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Research Article

REPORTING OF ADVERSE DRUG REACTIONS: EVALUATION OF KNOWLEDGE, ATTITUDE AND PRACTICE AMONG HOSPITAL PHARMACISTS IN FEDERAL MEDICAL CENTRE, YENAGOA, BAYELSA STATE

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ABSTRACT

Spontaneous adverse drug reaction (ADR) reporting helps in the detection of serious, unexpected, and unusual ADRs. Healthcare pharmacists play an integral part in the success of every pharmacovigilance program. Even though the pharmacovigilance program of Nigeria was launched in 2001, the under-reporting of ADRs by pharmacists and other health professionals has been the bane of the program. Data on factors that contribute to the low reporting rate in FMC, Yenagoa, Bayelsa State Nigeria is however limited. The main objective of this study was to assess the knowledge, attitudes, and practice of ADR reporting among hospital pharmacists in FMC, Yenagoa. The study was a cross-sectional survey of 74 hospital pharmacists. The self-administered questionnaires were distributed and wordings were rephrased to eliminate any ambiguity. Information from the returned questionnaire was coded and entered into SPSS version 20 software. The results were presented as mean ± standard deviation, frequencies, and percentages. Tables and Charts were drawn with MS Excel, 2013. The knowledge of the pharmacists in the ADR reporting procedure was assessed by their answers to 12 specific knowledge questions. The score obtained by each respondent was graded as poor, average, good, very good, or excellent. The rate of ADR reporting was calculated by dividing the number of pharmacists who reported an ADR by the number who saw an ADR, and the result was multiplied by 100. The participant response rate in this study was 79.2%. Of the 71 pharmacists who completed the questionnaire, 49 (69.01%) had seen a patient with suspected ADR in the past year before the study, however only 16 (22.54%) of them reported them by completing the ADR form. Reasons given for not reporting the ADRs included "reaction commonly reported for the suspected drug" (36.62%). Refresher training on drug safety and ADR reporting, making available ADR forms, introducing electronic reporting of ADRs, and introducing pharmacovigilance as a major course in the pharmacy education curriculum were some of the strategies suggested by respondents to improve ADR reporting. The ADR reporting rate among hospital pharmacists in FMC, Yenagoa was 22.54%. The majority of pharmacists involved in this study had adequate knowledge of the reporting procedure. Lack of time or heavy workload and, the inability of some pharmacists to recognize and diagnose ADRs were some factors that contributed to the under-reporting of ADRs in the FMC, Yenagoa. *To further improve the reporting rate, refresher courses in drug safety and ADR reporting should be periodically conducted for hospital pharmacists. ADR reporting forms should also be made readily available in the wards, consulting rooms, and pharmacies, and pharmacovigilance training in pharmacy schools should be intensified to equip the newly trained pharmacist to diagnose and report ADRs to align with NAFDAC and WHO policy and guidelies.*

KEYWORDS: Attitude, Pharmacist, adverse drug reactions, health facilities, knowledge, pharmacovigilance, Nigeria.

INTRODUCTION

All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period. Certain side effects may only emerge once these products have been used by a heterogeneous population, including people with other concurrent diseases, and over a long period[1]. To ensure the safe and effective use of medicines, the

establishment of robust systems for reporting undesired side effects, known as "adverse drug reactions" (ADRs), is crucial[1]. Unfortunately, underreporting of ADRs is a common challenge in all reporting systems and therefore requires pharmacovigilance experiences to keep it checked.

An adverse drug reaction (ADR) is a harmful, unintended result caused by taking medication. ADRs may occur following a single dose or prolonged administration of a drug or may result from the combination of two or more drugs. The meaning of this term differs from the term "side effect" because side effects can be beneficial as well as detrimental. The study of ADRs is the concern of the field known as pharmacovigilance. According to the World Health Organization, Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem. Such drug-related problems include adverse drug reactions (ADRs), unintended injuries, or complications that arise from iatrogenic drug-related causes or prolong hospital admission and result in disability or death (WHO, 2006).

An adverse event refers to any unexpected and inappropriate occurrence at the time a drug is used, whether or not the event is associated with the administration of the drug. An ADR is a special type of Adverse Effect (AE) in which a causative relationship can be shown. ADRs are only one type of medication-related harm. Another type of medication-related harm type includes not taking prescribed medications, which is also known as non-adherence. Non-adherence to medications can lead to death and other negative outcomes. Adverse drug reactions require the use of a medication.

MAIN OBJECTIVE

I sought to explore the ways that ADRs are monitored or reported in Federal Medical Centre, Yenagoa, and how consumers and health care professionals participate in ADR monitoring and reporting.

METHODOLOGY

Study setting and population

The study was carried out in the pharmacy department, Federal Medical Centre, Yenagoa, Yenagoa Local government area of Bayelsa State, Nigeria. The study facility provides tertiary Health care services to inhabitants and indigenes of the state. This hospital was chosen for the study because it is the most populous and accessed facility by the masses in the region with about 2.28 million in population. The pharmacy department has various subunits such as Accident and Emergency, General Outpatient Department, Medicals, Surgicals, Paediatrics, Obstetrics and Gynaecology, Mental health care, and many others with Pharmacists delivering pharmaceutical health care. In total, the hospital has an estimated seventy-four (74) licensed Pharmacists. A total of 74 questionnaires were administered to the pharmacists who were willing to take part in the study and signed a consent form.

Study design

A descriptive cross-sectional design was used for this study using self-reported questionnaires.

Recruitment process

Participants recruited for the study were hospital pharmacists, FMC, and Yenegoa who reported their current experiences of ADR reporting at the time of the study. The total population of pharmacists at the time of the study was 74 out of which 62 (sample size) were recruited for the study. They were also given leaflets containing information about the study to create more awareness about it. Those who agreed to participate in the study then signed the informed consent forms and consequently completed the self-report questionnaire. Ten research assistants were involved in the distribution and retrieval of the consent forms and questionnaires from the participants as well as checking the study instrument to ensure that they were filled out completely.

Research instruments/tools

A semi-structured self-report questionnaire was designed based on the objectives of the studies. The questionnaires were written in both “open and closed-ended questions and were divided into four sections. The first section elicited responses on participants’ socio-demographics. The demographic features investigated were gender, marital status, age, and educational level of participants. The second section contains questions on the knowledge about ADR reporting by respondents, while the third section requested responses on the attitude toward ADR reporting. The fourth section sought to find out the perception of the respondents on possible ways of improving the ADR reporting rates in FMC, Yenagoa. This study instrument was adopted from similar studies which investigated the knowledge, attitude, and practice of reporting ADRs among health workers in Nigeria (Oshikoya & Awobusuyi, 2009), the United Arab Emirates (Lisha, et al., 2012), India (Kamtane & Jayawardhani, 2012), Portugal (Herdeiro, et al., 2006) and UK (Green, et al., 2001). The questionnaire was designed to capture among other information, duration of practice, type of hospital, information about knowledge, and practice of ADR reporting, and factors that may affect their willingness to report ADRs. The self-report questionnaires were designed and administered after validation. The questionnaire consisted of 39 items, frequency scales (“strongly agreed”, “agreed” “strongly Disagreed”, “Yes” or “No”).

Inclusion/Exclusion Criteria

The study population involved pharmacists in clinical practice with at least one year of practice experience. Hospital pharmacists were chosen for the study because they were likely to see ADRs since they are the category of healthcare professionals who will be notified in case of any adverse drug reaction, and also because the pharmacovigilance “contact persons” in the hospitals are mostly pharmacists hence they will be contacted if a reaction to a particular medicine is suspected. Only

pharmacists and intern Pharmacists, practicing and involved in manufacturing, both administrative and clinical duties, and logistics management within the tertiary hospital, Federal Medical Center (FMC) Yenegoa were included in this study. Pharmacists who are on annual leave, thus unavailable during the period of the study, and Pharmacy technicians will be excluded from the study.

Ethical clearance

Ethical approval was obtained and certified from the Research Ethics committee of the study location (Federal Medical Centre, Yenagoa) with reference Number: FMCY/REC/ECC/2024/JANUARY/670 before the commencement of data collection.

Power calculation (sample size calculations)

The sample size was calculated using the Taro Yamane formula, $n = N/1 + N(0.05)^2$.

Sampling techniques

A simple stratified random sampling was used to conduct the research. This simple random technique provided an unbiased and better estimate of the parameters. In the simple random sampling (lottery) method, each of the respondents sampled had an equal pre-assigned chance of inclusion in the study. Thus, it provided a better estimate of population mean, and median standard deviation (parameter) in the studies in comparison to purposive sampling (Singh and Masuku, 2012; Sarma, 2015)

Study procedures

A brief explanation of study objectives, an overview of the questionnaire, and an information sheet were explained to them. They were assured of their confidentiality, and each of them signed a consent form before they took part in the study. The questionnaires were personally distributed to respondents and only pharmacists employed at FMC, Yenegoa were surveyed. The questionnaires were retrieved after they were completed by the respondents. The total of licensed Pharmacists in the facility is 74 in number. Of these 74 questionnaires were administered to the pharmacists who were willing to take part in the study having signed a consent form. The filled instruments were retrieved by the researcher personally with a total of 71 respondents across the ranks of pharmacists. This study was done between 23rd December 2023 to 15th February 2024. Data entry was done using Microsoft Excel for data cleaning and transformation. Statistical/Data analysis was done using Microsoft Excel 2021 and SPSS version 29. Then, subsequently to SPSS for further analysis.

RESULTS

Demographic characteristics of respondents

The study carried out with 71 pharmacists in FMC Yenagoa, Bayelsa state reported the attendance of 53.52% male and 46.48% female pharmacists mostly within the age range of 26 to 30 years (45.07%), mostly married (56.34%) and had gathered an average of 1-5 years of experience in practice (46.48%). Participants also reported that most of the information they get on adverse reactions to new drugs is from journals (84.51%). Information on the demographic characteristics of the participants is contained in table 4.1. Table 4.2 and Figure 4.1 contain information on the intersecting relationship between reported sources of ADR in the study environment.

Table 4.1 Demographic characteristics of respondents.

		Count	%
Age	<20	0	0.00
	20-25	7	9.86
	26-30	32	45.07
	31-35	8	11.27
	36-40	15	21.13
	41-45	7	9.86
	46-50	2	2.82
Gender	Male	38	53.52
	Female	33	46.48
Marital status	Single	40	56.34
	Married	31	43.66
	Others	0	0.00
Rank	Pharmacist	35	49.30
	Snr. Pharmacist	12	16.90
	Princ. Pharmacist	24	33.80
	Ddps	0	0.00
	Dps	0	0.00
Experience	<1 year	14	19.72
	1-5 years	33	46.48
	6-10 years	8	11.27
	11-15 years	16	22.54
	>15 years	0	0.00

Table 4.2 Source of information on ADR to new drugs												
	Textbook		Journals		Internet		Medical reps		Seminars/ conference		Direct mail brochures	
	Count	%	Count	%	Count	%	Count	%	Count	%	Count	%
Textbook	43	60.56	36	50.70	21	29.58	28	39.44	29	40.85	15	21.13
Journals	36	50.70	60	84.51	29	40.85	35	49.30	36	50.70	17	23.94
Internet	21	29.58	29	40.85	40	56.34	14	19.72	28	39.44	11	15.49
Medical reps	28	39.44	35	49.30	14	19.72	35	49.30	21	29.58	7	9.86
Seminars/conferences	29	40.85	36	50.70	28	39.44	21	29.58	43	60.56	15	21.13
Direct mail brochures	15	21.13	17	23.94	11	15.49	7	9.86	15	21.13	21	29.58

Knowledge about ADR reporting

A low percentage of knowledge on pharmacovigilance (27.82+/-30.91%) was reported in this study. About 70.42% of the study population described pharmacovigilance as the detection, assessment, understanding, and prevention of adverse effects. Also, a low knowledge of ADR (32.748+/-38.509%) knowledge on ADR was reported with the best insight on referring to ADR as a noxious and unintended response to drugs and occurs at doses normally used in men for prevention, diagnosis, and therapy of disease (90.14%). About 86.622+/-23.22% level of familiarity with current trends in ADR and 79.58+/-21.98% with that of the intended purpose of the ADR reporting system was also reported. All the participants of this study reported obtaining ADR forms from the internet and from the NAFDAC office, and 97.18% claim to usually submit their filled ADR forms to the State Ministry of Health. This is shown in table 4.3 below.

Table 4.3 Knowledge about ADR reporting			
	Count	Percent	Std Dev.
Knowledge on pharmacovigilance			
The science of monitoring ADR's happening in a hospital	8	11.27	
The process of improving the safety of drugs	21	29.58	
The detection, assessment, understanding, and prevention of adverse effects	50	70.42	
The science detecting the type and incidence of ADR after the drug is marketed	0	0.00	
Average	27.82	30.91	30.91
Knowledge on ADR			
Noxious and unintended response to drug and occurs at doses normally used in man or animal for prevention, diagnosis, or therapy of disease	8	11.27	
Noxious and unintended responses to drugs occur at doses normally used in humans for the prevention, diagnosis, and therapy of disease	64	90.14	
Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment	14	19.72	
Any adverse reaction identified in regulatory documents such as investigators' brochures or product monographs occurring within the expected frequency	7	9.86	
Average	23.25	32.748	38.509
Knowledge on awareness			
Are you aware of any formal reporting system available in Bayelsa state?	29	40.85	
Have you heard about adverse drug reaction reporting in Bayelsa state?	71	100.00	
Are you aware of any drug that has been banned in the world due to ADR?	60	84.51	
Do you know where to send the reporting form after completion?	71	100.00	
Have you ever seen the form for reporting ADRs?	71	100.00	
What is the color of the ADR reporting form? Yellow?	67	94.37	
Average	61.5	86.622	23.223
Purpose of ADR			
To identify safe drugs	60	84.51	
To calculate the incidence of ADRs	27	38.03	

To identify predisposing factors to ADRs	53	74.65	
To identify previously unrecognized ADRs	71	100.00	
To serve as an information resource about the characteristics of the ADR	64	90.14	
For comparison ADRs of drugs within the same therapeutic class	64	90.14	
		79.58	21.98
Obtaining ADR form			
Contact persons in the hospital	46	64.79	
Download from the internet	71	100.00	
From the NAFDAC office	71	100.00	
Reporting ADR			
Nigerian medical and dental association	7	9.86	
Pharmacy Council of Nigeria	21	29.58	
Ministry of Health, state	69	97.18	
NAFDAC	16	22.54	

Attitudes towards reporting ADRs

All the study participants reported that ADR reporting is a professional obligation of a pharmacist and that ADR reporting would benefit the patient, but not very emphatic on the need for an increase in the number of reports (32.39%). The study also reported 91.55% experience of encouragement to reporting ADR by participants with consequent low experience of discouragement (10.79%) observed. Participants also suggested giving awards of credits for Continuous Professional Development for pharmacists (39.44%). Response patterns on the decision on who to make the ADR report in the health institution were almost evenly divided among medical doctors (53.52%), pharmacists (73.24%), and nurses (53.52%). A strong agreement to the necessity and mandatory nature of ADR reporting was also reported in the study. This is shown in table 4.4 below.

Table 4.4 Respondents Attitudes Toward Reporting ADRs

Obligation to ADR Reporting		**Count**	**%**
ADR reporting is a professional obligation of a pharmacist	Yes	71	100.00
Reporting of only one ADR makes no significant contribution to pharmacovigilance	Yes	23	32.39
Do you think that ADR reporting would benefit the patient?	Yes	71	100.00
Encouraging Factors			
if the reaction was serious	Yes	53	74.65
if the reaction was unusual	Yes	65	91.55
if the reaction was to a new product	Yes	71	100.00
if the reaction was well recognized for a particular drug	Yes	71	100.00
Average		65	91.55
Discouraging Factors			
Concern that the report may be wrong	Yes	4	5.63
Lack of time and heavy workload	Yes	18	25.35
Unaware of the reporting procedure and how the form can be obtained	Yes	0	0.00
No idea that ADRs are to be reported	Yes	0	0.00
The reporting form is not available in the hospitals	Yes	0	0.00
The occasional single case reported cannot contribute much to medical knowledge	Yes	0	0.00
All ADRs are well documented before medicines are placed on the market	Yes	9	12.68
Inability to recognize or diagnose ADRs	Yes	44	61.97
Fear of being legally accused of administering the wrong drug	Yes	2	2.82
Fear of the negative impact the report may have on the company that produces the drug	Yes	4	5.63
Lack of confidence in the reporting system	Yes	11	15.49
No reward or recognition for the pharmacist who reports ADRs	Yes	0	0.00
Average		7.67	10.79
Considerable Rewards			
Award credits for Continuous Professional Development	Yes	28	39.44
Publish the name of the pharmacist in a local scientific journal	Yes	0	0.00
Others	Yes	0	0.00

Who Should Report			
medical doctor	Yes	38	53.52
Pharmacist	Yes	52	73.24
Nurse	Yes	38	53.52
Surety For ADR Reporting			
ADR reporting is necessary	SA	71	100.00
ADR reporting should be mandatory	SA	71	100.00
ADR reporting increases patient safety	SA	71	100.00
ADR is time-consuming	SA	60	84.51
Side effects like headache fever and vomiting should not be reported.	SA	28	39.44

Practice Towards ADR Reporting

Suggestions for improvement of ADR reporting, according to the study, were the need for the provision of a designated ADR contact person in every hospital (100%), the confidentiality of the reporter and prescriber should be kept a secret (77.46%), and the need for the introduction of mobile apps for ADR reporting (6056%). The study also reported a poor level of possession of the ADR form in hospitals (9.86%) with a consequent low rate of active case reporting (22.54%) in the study population. Participants also claim to have shared ADR information with others (100%), mostly when it comes to serious reactions to established products (100%). Reasons for not reporting ADR were those considering drug reactions as "normal" (36.62%), or as "not important/serious" (36.62%), and not knowing that one was supposed to make a report (32.39%). This is shown in table 4.5 below.

Table 4.5 Practice Towards ADR Reporting

Suggestion for improvement of ADR	**Count**	**%**
Continuous professional education, training, and refresher courses	42	59.15
Introduce pharmacovigilance and ADR reporting into pharmacy school curriculum	41	57.75
Publicity about ADR reporting in the local scientific journals	64	90.14
Designated ADR contact person in every hospital	71	100.00
Introduce mobile apps and online reporting of ADRs	43	60.56
The identity of the reporter and prescriber should be kept a secret	55	77.46
Others	20	28.17
Involvement in Active ADR Reporting		
Do you have the reporting form in your hospital?	7	9.86
Have you ever shared information about ADRs with anyone?	71	100.00
Have you ever been trained on drug safety and reporting ADRs?	67	94.37
Should all ADRs be reported for newly marketed agents?	69	97.18
Have you ever been trained on drug safety and reporting ADRs?	67	94.37
Serious reactions should be reported for established products	71	100.00
Have you seen a patient with an ADR in the past year?	49	69.01
If "YES", did you report the ADR by completing the form?	16	22.54
Reasons For Not Reporting ADRs		
I did not know I was supposed to report	2	2.82
I do not know the reporting procedure	0	0.00
The reporting form was not available	0	0.00
I did not have time to report	0	0.00
I did not think it was important/serious	23	32.39
The reaction is very commonly reported with that medication so I considered it "normal"	26	36.62
Others	8	11.27

DISCUSSION

The rate of adverse drug reaction reporting among the hospital pharmacists studied in Federal Medical Centre, FMC, Yenagoa, Bayelsa State was 22.54%.; lower than the 42.5% found in the study carried out in Northern Nigeria (Fadare, et al., 2019). the 41% found in medical practitioners in India (Ramesh & Parthasarathi, 2009), the 21% found among doctors in the Greater Accra Region of Ghana (Sabblah, 2012), and 14.7% among pharmacists in Hong Kong (Lee, et al., 1994).

The top two reasons given by pharmacists who failed to report suspected ADRs were complacency i.e. the belief that the reaction was commonly reported so considered normal (36.62%) and those who thought it was not important or serious (32.39%). This finding was not similar to the observation in a similar study among

pharmacists in Ibadan, Nigeria where it was found that unawareness of the presence of the ADR form and ignorance of the reporting procedure prevented reporting among pharmacists (Enwere & Fawole, 2018).

These findings suggest that training, reporting of serious reactions for established products, and sharing of information about ADRs with anyone, have the potential to increase ADR reporting. Interestingly, 69.01% of the forty-nine respondents who said they saw an ADR were trained in drug safety and ADR reporting. Of this number, only 22.54% (n=16) reported an ADR in the year before the study. However, there was no statistically significant difference between training and ADR reporting (X2=2.167, p=0.141) in this study. Training was found in other studies (Figueiras, et al., 2016) to be a positive determinant of ADR reporting. Figueiras, et al., 2016 found that an hour-long training for pharmacists increases ADR reporting ten-fold within the first twelve months following the training (95% CI 3.81-27.51). Another study in Great Britain (Green, et al., 2011) evaluating attitudes and knowledge of hospital pharmacists in reporting adverse drug reactions also found that pharmacists who are trained in ADR reporting were more likely to report than those not trained (P0.0001, 95% CI, 15.4-36.7%).

It was also observed from this study that even though pharmacists participated more than other ranks, there was no statistically significant difference in ranks and ADR reporting (X2 = 3.049, p = 0.384). Again, there did not appear to be a relationship between ADR reporting and level of practice (X2 = 1.292, p = 0.524), or place of practice (X2 = 0.624, p = 0.732), or age (X2 = 4.106, p = 0.534), contrary to findings by the study of Irujo, et al., 2017 who observed that factors which were positively associated with ADR reporting were age, years of work experience as a pharmacist, and participation in educational activities related to drug safety.

The knowledge of respondents about the reporting system was excellent with 100% (n=71) having an excellent to good level of knowledge from the knowledge score. The level of knowledge obtained from this study was however higher than what was found by Sabblah et al in their study, where 59.3% of doctors and Pharmacists in the Greater Accra Region had either excellent or good knowledge of the reporting system in Ghana. It can be observed that knowing what to report, and how to report it is a positive factor in reporting ADRs because in the Sabblah study, 59.3% of respondents who had at least a good knowledge of the reporting system produced a reporting rate of 21%, while 100% of respondents in this study with at least a good knowledge produced a reporting rate of 22.52%. Therefore, refresher courses in pharmacovigilance and ADR reporting systems could improve the reporting rate among pharmacists in the study facility.

The perception of pharmacists about the benefits of adverse drug reaction reporting is positive, with all of them agreeing that ADR reporting could be beneficial to patient drug safety, 100% (n=71) agreeing that it is their professional responsibility to report ADRs, and also believe ADR reporting should be made compulsory for all pharmacists. Other health professionals whom respondents believed should also report ADRs are doctors, nurses, and other health practitioners in that order. It was found in the Lisha, 2012 study that only 31% of doctors in the United Arab Emirates see ADR reporting as their professional responsibility and only 57% of them agree that ADR reporting should be compulsory. Kamtane, 2012 also found that 93.61% of physicians in India agree that ADR reporting and monitoring systems would benefit the patient, with 85.1% of them agreeing that ADR reporting should be made mandatory. In the study by Green et al, 2001, only 50% of hospital pharmacists in Great Britain felt ADR reporting should be made compulsory, even though 75% agreed that reporting ADRs is their professional responsibility. The Sabblah study found that only 3.6% of doctors felt ADR reporting was their professional responsibility, with 70% preferring pharmacists to report instead. It can therefore be observed in this study that the high sense of responsibility among the respondents was evident in the reporting rate that was found, which is higher than those found in the studies earlier mentioned.

The major factors that would encourage a pharmacist to report a suspected ADR were if the reaction was well recognized for a particular drug 100% if the ADR is unusual (91.55%), and serious (74.65%). This finding was similar to those observed in the Green study, Lisha study, and Lee study, in Great Britain, the United Arab Emirates, and Hong Kong respectively. This finding was also consistent with reasons given by respondents who did not report a suspected ADR in this study, the highest being that the reaction was commonly reported for that medicine hence they did not report it. This belief is in contrast with the guidelines from the FDA on ADR reporting, which directs health professionals to report even if the reaction is known to be associated with the suspected drug, and even if the reporter is not sure the reaction is caused by the suspected medicine. The fact that some respondents did not know means more training is required if more gains are to be made in the area of pharmacovigilance in the region.

The top three factors found from this study that may deter a pharmacist from reporting an ADR were the inability to recognize or diagnose ADRs (61.97%), lack of time or heavy workload (25.35% of cases), and lack of confidence in the reporting system (25.49%). Similar findings were observed in the Sabblah study, where lack of time and heavy workload were the main barriers to ADR reporting. However, “lack of confidence in the reporting system” was mentioned more frequently by respondents than the absence of a reporting form in the Sabblah study as a barrier to ADR reporting. In the Lisha study, however, the top three factors that discouraged doctors from reporting

were found to be respondents not knowing how to report, non-remuneration for reporting, and lack of time to actively look for ADRs. In another study among hospital pharmacists in Great Britain (Sweis & Wong, 2000), it was found that being busy at work, lack of confidence in recognizing ADRs, and fear of breaching patient confidentiality were deterring factors from reporting ADRs. It can therefore be observed from the study that factors that discouraged ADR reporting differ from one country to the other and from one region to another.

The respondents' perception of how reporting can be improved included mainly publicity about ADR reporting in the local scientific journals, designated ADR contact persons in every hospital, and training, and sending periodic reminders to health professionals about ADR reporting from the national pharmacovigilance center. They also believed that dedicating more teaching hours to pharmacovigilance in pharmacy schools across the country would improve the confidence of the pharmacist in recognizing and hence reporting suspected ADRs. This finding is similar to that observed by Ramesh et al in India, Sabblah et al in Ghana, Herdeiro et al in Portugal, Sweis et al, and Green et al both in Great Britain who all find training as the best means of improving the rate of reporting ADRs.

Some (60.56%) of respondents also agreed that the introduction of electronic reporting of ADRs, e.g. cell phone text messaging, email, and telephone call reporting can also improve the reporting rate. This finding was consistent with a study by Lynn et al, in comparing the traditional yellow card (APPENDIX) system to a piloted email system, observed that ADRs in 67 children were reported by email compared to only 8 children whose ADRs were reported using the MHRA yellow card system, and respondents in that study were more willing to use the electronic reporting system (Lynn, et al., 2017). The pharmacists in this study also believed that rewarding reporters of ADRs can motivate them to do more. This, they believed can be done through giving (CPD) credits awards for continuous professional development (39.44%). But other studies viewed these rewards to be by publishing the name of the reporter in journals and periodicals of pharmacovigilance (61.8%), and then financial rewards for reporters. The Food and Drug Authority already has a newsletter called the DrugLens which is published once a year, in which pharmacovigilance activities and a summary of ADR reporting trends and patient outcomes from drug reactions are shared with healthcare professionals. Persons who contribute immensely to the success of the program are acknowledged in this newsletter. The fact that most respondents do not know this already means the coverage of Drug Lens is not adequate. Therefore, if the circulation of the FDA periodical on pharmacovigilance is increased then more awareness could be created among healthcare professionals.

CONCLUSION

The ADR reporting rate among hospital pharmacists studied in the Federal Medical Centre, Yenagoa, Bayelsa State was 22.54%. Hospital pharmacists in FMC, Yenagoa, Bayelsa State had adequate knowledge of the ADR reporting procedure. Lack of time or heavy workload, absence of an ADR reporting form, and the inability of some pharmacists to recognize and diagnose ADRs were some factors that contributed to the under-reporting of ADRs in the FMC, Yenagoa.

RECOMMENDATIONS

ADR reporting forms must be readily available in the hospitals and scheduled reporting by pharmacists must be instituted and monitored.

- The NAFDAC should increase the number of training in pharmacovigilance for hospital pharmacists to improve their capacity in diagnosing and reporting ADRs.
- Pharmacovigilance training in pharmacy schools should be intensified to align with the FDA policy.
- Other forms of ADR reporting, like smartphone Apps, could also be implemented.
- Because this study involves just one region out of ten, it will be necessary to conduct this study among pharmacists in other regions and results compared before findings can be generalized.

CONTRIBUTION TO LITERATURE

This study's findings have contributed to an existing body of knowledge that cough and other minor reasons are implicated in the management of pharmacovigilant in this part of the world.

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CONFLICT OF INTEREST

The researchers declare that there was no conflict of interest.

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