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HEALTH PROFESSIONALS' KNOWLEDGE,
ATTITUDE AND PRACTICES TOWARDS
ADVERSE DRUG REACTION REPORTING IN
NEKEMTE HOSPITAL, ETHIOPIA

ZNANJE ZDRAVSTVENIH RADNIKA,
STAV I ISKUSTVA PREMA PRIJAVLJIVANJU
NEŽELJENIH DEJSTAVA LEKA U BOLNICI
NEKEMTE, ETIOPIJA

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Abstract

Background: Adverse drug reaction results in morbidity, mortality and increases hospital admission which affects the economy and health care systems. Health care professionals should consider ADR reporting as their professional duties to protect patients from adverse effects of medications. Therefore, the present study is aimed to determine current status of Knowledge, practices and attitudes towards adverse drug reaction (ADR) reporting among health professionals in Nekemte Hospital.

Method: A cross sectional study using structured questionnaire was conducted to determine the level of Knowledge, practices and attitudes towards adverse drug reaction (ADR) reporting among health professionals in Nekemte Hospital.

Result: 115 questionnaires were filled with 76.6% response rate. 80%, 66.1 %, 45.2 % and 48.7 % of the health professionals don't know the difference between ADR and side effect, the term Pharmacovigilance, the national ADR reporting system and availability of ADR reporting form, respectively. Out of 13 (11.3%) respondents who had encounter with ADR only 4(30.8%) had reported it. 97.43% of respondents agree towards the fact that an ADR should be reported and (78.3%) agree that it is part of the professional duty of a health professional.

Conclusion: Most of the health professionals had inadequate knowledge about ADR. Though they had positive attitude towards ADR reporting, only few of them had ever reported.

INTRODUCTION

Adverse drug reaction (ADRs) is defined by the World Health Organization (WHO) as „a reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions” (1). This definition clearly shows the difficulty of getting 100% safe drugs (2). It results in morbidity, mortality and increases hospital admission which affects the economy and health care systems (2, 3). Even though the degree of effect varies, children and adults are the most vulnerable groups(4).

For century post marketing surveillance was used as an important tool in controlling drug safety. It contributed a lot in the withdrawal of drugs like rofecoxib, rosiglitazone, and

aprotinin from the market due to safety problem. This highlights the importance of reporting of adverse drug reactions of all the drugs, whether they are new or old (2, 5). However, the practice is very poor because it requires adequate knowledge, skills and attitude by health care professionals (2,6). In western countries the incidence of ADR is 2.4-6.5% of which only 6-10% of all ADRs being reported (7). An estimated 15% to 59% of these ADRs are considered preventable (8). Out of the several methods of detecting ADRs, spontaneous reporting is one that has contributed significantly to improved levels of pharmacovigilance in many countries (9). Therefore, the present study aimed at assessing knowledge, attitude and practice (KAP) of health professionals toward ADR reporting in Nekemte hospital, Ethiopia.

MATERIALS AND METHODS

Study design

A cross-sectional study design with convenience sampling technique was carried out using structured questionnaire among health professionals working in Nekemte zonal hospital from Jan 24-Feb 7, 2014. All physicians (doctors), pharmacy personnel (diploma and above), health officers, anesthesiologist and nurses (diploma and above) who were willing and working in Nekemte hospital during the study period were included. The study site is located at 328 km from the capital city Addis Ababa in Nekemte town. Nekemte is found in Eastern Wollega zone of the Oromia region with an estimated total population of 84,506 of which males and females accounts for 42,121 and 42,385, respectively.

Well structured questionnaires with information about socio-demographic characteristics, knowledge, attitude, and practice about adverse drug reaction reporting was used to collect the data. Then, the information was reviewed and checked for completeness and consistency. Finally, the association among different variables was made by using the Statistical Package for the Social Sciences (SPSS) version 16.0 software. Chi-square test was used and p value <0.05 considered significant.

The variables of the study were knowledge about adverse drug reaction, attitude towards ADR reporting, practice of reporting ADR, demographic factors, level of specialization, difference in profession, and year of service.

Operational/Standard Definition ⁽¹⁾

Adverse drug reaction: A reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions.

Pharmacovigilance: It is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug-related problem.

Serious ADR: An adverse drug reaction that requires hospitalization, prolongs hospitalization, is permanently disabling, or results in death of the patient.

Ethical consideration

An official letter was written from Department of Pharmacy, College of Public Health and Medical Sciences, Jimma University. Then officials at different levels in the study area were communicated to get permission for data collection. Verbal consent from the respondents was obtained and they were convinced on confidentiality of the information that they give.

RESULTS AND DISCUSSIONS

Of total 150 questionnaires, 115 were filled and returned with 76.6% response rate. The majority of the respondents were male (53.4%), in the age range of 26-35 years (66.1%), nurses (64.3 %) and with service year of 0-5 years (35.7%) [Table 1].

Knowledge

As shown in Table 2 below 80%, 66.1 %, 45.2 % and 48.7 % of the health professionals don't know the difference between ADR and side effect, the term Pharmacovigilance,

Table-1: Socio-demographic characteristics of health professionals in Nekemte Hospital, Ethiopia, January 24-Feb.7/2014.

Variable	Frequency (115)	Percentage (%)
Sex		
Male	61	53.8
Female	54	47
Age		
18-25	25	21.7
26-35	76	66.1
36-45	8	7
>45	6	5.2
Profession		
Physician	24	20.86
Pharmacy personnel	13	11.3
Nurses	74	64.3
Health officer	2	1.7
anesthesia	2	1.7
Level of education		
Specialist	2	2.6
General practitioner	22	18.26
Bachelor degree pharmacy	4	3.48
Bachelor degree nurse	44	36.52
Diploma pharmacy	9	7.82
Diploma nurses	30	25.21
Bachelor degree in anesthesiology	2	1.7
Bachelor degree in public health	2	1.7
Years of experience		
0-5years	41	35.7
6-10years	35	30.4
11-15years	23	20
>=16years	16	13.9

Table 2 Knowledge health professionals regarding adverse drug reaction reporting in Nekemte Hospital, Ethiopia, January 24-Feb.7/2014.

Variables		Frequency (115)	Percent (%)
Do you know the difference between ADR and side effect?	Yes	23	20
	No	92	80
Do you know the term Pharmacovigilance?	Yes	39	33.9
	No	76	66.1
Do you know national ADR reporting system?	Yes	63	54.8
	No	52	45.2
Do you know the availability of ADR reporting form?	Yes	59	51.3
	No	56	48.7
Are you aware of any drug withdrawn from market due to safety reason?	Yes	41	35.7
	No	74	64.3

the national ADR reporting system and availability of ADR reporting form, respectively. Similar study done in South West Ethiopia showed that 79% and 80% of the participants don't know the difference between ADR and side effect, and the term Pharmacovigilance, respectively ⁽¹⁰⁾. The finding from teaching hospital in Lagos, Nigeria confirmed only 32.3% of physicians were aware the existence of ADR reporting form ⁽⁴⁾; 34.6% and 77% of South India's pharma-

Table 3: Practices regarding adverse drug reaction reporting the among health professionals in Nekemte Hospital, Ethiopia, January 24-Feb.7/2014.

Variables	Frequency	Percent (%)
Have you ever encountered patient with ADR in your clinical practice, in the last 12 months?		
Yes	13	11.3
No	102	88.7
How many patients with ADR did you see?		
One	10	9.6
Two	1	0.9
Three	1	0.9
Four	1	0.9
Have you noted the ADR you encountered on the patient clinical record?		
Yes	4	30.77
No	9	69.23
Have you reported the ADRs?		
Yes	4	30.77
No	9	69.23
Where will ADR be reported to?		
FMHACA	60	52.2
DTC	34	29.6
Pharmacy department	11	9.6
MOH	8	7
Manufacturers	2	1.7

Table 5: Reasons for not reporting adverse drug reaction reporting among health professionals in Nekemte Hospital, Ethiopia, January 24-Feb.7/2014.

Statement	SA	A	N	D	SD
Need to be certain association between the drug and ADR	8,7%	13, 11.3%	19,16.5%	33,28.7%	42,36.5%
ADRs are well documented during marketing	4,3.5%	60,52.2%	6,5.2%	27,23.5%	18,15.7%
Reporting form is too complicated	8,7%	28,24.3%	17,14.8%	22,19.1%	40,34.8%
Reporting is time consuming	15,13%	9,7.8%	12,10.4%	45,39.1%	34,29.6%
One report makes no difference	17,14.8%	9,7.8%	8,7%	10,8.7%	71,61.7%
Reporting form is not available adequately	42,36.5%	32,27.8%	29,25.2%	12,10.4%	-
There is no national ADR reporting system	2,1.7%	44,38.3%	12,10.4%	35,30.4%	22,19.1%
Reporting is not useful to the patient	-	5,4.3%	36,31.3%	24,20.9%	50,43.5%
Reporting creates an additional workload	2,1.7%	12,10.4%	58,50.4%	35,30.4%	8,7%

SA- Strongly Agree, A- Agree, N-Neutral, D- Disagree, SD- Strongly Disagree

cists and North India’ physicians (11), respectively, could define the term ‘pharmacovigilance’ (12). Lack of adequate knowledge is a major contributing factor for underreporting of ADR. When health professionals from Nepal were asked

Table 4 Attitudes towards adverse drug reaction reporting among health professionals in Nekemte Hospital, Ethiopia, January 24-Feb.7/2014.

Statements	Level of Agreement				
	SA	A	N	D	SD
ADR Should be reported regularly	77	35	3	-	-
Reporting is part of the professional duty of a health professional	56	34	2	13	10
Even if they are not known, non serious ADRs should not be reported	10	14	2	45	44
There is a need to be sure that an ADR is related to the drug before reporting	55	31	4	23	2
Monitoring drug safety is important for the public	61	43	9	2	-
Monitoring drug safety is important for the patient	68	43	-	3	-
Only ADRs of prescription drug need to be reported	5	6	3	52	49
Monitoring drug safety is important for health care system	65	48	2	-	-
Only ADRs that cause persistent disability or incapacity should be reported	8	6	14	27	60
Reporting an ADR is part of the patient care	34	58	12	11	-
Monitoring ADR improves quality of patient care in health facility	84	15	9	3	4

SA- Strongly Agree, A- Agree, N-Neutral, D- Disagree, SD- Strongly Disagree

about their views on important factor necessary to report an adverse drug reaction, 20.3% stated the role of adequate knowledge(13). A study done in Amhara region, Ethiopia, also confirmed that health professionals with adequate knowledge about ADR were six times more likely to report than those with insufficient knowledge [AOR: 5.99(3.61, 9.94)95%CI] (14)

As shown in table 6 pharmacists have adequate knowledge about the difference between ADR and side effect, the term pharmacovigilance, about drug withdrawn from market due to safety reason, availability of national reporting system and ADR reporting form. Most (70.8%) physicians didn’t know the difference between ADR and side effect. Majority of Nurses, health officers and anesthetists didn’t know the difference between ADR and side effect, the term pharmacovigilance, about drug withdrawn from market due to safety reason, availability of national reporting system and ADR reporting form. Physicians, pharmacist and nurses raised polypharmacy and comorbidity as the factor commonly associated with ADR. There is an association between profession of the respondents and knowledge about ADR [Table 6]. The study clearly indicated that all health professionals don’t have required knowledge on ADR. Many studies also link under reporting with knowledge. (14)

When knowledge is compared with year of experience only two knowledge questions like „Are you aware of any

Table 6: Distribution of respondent's knowledge about ADR by profession among health professionals Nekemte Hospital, Ethiopia, January 24-Feb.7/2014

Variables	Physician	Pharmacist	Nurse	Anesthesia	Health	p-value
Do you know the difference between ADR and side effect?						
Yes	7	9	7	-	-	0.00
No	17	4	67	2	2	
Do you know the term Pharmacovigilance?						
Yes	22	9	6	1	-	0.00
No	2	4	68	1	2	
Do you know national ADR reporting system?						
Yes	22	12	29	-	-	0.00
No	2	1	45	2	2	
Do you know the availability of ADR reporting form?						
Yes	22	10	26	-	2	0.00
No	2	3	48	2	-	
Are you aware of any drug withdrawn from market due to safety reason?						
Yes	20	13	17	2	2	0.00
No	4	-	57	-	-	
Factor commonly associated with ADR						
Old age	4	1	9	1	-	0.675
Poly pharmacy	9	4	31	1	1	
Comorbidity	9	4	22	-	-	
Patient in ICU	2	3	6	-	1	
Children aged between 1-4yrs	-	1	6	-	-	

drug withdrawn from market due to safety reason?" and „Do you know the term Pharmacovigilance and year of experience?" are strongly associated with year of experience. But for other knowledge questions there is no association with year of experience [Table 7].

Practice

Only 13(11.3 %) of the participants encountered ADR for the past one year of which four (30.8%) reported the ADR. Sixty (52.2 %) of the respondent believed that FMHACA is the responsible body where ADR should be reported. Sixty three (54.8%), 29(25.2%) and 23(20%) of the study participants advice patients on possible adverse effects of drugs usually, sometimes and rarely, respectively [Table 3]. Different research done in many countries also proved less ADR report (2, 14, 15). It would be very difficult to assess medicines safety so as to evaluate the benefit/risk, in places where under reporting is very common. Particularly when spontaneous reports are the only tool to assess drugs safety, reporting and monitoring of a suspected ADRs should be a must (16). Different from study done in different part of Ethiopia (10, 14) more than half of the study participants clearly identified where ADR should be reported [FMHACA]. The present finding is also better as compared to research done on North India' physicians (11) and

Table 7: Association between knowledge towards ADR and ADR reporting and year of experience of health professionals in Nekemte Hospital, Ethiopia.

Variables	0-5yrs	6-10yrs	11-15yrs	>16yrs	p-value
Do you know the difference between ADR and side effect?					
Yes	13	3	3	4	0.063
No	28	32	20	12	
Do you know the term Pharmacovigilance?					
Yes	21	2	7	8	0.00
No	20	33	16	8	
Do you know national ADR reporting system?					
Yes	25	16	12	10	0.523
No	16	19	11	6	
Do you know the availability of ADR reporting form?					
Yes	27	13	11	9	0.089
No	14	22	12	7	
Are you aware of any drug withdrawn from market due to safety reason?					
Yes	27	-	8	6	0.00
No	14	35	15	10	
Factor commonly associated with ADR					
Old age	7	3	1	4	0.298
Poly pharmacy	16	19	8	3	
comorbidity	13	8	7	7	
Patient in ICU	3	3	4	2	
Children aged between 1-4yrs	2	2	3	-	

United Arab Emirates' clinicians (1) where 60.6% and 55% did not know where the ADRs had to be reported, respectively. The result of our study site and different part of Ethiopia may be an evidence of the organizations' less concern over ADR reporting.

Attitude

One hundred and twelve health professionals (97.43%) agree with regular reporting of ADR and 78.3% believed as their duty to report ADR. The importance of ADR monitoring for the public, the patient, and the health care system was agreed by 90.4%, 96.5% and 98.2% of the participants, respectively. Some of the responders (9.5%) believe that only ADR of prescription drugs need to be reported whereas most of them don't think so (87.8%) [Table 4]. This finding is higher in participants' belief on professional duty as compared to the study finding of Iran (17) where only 26% of the study participants believed ADR reporting should be professional duty; closer to study done in Lagos, Nigeria (64.6%) (4) and South West Ethiopia (57.31%) in which the respondents felt that ADR reporting should be a professional obligation; lower than KAP finding of Nepal (13) health professionals where 96.6% thought the necessity of reporting ADR. The importance of ADR reporting to the public, the patient, and the health care system was agreed by more than 90% of the responders unlike participants of South West Ethiopia (57.31%) (10). However, survey done among physicians living in South India showed that almost all of them believed the benefit of ADR reporting to patients (18).

Table 8: Association between profession of the respondents and attitude of health professionals towards ADR monitoring and reporting in Nekemte Hospital, Ethiopia.

Variables	Profession of the respondents	
	ADR Should be reported regularly	Chi-Square
	df	8
	Asymp. Sig.	.000
Reporting is part of the professional duty of a health professional	Chi-Square	1.698
	df	16
	Asymp. Sig.	.000
Even if they are not known, non serious ADRs should not be reported	Chi-Square	1.526
	df	16
	Asymp.sig	0.00
There is a need to be sure that an ADR is related to the drug before reporting	Chi-square	47.457
	df	16
	Asy-square	0.00
Monitoring drug safety is important for the public	Chi-square	56.405
	df	12
	Sig.	0.00
Only ADRs of prescription drug need to be reported	Chi-square	1.2872
	df	16
	Sig.	0.000
Monitoring drug safety is important for health care system	Chi-square	29.889
	df	8
	Sig.	0.000
Reporting an ADR is part of the patient care	Chi-square	48.917
	df	12
	Sig.	0.000
Monitoring ADR improves quality of patient care in health facility	Chi-square	30,614
	df	16
	Sig.	.015

As many surveys prove ADR causes not only death and injury to patients but also it affects public and health care system by increasing cost of healthcare and decreasing productivity (14, 19). The present study showed that most of the study participants disagree on statements such as „Even if they are not known, non serious ADRs should not be reported” (77.4%); „Only ADRs that cause persistent disability or incapacity should be reported” (75.7%); „Only ADRs of pre-

scription drug need to be reported” (87.8%). However, they agreed on „There is a need to be sure that an ADR is related to the drug before reporting” (74.8%). This result is comparable to study done among healthcare workers in a tertiary centre in Northern Nigeria in which > 70 % of them believed suspected, serious and certain reactions should be reported (9). Regarding the type of ADR to be reported our study participant’s knowledge is better than private practitioners from Klang Valley in Malaysia where 46.2% and 58.6% of the participants said that only proven reactions and all suspected reactions need to be reported, respectively (5). Table 8 demonstrated significant association between attitudes of ADR reporting and profession of the respondents.

Reason for not reporting an ADR

More than half of the respondents agreed that ADRs are well documented by the time a drug is marketed (55.7%) and said reporting forms are not available adequately (64.3%). Nevertheless, 38.3% and 31.3% of the participants listed absence of national ADR reporting system and complexity of ADR reporting form as the main reasons that affect reporting of an ADR, respectively (Table 5). The reasons mentioned here are different from that of South Australian healthcare providers who listed time constraints and unsatisfactory reporting processes as main obstacle to reporting (20)] and UAE clinicians where 71% of the responders felt not knowing how to report ADRs as reasons for reporting failure (1).

In conclusion, Even though most of the participants have positive attitudes about ADR reporting most had inadequate knowledge and showed poor practice of ADR reporting. Therefore, there is a need to increase the awareness regarding the importance of ADR reporting through Continuous Medical Education at regular intervals, training the health professionals on how to report an ADR and also including pharmacovigilance awareness programs for undergraduates

Sažetak

Uvod: Neželjena dejstva leka dovode do morbiditeta, mortaliteta i povećanja u broju prijema u bolnicu što utiče na ekonomski i zdravstveni sistem. Zdravstveni radnici treba da uzmu u obzir prijave neželjenih dejstava leka kao deo profesionalne obaveze da bi zaštitili pacijente od njihovih neželjenih dejstava. Dakle, cilj date studije je bio da odredi trenutni nivo znanja, iskustva i stavove prema prijavljivanju o neželjenim dejstvima leka među zdravstvenim radnicima u bolnici Nikemte.

Metoda: Primenjena je studija poprečnog preseka koristeći formulisan upitnik za određivanje nivoa znanja, iskustva i stavove prema prijavljivanju o neželjenim dejstvima leka među zdravstvenim radnicima u bolnici Nikemte.

Rezultat: **Ispunjeno je 115 upitnika sa stopom odgovora od 76.6%. U odnosu od 80%, 66.1%, 45.2% i 48.7% od ukupnog broja zdravstvenih radnika, ne zna razliku između neželjenog dejstva leka i sporednog dejstva, termin farmakovigilanca, Nacionalni sistem o prijavljivanju neželjenih dejstava leka i dostupnost formulara za prijavljivanje o neželjenom dejstvu leka. Od 13(11,3%) koji su dali odgovor a susreli se sa neželjenim dejstvima leka samo 4 (30.8%) je izvršilo prijavljivanje. 97.43% ispitanika koji su odgovorili slaže se sa činjenicom da neželjena dejstva leka treba prijaviti a (78.3%) se slaže da je to deo profesionalne dužnosti zdravstvenih radnika.**

Zaključak: Najveći broj zdravstvenih radnika ima nedovoljno znanje o neželjenim dejstvima leka. Premda imaju pozitivan stav prema prijavljivanju o neželjenim dejstvima leka, samo je nekolicina od njih nekada izvršila prijavu.

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