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ATTITUDE AND PRACTICE OF DOCTORS TOWARD ADVERSE DRUG REACTIONS (ADRs) REPORTING IN A NIGERIAN TERTIARY HEALTH FACILITY

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ABSTRACT

***Background*: Adverse drug reactions, (ADRs), constitute an important cause of morbidity and mortality worldwide. Spontaneous adverse drug reaction (ADR) reporting is the bedrock of post-marketing surveillance but under-reporting remains its major drawback.**

***Objectives*: This study aimed at evaluating the attitude and practice of ADR among doctors in a tertiary health facility in Oyo State, Nigeria, with a view to improving ADRs reporting.**

***Methods*: This was a cross-sectional questionnaire based study involving medical doctors working at the Ladoke Akintola University of Technology (LAUTECH) Teaching Hospital, Ogbomoso. Consenting doctors were evaluated on their attitude and practice of ADRs through self-administered questionnaire. Data obtained were entered and analyzed using SPSS version 17.**

***Results*: A total of 35 doctors responded to the questionnaires. Only about 57.1% considered ADR before prescribing, all of whom were also aware of the procedure for reporting. Awareness of the existence of National Pharmacovigilance Center (NPC) was 71.4%. Thirty (85.7%) of the respondents have encountered ADR, but only 2.9% have ever reported it with yellow form. Majority (85.7%) of the respondents did not consider ADR reporting as a useful tool in the prevention of drug related morbidities and mortalities. Other factors that may hinder ADR reporting include: lack of awareness of the existence of yellow forms for reporting (68.6%) and poor knowledge of procedure for reporting (48.6%).**

***Conclusion*: ADR reporting rate was very low among the participants in this small study; large studies aimed at evaluating the determinants of ADR reporting should be considered. Should these findings be confirmed, training and re-retraining through Continuing Medical Education (CME), and establishment of pharmacovigilance committee would be required to ensure a national pharmaovigilance system.**

Keywords: Adverse drug reactions, Attitude, Practice, Reporting, Clinical Pharmacology

INTRODUCTION

Adverse Drug Reactions (ADRs) constitute an important cause of morbidity and mortality affecting all age groups. An ADR is any noxious, unintended and undesired effect of a drug, which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or the modification of physiological functions.[1] It is known that ADR may occur with any drug even when used correctly.[2] However, certain factors may predispose or contribute to development of ADR and these may include: irrational use of drugs and poor prescribing patterns; promotional activities by pharmaceutical company; inadequate access to objective sources of information; liberal drug outlets and unhealthy pharmaceutical practices; self-medication practices; "drug gifts" from overseas; lack of public awareness and low literacy level .[3]

The burden of ADRs is borne by all populations and throughout the world is expected to be higher in developing countries because of ignorance, poverty, self-medication and increase prevalence of fake and adulterated medicines.[4] The economic burden of ADRs on the society is enormous, for example, in the

US, an estimated annual cost of drug-related problems is 30 billion Dollars.[5]

Consequent upon the thalidomide disaster, drugs are only approved for the use of humans after they have been properly evaluated and found to be safe. This pre-marketing evaluation of drugs has some major drawbacks: there is under-estimation as adverse drug reactions with incidence of less than 1% are frequently not identified; there is selection bias imposed by the standard protocols of clinical trials; and there is incomplete or lack of information on chronic toxicity.[6,7] Post-marketing surveillance is a very important tool for ensuring safety of drugs and complements the clinical drug evaluation done before approval. It is instructive that when drugs are administered to all populations the probability of adverse and other drug-related problems will manifest more easily than during the clinical evaluation stages. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other drug related problem.[7]

The role of medical doctors is vital in recording and reporting suspected ADRs in order that regulatory agencies are alerted of emerging safety concerns and thereby facilitating timely and appropriate action. Evaluating the attitude and practice of doctors may assist in developing strategies to improve ADRs reporting.

METHODOLOGY

Setting

The study was conducted at LAUTECH Teaching Hospital, Ogbomoso, Nigeria. The hospital provides medical services to communities in Oyo and the neighbouring Kwara and Osun States. Presently, the hospital does not have a consultant grade Clinical Pharmacologist and pharmacovigilance committee.

Design and data collection

This was a cross-sectional study involving doctors who were surveyed with a questionnaire. The self-administered questionnaire sought details of biosocial information of the consenting doctors and the elements of attitude and practice of ADRs.

Data analysis

Data obtained were entered into SPSS version 17 software for analysis. The results were presented as mean ± standard deviation for quantitative variable and numbers with percentages for categorical variables. Tests of association between categorical variables were determined with the Fisher's exact test and continuous variables with student's t-test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Thirty-five consented medical doctors participated in the study. The mean age of the respondents was 32.1±4.7years.Only 8 respondents were females whereas the remaining 27 were males. The mean years of practice was 5.9 years, and majority of respondents 26 (74.3%) had practised for between 3-6 years. More than one-quarter of the respondents were in family medicine, 10 (28.6%), Internal medicine, 5 (14.3%), Surgery, 2 (5.7%), Paediatrics, 4 (11.4%), Obstetrics and Gynaecology, 5 (14.4%), Psychiatry, 2 (5.7%), Ophthalmology, 2 (5.7%), Laboratory Medicine, 3 (8.6%) and others who did not indicate their specialty, 2 (5.7%). More than three-quarter of the respondents 27 (77.1%) were Registrars, 2(5.7%) were Senior Registrars and 6(17.2%) were Consultants.

Majority of the respondents, 30 (85.7%) agreed that ADR constitute an important problem in medical practice but only 20 or 57.1% of all the respondents

Table 1: Demographic data of the respondents

Variable	Response
Gender	
Male	27(77.1%)
Female	8(22.9%)
Age	
Mean	32.1 ± 4.
Year of experience	
Mean	5.9 ±2.5

Table 2: Relationship between the cadre of respondents and reporting of suspected ADR with yellow form

Cadre of Respondent	Yes	No	Total	Fisher's Exact test
Residents	1	28	29	0.829
Consultants	0	6	6	
Total	**1**	**34**	**35**	

Table 3: Relationship between the specialties of the respondents and reporting of suspected ADR with yellow form

Specialties	Yes	No
Family medicine	0(0.0%)	10(100.0%)
Internal medicine	0(0.0%)	5(100.0%)
Surgery	0(0.0%)	2(100.0%)
Paediatrics	0(0.0%)	4(100.0%)
Obs. & Gyn	0(0.0%)	5(100.0%)
Psychiatry	0(0.0%)	2(100.0%)
Ophthalmology	0(0.0%)	2(100.0%)
Laboratory medicine	1(33.3%)	2(66.7%)
Others	0(0.0%)	2(100.0%)

Table 4: Suggested ways of improving ADR reporting

Suggest possible ways of improving ADR reporting	Number of respondents	Percentage
Increase awareness via CME	10	28.6
Inclusion in the under- and post-graduate training curriculum	1	2.9
Yellow forms for reporting must be readily available	4	11.4
Training and retraining of medical personnel	6	17.1
Lecture and publicity	3	8.6
Incorporate it into employment procedure	1	2.9
Set up pharmacovigilance team in hospital and clinical presentation of previously documented ADRs etc.	3	8.6
No response	7	20.0
Total	**35**	**100.0**

considered ADR before prescribing for patients. The awareness of procedure for ADR reporting was low among respondents, 17 (48.6%). Majority 25 (71.4%) of the respondents were aware of the National Pharmacovigilance Center (NPC) but only 20 (57.1%) were aware of the ADR form and procedure. Thirty respondents (85.7%) have observed a suspected ADR in their practice but only 1 (2.9%) have ever reported it with yellow form. Respondents' views on factors that may hinder ADR reporting were: not knowing ADR should be reported 4 (11.4%), information on ADR is not useful 30 (85.7%), not sure of the type of ADR to report 10 (28.6%), lack of awareness of the forms for reporting 24 (68.6%), complexity and time-consuming ADR form 3 (8.6%), uncertainty about reaction related to drug 17 (48.6%), fear of litigation 5 (14.3%), lack of remuneration (11.4%), report generate extra work 6 (17.1%), lack of time to actively look for ADR while at work 8 (22.9%) and the negative impact the reporting will have on the drug manufacturer 4 (11.4%). In all, 31(88.6%) of the respondents agreed that ADR reporting is a professional obligation. There was no statistically significant relationship between respondents' cadre and reporting of ADRs with yellow form as shown in table 2 (p =0.829). The respondents' specialties and reporting of suspected ADRs with yellow form is shown in table 3. Only 3 (8.6%) respondents have been trained on how to report ADR.

Suggested ways of improving ADR reporting were: training on ADR reporting and increase awareness through the Continuing Medical Education (CME) 10 (28.6%); training and retraining of medical personnel 6 (17.1%); making yellow forms readily available in the hospital 4 (11.4%); setting up a pharmacovigilance committee 3(8.6%); increase awareness of ADR reporting through public lecture and mass media publicity 3 (8.6%); inclusion of the pharmacovigilance training in undergraduate and postgraduate training curriculum 1(2.9%); incorporation of the training into pre-employment orientation programme 1(2.9%).

DISCUSSION

In this study, less than 60% of the consenting physicians returned the questionnaire though, the response rate was similar to an earlier report in Nigeria.[8] Of the respondents, consultants constituted 17.2%, an impressive proportion, given the fact that consultants are rarely invited to participate in such surveys. Majority of the respondents appreciated the importance of ADR in medical practice but fewer of them actualize such appreciation in their practice. The reason was not immediately obvious but the lack of emphasis of pharmacovigilance in the undergraduate and postgraduate medical curricula may have contributed. Other possible reasons may include: poor knowledge of the procedure for reporting and lack of awareness of the existence of yellow forms for reporting.[8]

The level of awareness of ADR reporting process was low and was similar to findings from similar studies in Nigeria,[8-13] thus suggesting major information gaps. The study center was just established with no pharmacovigilance committee and no programme on ground for ADRs reporting. This may be responsible for the respondents' low level of awareness. It is interesting to note that Awodele *et al.*[14] reported a dissimilar finding in a study that involved doctors in private hospitals in Lagos. No immediate reason(s) could be proffered for this but an interaction of the environment, the attitude and awareness of patients may be a possible explanation.

Majority of the respondents in this study indicated their willingness to undergo training in pharmacovigilance and have suggested increased awareness through the continuing medical education (CME). In addition,

respondents would like the inclusion of pharmacovigilance in the undergraduate and postgraduate training of doctors and the establishment of functional pharmacovigilance committee in the hospitals.

CONCLUSION

ADR reporting rate was very low in this study. That the respondents practice in a tertiary health facility and are mainly undergoing postgraduate medical training should raise serious concerns. However, larger well designed epidemiological studies should be considered, and if these findings are confirmed efforts should be geared towards addressing the poor attitude and practice of pharmaovigilance among medical practitioners.

LIMITATION OF THE STUDY

The study population was small and may be difficult to be generalized, and the responses of the participants may also have been biased since the information obtained was not validated.

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