and Kruskal Wallis tests were used to find the association between age, sex and year of study with the participants' opinion scores on the National Pharmacovigilance Centre adverse drug reaction reporting guidelines.

RESULT

The mean age of the respondents was 23.42 ± 2.603 (years ± SD). The response rate was 79.3% and the distribution of the respondents' age, sex and the

year of study are shown in **Table 1**. Among the students surveyed only 1 (1.4%) was married.

Table 1: Demographic distribution of participants

Demographic variables	Frequency distribution N (%)
AGE	
≤ 22 years	33 (47.8%)
23 – 24 years	18 (26.1%)
≥ 25 years	18 (26.1%)
SEX	
Male	33 (47.8%)
Female	36 (52.2%)
YEAR OF STUDY	
Fourth	45 (65.2%)
Fifth	24 (34.8%)
MARITAL STATUS	
Not married	68 (98.6%)
Married	1 (1.4%)

All the participants had heard of the term "pharmacovigilance" prior to the study but through informal avenues like symposiums 40 (58.0%), student organised seminars, 20 (29.0%), professional magazines 24 (34.8%), internet 12 (17.4%), industrial training posting 9 (13.0%), clinical clerkship posting 7 (10.1%) and National Agency for Food Drug Administration and Control (NAFDAC) media jingles 18 (26.1%) in various combinations. Twenty-nine (42.0%) of the students reported that pharmacovigilance and ADR reporting was in their curriculum. When asked to define pharmacovigilance using a standard definition such as that of the World Health Organization (WHO), 16 (23.2%) defined it correctly, 20 (29.0%) gave wrong definitions while 33 (47.8%) gave incomplete definitions. Some of the participants, 15 (21.7%), claimed to have seen the form used in reporting ADR, but when asked for the colour of the form, only one participant (6.7%) got the colour right. None of the respondent knew what the sequence of reporting ADR was. Likewise, no participant was aware of the WHO causality classification of ADR.

Forty-one (59.4%) of the students who took part in the study had personally experienced ADR prior to the study. The ADRs experienced include urticaria 16 (39.0%), weakness and dizziness 4(9.8%), nausea and vomiting 3 (7.3%), syncope 2 (4.9%), hyperpigmentation 2 (4.9%), severe headache 2 (4.9%), others include dyskinesia 1 (2.4%), palpitation 1 (2.4%), blurred vision 1 (2.4%), "peeling of the skin" 1 (2.4%), insomnia 1 (2.4%), tremor 1 (2.4%), dysphagia 1 (2.4%), stomach ache 1 (2.4%), mouth ulcer 1 (2.4%) and erythema multiforme 1 (2.4%). Some of the drugs that were implicated in these ADRs were: chloroquine 12 (29.3%), sulphadoxine-pyrimethamine 7 (12.2%), artemether-lumefantrine 4 (9.8%), cotrimoxazole 3 (7.3%), tramadol 2 (4.9%), and sulphamethoxazole 2 (4.9%). Other drugs were: amoxicillin 1(2.4%), amodiaquine 1 (2.4%), artesunate-amodiaquine 1 (2.4%), propranolol 1 (2.4%), artesunate 1(2.4%), erythromycin 1 (2.4%), amoxicillin-clavulanic acid 1 (2.4%), diclofenac 1 (2.4%), cyproheptadine 1 (2.4%), ferrous gluconate 1 (2.4%), amodiaquine-sulphadoxine-pyrimethamine 1 (2.4%), pyrimethamine-sulphametopyrazine (Metakelfin®) 1 (2.4%) and metronidazole 1 (2.4%).

The onset of action of these ADRs as experienced by the students varied from immediately after the administration of the drug, less than an hour, 1 (2.4%); to few hours after the administration of drug, less than 24 hours, 29 (70.7%) and days after the administration of the drug, more than a day, 11 (26.8%). Twenty-three (56.1%) of those who had personally experienced a form of ADR prior to the study reported the incidence to their parents 17 (73.9%), physicians 3 (13.0%) and pharmacists 3 (13.0%). These ADRs were alleviated by stopping the intake of the medication in twelve (29.3%) of the participants. Sixteen (39.1%) took another medication for the relief of the ADR, while 11 (26.8%) did not stop their medication but waited for the ADR to wear off. Other respondents, 2 (4.9%), could not remember what action they took. None of the ADRs experienced caused death but 5 (12.2%) of those who experienced ADR were hospitalized as a result of the ADR.

Though the participants in this study were unaware of the existence of national pharmacovigilance center guidelines on adverse drug reaction reporting, the final year students' opinions agreed more with some of the guidelines such as nurses, traditional medicine practitioners or any health care worker engaging in reporting adverse drug reactions (**Table 2**). However, there were significant differences in the association of the students' year of study with the participants' opinion scores on the NPC guidelines on ADR reporting ($p<0.05$) while there were no significant differences in the association of age and sex with the participants' opinion scores on the national pharmacovigilance center adverse drug reaction reporting guidelines $p>0.05$ (**Table 3**).

Table 2: Participants' opinions on some NPC ADR guidelines

	Strongly disagree N (%)	Disagree N (%)	Undecided N (%)	Agree N (%)	Strongly agree N (%)
Who should report ADR?					
Physicians	-	1 (1.4%)	1 (1.4%)	29 (42.0%)	38 (55.1%)
Pharmacists	-	-	1 (1.4%)	8 (11.6%)	60 (87.0%)
Dentists	3 (4.3%)	3 (4.3%)	18 (26.1%)	20 (29.0%)	25 (36.2%)
Nurses	4 (5.8%)	5 (7.2%)	11 (15.9%)	25 (36.2%)	24 (34.8%)
Traditional medicine practitioners	16 (23.2%)	6 (8.7%)	24 (34.8%)	9 (13.0%)	14 (20.3%)
Any health provider	10 (14.5%)	5 (7.2%)	18 (26.1%)	13 (18.8%)	23 (33.3%)
What are the basic principles of reporting ADR?					
Timeliness of reporting ADR	-	-	5 (7.2%)	23 (33.3%)	41 (59.4%)
Reliability of suspect judgement	-	-	6 (8.7%)	22 (31.9%)	41 (59.4%)
Completeness of report	-	-	3 (4.3%)	19 (27.5%)	47 (68.1%)
Steps in assessing possible drug related ADR					
Medical and drug history should be taken	-	-	4 (5.8%)	29 (42.0%)	36 (52.2%)
Other causes of ADR should be considered e.g. disease, food, herbs	-	-	7 (10.1%)	24 (34.8%)	38 (35.1%)
Drug related causes should be considered for ADR that is a new medical problem	-	2 (2.9%)	8 (11.6%)	35 (50.7%)	24 (34.8%)
Thorough physical and medical examinations should be carried out if necessary	-	1 (1.4%)	3 (4.3%)	35 (50.7%)	30 (43.5%)
Establishing onset of ADR is important	1 (1.4%)	1 (1.4%)	8 (11.6%)	27 (39.1%)	32 (46.4%)
Determination of the effect of dechallenge and rechallenge	1 (1.4%)	-	24 (34.8%)	28 (40.6%)	16 (23.2%)
Cross checking the pharmacology of the drug	-	-	9 (13.0%)	31 (44.9%)	29 (42.0%)

NPC – National Pharmacovigilance Centre, ADR – Adverse Drug Reaction

Table 3: Association between demographic characteristics and participants' opinion scores on some NPC ADR reporting guidelines

Demographic variables	**Total opinion scores for:**					
	Who should report ADR?		**Principles of reporting ADR**		**Steps in assessing possible ADR**	
	N (Mean rank)	*P*	N (Mean rank)	*P*	N (Mean rank)	*P*
AGE						
≤ 22 years	33 (34.80)	0.656[a]	33 (35.97)	0.597[a]	33 (36.22)	0.869[a]
23 – 24 years	18 (38.22)		18 (31.22)		18 (33.56)	
≥ 25 years	18 (32.14)		18 (37.00)		18 (34.03)	
SEX						
Male	33 (30.97)	0.108[b]	33 (34.76)	0.918[b]	33 (31.56)	0.170[b]
Female	36 (38.69)		36 (35.22)		36 (38.15)	
Year of study						
Fourth	45 (29.23)	0.01[b]	45 (31.47)	0.031[b]	45 (29.90)	0.004[b]
Fifth	24 (45.81)		24 (41.63)		24 (44.56)	

[a]Kruskall Wallis test, [b]Mann-Whitney U test, $P < 0.05$ was considered significant. NPC – National Pharmacovigilance Centre, ADR – Adverse Drug Reaction

DISCUSSION

Less than half of the participants in this study were not clearly sure if pharmacovigilance was one of the courses listed in their curriculum, showing that the students were not familiar with the contents of their curriculum. The current course outline, as listed by the Pharmacists Council of Nigeria (PCN) which is the regulatory body for pharmacy education and practice in Nigeria, did not contain pharmacovigilance as a course[22]. In addition, the University students' prospectus handbook which lists the course outlines at various stages of the undergraduate study did not contain pharmacovigilance or ADR reporting as a topic[23]. These may explain why the course was not taught to the students. Furthermore, the participants had heard about pharmacovigilance and ADR reporting through informal means like seminars, professional magazines, and during clerkship training but not through formal classroom lectures. At a stakeholders meeting in 2008 between pharmacy

professionals and the representative of the Minister of Health in Nigeria, the Doctor of Pharmacy (Pharm. D) programme for pharmacy students was adopted. New courses including pharmacovigilance were to be introduced[24], but up till the time of this study the new curriculum had not been implemented in twelve out of the thirteen pharmacy schools in the country. Nigerian pharmacy students are not the only one not well trained in ADR reporting. A study showed that the medical school curriculum was lacking in pharmacovigilance courses[25].

Students in the fourth and final years showed deficiency in knowledge on pharmacovigilance activities since only one quarter of the participants could define pharmacovigilance correctly according to the World Health Organisation definition[1,26]. None of the participants in the study had used a copy of the ADR-reporting form prior to the study. All the participants agreed that they do not know how to go about processing and documenting ADR report. This lack of adequate knowledge could translate to inadequate or lack of participation of these students in reporting ADR when they eventually become pharmacists. This may be one of the reasons why a study conducted among community pharmacists in Lagos, Nigeria, on knowledge and attitude to ADR reporting showed poor knowledge and participation in pharmacovigilance activities[12]. Nonetheless, poor knowledge in pharmacovigilance activities is not restricted to pharmacists and pharmacy students, medical students and physicians also showed the same trend as reported by Okezie & Olufunmilayo[13] where less than one third of the physicians surveyed in a city in Nigeria had ever reported an ADR. Ohaju-Obodo & Eribhogbe[27] also observed that more than three-quarters of resident doctors in another major city in Nigeria had inadequate knowledge about pharmacovigilance. Another survey among medical students in France showed that majority lacked knowledge of pharmacovigilance[28] and in a northern Italian district it was observed that physicians have little knowledge on ADRs and their reporting systems[29]. The reasons given were lack of knowledge that ADR reporting forms were available and ignorance of the reporting procedure.

A deficiency in ADR reporting is poor-reporting[30] even though this is a worldwide phenomenon; ADRs are much more under-reported in Nigeria[31]. This stems from lack of knowledge of professionals on pharmacovigilance activities and ADR reporting procedures as evidenced by various studies[12,13,27,31], and also noticed in the present study. Between 2004 and 2008 only 672 cases of ADR had been reported in Nigeria[32], a country with a population of 150 million.

Participants who had reported personally experienced ADRs to pharmacists and physicians were grossly low. This may be due to lack of awareness about the appropriate persons to report ADR to. The students showed good familiarity with what an ADR is. They easily described the types of ADR they had experienced and were able to identify the medications responsible. They were also able to identify the onset of the ADR and what was done to alleviate or stop the ADR. These knowledge are partly needed in conducting detail ADR reporting, however, the participants could not utilize this knowledge to conduct proper ADR report since it was not part of their curriculum. As stated by Nwokike[10] in his study that attention should shift from spontaneous reporting by health care workers to self-report or patient initiated reporting of ADRs; encouraging pharmacy students to self report incidences of personal experiences of ADR may motivate them into engaging in pharmacovigilance activities after graduation.

Probably based on the little knowledge the students had acquired from various sources on pharmacovigilance activities and related courses, the final year students' opinions on the national pharmacovigilance centre guidelines on adverse drug reaction reporting agreed more with some contents of the guidelines, though they were not aware of the existence of such guidelines prior to the study but were slightly more informed than the participants in the penultimate year.

CONCLUSION

Non inclusion of pharmacovigilance and ADR reporting in the pharmacy curriculum is probably ascribed with deficiency in knowledge of undergraduate pharmacy students in Nigeria on ADR reporting and other pharmacovigilance activities. As future pharmacy practitioners, pharmacy students need to be well grounded in pharmacovigilance activities to reduce the incidence of ADR under-reporting. Pharmacists Council of Nigerian in conjunction with the Nigerian University Commission should ensure the speedy implementation of the new curriculum which includes courses like pharmacovigilance to equip and encourage future participation of pharmacists in pharmacovigilance activities.

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