ORIGINAL ARTICLE

A Preliminary Study of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting in a Teaching Hospital in Lusaka, Zambia

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ABSTRACT

Objectives of the Study: The study was aimed at examining ADR reporting practices and barriers among medical doctors, pharmacists, nurses, clinical officers, and medical residents at the University Teaching Hospital, Lusaka, Zambia. The specific objectives were: a) to assess the knowledge of ADR reporting among health professionals, b) to assess attitudes of health professionals towards ADR reporting, and c) to assess the practice of ADR reporting among health professionals.

Materials and Methods: The study adopted a questionnaire-based cross-sectional method. One hundred and forty questionnaires were administered to health professionals working at the University Teaching Hospital, Lusaka.

Statistical Analysis Used: The Statistical Package for the Social Sciences (SPSS) version 20 was used to run various descriptive statistics and to draw charts. Pearson's Chi-square test was used to observe the association of knowledge and attitude with experience and position, at significance level of 0.05.

Results: One hundred and twenty-eight questionnaires were successfully filled in and returned, giving a response rate of 91.4%. Knowledge of ADR reporting among the professionals was extremely very low. Only one respondent obtained 50% of the total scores, i.e. 19 marks out of 34 marks; and no respondent got above 50%. The minimum score obtained was 0, the maximum score was 19, and the average score was 12.6 with a standard deviation of 3.555. There was no association between knowledge level of ADR reporting and age of the respondent (r=0.003 (n=123); p=0.973). Furthermore, there was no association between knowledge levels of ADR reporting and length of respondents' practice at UTH (r=0.013 [n=120]; p=0.886). Low knowledge levels of ADR reporting were attributed to lack of training. Only 17.7% of respondents had been trained in ADR reporting. The major factors that encouraged ADR reporting included: if the reaction was serious (84.7%); if the reaction was unusual (77.4%); if the reaction was to a new product (73.4%); if the reaction was well recognized for a particular drug (60.5%); and confidence in diagnosis of an ADR (46.0%). Factors that discouraged ADR reporting included: lack of feedback (73.5%); the level of clinical knowledge to decide whether an ADR had occurred (49.0%); lack of time to actively look for ADRs (46.9%); the information reported may be wrong (37.8%); lack of time to fill in a report (36.7%); and lack of need to report a recognized ADR because it will make little difference to knowledge (30.6%). Very few (12.7%) respondents had reported an ADR case. The major factors found to be responsible for under reporting of ADR include ignorant of reporting procedures (52.0%), lack of reporting forms (31.8%), and lack of appreciation of the importance of ADR reporting.

Conclusion: This study observed that knowledge of ADR reporting was very low among health professionals at UTH. These deficiencies in knowledge and attitudes

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require urgent attention not only to improve the rate of ADR reporting, but also in order to improve the safety of the patients. Furthermore, the hospital management should improve awareness and training on ADR reporting among the health professionals.

INTRODUCTION

The definition of adverse drug reactions (ADRs) has changed over time as the art of diagnosing and treating has developed into a more advanced form of practice[1]. As treatment regimens have become more complex with the inclusion of non-pharmaceutical interventions, medical practice errors are bound to increase[1]. Additionally, alternative medicines such as herbal medications have gained popularity among westernized nations and traditional medicine continues to play a large role in the lives of many Africans[1]. But to determine a causal relationship between an adverse effect and a pharmaceutical intervention is not always possible, therefore, for the purpose of this research project, ADR was defined as "an appreciable harmful or unpleasant reaction, resulting from an intervention related to the use of medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment or alteration of the dosage regimen or withdrawal of the product". This allowed for the ability to broadly capture information about adverse effects regardless of causality[1,2, 3]. It was important that the definition of ADRs is established in order to better understand its significance to the practice of pharmacoviilance (PV).

It is evident through many years of research that ADRs may have a major impact on public health services[4]. Not only do ADRs have "the potential to provide insights into structure-activity, relationships, pharmacokinetics, pharmacodynamics and genetic factors affecting the action of medicines" and provide means for creating new indications[5], there is considerable cost in treating ADRs, and with the financial environment in which we practice, reduction in frequency of ADRs both in-patient and outpatient provides an avenue by which health care costs could be maintained while assuring delivery of quality healthcare[4]

The financial burdens from ADRs emphasize the need to better address and improve ADR reporting. Additionally, as stated earlier, studying adverse drug reactions provide the means for researching novel indications for medications[5]. This further illustrates the need to promote, educate and encourage ADR reporting among healthcare professionals. Despite the publicized importance of ADR reporting, this activity continues to be a struggle among many healthcare institutions, especially in developing countries.

Sub-Saharan African (SSA) countries still experienced an estimated 6.3% of ADR-related hospitalizations[4]. When assessing adverse reporting rates, only two of the forty-six SSA countries surveyed collected more than 100 reports per million population while most countries generated only less than 20 reports per million population each year[6]. According to, Management Sciences for Health (MSH), in the last five years, only forty-eight percent of countries carried out active surveillance, twenty-eight percent drug use studies and only thirty-seven percent conducted product quality studies [6].

Data dissemination was also found to be very weak among most of the surveyed Sub Saharan African (SSA) countries [6]. The MSH report (2009) indicated that only twenty percent of countries published medicine safety newsletters, thirty-three percent distributed safety alerts, and only thirty-seven percent used pharmacovigilance (PV) data collected to pursue regulatory action for improvement of medication safety [6]. It is clear that a vast gap exists in procedures for minimizing and managing adverse drug reactions in many SSA countries [6].

Until recently, national post marketing surveillance for all drugs has also been inadequate in Zambia[7]. Having recognized the need to improve PV activities within Zambia, new legislation was introduced in 2005 that granted the Zambia Medicines Regulatory Authority (ZAMRA) the authority to oversee all PV activities[7]. Their approach was to revise the current PV protocol which was focused on anti-malarial drugs to include all drugs[7]. The revised plan was to be instituted at the national and district level[7].

Between 2006 and 2008, the Zambian Medical Regulatory Authority (ZAMRA) established the Zambian Pharmacovigilance Centre (ZPCV) to oversee PV activities nationally as well as at district centers to manage district level activities[7]. The Centre's main objectives are to establish a national database of ADRs of registered drugs; to provide triplicate ADR forms; to collect and archive information; to provide timely responses to signals and feedback. ZAMRA's vision of roles at the health facility level involves ADR reporting, forwarding reports to their respective district office and instituting interventions based on in-house ADR review and ADR feedback[7]. Despite their awareness and training efforts, ADR reporting from our teaching hospital continues to be a challenge.

METHODOLOGY

This was a cross sectional, observational; knowledge, attitude and practice; questionnaire-based study conducted at University Teaching Hospital (UTH), Lusaka, Zambia. The medical doctors, resident pharmacists, nurses and clinical officers from the following departments were recruited: Department of Internal Medicine, Department of Obstetrics and Gynecology, Department of Paediatrics, Department of Surgery, Department of Anesthesiology, Pharmacy Department, Adult Infectious Disease Centre and Department of Psychiatry. The KAP questionnaire containing of six demographic questions, nineteen knowledge-based questions, six attitude-based questions, and ten practice-based questions (specific objectives 1-3) as well as a "suggestion for improvement" section was designed using the precedence set by similar studies[8,9,10].

The questionnaire was validated through a pilot study at Levy Mwanawasa Hospital (LMH) where the drafted questionnaire was administered via convenience sampling and with the assistance of the Medical Superintendant of the hospital to twenty (20) health care professionals. Non-willing participants and incomplete questionnaires were excluded. The purpose, procedure and methodology was explained to the attendees at respective departmental meetings and envelopes containing the amended questionnaire and labeled,' ADR Reporting Study, Department of …..,' was distributed to the willing participants. The participants were instructed to fill in the department name in which he or she practices and to return the sealed envelope with the filled questionnaire to the respective Head of Department secretary. The participants were given four (4) weeks for completion of the surveys.

The data from completed forms was entered into, The Statistical Package for the Social Sciences (SPSS); version 20, which was used to run various descriptive statistics and to draw charts. Pearson's Chi-square test was used to observe the association of knowledge and attitude with experience and position, at significance level of 0.05.

RESULTS

Biographical characteristics of the respondents

A hundred and forty questionnaires were distributed to health professionals at UTH. One hundred and twenty-eight questionnaires were successfully filled in and returned, giving a response rate of 91.4%. . Fifty-nine respondents (46.1%) were males and 67 (52.3%) were females; two did not state their gender (1.6 Fig1. shows the distribution based on work experience in years.

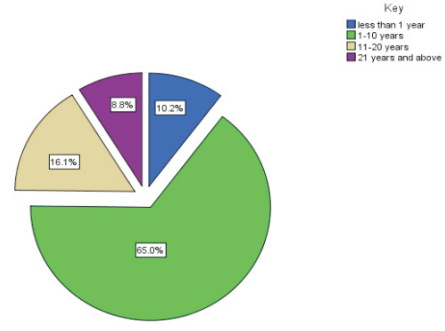

Fig 1: Work experience (in years)

Knowledge of ADR Reporting Among Health Professionals

Nineteen questions in the questionnaire assessed the knowledge of ADR reporting among health professionals. The total number of scores obtainable in this section is 34

marks. Only one respondent obtained 50% of the total scores, i.e. 19 marks; and no respondent got above 50%. The minimum score obtained was 0, the maximum score was 19, and the average score was 12.6 with a standard deviation of 3.555. A correlation coefficient test was conducted to establish whether there was any association between: a) knowledge level and age and b) knowledge level and length of practice at UTH, at a significance level of 0.01. The results indicated that there no association between knowledge level of ADR reporting and age of the respondent (r=0.003 (n=123); p=0.973). Furthermore, there was no association between knowledge levels of ADR reporting and length of respondents' practice at UTH (r=0.013 [n=120]; p=0.886). One respondent obtained zero scores.

Analysis of various (ANOVA) was conducted to establish whether there was an association between knowledge levels of ADR reporting and occupation of respondents, at a significant level of 0.05. Medical resident and clinical officers were excluded from this test as their numbers were minimal. The findings [F=12.241(2, 129); p=0.001]. Pharmacists performed better than medical doctors and nurses (p=0.001, respectively). There was no significant difference in the knowledge levels of ADR reporting among medical doctors and nurses (p=0.121). These results are illustrated in Figure 2 below.

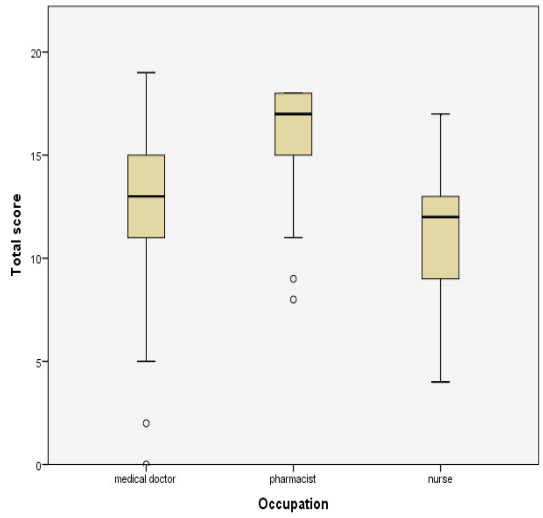

Fig 2: Knowledge levels of participants according to occupation

Assessment of Attitudes of the Health Professionals towards ADR Reporting Factors that encourage reporting of an ADR

Respondents were asked to indicate factors that may encourage them to report an ADR. This was a multiple response question. Table 1 below presents a summary of the findings on this question, arranged according to the order of their importance.

Factors	Frequency	Percentage
If the reaction was serious	119	84.7
If the reaction was unusual	109	77.4
If the reaction was a new product	105	73.4
If the reaction was well recognized for a particular drug	85	60.5
confidence in diagnosis of an ADR	69	46.0

Table 1: Factors that may encourage medical professionals to report an ADR

Respondents were asked to indicate what factors they thought discouraged reporting of an ADR. Table 2 presents a summary of the findings, in their order of importance.

Factors	Frequency	Percentage
Lack of feedback	76	52.78
Lack of time to actively look for ADRs	52	36.11
The level of clinical knowledge makes it difficult to decide whether an ADR has occurred	52	36.11
Lack of time to fill in a report	42	29.17
Information reported may be wrong	39	27.08
Lack of need to report a recognized ADR	32	22.22
Non-remuneration	20	13.89
Fear of incriminating oneself or colleagues	20	13.89
Lack of confidence to discuss an ADR with colleagues	19	13.19
Fear of the negative impact the report may have	5	3.47

Table 2: Factors that discouraged health professionals to report an ADR

Respondents were further asked whether they thought the reporting of ADR was a professional obligation. Of the hundred and twenty-five respondents answered this question, 95.2 % (199) agreed that reporting an ADR was a professional obligation.

Assessment of Practice of ADR Reporting Among the Health Professionals

Only 75 (59.5%) respondents reported that they had ever read an article on ADRs while 51% respondents indicated that they had not. 32.8% (42) respondents said they had access to ADR reference materials. Table 3 shows the major sources of reference materials on ADRs. Out of the 77 respondents who had no access to ADR references materials, 21 (27.3%) reported that they had ever asked for reference materials relating to ADRs. Two indicated that they had asked this information from their satellite pharmacies. When asked whether they had received information they had requested for, only five (19.2%) respondents indicated that they had.

Mode	Frequency	Percent
Internet	19	55.9
British National Formulary	6	17.6
B ooks	2	5.9
Pharmacy	2	5.9
Guidelines	1	2.9
Journals	1	2.9
Ministry guidelines	1	2.9
Personal library	1	2.9
ZNF	1	2.9
Total	34	100.0

Table 3: Major Sources of ADR information

When respondents were asked whether they had easy access to adverse drug reaction reporting forms at UTH, only 14 (11.4%) reported that they had access to reporting forms while 109 (88.6%) reported that they had no access. When asked where the reporting forms where located, only sixteen respondents answered this questions. The responses were varied; ten indicated that the reporting forms were located in the principle pharmacist's office; other locations mentioned were: the immediate supervisor's office, the medical officer on duty, the medical doctor, the principle investigator, and the senior pharmacist. Furthermore, only 17.7% (22) had been trained on ADR reporting. Only 13.2% (9) respondents were aware that could receive training on ADR reporting.

Respondents were further asked whether they had ever come across patients who had experienced adverse reactions. A hundred and five (84.7%) respondents indicated that they had come across patients who had experienced adverse ADR reactions. Twenty-four (24.5%) had not seen any patients experiencing adverse ADR reactions; 25 respondents had seen only one patient; 33 respondents had seen 2-3 patients, ten had seen 4-5 patients; three had seen 8-10 patients; one had seen 15 patients; and two respondents had seen fifty patients.

12.7% respondents (14) indicated that they had submitted adverse reaction reporting forms. Of these three (3) had submitted to Head of Pharmacy (UTH), three (3) to immediate Head of Department, three (3) to ZAMRA, two (2) to the Head of Admission Ward, and two (2) to pharmacy, medical ward at UTH.

Lack of reporting of ADR cases was attributed to ignorant of the reporting procedures (52.0%), lack of reporting forms (31.8%), lack of appreciation of the importance of ADR reporting (6.1%), and lack of feedback on previous reports (3.0%).

Only 22 (17.7%) respondents indicated that they had been trained on how to report ADRs. Six respondents had been trained as part of their medical training, three were trained at UTH, two were trained by Centre for Infectious Disease Research in Zambia (CIDRZ), and two were trained during their clinical meetings. Others were trained by various organizations like CHPAZ, ECP, Centre for Communication Programmes (CCP), Ministry of Health (MoH), and ZAMRA

Table 4 below summarizes the preferable methods of reporting.

Method of reporting	Frequency	Percentage
Email/on Website	77	53.47
Direct contact	45	31.25
Telephone	33	22.92
Post office	5	3.47

Table 4: Preferred methods of reporting ADRs

DISCUSSION

ADR reporting plays an integral part in providing patient care. Zambian Pharmacovigilance Centre (ZPVC) was established in Zambia recently. The present Knowledge,

Attitude and Practice (KAP) study on health professionals working in the main teaching hospital (UTH) in the capital city had a response rate of 64% which was found to be similar to other studies done elsewhere[8,11]. Majority of the respondents were females (52.3%) and most of the respondents belonged to the middle age group (32 – 41 Years). 77 respondents (60.2%) had practiced at UTH for 1-10 years.

The scores on knowledge indicated lack of knowledge of ADR reporting system with only 1 respondent obtaining the score of 50%. No association was found between knowledge level; age or years of practice. This is an interesting finding since this study included response from all health professionals including Doctors, Nurses, and Pharmacists working in the oldest and re known teaching hospitals.

Under-reporting of ADRs is common worldwide[11,12]. In our study the major factor that discouraged reporting included; ignorance of reporting methods, lack of reporting forms, lack of feed back, followed by; the level of clinical knowledge to decide whether an ADR had occurred; lack of time to actively look for ADRs, the information reported may be wrong and lack of time to fill the report. The factor of ignorance was also seen to be a major contributor in our study. This finding was similar to other studies done in, Nigeria, Malaysia, India and China[8,11,13,14,15]. A large majority of patients (95.2%) agreed that reporting of an ADR is a professional obligation. This shows that while the right attitude exists the practice of ADR reporting remains poor. Similar general findings were seen in several studies done in India[8]. Only 77 (59.5%) of patients indicated that they had ever read an article on ADR reporting or have access to ADR reference material and 21 reported that they had ever asked for reference material related to ADR reporting. Only 22 (17.7%) had received training on ADR reporting of which, only 16, respondents knew where the ADR reporting forms are located in UTH. 14 (12.7%) of respondents had ever reported an ADR and had access to reporting forms, but the reporting forms were submitted to different offices. Above 80% of patients felt that reporting of ADR is encouraged only if it is serious or unusual. This was also seen in a study done in Nigeria and Mumbai[9,16]. Only 9 (13.2%) were aware that they could have training in reporting of ADRs.

When asked what the most favorable method should be followed for reporting, 60.9% of respondents indicated email. It was surprising to note that 84.7% agreed that they have seen patients with ADRs during their years of practice and yet only 12.7% had ever reported an ADR. 52% of these patients indicated that they did not report as they are ignorant of reporting procedures. This finding is in line with similar studies done in Nigeria[9,11]. This is an indication of seriousness of the matter, and calls for regular training methods and updates on information regarding ADR reporting to health professionals, which can be done in conjunction with Ministry of Health and ZAMRA. ADR reporting forms require being regularly available in all the wards and the health care workers need to be regularly sensitized on the system of pharmacovigilance. This will help reduce morbidity and mortality related to ADRs. The most suggested method of reporting to increase the response rate that is by email ought to be considered.

CONCLUSION

This study observed that knowledge of ADR reporting was very low among health professionals at UTH. These deficiencies in knowledge and attitudes require urgent attention not only to improve the rate of ADR reporting, but also in order to improve the safety of the patients.

This study was an attempt to understand the practice of ADR reporting among health professionals but as a KAP study it has its own limitations[17]. Nevertheless just introducing ADR reporting system in a hospital is not enough it requires further input from the hospital management and ZAMRA to improve awareness and training across all health practitioners including doctors, nurses and pharmacists to strengthen the existing ADR reporting system.

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