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Mohammed Hussen Bule
Ambo University College of Medicine and Health Sciences Department of Pharmacy

Beyan Abrahim Hamido
Ambo University College of Medicine and Health Sciences Department of Pharmacy

Tesemma Sileshi Chala
Ambo University College of Medicine and Health Sciences Department of Pharmacy

Gabisa Tuji Kefeni
Department of Chemistry, College of Science, Bahir Dar University, Bahir Dar, Ethiopia.

Correspondence
Mohammed Hussen Bule
Ambo University College of Medicine and Health Sciences Department of Pharmacy

Knowledge, attitudes and practices of healthcare professionals towards adverse drug reaction reporting in Adama hospital medical college, east Shoa zone, Oromia regional state, Ethiopia

Mohammed Hussen Bule, Beyan Abrahim Hamido, Tesemma Sileshi Chala and Gabisa Tuji Kefeni

Abstract
Background: Spontaneous reporting is currently the major back bone for the detection of adverse drug reactions.
This study assessed the knowledge, attitude and practices of adverse drug reaction reporting among health professionals in Adama Hospital Medical College. The study is a descriptive quantitative cross sectional study. A questionnaire was used to collect data. A test of association of selected variables was done using Pearson chi–square and logistic analysis to measure the association. The study included 130 health professionals to assess the knowledge, attitudes and practices of adverse drug reaction reporting. From a total of 130 health professionals, 100 (76.9%) of the respondents were able to differentiate ADR from side effects and only 22 (16.9%) respondents felt that they are adequately trained in ADR reporting. Out of 130 respondents 76 (58.5%) and 62 (47.7%) knew the availability of national reporting system and ADR reporting form in Ethiopia respectively. Out of 130 health professionals, 84 (64.6%) encountered ADR in their clinical practice, but only 59(45.4%) of them recorded in patient card and only 38(29.2%) of them reported to responsible body. Underreporting of ADR by healthcare professionals were identified in this study. Training sessions to clarify the role of various healthcare professionals in ADR reporting, will hopefully fill the observed gap in knowledge and practices.

Keywords: Adverse drug reactions, Side effect, Known reaction, Unknown reaction

1. Introduction
Adverse drug reactions (ADRs) are an important cause of mortality and morbidity worldwide. [1] ADRs are defined as type A, type B, type C and type D. [2] Type A reaction (predictable) is related to dosage and is an extension to the normal pharmacology of the medication. Type B reaction (unpredictable) is unrelated to normal pharmacology. Type C reactions are associated with prolonged therapy e.g. analgesic nephropathy. Type D reactions are delayed reactions e.g. carcinogenesis and teratogenesis. [3] Most ADRs resulted from inadequate monitoring of therapy or inappropriate dosing. Patient noncompliance and drug interactions were also common causes [4].
The contribution of health care professionals, in this regard, to ADRs databases is enormously significant [5]. All health care professionals should be encouraged to report all suspected adverse reactions resulting from medicines (including vaccines, X-ray contrast media, traditional and herbal remedies) potentially serious or clinically significant [6]. Prevention of ADRs helps to minimize the consequential undesirable effects [7]. A number studies determine the incidence of ADRs in the health care systems as a cause to drug related mortality and morbidity in both developed and developing countries [8, 9]. Some studies in USA and France had shown that ADRs contribute significantly to morbidity and mortality in clinical practice with its associated economic consequences [10, 11]. Post-marketing surveillance programs are essential in every country for monitoring the occurrence of ADRs, as the data derived from within the country may encourage national regulatory decision making [12].
In Ethiopia voluntary reporting has been effective as of 2002 E.C. through the rigorous activities performed by the ADR monitoring division of the Drug Administration and Control Agency. But the level of awareness of health care providers towards ADR reporting was not satisfactory [4]. Evaluating their KAP can help in devising strategies to improve reporting schemes and habits in this particular hospital. Hence, this study is intended carryout to analyze

KAP of health care professional toward ADR reporting and to evaluate association between, (if any) knowledge, attitude and practice of health care professional with their demographic profile.

2. Methods

The study was conducted in Adama Hospital Medical College, located 99 km South East of Addis Ababa, Ethiopia, Oromia region, East shewa Zone. The hospital has different units: internal medicine, pediatrics, gynecology/obstetrics, surgery, dentistry, psychiatry, ophthalmology, hospital pharmacy, dermatology.

2.1 Study design

A prospective cross sectional study was conducted from March 2014 to June 2014, among the healthcare professionals (nurses, doctors, and pharmacists) working at Adama Hospital Medical College located in East Shewa Zone. The study was performed at all wards and pharmacies of AHMC. A total of 130 registered health care professionals working in AHMC, who had access to adverse drug reaction reporting form were included in the study. Healthcare professionals who refused to participate in the study and were without access to adverse drug reaction reporting form were excluded.

2.2 Study Tool

The knowledge, attitude and practice of ADR reporting among health care professionals in AHMC were assessed through using self-administered structured questionnaire. Data collection tool was a questionnaire adapted from reviewing different literatures, guidelines and previous similar studies. The prepared questionnaire contains four different parts which include socio demographic characteristics, existing knowledge about ADRs, attitudes, and practices.

2.3 Ethical considerations

The approval from institutional ethics committee of AHMC was sought before the actual data collection process was started and official permission letter was obtained from Ambo University, Department of Pharmacy Research and Community Services office. The process of data collection was commenced after obtaining their informed consent. The anonymously filled questionnaire was collected on the same day.

2.4 Data Management and Statistical Tool

A descriptive data analysis was conducted using SPSS (Version 20). Data was coded and entered into excel spreadsheets and imported to SPSS for analysis. Each category of a variable was coded with a number. The mean, median, standard deviation and frequency were included in descriptive statistics. Cross tab was used to test this association. All tests were carried out at significance level of less than or equal or 0.05.

3. Result

A total of 130 health professionals were approached of which 76(58.5%) were nurses, 44 (33.8%) were physicians, and 10 (7.7%) were pharmacy personnel. Most of the respondents 84 (64.6%) were in the age range of 26-35 years and were males 76 (58.5%). Majority of the respondents 57 (69.51) had 0 to 4 years of experience (Table 1).

Table1: Socio-demographic characteristics of the respondents

Characteristics	Participants (n=130)	Participants (%)
Age		
18-25	17	13.1
26-35	84	64.6
36-45	23	17.7
>45	6	4.6
Sex		
Male	76	58.5
Female	54	41.5
Profession		
Nurse	76	58.5
Doctor	44	33.8
Pharmacist	10	7.7
Year of Experience		
0-4	71	54.6
5-9	46	35.4
10-14	9	6.9
15-19	4	3.1
20-29	0	0

3.1 Knowledge of the respondents

Majority of the respondents 100 (76.9%) were able to differentiate ADR from side effects and only 22 (16.9%) respondents felt that they are adequately trained in ADR reporting. Among the different professionals, Pharmacists (22.7%, P=0.021) significantly reported that they were adequately trained in ADR reporting to lesser extent. On the other hand 130 respondents 76 (58.5%) and 62 (47.7%) knew the availability of national reporting system and ADR reporting form in Ethiopia respectively. Similarly the Pharmacists (14.5%, P=0.013) significantly reported to have known the availability of ADR reporting form to a lesser extent. Forty-two respondents (32.3) didn't know the correct format in which ADRs were to be reported. The rest respondents indicated to have reported via Telephone 14(10.8%), Post 56(43.1%) and E-mail 18(13.8%) (Table 2).

Table 2: Knowledge regarding adverse drug reaction reporting among health professional in AHM

Variables	Profession (%)			Total 130 (%)	$\chi 2$	DF	$P \geq \lvert Z \rvert$
	Nurse 76(%)	Doctor 44(%)	Pharmacist 10(%)				
Do you think ADR is the same with side effect?							
Yes	22(73.3)	6(20)	2(6.7)	30(23.1)	6.264	3	.099
No	54(54)	38(38)	8(8)	100(76.9)			
Do you feel that you are adequately trained in ADR reporting?							
Yes	9(40.9)	8(36.4)	5(22.7)	22(16.9)	9.761	3	.021
No	67(62)	36(33.3)	5(4.6)	108(83.1)			
Do you know national ADR reporting system?							
Yes	44(57.9)	26(34.2)	6(7.9)	76(58.5)	.733	3	.865
No	35(62.9)	18(33.3)	4(7.4)	54(41.5)			

How are ADRs reported?	7(50)	4(28.6)	3(21.4)	14(10.8)	15.172	9	.086
Telephone							
Post	27(48.2)	24(42.9)	5(8.9)	56(43.1)			
E-mail	12(66.7)	6(33.3)	0(0)	18(13.8)			
Don't know	30(71.4)	10(23.8)	2(4.8)	42(32.3)			
Do you know the availability of ADR reporting form?	29(46.7)	24(38.7)	9(14.5)	62(47.7)	10.780	3	.013
Yes							
No	47(69.1)	20(29.4)	1(1.5)	68(52.3)			
Do you think ADR are well documented at time drug is marketed?	8(32)	17(68)	0(0)	25(19.2)	44.341	3	.000
Yes							
No	68(64.8)	27(25.7)	10(9.5)	105(80.8)			

3.2 Attitude of the respondents

Concerning the attitudes of health professionals about ADR reporting this study showed that (93.8%) respondents agreed that ADRs should be reported spontaneously at regular base and (85.4%) agreed that ADR reporting should be part of duty of them. Among the health professionals the Nurses (55.8%, P=0.013) significantly reported ADR should be reported spontaneously at regular base to a greater extent. In addition, most respondents (93.8%) and (94.6%) agreed that reporting ADR are important for the public and health care system respectively. In this particular scenario all the doctors (36.1%, P=0.001) significantly agreed on importance of reporting drug safety for the public. However, more than half of the respondents (58.5%, P=0.001) significantly reported that there should be a need to be sure that ADR is related to the drug before reporting (Table 3).

Table 3: Attitude of health professionals toward ADR reporting in AHMC

Variables	Profession (%)			Total 130(%)	χ2	DF	*P*≥|*Z*|
	Nurse 76(%)	Doctor 44(%)	Pharmacist 10(%)				
ADR should be reported spontaneously at regular base							
Agree	68(55.8)	44(36.1)	10(8.2)	122(93.8)	16.096	6	.013
Neutral	7(100)	0(0)	0(0)	7(5.4)			
Disagree	1(100)	0(0)	0(0)	1(0.8)			
Reporting ADR is part of duty of health professional							
Agree	59(53.1)	42(37.8)	10(9)	111(85.4)	11.212	6	.082
Neutral	15(88.2)	2(11.8)	0(0)	17(13.1)			
Disagree	2(100)	0(0)	0(0)	2(1.5)			
Reporting drug safety is important for the public							
Agree	70(57.4)	44(36.1)	8(6.6)	122(93.8)	29.428	6	.000
Neutral	6(100)	0(0)	0(0)	6(4.6)			
Disagree	0(0)	0(0)	2(100)	2(1.5)			
Reporting drug safety is important for the health care system							
Agree	70(56.9)	43(35)	10(8.1)	123(94.6)	3.000	3	.392
Neutral	6(85.7)	1(14.3)	0(0)	7(5.4)			
There is a need to be sure that ADR is related to drug before reporting							
Agree	33(43.4)	38(50)	5(6.6)	76(58.5)	31.969	6	.000
Neutral	16(88.9)	2(11.1)	0(0)	18(13.8)			
Disagree	27(75)	4(11.1)	5(13.9)	36(27.7)			
Only ADR that cause persistant disability should be reported							
Agree	8(72.7)	2(18.2)	1(9.1)	11(8.5)	11.305	6	.079
Neutral	10(83.3)	0(0)	2(16.7)	12(9.2)			
Disagree	58(54.2)	42(39.3)	7(6.5)	107(82.3)			
Reporting creates additional work load							
Agree	31(67.4)	11(23.9)	4(8.7)	46(35.4)	10.901	6	.091
Neutral	15(71.5)	5(23.8)	1(4.8)	21(16.2)			
Disagree	30(47.6)	28(44.4)	5(7.9)	63(48.5)			

3.3 Practice of the respondents

Majority of health professionals 84 (64.6%, *P*=0.008) significantly reported that they have encountered ADR in their clinical practice, but only 59(45.4%, *P*=0.008) of the respondents significantly recorded the ADR in patient card. Among the of health professionals half of the Doctors 22 (37.3%, *P*=0.008) significantly reported that they have recorded the ADR in patient card. However, only 38(29.2%) of them reported to responsible body and 79(60.7%) of respondent reported that they give advice sometimes on possible adverse effects of drugs they prescribed, dispensed or administered to their patients. On the other hand majority of the respondents 88(67.7%) significantly reported to have never reported ADRs to any of the responsible bodies (Table 4).

Table 4: General practices regarding adverse drug reaction reporting in AHMC.

Variables	Profession (%)			Total 130(%)	χ2	DF	$P \geq \|Z\|$
	Nurse 76(%)	Doctor 44(%)	Pharmacist 10(%)				
Have you encountered patient with ADR in last 12 months?							
Yes	48(57.2)	33(39.3)	3(3.6)	84(66.4)	11.747	3	.008
No	28(60.9)	11(23.9)	7(15.2)	46(35.4)			
How many patient did you see?	11(50)	10(45.5)	1(4.5)	22(16.9)	18.203	15	.252
One							
Two	8(44.4)	8(44.4)	2(11.1)	18(13.8)			
Three	13(65)	7(35)	0(0)	20(15.4)			
Four	3(50)	3(50)	0(0)	6(4.6)			
Above (specify)	13(72.2)	5(27.8)	0(0)	18(13.8)			
Zero	28(60.9)	11(23.9)	7(15.2)	46(35.4)			
Have you noted the ADR you encountered?							
Yes	35(59.3)	22(37.3)	2(3.4)	59(45.4)	7.571	3	.008
No	41(57.7)	22(31)	8(11.3)	71(54.6)			
Have you ever reported the ADR?	27(71.1)	10(26.3)	1(2.6)	38(29.2)	7.409	3	.060
Yes							
No	49(53.2)	34(37)	9(9.8)	92(70.8)			
Where did you report the reaction?	3(37.5)	4(50)	1(12.5)	8(6.2)	26.854	12	.008
Hospital							
Pharmaceutical company	2(100)	0(0)	0(0)	2(1.5)			
FMHACA	2(18.2)	7(63.6)	2(18.2)	11(8.5)			
Doctor	20(95.2)	0(0)	1(4.8)	21(16.2)			
Never reported	49(55.7)	33(37.5)	6(6.8)	88(67.7)			
How often do you give advice about ADR to the patients?							
Usually	21(48.9)	20(46.5)	2(4.7)	43(33.1)	10.191	6	.117
Sometimes	48(60.7)	23(29.1)	8(10.1)	79(60.8)			
Never	7(87.5)	1(12.5)	0(0)	8(6.2)			

4. Discussion

Adverse drug reaction monitoring is an area of pharmaceutical care which deals mainly with the detection, management and reporting of adverse reactions of drugs which may result from drugs that is taken in normal dose for prophylaxis, prevention or treatment. These adverse drug reactions may range from mere inconvenience to permanent disability and death. [13]

This study is conducted in AHMC among 130 health professionals majority of which were Nurse 76 (58.5%) followed by Doctors 44(33.8%) and Pharmacists 10(7.7%). In this study 30 (23.1%) of the respondents replied ADR was the same as side effects while 100 (76.9%) of them said ADR was different from side effect. But WHO recommended that in order to avoid inflating of the figures of drug induced diseases; it is convenient to retain the term side effect for minor effects which are related to the pharmacological properties of the drug. [14] This shows that they are good at differentiating ADR from side effects.

Among 130 respondents, only 22 (16.9%) respondents felt that they are adequately trained in ADR reporting and 62 (47.7%) knew the availability of national reporting form in Ethiopia. In addition 76 (58.5%) respondents knew the availability of national reporting system. This might be due to inadequate promotion of reporting form and reporting system and weak regulatory body contact with the health facilities in general and the health professionals in particular.

Among 130 health professionals, (93.8%) respondents agreed that ADRs should be reported at regular base and (0.8%) of them opposed this idea. A study done in British showed that 49.8% of the surveyed population felt that ADR reporting should be compulsory and another study done in Saudi Arabia showed that 98.3% of the respondents considered the reporting of ADR to be integrated to their professional duties. [10, 11]

Furthermore, (58.5%) of the respondents complain that there should be a need to be sure that ADR is related to the drug before reporting. A study in Saudi Arabia showed that 96% of hospital pharmacists mentioned that they must be sure of causality between drug and adverse drug reaction before reporting and in Netherlands 82% said that reporting should be as inherent part of pharmaceutical care. [11, 15] This finding is consistent with findings from Netherlands and Nigeria, were majority of the respondents agreed that ADR reporting is necessary even though a smaller proportion have ever reported. [16, 17] Moreover, there is significant association between practice and profession. This means physicians have high chance of diagnosing ADRs than other health professionals since others either have low confidence at diagnosing or have fewer roles at ward for intervention.

5. Conclusion

Underreporting of ADR by healthcare professionals were indentified on this study. Majority of the respondents reported to have diagnosed ADR. But, only few of them have ever reported to FMHACA, which might partly be explained by lack of knowledge and misconceptions about spontaneous reporting. The study strongly suggests that there is a great need to create awareness and to promote the reporting of ADR amongst health professionals, which will lay a solid foundation for healthcare professionals to be diligently involved in ADR reporting in their future practices. Training sessions to clarify the role of various healthcare professionals in ADR reporting, will hopefully fill the observed gap in knowledge and practices.

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