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Research Article

KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTION REPORTING AT INPATIENT WARDS OF TERTIARY HOSPITAL, ETHIOPIA

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ABSTRACT

Background: Drugs have become one of an essential component of healthcare systems worldwide. However, there is a concern for their safety. Adverse drug reaction (ADR) is common during usual clinical practice and it is associated with increased morbidity, hospitalization and mortality.

Objective: To assess knowledge, attitude, and practice of healthcare professionals (HCPs) towards ADRs reporting at inpatient wards of Tikur Anbessa Specialized Hospital (TASH), Ethiopia.

Methods: Hospital based descriptive cross-sectional study was conducted among 280 HCPs at the inpatient wards of TASH. The data required for the present study was collected using self-administered structured questionnaire and samples were selected through both stratified and systematic random sampling methods, where the type of profession was used as a stratum. The collected data was analyzed using SPSS version 21.00 for the window.

Results: Of 280 HCPs to whom the questionnaire initially administered, 213 respondents filled and returned the questionnaire, giving a response rate of 76.1%, and were included in the analysis. The study revealed that 78.9% and 47.9% of HCPs have poor knowledge and negative attitude towards ADR reporting respectively. Among respondents, 38% of HCPs encountered patient with ADR, 90.2% of them reported the ADR they encountered, of them only 10.8% were reported to Ethiopian food, medicine, and healthcare administration and control authority, a regulatory body for receiving and monitoring ADR throughout the country.

Conclusion: HCPs in TASH had poor knowledge, attitude and practice towards ADRs reporting. The hospital should devise strategies to enhance detection and reporting of ADRs.

Key words: ADR reporting, pharmacovigilance, spontaneous reporting, TASH

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INTRODUCTION

According to World Health Organization (WHO) definition, an ADR is any noxious and unintended effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis or cure of a disease¹. Drugs play important role in day to day life of the human being to prevent and treat diseases as well as maintain overall wellbeing. Despite multiple benefit of drugs, they are not totally free from untoward effects.^{2,3}

Post-marketing surveillance of drugs was used as an important tool in controlling drug safety for century; contributed a lot in the withdrawal of drugs from the market due to safety problem. Reporting ADRs is important for all types of drugs, whether newly released into market or renowned since ADR can be caused by any type of drug at any time. In spite of the necessity of continuous reporting and monitoring of ADRs to minimize its consequence, the practice is still poor

particularity in developing countries because it requires adequate knowledge, skills, attitude and commitment by healthcare professionals and strict regulation and monitoring by drug regulatory bodies^{2,4}.

Spontaneous reporting structure, a system whereby reports of ADRs are voluntarily submitted by HCPs and pharmaceutical manufacturers to national regulatory authority, is the most common way through which regulatory bodies collect information on ADRs^{5,6}. Spontaneous reporting of ADRs remains the cornerstone of pharmacovigilance. However, the success of this activity is dependent on the reporting of all suspected ADRs by HCPs, which in turn affected by knowledge, attitude and commitments of HCPs. In western countries the incidence of ADRs is 2.4-6.5% of which only 6-10% of all ADRs being reported^{7,8}.

A Number of factors might be attributed for underreporting of ADRs which include fearing to report, lack of time, different care priorities, uncertainty about the drug causing the ADR, difficulty in accessing reporting forms, lack of awareness of the requirements for reporting, unawareness about where to report and how to report, lack of feedback from regulatory authority and lack of understanding the purpose of spontaneous reporting systems⁹⁻¹².

In Ethiopia voluntary ADR reporting has been effective since 2002 through the rigorous activities performed by the ADR monitoring division of the EFMHACA aimed to reduce ADR. A simple ADR reporting form was developed and it is made available in all health facilities across the country for identifying and reporting ADR. However, the number of reports received by the center still is small^{6,13}.

METHODS

Study Setting

The study was conducted at inpatient wards of Tikur Anbessa Specialized Hospital (TASH), the largest referral hospital with over 700 beds, located in Addis Ababa, Ethiopia. The hospital provides services for people coming from different corners of the country. The hospital inpatient wards provide services with 14 physicians, 633 nurses and midwives, 76 pharmacists and 33 anesthetists who were hired to provide healthcare services. There was no well-established pharmacovigilance center in TASH.

Study Design and Period

A cross sectional study with two stage sampling, both stratified and systematic random sampling techniques, was conducted among HCPs. The data was collected from March 3-25, 2016 at inpatient wards of TASH. Respondents included in this study were those HCPs working at inpatient wards of TASH who were available during data collection period and willing to participate. HCPs practicing in TASH but not hired by the hospital (i.e. students) were excluded from the study.

Sample size determination and sampling procedure

Sample size required for the present study was calculated using the following single population proportion formula.

$$n = \frac{Z_{\alpha/2}^2 P(1-p)}{d^2}$$

When we take two tailed $Z_{\alpha/2}$ value of 95% confidence interval (1.96), 50% prevalence of ADR reporting knowledge and 5% of marginal error (d), the sample size was 384. There were 756 HCPs (N= 756) who fulfilled the inclusion criteria of the study. Since this number is less than 10,000, the sample size has been corrected using the following sample correction formula. The corrected sample size hence was 255; including a 10% non-response rate yielded a final sample size of 280.

$$\text{Corrected sample size} = \frac{n \times N}{n + N}$$

After having the determined sample size, samples for the study were proportionally stratified based on profession. Systematic random sampling technique was used with sampling fraction (k) which was varied for each profession. The sample size was distributed over professions based on their proportion from the total HCPs. Accordingly; questionnaires were administered to 5 physicians, 12 anesthetists, 28 pharmacists and 235 nurses.

Data collection Instrument and interpretation of result

Data was collected using structured self-administered questionnaire with information on socio-demographic characteristics, knowledge, attitude and practice on ADRs reporting adapted from reviewing different literatures and previous studies^{11,14-18}.

The questionnaire includes 7 questions to assess HCPs' knowledge on ADRs reporting. A knowledge score was prepared as a guiding tool to assess knowledge, whereby one point for correct answer and zero for wrong answer. HCPs were categorized based on their overall knowledge scores using original Bloom's cutoff points. The score ranges with their respective knowledge levels were: 80-100%, 60-79% and <60% of maximum score as good, moderate and poor knowledge respectively.

There were 9 questions in the attitude part. Respondents were asked to indicate their level of agreement or disagreements on a five point Likert scale containing 'Strongly agree', 'agree', 'neutral', 'disagree' and 'Strongly disagree' on the scale, valued 5 to 1 respectively. The interpretation for negatively worded questions was reversed. The sum of all items will give maximum score of 45. Seventy five percent of the maximum score i.e. a score of 33.75 was taken as a cutoff point to categorize respondents into two categories, greater than and equal to 33.75 were categorized as having positive attitude and those who scored less than 33.75 were categorized as having negative attitude towards ADR reporting. Five questions were used to assess respondents' practice towards ADRs reporting. The data was entered and analyzed using SPSS version 21.0. It was summarized as frequency and percentage.

Data quality assurance and quality control

The questionnaire was pretested on 14 HCPs working at Mizan Tepi University Teaching hospital to check its suitability for the actual data collection. Before starting data collection, brief explanation on how to fill the questionnaire was given for each health professionals. The questionnaire was checked for completeness by principal investigator.

Ethical consideration: Before the actual data collection process, an official cooperation letter was obtained from Mizan-Tepi University, college of health sciences and submitted to clinical director of TASH, then data collection was commenced after permission from the director. Brief explanation on objective of the study was given for HCPs and written consent was secured.

RESULTS

Background characteristics of participants

Self-administer questionnaire was distributed to 280 HCPs working at inpatient wards of TASH. Among HCPs initially approached, only 213 HCPs adequately filled and returned the questionnaires, giving a response rate of 76.1 %. Hence, 213 HCPs were considered for analysis. Females comprised 54% of the respondents. Most of the respondents were in the age range of 26-35 years, which accounted for 51.1%. Nurses comprised the major type of HCPs included in the study accounted for 75.6% of the respondents. Majority, 192(90.1%) of the respondents were bachelor degree holders. One hundred twenty two (57.3%) HCPs were having a clinical experience of 1-5 years (**Table 1**).

Table 1: Background characteristics of HCPs at inpatient wards of TASH (N=213), March, 2016

Variables	Category	Frequency (%)
Sex	Female	115(54.0)
	Male	98(46.0)
Age	≤ 25	85 (39.9)
	26-35	109 (51.1)
	36-45	11 (5.2)
	> 45	8 (3.8)
Profession	Nurse	161(75.6)
	Pharmacist	27(12.7)
	Anesthetist	10(4.7)
	Midwife	10(4.7)
	Physician	5(2.3)
Level of education	Diploma	8(3.8)
	Bachelor degree	192(90.1)
	MSc or equivalent	13(6.1)
Years of clinical experience	< 1 year	33 (15.5)
	1-5 years	122 (57.3)
	> 5 years	58(27.2)

Table 2: Knowledge of HCPs at inpatient wards of TASH on ADR Reporting, March, 2016

Questions	Yes, Number (%)
Differentiate ADR from drug side effect	114(53.5)
Know the term pharmacovigilance	66(31.0)
Know the existence of national ADR monitoring system	78(36.6)
Know the ADR reporting form	59(27.7)
ADRs are not well documented at the time the drug is marketed	140(65.7)
Where to send ADR report	
. MOH	29(13.6)
. FMHACA*	106(49.8)
. PFSA	18(8.4)
. EPA	45(21.2)
. Do not know	15(7)
Types of medication candidate for ADR reporting	
. Conventional medicines	117(54.9)
. Vaccines and blood products	106(49.8)
. Traditional medicines	35(16.4)
. Medicated cosmetics	64(30.0)
. Medical devices	86(40.4)
. All (7.1. to 7.5)*	7(3.3)

*correct knowledge, MOH: Ministry of health, FMHACA: food, medicine, healthcare administrative and control authority, PFSA: pharmaceutical fund and supply agency, EPA: Ethiopian pharmaceutical association

Knowledge of HCPs on ADRs reporting

Upon analysis of questions that were used to assess knowledge, the result revealed that 21(9.8%), 24(11.3%) and 168(78.9%) HCPs have good, moderate and poor knowledge on ADR reporting, respectively. Among the respondents, 106 (49.8%) knew the responsible body to whom ADR should be reported (Table 2). As per Ethiopian context, FMHACA is a regulatory body responsible for receiving and monitoring ADR reports.

Attitude of the HCPs towards ADR reporting

The present study found that 186 (87.3%) HCPs agreed on regular reporting of ADR, and 179(84%) HCPs agreed on ADR reporting as part of duty of health professionals. In addition, 192(90.1%) agreed on its importance for the patient and 117(54.9%) agreed on reporting ADR should be mandatory (Table 3). Overall, 52.1% of HCPs had positive attitude towards ADR reporting.

Table 3: Attitude of HCPs at inpatient wards of TASH on ADR Reporting, March, 2016

Statements	SA	Agree	Neutral	disagree	SDA
ADR should be reported regularly	118(55.4)	68(31.9)	5(2.3)	10(4.7)	12(5.6)
ADR reporting is part of duty of health professionals	107(50.2)	72(33.8)	12(5.6)	11(5.2)	10(4.7)
ADR reporting is important for the patient	140(65.7)	52(24.4)	11(5.2)	10(4.7)	0(0)
ADR reporting is important for the public	103(48.4)	79(37.1)	18(8.4)	4(1.9%)	9(4.2%)
ADR reporting is important for the health care system	131(61.5)	66(31)	11(5.2)	2(0.9%)	2(0.9)
There is a need to be sure that ADR is related to the drug before reporting	98(46.0)	66(31.0)	29(13.6)	18(8.4)	2(0.9)
Only ADRs of prescription drugs need to be reported	36(16.9)	58(27.2)	31(14.6)	67(31.4)	18(8.4)
Only ADRs that cause persistent disability or incapability should be reported	32(15)	43(20.2)	18(8.4)	62(29.1%)	58(27.2)
Reporting of ADR should be voluntary	36(16.9)	31(14.5)	29(13.6)	51(23.9)	66(31)

SA: strongly agree, SDA: strongly disagree

Practice of the HCPs towards ADR reporting

This study revealed that 82(38.5%) HCPs encountered at least one patient with ADR during their clinical practice in the last one year. Seventy four (90.2%) HCPs

reported the ADR they encountered, of which only 8(10.8%) reported to the appropriate body, FMHACA. Among the respondents 82(38.5%) HCPs claimed they usually give advice to their patients on possible ADRs of drugs (Table 4).

Table 4: ADR reporting practice of HCPs at inpatient wards of TASH, March, 2016

Variables	Yes, Frequency (%)
Encountered patient with ADR during the last 12 months	82 (38.5%)
Number of patients encountered with ADR (N=82)	
One	30(36.6)
Two	30(36.6)
Three	8(9.8)
Four	9(11.0)
≥ Five	5(6.0)
Usually give advice to patients on possible adverse effects of the drugs	82 (38.5%)
Reported the ADRs encountered	74 (90.2%)
To whom ADR reported (N=74)	
Head of the pharmacy	28(37.8)
Manufacturers	6(8.1)
MOH	16(21.6)
Physician	10(13.5)
FMHACA	8(10.8)
Head nurse	3(4.1)
Other*	3(4.1)
Advice patients about possible adverse effects of drugs	
Usually	82(38.5)
Sometimes	61(28.6)
Rarely	53(24.9)
Never	17(8)

*Ethiopian Pharmaceutical A association, wholesale

DISCUSSION

Adverse drug reactions result in an excessive healthcare costs through increased morbidity, mortality and hospital admissions. Therefore, monitoring of ADRs is an integral component of patient care. The study was conducted among 213 HCPs working at TASH inpatient wards to assess their knowledge and attitude towards ADR reporting as well as to evaluate the practice of encountered ADR reporting. The study included physicians, pharmacists, nurses, midwives and anaesthetists.

In the current study, out of 213 HCPs, only 53.5% said that ADR is different from side effect, but only 31% reported that they knew the term pharmacovigilance. As per WHO recommendation, the term side effect should be reserved for minor effects of drug which are related with its pharmacological properties¹⁹. There is a need to work to upgrade knowledge of professionals on different form of unintended effects of drugs. This helps for professionals to differential things to be reported from minor side effects.

Among the respondents, 63.4% knew the presence of national ADR reporting system, which is greater than 45.2%¹⁶, 37.4%²⁰, 23.2%¹⁸ reported by previous studies conducted in other health facilities in Ethiopia. This might be the difference in access to information about the presence of ADR reporting centre. Health professionals in TASH could have better information access than those working in peripheral part of the country, with better media outlet in the capital, Addis Ababa. Despite slightly higher knowledge about physical presence of ADR reporting centre as compared with reported from other part of the country, only 27.7% of HCPs knew the ADR reporting form. This result is almost consistent with 25.6% reported by Angamo et al¹⁸, but higher as compared to 20.6% reported from Jimma zone hospitals in Ethiopia²⁰. However, this finding was lower than the result found in Uganda, 37.7%¹⁵ and Ethiopia, 48.7%¹⁶. The regulatory body should enhance the distribution of prepaid report form to different wards of TASH.

This study found out that 87.3% of HCPs agreed the fact that ADR should be reported spontaneously at regular basis, which is in line with the findings from similar study in Addis Ababa, 88.9%²¹. The present study showed that 84% of healthcare professionals believed ADR reporting as part of duty of health professionals,

which is relatively comparable with the 78.3% obtained from Nekemte, Ethiopia¹⁶, but lower than the results reported from Addis Ababa, 96.6%²² and 92.7%²¹. The result of this study revealed that 90.1%, 85.5% and 92.5% of HCPs believed that ADR reporting is important for the patient, public and healthcare system respectively. One hundred six four HCPs (77%) claimed that there is the need to be sure that ADR is related with the drug before reporting. The study conducted in Jimma and Addis Ababa revealed that 85.4% and 76.9% of study respondents, respectively, believed the need to be sure that ADR is attributed to the suspected drug^{18,21}.

This study revealed that 38% in contrast with 81% in Northern Nigeria¹⁴ and 11.3% in Nekemte hospital¹⁶ of the respondents encountered at least one patient with ADR during their clinical practice in the last one year. Among those HCPs who encountered ADRs, 90.2% claimed that they have reported the ADR, despite only 10.8% reported to appropriate body, FMHACA. This showed that most of the healthcare professionals who recognized ADR did not report to the concerned body. This might be due unavailability of reporting form in wards and lack of awareness of the existence of reporting centre.

Limitations of the present study includes possibility of recall bias and the result of the study does not claim to represent all healthcare professionals in TASH, as the respondents were recruited only from inpatient wards.

CONCLUSIONS AND RECOMMENDATIONS

The present study identified that healthcare professionals working in the TASH, Addis Ababa, Ethiopia had poor knowledge, attitude and practice towards ADRs reporting. This study strongly suggests TASH inpatient ward coordinators to facilitate training programs regarding the importance of ADR reporting to improve knowledge, attitude and practice of healthcare professionals.

Conflict of interest: The authors of this paper declared that there is no competing conflict of interest.

Authors' contribution: All authors conceived design of the study and involved in data acquisition, analysis and interpretation. **AT** draft the manuscript while **TT** revise for its intellectual contents. All authors read and approved the manuscript.

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