Case Management Of Adverse Drug Reaction In Patients: Resident Doctors In Nigeria As Case Study.

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ABSTRACT: This cross sectional survey was designed to assess the quality and pattern of case management of observed adverse drug reaction by resident doctors in Nigeria. To this end, 350 structured questionnaires were distributed to resident doctors between June and September 2007, in 4 tertiary health centers in Nigeria involved in residency training programme (Lagos University Teaching Hospital, Lagos State University Teaching Hospital, University of Benin Teaching Hospital and Irrua Specialist Teaching Hospital respectively). Result revealed that 47% of observed adverse drug reactions were managed by immediate withdrawal of the implicated drug while 12.6% were managed using alternative drugs. 231 (70.0%) of the observed cases recovered fully after the withdrawal of the implicated drugs, administration of intravenous fluids (0.9% normal saline) and intravenous corticosteroid (hydrocortisone). 40 (12.1%) of the observed cases had a fatal outcome despite appropriate interventions. Conclusively, appropriate and timely case management of observed adverse drug reaction in patients improves the clinical outcome of adverse drug reactions.

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INTRODUCTION

Adverse drug reactions embodies a wide variety of toxic drug reactions, dose or non-dose related that occur in therapeutic situations, usually the term excludes non therapeutic over dosage such as attempted suicide or accidental exposure or the failure of the drug to have its intended therapeutic effects (Lack of efficacy). The incidence of adverse drug reaction varies widely from about 1-30%. Admission to the hospital because of an adverse drug reaction has been shown to account for 3-7% of all admissions (Belton, 1997). Most prospective studies in hospitalized patients show that adverse drug reactions occur in about 10-20% of cases, of which about 10-20% is severe (Mc Gettigen and Feely, 1995). The incidence of death due to adverse drug reaction is unknown, but rates of 0.5-0.9% of medical patients have been suggested and these include patients with serious and complex disease. However, it is responsible for several deaths each year (Brent, 2000). It has been estimated that adverse drug reaction is the 4th to 5th largest cause of death in the USA (Donald and Teck, 2002). Some studies conducted in developed countries have shown that approximately 5% of hospitalized patients are admitted into the hospital as a result of adverse drug reaction while 6-10% of in-patients experience a serious adverse reaction during hospitalization (Martin et al., 1998). The prevalence of hospital admissions due to adverse drug reaction in some countries is about or more than 10%. It is 11.5% in Norway, 13% in France, 16% in UK and 10-30% in developing countries (Hasford et al., 2002). Even these startling figures do not represent the whole picture. These studies generally exclude adverse drug reaction caused by drug related problems such as overdose, drug abuse, misuse, poisoning, medication errors and therapeutic failures.

MATERIALS AND METHODS

Study Area: The study involved four tertiary health institutions in urban centers of Edo and Lagos States of Nigeria (two from each State) involved in the residency training programme. Edo State with an estimated population of 5.4 million (NPC, 2007) is located in the south-south geopolitical zone of Nigeria. It has four tertiary health institution involved in residency training. Lagos State with an estimated population of 9.1 million

according to the 2007 census figure released by the National Population Commission (NPC), has four tertiary health centers involved in residency training.

Study Population: The study population consists of medical doctors undergoing residency training in different fields of medicine and surgery.

Study Design: This is a cross-sectional study evaluating the participation of resident doctors in case management of adverse drug reactions in patients.

Sample Size Estimation: The prevalence of adverse drug reactions in developing countries is between 10-30%. Adverse drug reaction report from the south-south, south-west and north-central geopolitical zone is 39%, 22% and 22% respectively (Isah, 2007). Hence sample size was determined using the formulae $N = Z^2Pq/d^2$ where Z = confidence interval 95% = 1.96, P = prevalence = 30% = 0.3, q = 1-p = 1-0.3, d = absolute sampling error of 5% = 0.05. Statistically calculated minimum sample size is approximately 350.

Sampling Technique: From four tertiary health centers involved in residency training in each state, two centers were selected by random sampling technique using balloting by non-replacement method. The centers are; University of Benin Teaching Hospital (UBTH) and Irrua Specialist Teaching Hospital (ISTH) in Edo State; Lagos University Teaching Hospital (LUTH) and Lagos State University Teaching Hospital (LASUTH) in Lagos State respectively.

Instruments/Method of Data Collection: 350 open and fixed alternative structured questionnaires were used in this study. The questionnaires were serially numbered and distributed to the study population between June and November, 2007.

Data Analysis: Data generated were manually reviewed for accuracy and then fed into a central data base. Data was analyzed using statistical soft ware package SPSS 16. Proportions, tables, bar charts and pie charts were used to present analyzed data. Chi-square test was done and a P value of <0.05 was considered significant.

RESULTS

A total of 330 questionnaires were returned by the respondents. The mean age of the respondents was 32.59±3.86 years. 202 (61.2%) and 128 (38.8%) of the respondents were males and females respectively. The mean number of years post-qualification was 4.65±1.87 years. 92.7% of respondents observed and managed cases of adverse drug reaction in the course of their training and practice. As shown in Table 1, 262 (47%) of respondents managed observed cases of adverse drug reaction by immediate withdrawal of implicated medication while 70 (12.6%) of respondents prescribed alternative drugs. Outcome of management was fatal in 40 (12.1%) of cases, no response to instituted measures in 13 (3.9%) while 231 (70%) of the observed cases fully recovered. The number of years post-qualification significantly influenced ($X^2 = 27.231$, df =11, P <0.05) the case reporting and outcome of management of adverse drug events by doctors undergoing residency training in Nigeria (Table 3).

Table 1. Management of Observed Cases of Adverse Drug Reaction

Management of ADR	Frequency	Percentage (%)
*Withdrawal of Implicated Drug	262	47.0
IV fluid administration	134	24.1
Corticosteroids (IV route)	91	16.3
Alternative Drugs Prescribed	70	12.6
Total	**557**	**100.0**

*multiple response provided!

*****multiple responses were provided by some respondents. Some indicated that other measures were instituted after drug withdrawal while others did not. This accounted for a slight disparity in data reflected in the table.

Table 2: Outcome of Management of Adverse Drug Reaction Observed by Resident Doctors

Outcome of Management	Frequency	Percentage (%)
Fatal	40	12.1
Recovering	46	13.9
Recovered	231	70.0
Continuing	0	0.0
No Response	13	3.9
Total	**330**	**100.0**

Table 3: Cross Tabulation of Respondents' Years Post Qualification and Experience in Adverse Drug Reaction Reporting and Management

Number of Years Post qualification	Experience in ADR reporting & Management		Total
	No	Yes	
2	12 (92.3%)	1 (7.7%)	13 (100%)
3	65 (81.3%)	15 (18.8%)	80 (100%)
4	81 (88.0%)	11 (12.0%)	92 (100%)
5	61 (83.6%)	12 (16.4%)	73 (100%)
6	21 (84.0%)	4 (16.0%)	25 (100%)
7	11 (45.8%)	13 (54.2%)	24 (100%)
8	7 (77.8%)	2 (22.2%)	9 (100%)
9	1 (50.0%)	1 (50.0%)	2 (100%)
10	6 (66.7%)	3 (33.3%)	9 (100%)
11	1 (100%)	0 (0%)	1 (100%)
13	1 (100%)	0 (0%)	1 (100%)
15	1 (100%)	0 (0%)	1 (100%)
Total	**268 (81.2%)**	**62 (18.8%)**	**330 (100.0%)**

X^2 = 27.231, df = 11, *P = 0.004 is significant (<0.05)

DISCUSSION

Adverse drug reactions are common. Identifying true drug allergy, however, can be challenging. Complicating factors of adverse drug reactions include the myriad clinical symptoms and multiple mechanisms of drug-host interaction, many of which are poorly understood. In addition, the relative paucity of laboratory testing that is available for adverse drug reactions makes the diagnosis dependent on clinical findings (Einarson, 1993; Marc and Adrian, 2003). In our study 97.2% of resident doctors were able to clinically assess and manage patients with symptoms of adverse drug reactions. This further emphasizes the role of clinical evaluation in the diagnoses of adverse drug reactions. The need for appropriate case management of adverse drug reactions can not be overemphasized. In this study, most of the observed cases were managed by withdrawal of implicating drugs (47%). In some cases intravenous fluids were administered (24.1%), intravenous corticosteroids were used (16.3%) and alternative medications were instituted (12.6%). These findings corroborates the fact that the most important and effective therapeutic measure in managing adverse drug reactions are the discontinuation of the offending medication, if possible. Alternative medications with unrelated chemical structures should be substituted when available (Patterson, 1995).

The clinical consequences of medication cessation or substitution should be closely monitored. In the majority of patients, symptoms will resolve if the diagnosis of adverse drug reaction is correct. Additional therapy for adverse drug reactions (ADRs) is largely supportive and symptomatic. Systemic corticosteroids may speed recovery in severe cases of adverse drug reaction. Topical corticosteroids and oral antihistamines may improve dermatologic symptoms. The severe drug reactions of Stevens-Johnson syndrome and toxic epidermal necrolysis require additional intensive therapy (Craven, 2000). In our study the outcome of management following the implementation of these therapeutic measures by residents showed that 70% of cases recovered fully. This suggests that when appropriate measures are instituted in patients with adverse drug reaction the outcome of management is usually encouraging. Post-qualification experience also contributed significantly ($X^2 = 27.231$, $P<0.05$) to the extent of reporting cases of ADRs and the quality of management of observed cases by resident doctors.

CONCLUSION

Appropriate and timely case management of ADRs is a sin qua none to a good clinical outcome. However, assessing the extent of involvement of resident doctors in monitoring and management of cases of ADRs will further help to reinforce the need for adequate drug surveillance in clinical practice.

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