Assessment of Knowledge, Attitude and Practices on Adverse Drug Reaction Reporting among Pharmacy Personnel Working at Community Pharmacy, Addis Ababa, Ethiopia

Alaynesh Goshime (B.Pharm)

Under the Supervision of Dr. Teferi Gedif

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This is to certify that the thesis prepared by Alaynesh Goshime, entitled: *Assessment of Knowledge, Attitude and Practices on Adverse Drug Reaction Reporting Among pharmacy Personnel Working at Community Pharmacy, Addis Ababa, Ethiopia* and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Pharmacoepidemiology and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee:

Examiner: Dr. Ephrem Engidawork signature _____ date_____

Examiner: Dr. Teshome Nedi signature _____ date_____

Advisor: Dr. Teferi Gedif signature _____ date_____

ABSTRACT

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Alaynesh Goshime

Addis Ababa University, 2015

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse drug reactions (ADRs) are common cause of illness, disability and even death. Knowledge, attitude and practices of health professionals towards ADR reporting are known to have crucial contribution in the detection and reporting of the reactions. A cross sectional study was conducted on a sample of 379 pharmacy personnel working at randomly selected community pharmacies of Addis Ababa to assess their knowledge, attitude and practice towards ADR reporting. Data was collected using self administered questionnaire. Majority of the respondents were male (57.5%) and in the age group 26-30 (55.1%). Over half (70.7%) of the respondents had poor knowledge. One hundred seventy three (45.6%) participants encountered ADRs in the past 12 months but none of them reported to the relevant authority. The majority of respondents (82.8%) had a positive attitude towards ADRs reporting. The study revealed that majority of pharmacy personnel at community pharmacy in Addis Ababa had poor knowledge, positive attitudes and very limited practices towards ADR reporting. The Ethiopian Food, Medicine and Health Care Administration and Control Authority should create awareness

on the existence of ADR monitoring system and the purpose and importance of ADR reporting and should also conduct continuous trainings and seminars about ADR reporting with community pharmacies dispensers and finally ADR reporting forms should be made available at community pharmacies.

Keywords: Pharmacovigilance , ADR reporting, Community Pharmacy Personnel, Knowledge, Attitude, Practice

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List of Abbreviations

ADR:	Adverse Drug Reaction
AIDS:	Acquired Immunodeficiency Syndrome
ART:	Antiretroviral Therapy
DACA:	Drug Administration and Control Authority
FMHACA:	Food, Medicines and Health Care Administration and Control Authority
HIV:	Human Immunodeficiency Virus
MSH:	Management Science for Health
PV:	Pharmacovigilance
SPS:	Strengthening Pharmaceutical Services
SRS:	Spontaneous Reporting System
TB:	Tuberculosis
UMC:	Uppsala Monitoring Center
WHO:	World Health Organization

1. Introduction

1.1 Background

Drugs can treat diseases, reduce symptoms, and enhance patients' health and quality of life. However, taking a drug is not always as easy as just swallowing a pill. This is because drugs have some side effects. With the use of any drug comes the possibility of unintended consequences which when harmful are referred to as adverse drug reactions (ADRs) (WHO, 2006). An adverse drug reaction is defined by the World Health Organization (WHO) as any noxious, unintended and undesired effect of a drug that occurs at doses used for prevention, diagnosis or treatment (WHO, 2002)

ADRs are a common problem, which affect patients in the hospital and community setting. Most ADRs are relatively mild, and many disappear when the drug is stopped or the dose is changed. Some gradually subside as the body adjusts to the drug. Other ADRs are more serious and last longer. Even though some ADR are minor and can be resolved quickly some can cause permanent disability or death (WHO, 2006).

The WHO initiated an international program for monitoring the safety of medicines in 1968, known as pharmacovigillance which is defined by WHO as 'the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problems'. It is all observational (nonrandomized) post approval scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events. This includes the use of pharmacoepidemiologic safety studies (WHO, 2002).The program is coordinated by the

Uppsala Monitoring Center (UMC) and has 118 full members and 29 associate members as of June 2014 (Uppsala Monitoring Center, 2014).

Pharmacovigillance is essential because the clinical information about a medicinal product during the development phase (Phase I-II and III) is usually incomplete on account of a limited number of subjects involved , controlled condition under which the trials are conducted and short duration of the trials(WHO, 2002). Pharmacovigillance practices not only help early detection of ADRs, but also facilitate in identifying both risk factors and mechanisms underlying the adverse reactions (WHO, 2006).

Pharmacovigilance is crucial to quantify previously recognized adverse drug reactions, to identify unrecognized adverse drug events, to evaluate the effectiveness of medicines in real-world situations, and to decrease mortality and morbidity associated with adverse events (Eguale et al., 2008). The scope of pharmacovigilance therefore covers product quality; medication errors, including therapeutic ineffectiveness; and previously known or unknown ADRs (Management Sciences for Health /SPS, 2009)

Most of the pharmacovigilance systems around the world depend on spontaneous reporting systems to collect information about ADRs, where the reports are submitted on a voluntary basis from health care professionals and then the information is entered onto a data base which is assessed regularly for signal generating. This spontaneous reporting is considered the main mechanism in the pharmacovigilance system by which the ADRs

are identified after the drug is released onto the market and it is the foundation of the WHO data base (WHO, 2006).

All healthcare professionals including doctors, pharmacists, nurses and other healthcare professionals are encouraged to report ADR. All healthcare providers have roles to play in maintaining a balance between a medicine's benefits and risks. (Zolezzi and Parsotam, 2005). Healthcare professionals outside the government system should also report adverse reactions (WHO, 2006).

Unfortunately, the spontaneous ADR reporting system is affected by a number of weaknesses, the most noticeable of these being the phenomena of ADRs underreporting from healthcare professionals. The reasons behind underreporting were not well documented in the developing countries although it had been proposed early in the developed countries, there were numerous obstacles preventing health care professionals from ADRs reporting as noted in the literature some of these are lack of knowledge giving less value for the importance of ADR reporting (Bateman et al., 1992; Vallano et al., 2005).

In Ethiopia, ADR reporting and monitoring was initiated in 2001 through the former Drug Administration and Control Authority (DACA). Spontaneous ADR reporting has been put in place as of 2002 and all health care professionals are encouraged to report ADRs using spontaneous ADR reporting form. A simple ADR reporting form was developed and was made available throughout all health facilities. Various trainings were

given and face to face discussions about ADR monitoring were also performed (DACA, 2008).

1.2 Statement of the problem

Post marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for the use of the general population. Spontaneous (yellow card) reporting of ADRs remains to be the foundation of successful pharmacovigillance (WHO, 2006). The contribution of health professionals including pharmacists to ADRs reporting is significant and has encouraged ongoing ascertainment of the safety of drugs (Ahmad, 2003). In spite of these benefits, under-reporting remains a major draw-back of spontaneous reporting. It is estimated that only 6–10% of all ADRs are reported (Lisha et al., 2012; Lorna and Saad, 2006). This high rate of under reporting can delay signal detection and this will have negative impact on the public health.

According to WHO standards, countries with the best reporting rates must generate over 200 reports per 1,000,000 inhabitants per year (UMC, 2015). However, reporting of ADR is usually below 10% (Rawlins, 1995). Studies in Malaysia and in Iran showed this reality (Aziz et al., 2007; Ramezani et al., 2007).

Under reporting of ADRs by health professionals is not the problems of developing countries only. It is the problem of developed countries also. For instance studies have shown that ADRs reporting rate in USA to be as low as 1 - 6% (Chyka, 2000).

The situation is not different in Ethiopia where the level of ADR reporting is showed to be alarmingly very low (Ermias et al., 2011; DACA, 2008; Angamo et al., 2012). Even though the spontaneous reporting system has been put in place as of 2002 and all health professionals are encouraged to report, the number of reports received by FMHACA remains very low. It has only 238 reports in the six years: from 2002 to 2007 (Ermias et al., 2011). Even though there is an increase in the number of adverse drug events received by FMHACA (123 reports in the year 2010/2011, 79 reports in the year 2011/2012 and 223 reports in the year 2013/2014), there are still lots of ARDs remaining to be received by FMHACA as a country must send over 200 ADR reports per million inhabitants per year to the UMC to be considered as having an optimal National Pharmacovigillance Center according to WHO standards (UMC, 2015).

Adequate knowledge, good practices and positive attitude are essential element in ADR reporting. Previous studies in Ethiopia have concentrated on the assessment of knowledge, attitude and practice of ADRs reporting at public health facilities only excluding private health facilities, particularly community pharmacies (Ermias et al, 2011; DACA, 2008; Angamo et al., 2012). Furthermore there are no published studies that assessed the status of private health facilities, particularly community pharmacies towards ADR reporting.

With this in mind the aim of this study is to assess the knowledge, attitude and practices on ADR reporting among pharmacy personnel at community pharmacies in Addis Ababa, Ethiopia.

1.3 Literature review

1.3.1 Epidemiology of adverse drug reactions

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death. In some countries, ADRs rank among the top 10 leading causes of mortality. (WHO, 2004).

Many retrospective and prospective studies have been conducted aiming at estimating ADRs incidence in different settings. These studies started in the 1960s were the epidemiological data basis of ADRs that has been established. The early studies concerned with the epidemiology of ADRs estimated that the incidence of ADRs ranged from 10 to 20 per cent in general practice setting (Seidl et al., 1965; Smith et al., 1966; Ogilvie and Ruedy, 1967).

ADRs are a major public health problem globally and are one of the leading causes of mortality and morbidity in health care facilities worldwide (Patel et al., 2007). A meta-analysis of 39 prospective studies in USA found ADRs to be the fourth to sixth leading cause of death in the United States and serious ADRs accounted for 6.7% of hospitalized admissions; out of which 0.32% are fatal (Lazarou et al., 1998). Death rate among patients who have experienced ADRs is as high as 19.18% (Bond and Raehl, 2006).

ADRs are known important causes of hospitalization resulting in high economic burden on society (Janaje and Singer, 2001). For example in USA, more than one hundred thousand death-induced by ADRs occur yearly, and also 7% of hospitalizations are related to ADRs (Wasser et al., 2001; Pirmohamed et al., 2004). A study in the UK reported on 530 000 ADRs per year in the outpatient setting (Gurwitz et al., 2003).A study carried out in a tertiary referral center in South India showed that admissions due to ADRs accounted for 0.7% of total admissions and deaths due to ADRs accounted for 1.8% of total ADRs (Ramesh et al., 2003).

A prospective observational study which was conducted in a State University Teaching Hospital in Nigeria determined the incidence of pediatric ADRs and the estimated cost of treatment over an 18-month period. According to this study the overall incidence rate of ADRs was found to be 1.8% and about 15,466.6 USD was expended to manage all the pediatric patients admitted due to ADRs (Oshikoya et al., 2009).

A year-long, prospective observational cohort study of which was conducted in a single UK pediatric medical and surgical secondary and tertiary referral center to assess the incidence, characteristics and risk factors ADRs estimated the incidence rate to be 7.7% (Thiesen et al., 2013).

1.3.2 Adverse drug reaction related costs

ADRs have major public health, financial and economic implications. The financial burden of ADRs increases substantially when ADRs either cause or extend hospitalization. It is also important to note that most of the studies to date have largely concentrated on direct costs, and there are no reliable estimates of the social and indirect costs of ADRs, making it difficult to measure the overall economic burden to the patient and society (Lundkvist and Jonsson, 2004).

In USA, a study managed to include some of the indirect costs of ADRs and the results of the study showed that the estimate costs, including lost income, lost household production, disability, and healthcare costs, due to preventable ADEs was US$17 billion to US$29 billion (Kohn et al., 1999).

Another study in London indicated that ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications (Gannon, 2008).
In the UK ,it was found that the estimated costs of a hospital bed was €228 per day and that 5% of the 8.5 million patients admitted to hospitals in England and Wales each year experience preventable adverse events, leading to an additional three million bed days (Chartered Institute of Public Finance and Accountancy, 2002). Another study reported that the financial burden of ADRs is significant; the preventable ADRs provide the potential to save costs, and also that there is an urgent need to develop preventive strategies to reduce this cost burden (Lundkvist and Jonsson, 2004).

A retrospective cohort design based study which was conducted to estimate the incidence and costs of related to ADRs for patients greater than 65 years of age in Ontario Emergency Department (ED) for the period April 2003–March 2008 revealed that approximately 0.75% of total annual ED visits among adults aged 66 years and above were found to be ADR-related, and among these patients 21.6% were hospitalized. In 2007, the cost of ADR-related visits was $333 per ED visit and $7528 per hospitalization for a total annual cost of $13.6millionin Ontario, or an estimated $35.7million in Canada (Wu et al., 2012).

1.3.3 ADRs reporting knowledge, attitude and practice

There are many studies worldwide conducted on knowledge, attitude and practice of health professionals towards ADR reporting, factors that affect ADR reporting and related issues. But few studies were conducted on the assessment of the knowledge, attitude and practice of community pharmacy personnel towards ADR reporting. In a cross sectional study which was conducted to determine and evaluate awareness, knowledge and attitude of community pharmacists towards ADRs reporting in the Makkah in Kingdom of Saudi Arabia (KSA), Only 18% participants were aware of the ADR reporting system and 56% of the respondents were not aware of the existence of the Saudi National Pharmacovigilance centre. The main factors that discouraged ADR reporting were the lack of reporting forms being available, that it was time consuming, that they did not know how to report them and reporting forms are too complicated. According to 38.80% of participants ADR reporting was the responsibility of pharmacists

whereas 32.90% stated that it was the responsibility of physicians (Al-Hazmi and Naylor, 2013).

A study conducted to assess the knowledge, attitude and behavior of community pharmacists towards ADR related aspects in two districts of South India revealed that only 30.5% of pharmacists had knowledge about ADRs, 11.7% and 10.9% were aware of National Pharmacovigilance Program (NPP) and regional reporting centers respectively. Only 54 (43%) of the respondents agreed that ADR reporting is a professional responsibility of pharmacists and none of the respondents reported ADRs to the relevant body. This study showed that the community pharmacists were having least scores towards knowledge, attitude and behavior (practice) on ADRs (Mahendra et al., 2012).

In a study conducted among Texas pharmacists to assess their knowledge of adverse drug event (ADE) reporting to the Food and Drug Administration (FDA), the Pharmacists had low knowledge scores on ADE reporting. Most (67.9%) pharmacists had never reported ADEs to FDA. (Gavaza et al., 2011)

In Ethiopia, National ADR monitoring system was first established in 2002 G.C. This establishment created the center at the former Drug Administration and Control Authority. Since then the center carried out different activities (DACA, 2008). Ethiopia has become 88th full member of the WHO Programme for International Drug Monitoring in 2008 (Uppsala Monitoring Center, 2009).

The pharmacovigilance system In Ethiopia is a spontaneous voluntary ADR reporting system. The FMHACA is responsible for collecting ADR reports in the country. All health professionals, working either at public health facilities or private health facilities, are encouraged to report suspected ADRs (DACA, 2008). This Spontaneous Reporting System in Ethiopia like other SRSs around the world suffers from ADR under-reporting from health professionals and it was reported that the rate of ADR reporting in Ethiopia is alarmingly low (Ermias et al, 2011).

There are only few studies conducted on ADR reporting and related issues. All these studies concentrated on public health facilities. No published article was found which talks about the status of private health facilities, particularly community pharmacies towards ADR monitoring and reporting.

In a cross sectional study which was conducted to assess health care providers' knowledge, attitude and practice on ADR reporting and its monitoring showed that 70.9% of the participants think that DACA should be responsible for monitoring ADRs. About 56% of the participants had encounter with an ADR in their practice during the last 12 months. Only 14.6% of the respondents had reported the ADR they encountered. Out of the total of ADRs encountered (413) only 22 is reported to DACA making the total reported to 5%. Almost all respondents agree towards the fact that an ADR should be reported (96%) and it is part of the professional duty of a health professional (95%). Complexity of the reporting form and unavailability of ADR reporting form were mentioned as reasons for not reporting ADRs by 22.9% and 68.8% of respondents,

respectively. Further factors that affect reporting showed that reporting is time consuming (28.1%), reporting creates an additional workload (34.7%). The result surprisingly shows the responders belief that there is no ADR reporting system in the country by a significant amount (45.5%) (DACA, 2008).

In one study, a descriptive analysis of ADR case reports was carried out to explore the magnitude of ADR monitoring and suggest some practical improvement in Ethiopia. According to this study a total of 249 ADR cases were reported between 2002 and 2007 and an average of 0.5 ADR cases per million populations were reported annually. Most cases were detected and reported to DACA by physicians; 185 (76%). Druggists, pharmacy workforces who have a diploma qualification in pharmacy, detected 39 (16%) of the total cases. The remaining was reported by nurses (5.7%) and pharmacists (2.4%). This study showed that the level of ADR under reporting is alarmingly low. (Ermias et al, 2011)

A study which assessed the knowledge, attitude and practices on ADR reporting and its monitoring among health care providers in south west Ethiopia revealed that only 23.17% and 25.61% of the participants knew the existence of national reporting system and a yellow card of adverse drug reaction reporting form. About 16% of the participants encountered adverse drug reaction in the past 12 months in their clinical activities, but none of them reported to responsible body. Even though the participants' knowledge and practice in this study were inadequate, most of the respondents (57.31%) agreed that

adverse drug reaction reporting is part of duty of them and important to the public in general and to the patient in particular(Angamo et al., 2012).

The result of a study conducted in 2012 to assess the knowledge, attitude and practice of health professionals towards ADR 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 ADR reporting system in Ethiopia. The majority of respondents (95.4%) strongly agreed or agreed that reporting ADR is the duty of health professionals. A very small proportion of respondents (16.2%) had ever reported ADR they encountered during their professional practice. Of those health professionals who reported ADR, only 27.7% reported to FMHACA (Necho and Worku, 2014).

2. Objective of the study

2.1 General objective

To assess the knowledge, attitude and practices on ADR reporting among pharmacy personnel working at community pharmacies in Addis Ababa, Ethiopia

2.2 Specific objectives

- To assess the knowledge of pharmacy personnel working at community pharmacies towards ADR reporting.
- To assess attitude of pharmacy personnel working at community pharmacies towards ADR reporting.
- To assess practices of pharmacy personnel working at community pharmacies towards ADR reporting.
- To identify the factors that affect ADR reporting among pharmacy personnel working at community pharmacy

3. Methodology

3.1 Study area

The study was conducted in Addis Ababa City Administration. Addis Ababa is the capital and largest city of Ethiopia. It is located at the geographic center of the nation and covers about 540 Km2; of which 18.2 Km2 is rural. It has 10 sub cities. According to the Ethiopian 2007 census Addis Ababa has a total population of 2.7 million (CSA, 2008). According to Health and Health related Indicators of Ethiopia 2011report, the city had 46 hospitals; of which 5 were managed by Addis Ababa City Administration Health Bureau, four by the Federal Ministry of Health and the rest (37) either privately owned or owned by non-governmental organizations or other governmental agencies. It also had 189 pharmacies and 232 drug stores (Policy Planning Directorate, 2012). According to the data obtained from Addis Ababa Food, Medicine and Health care Administration and Control Authority (AAFMHACA) at the time of the data collection the city had 251 community pharmacies.

3.2 Study design

A descriptive cross sectional study was conducted from April to June, 2014.

3.3 Source and study population

All pharmacy personnel working at the selected community pharmacies of Addis Ababa city were taken as source population. The study population consists of all pharmacy professionals who were available at the selected community pharmacies during the study and willing to participate in the study.

3.4 Sample size determination and sampling procedure

To determine the number of pharmacy professionals to be included in the study, single population proportion formula was used (Gorstein, 2007):

$$N = \frac{z^2 p(1-p)}{d^2} + 10\% \text{ for non response}$$

Where: N = minimum required sample size

Z = percentage point of the normal distribution corresponding to the level of significance (for 5% significance level, Z =1.96)

P= expected percentage of pharmacy professionals having good knowledge on ADRs reporting; p is assumed to be 50%

d= standard of error taken as 5%

Considering 10% for non-response, the sample size was determined to be 422 pharmacy professionals.

Addis Ababa city had 251 community pharmacies at the time of the study. Information on the number of community pharmacies and list of community pharmacies was obtained from AAFMHACA. A sample of 26 (10% of the 251 pharmacies) pharmacies were taken to know the average number of registered pharmacy professionals working in each pharmacies and the average number of pharmacy professionals working in the selected community pharmacies was found to be 3.34. The total sample size was divided by the average number of pharmacy professionals working at the community pharmacies; i.e. 3

to find the number of community pharmacies where the 422 pharmacy professionals to be taken from.

141pharmacies were selected from the list of 251 community pharmacies obtained from AAFMHACA by simple random sampling whereby each pharmacy was given a number (1 to 251) written on small pieces of paper. All the 251papers were placed in a box and shaken to ensure randomization. After each shaking of the box, a paper was picked until a total of 141 papers were picked to constitute a sample of pharmacy professionals for the study.

3.5 Inclusion criteria

Registered pharmacy personnel employed as pharmaceutical dispenser in the respective pharmacy with a minimum dispensing experience of one year.

3.6 Exclusion criteria

Pharmacy personnel not willing to participate in the study or on leave during the study.

3.7 Study variables

I. Dependent variables

Knowledge about ADR reporting

Attitude towards ADR reporting

Practice of ADR reporting (report or not report)

II. Independent variables

Demographic factors (Age, sex)

Difference in level of qualification

Years of service

On job training on pharmacovigillance (ADR)

Patient load

3.8 Data collection instrument and data collectors

Data was collected by using self administered questionnaire (Annex II) which was adapted from previous studies on the knowledge, attitude and practices of healthcare professionals on ADR reporting (DACA, 2008; Angamo et al., 2012). Prior to the study, a pilot testing of the questionnaire was carried out by administering it to 22 pharmacy personnel from 7 selected community pharmacies which were not included in the study.

The questionnaire included five parts containing 45 questions. The first part consisted of ten questions which covered socio demographic and continuing education information. The second part contained six questions which were used to assess respondents' knowledge towards ADR reporting and additional six questions assessed participants' general awareness about ADR reporting.

The third part of the questionnaire included five questions which assessed respondents practice towards ADR reporting. The fourth part consisted of ten questions which assessed respondents' attitude towards ADR reporting. For the assessment of the

participants attitude level a Likert scale was used and each item was scored on a five point Likert scale ranging from 1(Strongly disagree) to 5 strongly agree. Reasons for not reporting ADRs were captured using the last eight questions. Data was collected by five trained pharmacists.

3.9 Data quality assurance

All the data collectors were given a one day training prior to data collection about how to distribute the questionnaire, approach respondents, secure their consent and collect back the questionnaire. The questionnaires were checked for completeness, coded and stored properly.

3.10 Data analysis

Each questionnaire was given a code number and identified by this code number. SPSS version 16 was used for data entry, cleaning and analysis. Frequency distribution was used to show distribution of the outcome and independent variables.

A knowledge score was prepared as a guiding tool in assessment of knowledge level, whereby one point was awarded for each correct answer and zero for each wrong answer. Respondents were categorized based on their overall knowledge scores using Original Bloom's Cut off Points (60-80%) (Mulat et al., 2014). Therefore the score ranges with their respective knowledge levels were:

i. 80-100% of maximum score – Good Knowledge

ii. 60-79% of maximum score - Moderate knowledge

iii. <60% of the maximum score – Poor knowledge

There are 10 items in the attitude part and each item had a maximum score of five making the maximum attitude score for the ten items 50. The ratings for negatively worded items were reversed while analyzing the data. Seventy five percent (75%) of the maximum score, i.e. a score of 37.5 was taken as a cut of point in order to categorize respondents in two categories. participants whose attitude scores were greater than and equal to 37.5 were categorized as having ― positive attitude and those who scored below 37.5 were categorized as having ―negative attitude towards ADR reporting.

Chi-square and logistic regression tests were used to test the presence of association between the outcome variables and the explanatory variables and P value of less than 0.05 was considered significant.

3.11 Ethical consideration

Ethical approval was obtained from the ethics review committee of the School of Pharmacy, Addis Ababa University. Participants of the study were asked for consent before participating in the study by providing them with information regarding the purpose of the study, how they were selected to be involved in the study and that they can withdraw from the study at any time. They were also assured about the confidentiality of their information obtained in the study. Any information that can potentially expose recognition of a particular study respondent such as respondent's name was excluded from the data collection tools.

3.12 Operational definition

Adverse drug reactions: Is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.

Community pharmacies: Drug retail outlets led by degree holder pharmacy professionals

Pharmacy personnel: degree or diploma holder pharmacy professional working as dispenser at community pharmacies of Addis Ababa

4. Results

Out of the 422 questionnaires, 379 were adequately filled and returned to the investigator resulting in the response rate of 89.8%.

4.1 Socio-demographic characteristics

Out of the 379 pharmacy professionals, 352(92.9%) were from private community pharmacies and 27(7.1%) were from public community pharmacies. The participants' socio demographic information is summarized in Table1:

Table1: Socio-demographic characteristics of pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014 (n=379)

Variables		Number	Percent
Sex	Male	218	57.5
	Female	161	42.5
Age distribution (years)	20-25	80	21.1
	26-30	209	55.1
	31-35	34	9.0
	>35	56	14.8
Profession	Pharmacists	245	64.6
	Druggist/Pharmacy technician	134	35.4
Level of Education	Diploma	134	35.4
	Bachelor and above	245	64.6
Dispensing experience (years)	1-3	184	48.5
	4-6	112	29.6
	>6	83	21.9
Pre-service pharmacovigilance course	Yes	237	62.5
	No	142	37.5

The majority of respondents, 218 (57.5%) were males and fell in the age group 26-30(55.1%). Professionally, 245(64.6%) of respondents were pharmacists and 134(35.4%) were Druggists/Pharmacy technicians. The result also indicated that most of the participants, 184(48.5%) were having 1-3 years of dispensing experience.

The majority of respondents 237 (62.5%) had been introduced to pharmacovigillance in their basic training and only 77(20.3%) of the participants had taken on job ADR reporting trainings among which majority were pharmacists i.e. 98.7% of the respondents who had taken on-job ADR training were pharmacists while the rest are Druggist or Pharmacy Technicians(Figure 1).

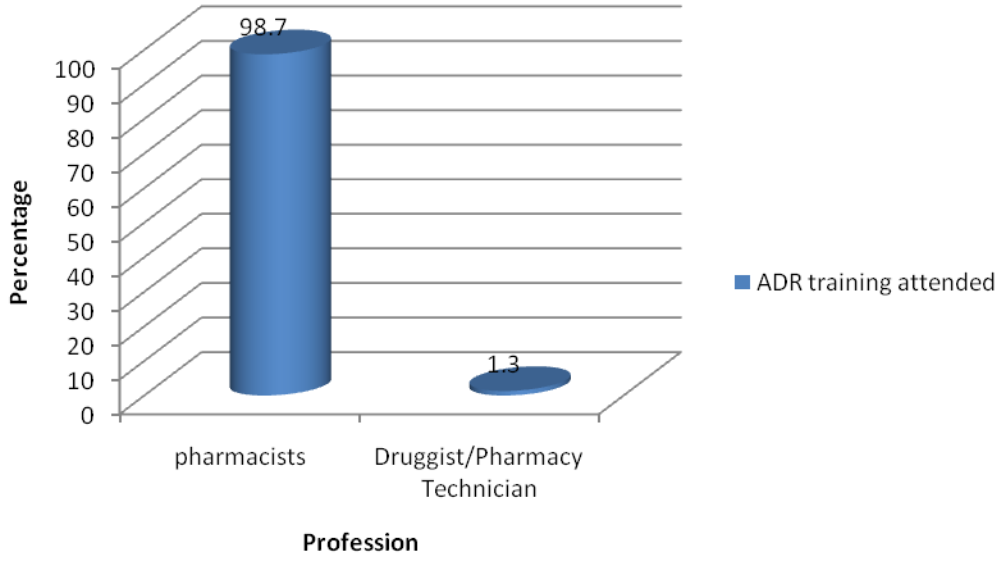

Figure 1: On job ADR training attendance of pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014.

As indicated in Table 2, 118(31.1%) of the respondents use standard text books together with national drug formulary and standard treatment guidelines as a source of information about adverse drug reactions .Some of them use British drug formulary 12 (3.2%) or standard text books, national drug formulary and standard treatment guideline together with drug sales man 50(13.2%).

Table 2: Source of information about ADRs for pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014 (N=379)

Source of Information	Number	Percent
1. Standard text books	76	20.1
2. National drug formulary and standard treatment guideline	57	15.0
3. British drug formulary	12	3.2
4. Notes from university training	5	1.3
5. Drug sales person	3	0.8
6. 1 and 2	118	31.1
7. 1, 2 and 3	42	11.1
8. 1 and 5	16	4.2
9. 1, 2 and 5	50	13.2
Total	379	100

4.2 Knowledge on ADR reporting

The overall knowledge score of the respondents ranged from 0 to 8, with a mean knowledge score of 3.79 (SD= 1.654) (percent mean score=47.4%); out of the 8 knowledge questions. One hundred eighty seven (49.3%) of the respondents had a knowledge score of equal to or greater than the mean. Only 37 (9.8%) of the respondents had good knowledge; while 268 (70.7%) and 74 (19.5%) of the respondents had a poor and moderate knowledge level, respectively.

As shown in Table 3, about 157 (41.4%) of the respondents did not know the existence of national ADR monitoring system and only 46 (12.1%) of the respondents knew the ADR reporting form. The respondents' response as to which profession they think should report ADRs shows that 213(56.2%) of them thought that only pharmacy professionals should report and only 14(16.6%) of them believed that the doctor, pharmacy professional and the nurse should report. In addition, only 54(14%) of the respondents thought that traditional medical practitioners should also report ADRs in addition to doctors, pharmacy professionals and nurses.

Regarding dispensers' knowledge about the type of reactions to be reported, 119 (31.4%) of the respondents reported that only ADRs due to conventional medicines should be reported and only 127 (33.5%) of the respondents knew all types of the reactions to be reported (reactions due to conventional medicines, vaccines and blood products, herbal medicines, medicated cosmetics and medical devices).

Table 3: Knowledge on ADR reporting among pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

Questions	Number of Respondents (n = 379)	
	Number	Percentage
Differentiate ADR from drug side effect	323	85.2
Know the term pharmacovigillance	176	46.4
Know the existence of National ADR monitoring system	222	58.6
Know the ADR reporting form	46	12.1
ADRs are not well documented at the time the drug is marketed	220	58
Where to send reports of ADR		
MOH	60	15.8
FMHACA*	269	71.0
PFSA	14	3.7
MOH & FMHACA	21	5.5
Others**	15	4
Who are responsible in reporting ADR		
Physicians(P)	14	3.7
Pharmacy professionals(PP)	213	56.2
Nurses	2	.5
P and PP	33	8.7
P, PP and Nurses	63	16.6
P, PP, Nurses and TMP*	54	14.2
Which reactions should be reported? Those due to		
1. Conventional medicines	119	31.4
2. Vaccines and blood products	13	3.4
3. Herbal medicines	14	3.7
4. Medicated cosmetics	5	1.3
5. Medical devices	18	4.7
6. 1 and 2	51	13.5
7. 1, 2 and 5	22	8.4
8. All (1, 2, 3, 4 and 5) *	127	33.5

*Correct knowledge, **Manufacturers, AACAHB, Hospitals, EPA

Regarding the knowledge level at different level of profession of the respondents, The proportion of pharmacists that had good (15.1%) and moderate (23.3%) knowledge levels were higher than that of Druggists/Pharmacy technicians which were 0% and 12.7%, respectively (Figure 2).

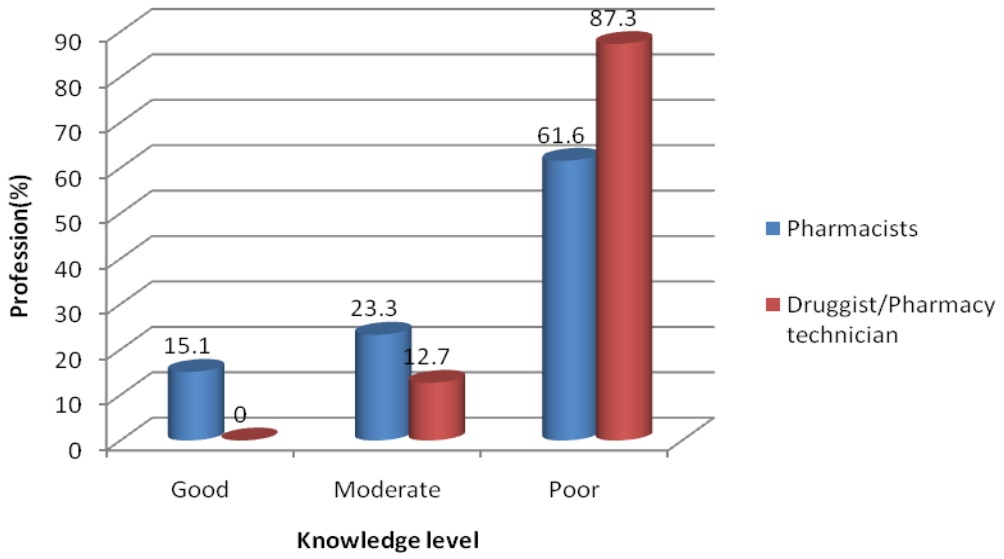

Figure 2: Knowledge levels towards ADR reporting of pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

4.3 ADRs reporting practices

Table 4 indicates that 173(45.6%) of the participants had encountered a patient with an ADR in their dispensing practice during the last 12 months. Among the respondents who had encountered patients with ADRs in the last 12 months, majority, 106(61.3%) of them encountered with more than four patients with ADR.

Among the 173 participants who had encountered ADRs during the last 12months, only 28(16.2%) had ever reported the ADRs and the rest 145(83.8%) had never reported the ADR they encountered.

Regarding the places where the participants reported the encountered ADR, the majority of them 17(61%) had reported to the Head of the pharmacy and none reported to FMHACA making the total reporting rate to 0%.

Table 4: Practices regarding ADRs reporting in the past 12 months among pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

Variables	Response	Respondents	
		Number	**Percentage**
Have you ever encountered patient with ADR in your dispensing practice, in the last 12 months? (n=379)	Yes	173	45.6
How many patients with ADR, did you see?(n=173)	One	5	2.9
	Two	13	7.5
	Three	25	14.5
	Four	24	13.9
	> Four	106	61.3
Have you ever reported the ADRs? (n=173)	Yes	28	16.2
To whom did you report? (n=28)	Head of the pharmacy	17	60.7
	Manufacturers	10	35.7
	FMHACA	0	0
	Others*	1	3.6
How often do you give advice to patients on possible adverse effects of the drugs you dispense (n=379)	Usually	45	11.9
	Sometimes	278	73.4
	Rarely	50	13.2
	Never	6	1.6

*Referred to the physician, to hospitals

The participants' response as to the frequency that they give advice to their patients about the side effects of drugs they dispense indicated that only 45(11.9%) of them said they usually give advice and the majority 278(73.4%) of them answered they sometimes give advice (Table 4).

4.4 Attitudes towards ADRs reporting

As shown in Table 5, the majority 365(96.2%) of respondents agreed that ADR should be reported regularly and ADR reporting is part of the duties of health professionals. Almost all 366(96.6%) of the respondents agree on the idea that reporting drug safety is important for the public, for the patient 365 (96.3%) and for the health care system 376(99.2%). The statement that stated "there should be a need to be sure that ADR is related to the drug before reporting" is agreed up on by the majority 321(90%) of the respondents. Around 164(43%) of the respondents did not agree on the idea that reporting of ADR should be voluntary and almost all of the participants believed that community pharmacy professionals can contribute to ADR reporting.

Table 5: Attitudes towards ADRs reporting among pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

Statements	Agree	Neutral	Disagree	Mean	Std. Deviation
	N (%)	N (%)	N (%)		
ADR should be reported regularly	365(96.2)	4(1.1)	10(2.7)	4.77	.612
ADR reporting is part of duty of health professionals	371(97.9)	3(0.8)	5(1.3)	4.80	.507
Reporting drug safety is important for the public	366(96.6)	6(1.6)	7(1.8)	4.78	.562
Reporting drug safety is important for the patient	365(96.3)	4(1.1)	10(2.6)	4.77	.626
Reporting drug safety is important for the health care system	376(99.2)	1(0.3)	2(0.5)	4.83	.426
There should be a need to be sure that ADR is related to the drug before reporting	321(90)	3(0.8)	35(9.2)	1.52	.949
Only ADRs of prescription drugs need to be reported	78(20.6)	3(0.8)	298(78.7)	3.81	1.269
Only ADRs that cause persistent disability or incapability should be reported	49(12.9)	4(1.1)	326(86)	4.01	1.090
Reporting of an ADR should be voluntary	200(52.8)	15(4.0)	164(43.3)	3.28	1.450
Community pharmacy professionals can contribute to reporting of ADR	371(97.9)	2(0.5)	6(1.6)	4.67	0.600

Smaller means scores show negative attitude. Many negative attitude level scores were obtained for the item stated as “there should be a need to be sure that ADR is related to the drug before reporting” and to the item “reporting of an ADR should be voluntary”.

Majority 314 (82.8%) of the respondents had positive attitude level towards ADR reporting as they had scores greater than 37.5 (75% of the maximum score) and among these respondents who had positive attitude towards ADR reporting the majority were Pharmacists (65.9%)(Figure 3).

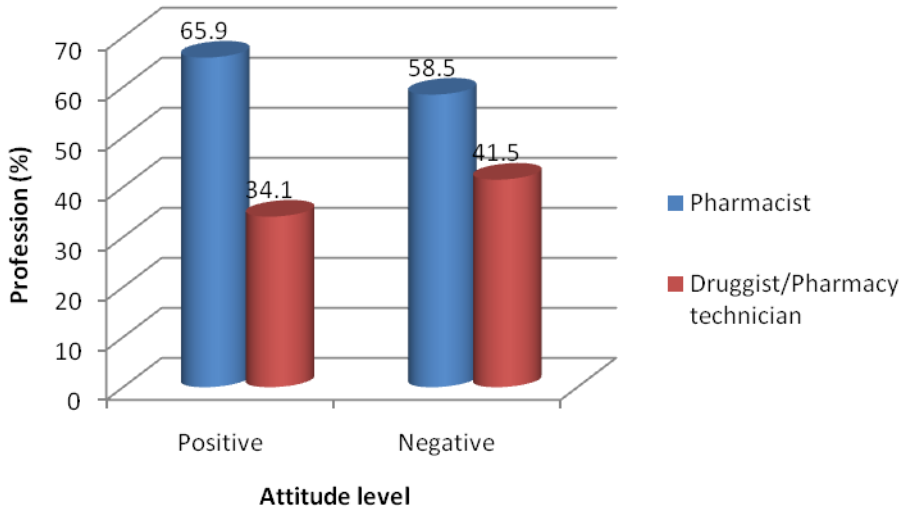

Figure 3: Attitude levels of pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

4.5 Reason for not reporting ADRs

The respondents were asked for their reasons why they were not reporting ADRs and the result is shown in Table 6 below.

Table 6: Reasons for not reporting ADRs, in community pharmacies of Addis Ababa, Ethiopa, June 2014

Statements	Agree N (%)	Neutral N (%)	Disagree N (%)
Need to be certain of the association between the drug and ADR	310(81.8)	8(2.1)	61(16.1)
Reporting ADR is breach of patient confidentiality	117(30.9)	22(5.8)	240(63.3)
One report makes no difference	49(12.9)	12(3.2)	318(83.9)
Reporting form is not available	341(90.0)	4(1.1)	34(8.9)
No ADR reporting system	160(42.2)	21(5.5)	198(52.2)
Reporting is not useful to patients	15(4.0)	-	364(96.0)
Reporting creates an additional work load	101(26.6)	5(1.3)	273(72.0)
Lack of motivation for reporting	190(50.3)	1(0.3)	188(49.4)

The majority 310(81.8%) of respondents agreed that the need to be certain of the association between the drug and ADR is one of the reasons for not reporting ADRs. About 117(30.9%) of the respondents reported "reporting ADR is breach of patient confidentiality" as a reason for not reporting ADR. Unavailability of reporting form and inexistence of reporting system were reasons for not reporting by 341(90%) and 160(42%) of the respondents, respectively. Few respondents, 49(12.9%) believed that it

would be worthless to report a single incident of ADR. Lack of motivation for reporting was also believed to be a reason for not reporting by 190(50.3%) of the respondents, respectively.

4.6 Determinants of ADR reporting knowledge and ADR reporting practice

Table 7 illustrates how ADRs reporting knowledge correlates with sex, age, profession, level of education, dispensing experience, patient load per day and on job ADRs training of the respondents. Respondents in the age group of 26-30years were more knowledgeable 14(6.7%) about ADR reporting than those aged below 26 years(0%), those in the age group 31.35 (2.9) and those aged above 35 years(2.7%) (P value = 0.000). Pharmacists were found to have more knowledge on ADRs reporting than druggists/pharmacy technicians (P value = 0.000).

Respondents who had more than 6 years experience in dispensing were more knowledgeable (27.7%) as compared to those with 4 to 6 years (3.6%) and 1 to 3 years(5.4%) experience (P value = 0.000). In addition, it was also observed that, respondents who had attended on job training on ADRs monitoring and reporting had more knowledge on ADRs reporting (37.7%) than those who had not attended (2.6%) (P value = 0.000)

Table 7: ADRs reporting Knowledge by some background characteristics of respondents, Addis Ababa, Ethiopia, June 2014

Background Characteristics		Knowlege level [count(percentage)]		Pearson X^2	p-value
		Poor& Moderate	Good		
Sex	Male	194(89.0)	24(11.0)	.603	0.437
	Female	148(91.9)	13(8.1)		
Age group	20-25	80(100.0)	0(0.0)	68.09	0.000*
	26-30	195(93.3)	14(6.7)		
	31-35	33(97.1)	1(2.9)		
	>35	34(60.7)	22(2.7)		
Profession	Pharmacist	208(84.9)	37(15.1)	20.745	0.000*
	Druggist/ pharm. technician	134(100)	0(0.0)		
Dispensing experience	1-3	174(94.6)	10(5.4)	62.772	0.000*
	4-6	108(96.4)	4(3.6)		
	>6	60(72.3)	23(27.7)		
Patient load per day	20-50	116(87.2)	17(12.8)	3.617	0.164
	51-79	125(94.2)	8(6.0)		
	>79	99(89.2)	12(10.8)		
On job ADR training	Yes	48(62.3)	29(37.7)	81.456	0.000*
	No	294(97.4)	8(2.6)		

The result of the study showed that as age increases, the proportion of dispensers reporting ADR decreases i.e. 31.7% for the age group 20-25 years to3.3% for the age group of 30 years and above; but the logistic regression result showed that age was not significantly associated with ADR reporting practice of the respondents. The percentage of diploma holder pharmacy professionals (Druggist/Pharmacy technicians) (28.8%) who practice ADR reporting was higher than those of degree holder pharmacy professionals (pharmacists) (9.6%). This difference was found to be significant (AOR=2.831, 95% CI=1.13-7.11). Eventhough high proportion of pharmacy personnel with dispensing experience of 1-3years reported ADRs as compared to those with dispensing experience of greater than three years, it was not found to have significant association in the logistic regression (Table 8).

Table 8: Determinants of ADRs reporting practice among pharmacy personnel working at community pharmacies of Addis Ababa, Ethiopia, June 2014

Variables		ADR reporting practice		OR (95% CI)	AOR (95% CI)
		Yes	No		
Age(Years)	20-25	13(31.7%)	28(68.3%)	1.00	1.00
	26-30	14(13.7%)	88(86.3%)	.343(.144,.815)	.527 (.186,1.493)
	>30	1(3.3%)	29(96.7%)	.074(.009,.606)	.176(.018,1.759)
Profession	Pharmacist	11(9.6%)	103(90.4%)	1.00	1.00
	Druggist/ Pharm. technician	17(28.8%)	42(71.2%)	3.79(1.638,8.771)	**2.831(1.127,7.114)***
Dispensing experience (Years)	1-3	20(22.2%)	70(77.8%)	1.00	1.00
	>3	8(9.6%)	75(90.4%)	.373(.155,.902)	.629(.208,1.901)
Patient load per day	20-50	14(23.3%)	46(76.7%)	1.00	1.00
	51-79	10(15.6%)	54(84.4%)	4.565(1.228,16.969)	.593(.228,1.543)
	>79	3(6.2%)	45(93.8%)	2.778(.720,10.710)	.258(.065,1.028)

5. Discussion

This study assessed the knowledge, attitudes and practices of pharmacy personnel working at community pharmacy towards ADR reporting.

The finding of this study showed that only 77(20.3%) of the participants had attended on job ADR monitoring and reporting trainings. This shows that majority of pharmacy personnel working at community pharmacies have no the proper training on ADR monitoring and reporting. The study also showed that 323 (85.2%) of the respondents said that ADR is different from drug side effect. This figure is higher than the result reported for health care professionals in South West Ethiopia in which only 65.5%of the respondents said that ADR is not the same as drug side effect (Angamo et al., 2012). This difference may be because all of the participants in the present study were pharmacy professionals that are experts on drugs and the participants of the other study were not only pharmacy professionals it also included physicians and nurses.

Only less than half of the respondents (41.4%) knew the existence of a national ADR monitoring center. This shows that majority of the respondents have no information on the authority who monitors ADR in Ethiopia. This result is in line with a study which was conducted in Saudi Arabia in which 56% of the community pharmacists were unaware of the existence of the Saudi National Pharmacovigillance Center (Al-Hazmi and Naylor, 2013).

The present study also showed that dispensing experience of 6 years and above was found to be associated with good knowledge score (p value = 0.000). This may be because as dispensing experience increases the probability of encountering patients with ADR will increase and the dispensers will ask themselves or colleagues or other health professionals what to do with the reaction and will have information on ADR reporting as a result. The study also indicated that there is a significant ADR reporting knowledge difference between pharmacists and diploma holder pharmacy professionals (druggists and pharmacy technicians) (p value = 0.000). This might be associated with the deficiency in addressing pharmacovigillance issues in the curriculum of the diploma program in addition to this, majority (98.7%) of the respondents who had taken on job ADR monitoring are pharmacists.

In addition, taking on job ADR monitoring training was found to be significantly associated with good ADR reporting knowledge (P value = 0.000). The importance of on job ADR monitoring and reporting training in promoting ADR reporting has been shown in studies in different countries. For example, the study in Saudi Arabia recommended that more knowledge about the importance of reporting ADRs through appropriate training courses should be encouraged in order to increase the role of community pharmacists in ensuring the use of safe medications by monitoring and reporting ADRs (Al-Hazmi and Naylor, 2013). Another study in Nigeria assessing the knowledge, attitude and practice of health care workers towards ADR reporting recommended the need for regular training on ADR reporting (Fadare et al., 2011).

The findings of the present study also showed that 173 (45.6%) of the participants had encountered patients with ADR in the last 12 months; of whom 61.3% encountered four and above patients with ADRs. This shows that there is a high probability of encountering patients with ADRs in community pharmacies which would increase the ADR reporting rate if the pharmacy professionals are made aware about the importance of ADR reporting and equipped with the required knowledge on ADR reporting and materials needed for reporting.

In a similar study in Ethiopia which assessed the knowledge, attitude and practices of health care professionals working at hospitals on ADR monitoring and reporting showed that 56% of the participants had encountered patients with ADRs in the last 12 months (DACA, 2008). Another study which was done in selected public health facilities of South West Ethiopia showed that only 15.9% of the health care professionals involved in the study had encountered patients with ADRs (Angamo et al., 2012). This shows that the probability of encountering patients with ADRs in community pharmacies could be either higher or equal to the probability of encountering patients with ADRs in public health facilities. This implies that the efforts that are made in public health facilities to promote ADR reporting should also be made at community pharmacies in order to increase ADR reporting rate and the pharmacy professionals in community pharmacies can play a great role in ADR monitoring and reporting.

From the 173 participants which encountered patients with ADRs, only 28 (16.2%) of them reported the ADRs and among these none of them submitted the reports to the

relevant authority (EFMHACA) which makes the reporting rate nil. This figure is the same as with the figures for the community pharmacists in India in which none of the community pharmacists reported the encountered ADRs to the responsible body (Mahendra, 2012). It is also the same as with the finding of the study done in South West Ethiopia in which none of the respondents that had encountered ADR reported the ADR to the responsible body (Angamo et al., 2012) but it is different from the result of the study done at public hospitals of Ethiopia. In this study 5% of the respondents who reported the encountered ADR had submitted the reports to the responsible/relevant body that is FMHACA (DACA, 2008). This might be because there were lots of efforts that are made at public health facilities especially hospitals to promote ADR reporting than what has been done for community pharmacies.

In spite of the poor knowledge among the respondents, the study showed that majority 314(82.8%) of the dispensers had positive attitude towards ADR reporting. Majority 371(97.9%), of the dispensers agreed that ADR reporting is part of duty of health professionals. Three hundred twenty one (90%) of the respondents in the present study agreed that there should be a need to be sure that ADR is related to the drug before reporting. This might be one reason for the very low reporting rate.

According to 310(81.8%) of the participants one of the reasons for not reporting ADR is the need to be certain of the association between the drug and ADR. Unavailability of reporting form and inexistence of reporting system were believed to be reasons for not reporting by 90% and 42% of the respondents respectively. The reason reporting form is

not available is also reported for health professionals at hospitals in Ethiopia (DACA, 2008). However, the figure is somewhat higher in the present study this might be due to the fact that promotion of ADR reporting and distribution of ADR reporting forms in our country mainly focuses at public health care facilities. One report makes no difference was not believed to be a reason for not reporting ADR by 83.9% of the respondents. This figure is similar to the figure which was reported for health professionals at public hospitals of Ethiopia which is 80.3 % (DACA, 2008).

Reporting ADR is breach of patient confidentiality, Reporting creates an additional worked load and lacks of motivation for reporting were also believed to be reasons for not reporting by 30.9% 26.6% and 50.3% of the respondents, respectively. These reasons are found to be in common in the findings of the study conducted at public hospitals of Ethiopia (DACA, 2008).

Assessment of ADR reporting practice determinants indicated that only being druggist and pharmacy technician was significant determinant of ADR reporting practice. According to the result of the logistic regression analysis druggist and pharmacy technicians were nearly three times more likely to report encountered ADRs than pharmacists. The others socio demographic characteristics were not found to be significantly associated with the ADR reporting practice.

Eventhough high proportions of pharmacists have good knowledge on ADR reporting than diploma holder pharmacy professionals, ADR reporting practice is better among diploma holder pharmacy professionals. This might implicate the presence of negligence

or lack of motivation among the pharmacists to report ADRs. In addition the pharmacists might be busy with managerial activities in the community pharmacies. These findings indicate the need for additional investigation on why pharmacists working at community pharmacies are not reporting ADRs as they had good ADR reporting knowledge than diploma holder pharmacy professionals.

6. Conclusion

From this study, it can be concluded that there is poor knowledge and low practice among pharmacy personnel working at community pharmacies in Addis Ababa towards ADR reporting. Majority of the dispensers did not know the ADR reporting form, the existence of the national ADR monitoring system and the type of reactions to report. There is a significant ADR reporting knowledge difference between pharmacists and diploma holder pharmacy professionals (druggists and pharmacy technicians). There is a high probability of encountering patients with ADRs at community pharmacies. The ADR reporting rate from pharmacy personnel working at community pharmacies to the responsible body (FMHACA) is zero. In spite of the poor knowledge among the respondents, majority of the dispensers had positive attitude towards ADR reporting.

7. Recommendations

Based on the findings of this study the following recommendations can be made:

- Ethiopian FMHACA should provide continuous and regular educational training to pharmacy personnel at community pharmacy on the importance of ADR monitoring and reporting in order to improve their ability to identify and report ADRs.
- Trainings should also be focused on exploring solutions for the reasons not reporting ADRs by pharmacy personnel at community pharmacies
- Awareness creation on the existence and purpose of ADR monitoring and reporting system at community pharmacies should be done by FMHACA.
- Reporting forms should be made available at community pharmacies

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Annexes

Annex I: Research participant information sheet and consent form

Research Participants Information Sheet

May, 2013

Dear Participant,

My name is Alaynesh Goshime, a Masters student in Pharmacoepidemiology and Social Pharmacy at Addis Ababa University School of Pharmacy. As part of this degree I am conducting a research. The research I am conducting is **Assessment of knowledge, attitude ad practice on ADRs reporting among pharmacy personnel working at community pharmacy of Addis Ababa**. I am inviting pharmacy personnel working at community pharmacies to participate in this study.

The purpose of the study is to assess the knowledge, attitude and practice towards Adverse Drug Reactions (ADRs) reporting as the basis for determining the factors contributing towards underreporting and therefore finding the mechanisms to enhance reporting of ADRs. If you agree to join the study, you will be required to answer and fill all the questions in the questionnaire which will be provided to you.

You will not receive any payment or other compensation for participation in this study. There is also no cost to you for participation but 20-25 minutes of your time.

We do not expect that any harm will happen to you because of joining in this study. Taking part in this study is completely your choice. If you choose not to participate in the

study or if you decide to stop participating in the study you will continue to be treated normally. You can stop participating in this study at any time, even if you have already given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study.

If you agree to take part in this study you will be among those who will contribute towards strengthening the system of ADRs reporting. Your information and other's participating in the study will collectively be used by policy makers in strengthening the system. You will receive the new information about this study upon completion.

Responses collected will form the basis of my study and will be put into a written report on an anonymous basis. It will not be possible for you to be identified personally. Only grouped responses will be presented in this report. All material collected will be kept confidential. The thesis will be submitted for marking to the School of Pharmacy and deposited in the School Library. It is intended that one or more articles will be submitted for publication in scholarly journals.

Please be honest in responding, as it will be solely used for research purposes

If you have any questions or would like to receive further information about the study, please contact me at: Cell phone +25191857771, E-mail: alaygoshime@yahoo.com or my Advisor, Dr. Teferi Gedif, School of Pharmacy, Addis Ababa University, P.O.Box 1176, E-mail: tgedif@gmail.com

Sincerely,

Alaynesh Goshime

Annex II: Questionnaire

Addis Ababa University

School of Pharmacy

Department of Pharmaceutics

Purpose: this study is designed to assess the knowledge, attitude and practices towards adverse drug reactions (**ADRs**) reporting among dispensers in community pharmacies in Addis Ababa. Your answers are very important and valuable to the successful completion of this study.

Please be honest in filling this questionnaire, as it will be solely used for research purpose.

The survey will be confidential and data will be analyzed in aggregates.

For questions/comments please contact Alaynesh Goshime (091857771) principal investigator for the study

Code No…….

INSTRUCTIONS

Answer the questions on the box provided. You are allowed to choose more than one answer **when necessary**. If you find difficult in understanding the question, please ask for clarification before answering.

Type of the community pharmacy

☐ 1.Private

☐ 2.Public

1. Sex

☐1. Male

☐2.Female

2. Age (in years) _____

3. Profession

☐1. Pharmacist

☐2. Druggist

☐3. Pharmacy technician

☐4. Other, specify _____

4. Highest level of Education

☐1. Diploma

☐ 2.Bachelor

☐ 3.Other (mention) _____

5. Year of experience in drug dispensing _____

6. How many minutes do you take to attend a patient? _____

7. What is the average number of patients that you encounter per day? _____

6. How many working hours per day do you spend in a pharmacy? _____

7. Have you been introduced to the ADR monitoring or pharmacovigilance in your under graduate study?

☐ 1.Yes

☐ 2.No

10. Have you ever participated in any seminar/training which includes topic on ADRs reporting?

☐ 1.Yes

☐ 2.No

Knowledge on ADRs Reporting

Please answer the following questions genuinely

11. Do you think that adverse drug reaction is the same as with side effect?
    - ☐ 1.Yes
    - ☐ 2.No

12. Do you know the term pharmacovigilance?
    - ☐ 1.Yes
    - ☐ 2.No

13. Do you know the existence of national ADR reporting system?
    - ☐ 1.Yes
    - ☐ 2.No

14. Do you know the ADR reporting form?
    - ☐ 1.Yes
    - ☐ 2.No

15. Do you think that ADRs are well documented at the time a drug is marketed?
    - ☐ 1.Yes
    - ☐ 2.No

16. Where are the reports for ADRs supposed to be sent?
    - ☐ 1.MOH
    - ☐ 2.FMHACA
    - ☐ 3.PFSA
    - ☐ 4.EHNRI
    - ☐ 5.EPA
    - ☐ 6.Other (mention) ……..

17. Which profession is required to report suspected cases of ADRs?

- ☐ 1.Doctors
- ☐ 2.Pharmacy profession
- ☐ 3.Nurses
- ☐ 4.Traditional medicine practitioners
- ☐ 4.Others mention …….

18. What reactions should be reported?

- ☐ 1.Those due to Conventional medicines,
- ☐ 2.Those due to vaccines and blood products,
- ☐ 3.Those due to Herbal medicines including traditional medicines
- ☐ 4.Those due to Cosmetics
- ☐ 5.Those due to Medical devices

19. Who do you think is primarily responsible to remind and follow up patients about side effects of drugs they are given?

- ☐1.Pharmacy professionals
- ☐2.Physicians
- ☐3.Nurses
- ☐4.Other, specify _____

20. Whom do you think is responsible for monitoring ADR in Ethiopia?

- ☐1. MOH
- ☐2. FMHACA
- ☐3. EPA
- ☐4.AAU
- ☐5. Other, specify _____

21. What is your source of information about adverse drug reaction?

☐ 1.Standard text books

☐ 2.National drug formulary and standard treatment guideline

☐ 3.British drug formulary

☐ 4.Notes from the university training

☐ 5.Drug sales man

☐ 6.Other, specify _____

Practices on ADRs reporting

22. Have you ever encountered patients with ADRs in your pharmacy practice, in the last 12 months?

☐ 1.Yes

☐ 2.No

If your answer to # 22 is yes, answer question no. 23 - 25. If your answer to # 22 is No, go to question 26.

23. How many patients with ADR did you see during the last 12 months?

☐ 1.One

☐ 2.two

☐ 3.Three

☐ 4.Four

☐ 5.greater than four

24. Have you ever reported the adverse drug reactions?

☐ 1.Yes

☐ 2.No

25. To whom did you report?

☐ 1.The head of the pharmacy

☐ 2.Manufacturers'

☐ 3.FMHACA

☐ 4.MOH

☐ 5.Others, specify _____

26. How often do you give advice to your patients on possible adverse effects of drugs you dispensed?

☐ 1.Usually
☐ 2.Sometimes
☐ 3.Rarely
☐ 4.Never

Attitudes on ADRs reporting
In the following table, please respond to the statements on your left hand side by putting a tick (√) on correct response at your right hand side

	Statement	**Strongly agree**	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
27	ADR should be reported regularly					
28	ADR reporting is part of duty of health professionals					
29	Reporting drug safety is important for the public					
	Statement	**Strongly agree**	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
30	Reporting drug safety is important for the patient					
31	Reporting drug safety is important for the health care system					
32	There is a need to be sure that an ADR is related to the drug before reporting					
33	Only ADRs of prescription drugs need to be reported					
34	Only ADRs that cause persistent disability or incapacity should be reported					
35	Reporting of ADR should be voluntary					
36	Community pharmacists can contribute to the detection and reporting of ADRs					

	Reasons for not reporting ADR					
37	Need to be certain of the association between the drug and ADR					
38	Reporting ADR is breach of patient confidentiality					
39	One report makes no difference					
40	Reporting form is not available adequately					
41	There is no national ADR reporting system					
42	Reporting is not useful to the patient					
43	Reporting creates an additional workload					
44	Lack of motivation for reporting					

Thank you very much for your cooperation!!!