Assessment of Knowledge, Attitude and Practices towards Adverse Drug Reaction Reporting among Health Care Professionals in Adama town Hospitals, East Shoa Zone, Ethiopia

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Abstract

Adverse Drug Reactions are associated with a significant morbidity and mortality and early detection of new and/or unusual adverse drug events and minimal patient exposure to such events is very crucial to health care. Lack of knowledge, giving less value for the importance of Adverse Drug Reactions reporting and not well documented research in the developing countries were problems related with Adverse Drug Reactions among health professionals.

To assess the knowledge, attitude and practices on Adverse Drug Reactions reporting among health care professionals in Adama town Hospitals, East Shoa Zone , Ethiopia

A cross sectional study was conducted from June 8-20, 2017 among 183 health care Professionals. Data was collected through a self- administered questionnaire from health professionals selected by simple random sampling method. Finally, data was cleaned and checked for its completeness; coded and analyzed using Statistical Package for Social Sciences (SPSS) version 20. Descriptive analysis like frequency, proportion, mean and SD were applied.

Overall, 62(33.9%) of the respondents had good knowledge on Adverse Drug Reactions reporting with there were significant differences on the level of knowledge among the health professionals. Out of 86 (47.0%) respondents who had encountered with Adverse Drug Reactions, 49(57.0%) had reported. In addition, 86.3% have positive attitude towards Adverse Drug Reactions reporting. The reasons why the participants not reporting Adverse Drug Reactions were lack of reporting form 68.8%, time consuming 28.1%, reporting process creates an additional workload was 34.7%.

In spite of the poor knowledge among the respondents, the study showed that majority of the health professionals had positive attitude towards Adverse Drug Reactions reporting. But there are gaps in practice of Adverse Drug Reactions reporting among health care professionals working in Adama town Hospitals; only few of them had ever reported Adverse Drug Reactions

they encountered. These gaps need to be filled by intensive training and awareness creations on Adverse Drug Reactions reporting and pharmacovigillance at various levels of healthcare system by concerned bodies.

Key words: Adverse Drug Reaction, Health professionals, Adama town, Hospitals

1. Introduction

As stated in World Health Organization (WHO) report, "drugs have a possible effect on diseases, reduce symptoms, and enhance patients' health and quality of life" (WHO, 2006). Because of its side effect, taking a drug is not always as easy as just swallowing a pill and even it may also have the possibility of unintended consequences". By their nature of toxicity, unintended and undesired drug effect which is Adverse Drug Reactions (ADRs) is associated with a significant morbidity and mortality. This would occur when doses used in humans for prophylaxis, diagnosis, or therapy and pharmacovigillance. Pharmacovigillance means it is the science and activities relating to the detection, assessment, understanding and prevention of ADR or any other possible drug related problems. Due to this reason, drugs are always requiring competency and close monitoring to lower/reduce risks and enhance healthy life (DACA, 2008). Regardless of this benefit, under-reporting remains a major source of unintended result which is estimated only 6–10% of all ADRs are reported (Jenny et.al. 2012; Hazell et.al 2006). This rate of under reporting can interrupt signal detection and this will have negative impact on the public health. A cross-sectional study conducted to evaluate knowledge, attitude and practice of ADRs reporting among healthcare professionals working at M.R. Medical College in India revealed that 71% of the healthcare professionals knew what ADRs are, 62.4% knew what is pharmacovigilance, 35.7% were aware of Pharmacovigilance Programme of India. But unfortunately only 8.1% of them have reported ADRs to pharmacovigilance center or concerned unit of their hospital (Siddeshwara et.al, 2016). In Ethiopia, according to Drug Administration and Control Authority (DACA) study conducted to assess health care providers' knowledge, attitude and practice on ADRs reporting and its monitoring, 70.9% of the participants think that DACA should be responsible for monitoring ADRs. This report showed that out of these health care providers, only 14.6% of the respondents had reported the ADRs they encountered (Drug Monitoring Activities, 2009).

In the study conducted on the knowledge, attitude and practices and its monitoring among ADRs reporting in west Ethiopia (Angamo et.al, 2012), among health care professionals only 23.17%

and 25.61% of the participants were aware of national reporting system and a yellow card of ADRs reporting form. Other different study on the assessment of knowledge, attitude and practice of health professionals towards ADRs reporting and factors associated with reporting in Amhara region, North Ethiopia showed that the mean knowledge score of the participants was 46.5%. About 57% of the respondents did not know about the existence of the ADRs reporting system in Ethiopia (Necho et.al, 2014). In some countries, ADRs are reflected as a major reason to be hospitalized and even ranked in top 10 leading causes of mortality (WHO, 2004) and resulting in high economic burden of a society (Patel et.al, 2007). In India, the total cost for hospitalization due to ADRs problems was found to be 36, 451 US$. The average cost per patient hospitalized with ADRs was 115 US$ (Rajakannan et.al, 2012).

As this event is very critical, all healthcare professionals including doctors, pharmacists, nurses and other healthcare professionals are encouraged to report ADRs. Adequate knowledge, good practices and positive attitude are essential element in ADRs reporting among healthcare professionals. Therefore, the purpose of this study was to assess the knowledge, attitude and practices on ADRs reporting among healthcare professionals in Adama town hospitals, Ethiopia.

2. Methods

2.1. Study Setting and Period

Adama is one of the towns in Oromia Regional State, East Shewa Zone and located 100km from capital city Addis Ababa to the east. A total population of the town is 388,295 (188,323 male and 199,972 female). Town has 6 sub cities with a total kebeles of 18 i.e. 14 urban and 4 rural kebeles. There are governmental and private health care institutions in the town i.e. 6 health Centers, one referral hospital, 4 general hospitals, over 83 private clinics, and more than 105 pharmacies. This study was conducted in Adama Hospital Medical Collage, Rift Valley General Hospital, Sr. Aklesia Memorial Hospital and Medhin Beza Hospital. The study was conducted from June 8- 20, 2017.

2.2. Study Design

A facility based cross sectional study design was used.

2.3. Source Population

The source population was all health professionals working in Adama town Hospitals in 2017.

2.4. Study Population

The study population was all health professionals those who were available during the study period.

2.5. Sample Size Determination

The sample size was calculated using a single population proportion formula by assuming the Knowledge, Attitude and Practice of ADRs report to be 50% since there were different findings from different studies; to get the maximum possible sample size as follows;

$n = \frac{(Z_{\alpha/2})^2 P (1-P)}{d2}$ where,

n = number of sample size required

$Z_{\alpha/2}$= is the confidence level which is 95% (1.96)

P = Prevalence of dependent variables assumed to be 50%

d = margin of error i.e. 5%

$$n = \frac{([1.96)]^2(0.5)(0.5)}{(0.05)^2} = 384$$

Since the size of source population was less than 10,000 i.e. 318 health professionals, correction formula was used to adjust the sample size. Therefore, the corrected sample size was;

$$n_f = \frac{n}{1 + \frac{n}{N}}$$

Where, n f =the final desired sample size

n = sample size from single population proportion formula

N =the total population size i.e. 318 (total number of health professionals in Adama hospitals)

$$nf = \frac{384}{1 + \frac{384}{318}} = 174$$

And 5% for non-response was added to the final sample size, and the final sample size was:

174+ (174 *0.05) = 182.7 ≈ 183

2.6. Sampling Techniques

All four hospitals (i.e. Adama Hospital Medical College, Rift Valley General Hospital, Sr. Aklesia Memorial Hospital and Medhin Beza Hospital) found in Adama town were included. The total sample size required was proportionate according to the size of each health professionals found in four hospitals i.e. Physicians, Pharmacy personnel and Nurses for the

study. Then health professionals list was used as a sampling frame from their payroll to select 183 study participants (i.e. 39 physicians, 22 Pharmacy personnel and 122 nurses) by using a simple random sampling technique.

2.7. Data Collection Procedure

A self-administered questionnaire was used for data collection after informed consent was made with respondents for confidentiality of data. The questionnaire was consisted of questions those assessing background variables, knowledge, attitude and practice of ADRs reporting by health professionals. The questionnaire was developed and standardized from different literatures on the knowledge, attitude and practices of healthcare professionals on ADRs relevant to this study. The data was collected in the afternoon, since the patient load in hospitals usually decreases at this time of the day to minimize non-response rate by four nurses.

2.8. Data Quality Assurance

The questionnaire was developed in English after different literature reviews were done. Pre-test was done on 5% of the sample size on Gada health center found in Adama town which was not included in the actual study setting. Accordingly ambiguous and vague words and questions, its sequence and inconsistency were corrected. During data collection, supervision was done by principal investigator and corrections were made as required. The collected data were checked for accuracy, consistency, omissions and incompleteness. Data were cleaned, coded and entered in to software. After entry; frequency was done to see missing values and outlier's for correction.

2.9. Data Processing and Analysis

Data was checked for completeness and consistency and then was coded and entered into SPSS version 20 for further analysis. Descriptive analysis was done by using frequencies, proportions, mean and SD. Text, tables and graphs were used to present the findings.

3. Results

3.1. Socio-Demographic Characteristics

All health professionals filled and returned the questionnaire which made the response rate 100%. Out of a total of 183 health professionals 122 (66.7%) were nurses, 39 (21.3%) were physicians and 22(12.0%) were pharmacy personnel. Most of the respondents 64 (35.0%) were in the age range of 31-40 years and 118 (64.5%) were females. About 31.7 % of health professionals had an experience from 6-10 years and 14.2% were having an experience of 16 years and above (Table 1).

Table 1: Socio-Demographic Characteristics of Health Professionals in Adama town Hospitals, Ethiopia, June, 2017

Variables	Category	Number	Percent
Sex	Male	65	35.5
	Female	118	64.5
Age	20-30	57	31.1
	31-40	64	35.0
	41-50	41	22.4
	51 and above	21	11.5
Profession	Physicians	39	21.3
	Pharmacy Personnel	22	12.0
	Nurses	122	66.7
Years of experience	1-5 years	57	31.1
	6-10 years	58	31.7
	11-15 years	42	23.0
	16 years and above	26	14.2

3.2. Health Professionals' Knowledge on ADRs Reporting

The mean score of knowledge is 2.63 ±1.62SD and in percent mean score was 53% out of the 5 knowledge assessing questions. Eighty three (45.4%) of the respondents had a knowledge score of equal to or greater than the mean. One hundred forty one (77%) of the respondents knew the difference between ADRs and side effect. Almost less than half (44.3%) of the respondents did not knows about the existence of the ADRs reporting system in Ethiopia and more than half (56.3%) of the health professionals did not knows availability of ADRs reporting form. Overall, only 62(33.9%) of the respondents had good knowledge on ADRs reporting; while 21(11.5%) and 100(54.6%) of the respondents had a moderate and poor knowledge on ADRs reporting, respectively. Regarding the knowledge level among different health professionals; 29(46.8%) of physicians, 18(29.0%) of pharmacy personnel and 15(24.2%) nurses had a good knowledge on ADRs reporting. Where 5(23.8%) of physicians, 3(14.3%) of pharmacy personnel and 13(61.9%) nurses had a moderate knowledge on ADR reporting (Table 2).

Table 2: Knowledge of Health Professionals Regarding ADRs Reporting in Adama Town Hospitals, Ethiopia, June, 2017

Questions	Category	Number of Respondents(n=183)	
		Number	Percent
Adverse drug reaction is different from side effect	Yes	141	77.0
	No	42	23.0
Know the term pharmacovigillance	Yes	95	51.9
	No	88	48.1
Know the existence of National ADR reporting system in Ethiopia	Yes	102	55.7
	No	81	44.3
Know the availability of ADR reporting form	Yes	80	43.7
	No	103	56.3
ADRs are well documented at the time the drug is marketed	Yes	63	34.4
	No	120	65.6
Overall Knowledge	Good	62	33.9
	Moderate	21	11.5
	Poor	100	54.6

3.3. Practices on Adverse Drug Reaction Encountered and it's Reporting

This study was tried to assess the health providers' practice with respect to adverse drug reaction by asking about their history of encounter and their actions towards it. The result showed that 86 (47.0%) of the participants had encountered with a ADRs in their professional practice during the last 12 months in their provision of health services. Out of 86 participants that were encountered ADRs in the past 12 months, 69 (80.2%) of the respondents had recorded the ADRs in the patient clinical record while the rest were not. As to the number of patients with ADRs they had encountered in their professional practice in the last 12 months, 27(41.9%) of them were encountered in average with at least three patients that were developed ADRs problems. Respondents were asked whether they reported ADRs during their practice as health professionals and as a result 49(57.0%) had ever reported ADRs they encountered during their

professional practice. Of those health professionals who reported ADRs, 35(71.4%) reported to FMHACA which is the responsible organization for monitoring and evaluating of ADRs, 7(14.3%) to the head of the pharmacy and the rest were reported to physicians. Slightly more than half 103(56.3%) of the respondents were usually gave advice for the patients, while 16(8.7%) were never gave advice to their patients (Table3).

Table 3: Practices Regarding ADRs Reporting in the Past 12 Months among Health Professionals in Adama Town Hospitals, Ethiopia, June, 2017

Variables	Response Category	Respondents	
		Number	Percent
Have you ever encountered patient with ADR in your professional practice, in the last 12 months? (n=183)	Yes	86	47.0
	No	97	53.0
How many patients with ADR, did you see?(n=86)	One	27	16.3
	Two	17	19.8
	Three	27	41.9
	Four and above	15	22.1
Have you noted the ADR you encountered on the patient clinical record?(n=86)	Yes	69	80.2
	No	17	19.8
Have you ever reported the ADRs?(n=86)	Yes	49	57.0
	No	37	43.0
To whom did you report ADR?(n=49)	To Pharmacy Department	7	14.3
	To FMHACA	35	71.4
	To Physicians	7	14.3
How often do you give advice about ADR to the patients??(n=183)	usually	103	56.3
	Sometimes	64	35.0
	Never	16	8.7

3.4. Attitudes towards ADRs Reporting

The participants were asked their agreement or disagreement towards ADRs reporting. Majority 161(88%) of the respondents were agreed that ADRs should be reported regularly and 139(76%) of respondents agreed that ADRs reporting is part of the duties of health professionals.

More than two-third, 133 (72.7%) of the health professionals agreed that on the idea of reporting drug safety to the public and 158 (86.3%) to the patient. About 138(75.4%) of the respondents were disagree on the idea that ADRs reporting creates additional work load (Table 4).

Table 4: Attitudes towards ADRs Reporting among Health Professionals in Adama Town Hospitals, Ethiopia, June, 2017

Statements	Level of agreement(n=183)		
	Agree No (%)	Neutral No (%)	Disagree No (%)
ADRs should be reported spontaneously at regular base	161(88)	6(3.3)	16(8.7)
Reporting ADR is part of duty of Health professionals	139(76)	5(2.7)	39(21.3)
Reporting drug safety is important for the public	133(72.7)	13(7.1)	37(20.2)
Only ADR of prescription drugs need to be reported	31(16.9)	10(5.5)	142(77.6)
Reporting is not useful to the patient	20(10.9)	5(2.7)	158(86.3)
Reporting creates additional work load	37(20.2)	8(4.4)	138(75.4)

Analysis of the variables on attitude revealed that majority158 (86.3%) of the respondents have positive attitude towards ADRs reporting as they had scores greater than 13.5 (75% of the maximum score), while 25(13.7%) had negative attitude towards ADRs reporting.

Among these respondents who had positive attitude towards ADRs reporting; majority 101(63.9%) were nurses, while 21(13.3%) were pharmacy personnel (Figure 1).

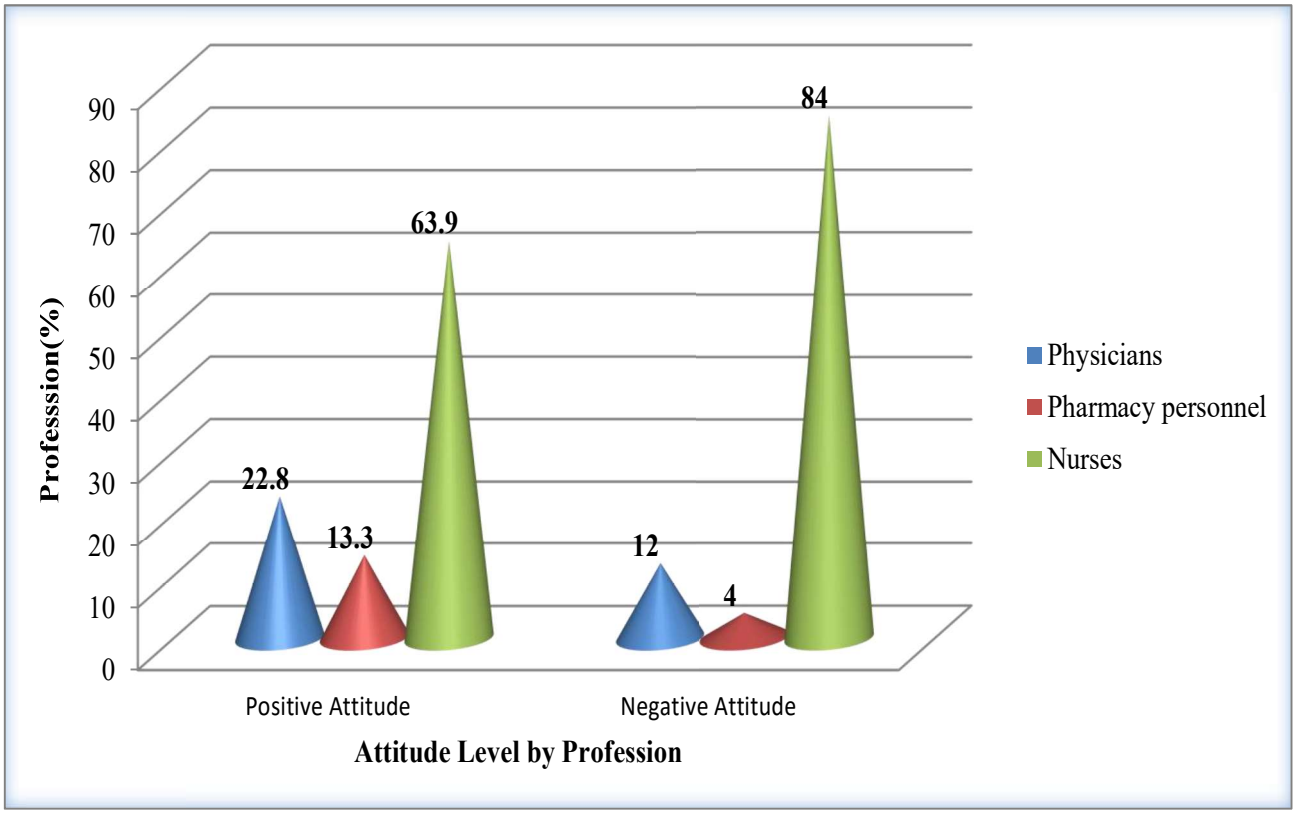

Figure 1: Attitude levels of Health Professionals by Profession in Adama Town Hospitals, Ethiopia, June, 2017

3.5. Participants Reason for Not Reporting ADRs

The respondents were asked for their reasons for non-reporting of observed ADRs. Thirty seven (46%) of the ADRs in the study had not reported. Among some of the reasons that affect reporting of a ADRs; majority (89.2%) of the respondents agreed that non availability of reporting form at work place and 81.1% of respondents agreed that they are busy to fill the form. In addition, 24.3% of respondents concerned that extra work is required to fill & send the report and 18.9% of respondents as well were believed that it is difficult to diagnose ADRs in clinical practice (Figure 2).

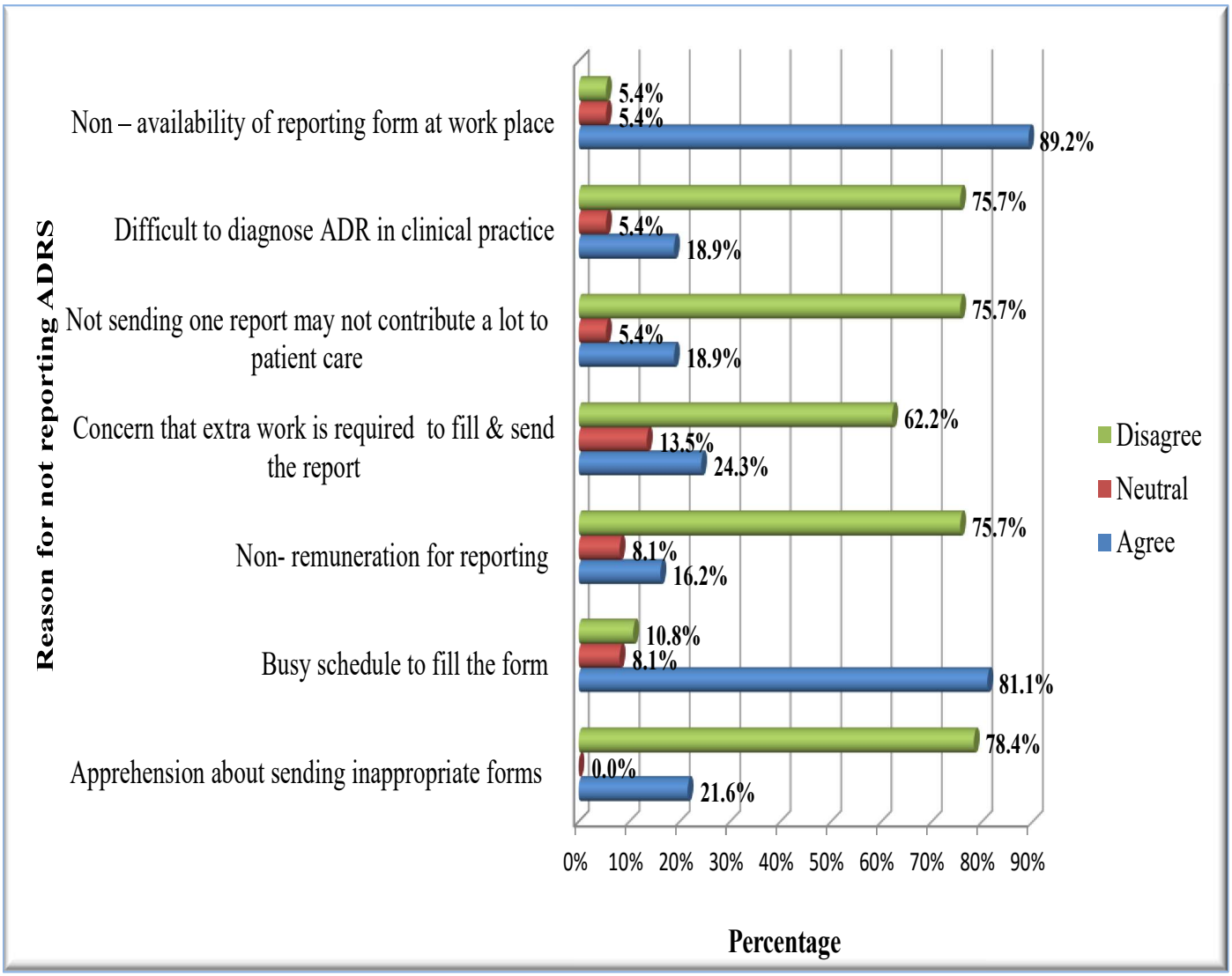

Figure 2: Health Professional's Reasons for Not Reporting ADRs in Adama Town Hospitals, Ethiopia, June, 2017

4. Discussion

The study was conducted in four hospitals found in Adama town among health professionals to assess the knowledge, attitudes and practices of ADRs reporting. Among the study participants, one-third of the respondents had good knowledge on ADRs reporting, while out of 86 (47.0%) respondents who had encountered with ADRs problems, more than half had reported to concerned bodies. In addition, majority (86.3 %%) of the respondents were had positive attitude towards ADRs reporting.

Adverse drug reactions 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 (DACA, 2008). Worldwide, underreporting of ADRs is a well-recognized problem associated with spontaneous ADRs reporting system. Amongst various factors knowledge, attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs (Lee, et al., 2003). Under reporting problems of ADRs was seen in this study as well that is expected to contribute for morbidity and mortality related with it.

In the present study the overall knowledge of ADRs reporting showed that only 33.9% of health professionals were good knowledge which is seems higher when compared with the study done in selected health facilities of Jimma zone, south west Ethiopia which is 23.17% of the respondents had adequate knowledge (Angamo and Tajure, 2012). This is may be due to the difference in time of the study period.

In this study majority (77%) of the participants replied that ADRs was different from side effects, but only (51.9%) the respondents knew the term "pharmacovigillance". Similar observations had been noted in study conducted in South West Ethiopia, where 79.3% of the respondents said that ADRs is not the same as drug side effect, but 16(19.51 %) respondents knows the term "pharmacovigillance" (Angamo et al., 2012). Another study conducted at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia, majority, 212 (99.1%) of participants were differentiate adverse drug reactions from side effects but, only 46(21.5%) respondents knows the term pharmacovigillance (Abewa, 2014). This finding is also comparable with study conducted in Karnataka, India in which 71% of the healthcare professionals knew the difference between ADRs and side effects and 62.4% health care professionals were knew the term Pharmacovigilance (Siddeshwara et al., 2016). 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 (Ramesh and Parthasarathi, 2009).

Almost all mentioned studies were similar with this study and this shows that they were good at differentiating ADRs from side effects but poor on the term pharmacovigillance. This might be due to inadequate promotion and awareness creation on the term pharmacovigillance and its

related activities by Food, Medicine, Health Administration and control authority of Ethiopia and concerned bodies in all health facilities across the country and may be due to study period differences.

In the present study less than half (44.3%) of the respondents did not knows about the existence of the ADRs reporting system in Ethiopia and more than half (56.3%) of the health professionals did not knows availability of ADRs reporting form. This result different from a study conducted in selected health facilities in South West Ethiopia in which (79.5%) and (74.4%) health professionals were don't know existence of the national ADRs reporting system and availability reporting form in Ethiopia respectively (Angamo et al., 2012). Another study conducted in Jimma Zone Hospitals, South West Ethiopia were more than half of (62.6%) health professionals don't know the existence of national ADRs system in Ethiopia (Teshale and Melaku, 2010). This difference may be due to the reason that this study is recent and the study participants may got the chance to expose to the reporting system and format than the previous studies. Moreover, study conducted in Amhara Regional State which is (57.1%) and (72.2%) health professionals don't know existence of the national ADRs reporting system and availability reporting form in Ethiopia respectively (Necho and Worku, 2014).This difference also may be due to less work done by the relevant organizations to advertise and promote the center through different media and the chance of getting relevant awareness.

In this study 47% of the participants had encountered with an ADRs in their professional practice during the last 12 months. Of these 80.2% of respondents had no experience to report ADRs they encountered on their clinical records but 57% actually reported one or more ADRs in their clinical practice. Among these health professionals who reported ADRs; 71.4% had reported to FMHACA which is responsible organization for monitoring and evaluating of ADRs, while 14.3% to the head of the pharmacy and the rest to physicians. This finding is different from study done in South West Ethiopia revealed that all the respondents (n=82) had never recorded ADRs on clinical records nor reported ADRs to the concerned body (Angamo and Tajure, 2012). Another study done in Amhara regional State in which a smaller proportion of respondents (16.2%) had ever reported ADRs they encountered during their professional practice; of those health professionals who reported ADRs, 2(4.5%) reported to FMHACA (Necho and Worku, 2014). This difference may be due to the time gaps between the studies. However, the proportion of participants who reported ADRs in the present study almost comparable to the

study done in India in which 64% of respondent reported the suspected ADRs (Madhan and Ramesh, 2009) and in study conducted which is 59 % of the respondents had reported at least one ADRs in their carrier (Elisabet, 2009).

In spite of the poor knowledge among the respondents in this study, it showed that majority 158 (86.3%) of the health professionals had positive attitude towards ADRs reporting. Majority 161(88%), of health professionals agreed that ADRs should be reported regularly and 139 (76%) of respondents agreed that ADRs reporting is part of duty of health professionals. One hundred thirty three (72.7%) of the health professionals agree on the idea that reporting drug safety is important for the public and 158 (86.3%) for the patient. It is a positive indication of the need for ADRs reporting. This finding is almost comparable with the study conducted in South West Ethiopia in which (57.31%) respondents agreed that ADRs reporting is part of duty and most respondents (71.95%) and (73.17%) agreed that reporting ADRs are important for the public and for the patient respectively (Angamo et al., 2012). The study conducted by DACA, almost all health providers agree towards an ADRs should be reported (96%) and it is part of the professional duty of a health professional (95%). Most of them also agree on the idea that monitoring an ADRs is important for the public (96%), and for the patient (95%) (DACA, 2008). Another study which was done in Saudi Arabia showed that 98.3% of the respondents considered the reporting of ADRs to be integrated to their professional duties (Mohammed et al., 2009).

According to this study, majority (89.2%) of respondents agreed that non availability of reporting form at work place and (81.1%) of respondents agreed that they are busy to fill the form are the common reasons for not reporting ADRs. In addition, 24.3% of respondents concerned that extra work is required to fill and send the report and 21.6% of respondents agreed that apprehension about sending inappropriate forms are another reasons reported by the participants. These all findings indicate the fact that there were gaps regarding knowledge, attitude and practice of ADRs report system which requires more appropriate intervention and further researches.

5. Conclusions and Recommendations

5.1. Conclusions

There was poor knowledge among the respondents, while majority of the health professionals had positive attitude towards ADRs reporting. In addition, there are gaps in the practice of ADRs reporting among health care professionals working in Adama town Hospitals. Low proportion of

respondents had ever reported ADRs they encountered. The major reasons for not reporting ADRs were non availability of reporting form at work place, non- remuneration for reporting, busy to fill the form, concern that extra work is required to fill and send the report of ADRs in clinical practice and apprehension about sending inappropriate forms mentioned.

5.2. Recommendations

Ethiopian FMHACA shall provide continuous and regular training to health care providers on the importance of ADRs monitoring and reporting in order to improve their knowledge to identify and report ADRs.

FMHACA and other stakeholders shall also be focused on report system establishment for the reasons not reporting ADRs by health care providers in hospitals.

Awareness creation on the existence and purpose of ADRs monitoring and reporting system at health facilities shall be done by FMHACA.

Ensuring the availability of reporting forms and introducing other reporting channels like internet and toll free numbers

Encouraging the involvement of all health care professionals in ADRs reporting and providing feedbacks on ADRs case reports

Further studies are recommended at a national level to exhaustively identify determinants of knowledge, attitude and practice of ADRs reporting and pharmacovigillance to bring better solutions.

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