Predictors of Health Professionals Knowledge, Attitude, and Practice related to Adverse Drug Reaction Reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia

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Abstract

***Background**: Prevention, monitoring and reporting of adverse drug reactions is still a challenge among health professionals. Even though some adverse drug reactions are minor and can be resolved quickly, some can cause permanent disability or death. Under reporting of adverse drug reactions by health professionals (such as Physicians, Pharmacists and Nurses) is a common problem of any pharmacovigilence programs.*

***Objective*:** *to assess predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting at Felege-Hiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia.*

***Methods* -** *Hospital based cross sectional study was conducted at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital from March 11, 2013 to April 12, 2013. Self-administered pre-tested questionnaire and in-depth-interview were used. Stratified random sampling technique was used to select study participants. Descriptive statistics, bivariate analysis and multivariable logistic regression analyses were employed.*

***Results**: The mean age of study participants was 33 (SD=5.6) years. Participants of 144(48.6%) were males, 214(72.3%) were nurses, 154 (51.4%) were Bachelor Nurses, their mean of experience was 5.7 years (SD = 3.5). Two hundred seventy six (83.2%) participants had inadequate knowledge on how to report ADR and Health professionals who categorized in the age of 26-35 years was 4.95 times more likely inadequate knowledge on adverse drug reaction reporting (AOR = 4.945, 95% CI = 20.965– 1.166, P=0.030), and participants who took training/seminar on pharmacovigilance had 0.12 times less likely to have inadequate knowledge on adverse drug reaction reporting (AOR = 8.098, 95% CI = 36.408– 1.801, P=0.006). There was no significant association of attitude and candidates in bivariate analysis. Health professionals who took training and/or seminar on pharmacovigilance had 0.054 times less likely not to report the encountered adverse drug (AOR = 18.465, 95% CI = (99.292-3.434), P=0.001).*

Busy schedule 181(61.1%) was detected as the most important reason for not reporting the encountered adverse drug reaction.

***Conclusions and recommendation**: Even though all health professionals felt adverse drug reaction monitoring to be essential and are willing to report, most of them were inadequate knowledge and not reporting regarding adverse drug reaction. So it requires urgent attention not only to improve the rate of spontaneous reporting, but also for enhanced safety of the patients and society at large.*

***Key words**: Adverse drug reaction reporting, Knowledge, Attitude and Practice, Health professionals.*

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Acronyms and Abbreviations

ADE	Adverse drug event
ADR	Adverse drug reaction
AOR	Adjusted odd ratio
ART	Antiretroviral treatment
ARV	Antiretroviral
CARM	Centre for Adverse Reactions Monitoring
CDSCO	Central Drugs Standard Control Organization
CE & T	Clinical Evaluation and Trials
CI	Confidence Interval
COR	Crude Odd Ratio
DTC	Drug and Therapeutic Committee
EMA	European Medicines Agency
FDA	Food and Drug Administration
FMHACA	Food, Medicine, Health Care Administration and Control Authority
FRH	Felegehiwot Referral Hospital
HPs	Health Professionals
FIV	Fires Interviewee
SIV	Second Interviewee
TIV	Third Interviewee
FIV	Fourth Interviewee
FFIV	Fifth Interviewee
SSIV	Six Interviewee
IOM	Institute of Medicine
JU	Jimma University
MCC	Medicines Control Council
MIC	Medicines Information Centre
MOH	Ministry of Health
NADMEC	National Adverse Drug Event Monitoring Centre
NCAs	National Competent Authorities
NHS	National Health System
NGO	Non Governmental Organization
NPC	National Pharmacovigilance Centre
NPP	National Pharmacovigilance Programme
OR	Odds ratio
UoGTH	University of Gondar Teaching Hospital
WHO	World Health Organization
SPSS	Statistical Package for Social Science

List of tables

List of figures

Table of Contents

1. Introduction

1.1 Background

Adverse drug reaction is defined as noxious and unintended effects resulting not only from the authorized use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorization, including the misuse and abuse of the medicinal product (1).

ADRs are often subdivided into six categories with accompanying mnemonics (2).

Table 1: Classification of adverse drug reaction

Type of ADR	Characteristics
Type A (augmented)	Dose-related Common (overall proportion of ADRs - 80%) Suggestive time relationship Related to a pharmacological action of the drug Predictable from known pharmacology Variable severity, but usually mild High morbidity Low mortality Reproducible
Type B (bizarre)	Not dose–related Uncommon Not related to a pharmacological action of the drug Not predictable from known pharmacology Variable severity, proportionately more severe than type A High morbidity High mortality Not reproducible
Type C (chronic)	Uncommon Related to cumulative dose Long term exposure required
Type D (delayed)	Uncommon Usually dose-related Seen on prolonged exposure to a drug or exposure at a critical time
Type E (end of use)	Uncommon Occurs soon after withdrawal of a drug
Type F (failure of therapy)	Common May be dose-related Often caused by drug interactions

ADRs have been creating headlines over the last forty years since the thalidomide tragedy. ADRs are common problem, which affect patients in the hospital and community setting (3).

The findings of the studies were that drug related mortality and morbidity is one of the health problems faced by both developed and developing countries (4-6).

Wester *et .al* (2008) concluded in his study that adverse drug reactions may be the fourth to the sixth leading cause of death in the US which is low when compared to a Swedish study that also implicated that ADRs are 7th most common cause of death (7).

A study conducted in South Africa of secondary hospital 6.3% of medical admissions were due to an ADR, which is similar to proportions found in developed countries (8).

The risk factors that may pre dispose to induce or influence the development, severity and incidence of adverse drug reactions in the population of can be:

- Patient factors**:** Genetics, racial differences, diets, diseases, prescribing practices, culture of drug use and traditions of the people e.g. high carbohydrate, fat diet etc.
- Drug interactions, drug distribution, storage and use including indications, dose, availability and other underlying conditions (9).

Pharmacovigilance is defined by the WHO as a science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identifying new information about hazards associated with medicines and preventing harm to patients (3)**.**

The National ADR Monitoring system of Ethiopia was first established in 2002. Pharmacovigilance is still in its infancy in Ethiopia discipline. Most drug safety monitoring programmes around the world rely heavily on spontaneous reporting of adverse reactions from health professionals. Spontaneous reporting systems (SRSs) play an important role in identifying adverse drug reactions. In Ethiopia, spontaneous reporting by health professionals is voluntary and is managed by the Food, Medicine, Health Care Administration and Control Authority (FMHACA).

Each hospital should establish a Drug and Therapeutics Committee (DTC) to promote the safe, rational and cost-effective use of medicines. All DTC members,

especially the chair and secretary, should be given sufficient time for their DTC functions, and this should be included in their job descriptions (10).

Roles and responsibilities of the DTC are: to develop and maintain the hospital formulary, to develop standard treatment guidelines, to develop policies and guidelines for managing formulary and non-formulary items, to establish mechanisms to identify and address drug use problems, to establish and oversee the drug information service, develop an annual action plan, receive regular reports from the ADR focal person and make any necessary decisions regarding the use of the drug in the facility (10).

Adverse drug reaction reporting is an area of drug information that has been given little attention yet. It is possible that drugs produce initially unanticipated effects (adverse or potentially useful) after their approval for marketing (11).

Knowledge on ADR reporting was not rated the same among health professionals who participated on this kind of study worldwide (4, 12-16).The attitude of health professionals was not the same towards ADR reporting (4, 12, 16-18).

Many conducted studies have shown that majority of the health professionals were having knowledge on how to diagnose ADRs. A challenge on those studies was that majority of the participants reported to have not send ADR to reporting centers due to lack of knowledge on where to send those reports (4, 12, 14, 19).

Adequate knowledge, good practices and positive attitude are essential element in ADR reporting. Different authors (4, 12, 15, 20) came up with different recommendations or conclusions on how to avoid not reporting of ADRs by health professionals. They recommended that:

(a) Training in pharmacovigillance (12, 21-24).
(b) ADR reporting forms must be available like a fax line, email, and online (20).
(c) Incentives should be given for ADR reporting. (20, 25).
(d) The process needs to be simplified, and feedback given to reporters (4).
(e) Pharmacovigillance leaflets should be provided to the healthcare professionals regarding drug safety issues (4, 12).

1.2 **Statement of the problem**

Adverse drug reactions have been regarded as worldwide major public health problem since they represent a sizable percentage of admissions, death and an economic burden (26).

A study in USA revealed that 108,000 Americans died in hospitals from adverse reactions to FDA-approved drugs properly administered by licensed medical professionals. In the same year, 2.2 million Americans had adverse reactions to FDA-approved drugs (28).

The burden of incidence of ADRs on health care and patients in Ethiopia not available but, it is likely that the problem is considerable in, with widespread irrational drug use, including preference for injections, misuse of antibiotics and other traditional/herbal medicines and extensive self-medication (29). Due to: It is known that different classes of adverse events might be displayed when drugs are exposed to different environmental and genetic influences (30).Studies have shown that the Ethiopian population has a distinct genetic makeup compared to Caucasian, Oriental or other Black populations that results higher probability of getting adverse drug reaction (31).

The finding of the studies performed at China (12),Northern India (13) and Italy (14) showed healthcare professionals knowledge on ADR reporting was very low.

The attitude of healthcare professionals towards ADR reporting were negative (17), (18).

A study done in Ethiopia showed that 137(26.6%) participants had adequately answered knowledge determining questions (32).

A study conducted in Southwest of Ethiopia showed that 19(23.17%) respondents have adequate knowledge towards ADR reporting (33).

A study done in Ethiopia showed that more than half participants had positive attitude (32).

A study done in Southwest of Ethiopia showed that 27 (75.00%) of the respondents had positive attitude towards ADR reporting (33).

In two Swedish studies, underreporting rates ranging from 86 to 100%, have been demonstrated(34-35). A systematic review on this topic from 2006 concludes that it is not possible to provide a reliable estimate of the level of underreporting but it is likely to be in excess of 90% (36).

In 2012 of Sweden, in an international comparison, approximately 500 reports per million inhabitants (highest population-based reporting ratio) are considered to be of high quality (38). In Namibia, average of 126 ADR cases per million populations was reported between 2007 and 2012. In Ethiopia, a total of 249 ADR cases were reported between 2002 and 2007. An average of 0.5 ADR cases per million populations were reported annually. According to WHO 2012 report, Ethiopia in the year between 2007 and 2012 307 reports (3.6 cases per million inhabitants) (39).

Although 225(52.25%) of Health care providers had encounter with an ADR in their practice during the last 12 months, only 34(14.6%) had reported to DACA (32).

A study conducted in Southwest of Ethiopia showed that 13 (15.85%) participants encountered adverse drug reaction in the past 12 months in their clinical activities, but none of them reported to responsible body (33).

A study done in Ethiopia showed that the most frequently reasons for not reporting ADRs were the ADR was not serious, the ADR was already known, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and lack of time (32).

According to the available data, no study has assessed *assess* predictors of health professionals knowledge, attitude, and practice related to adverse drug reaction reporting in the study areas. So to do this research will measure level of health professionals' knowledge, attitude and practice towards ADR reporting, and their independent predictors for knowledge, attitude and reporting practice. Therefore it can serve as a base line in the study areas to make an intervention.

2. Literature Review

2.1. Knowledge of health professionals regarding ADR reporting

All health professionals including physicians, pharmacists, nurses and other health professionals are encouraged to report ADR (40). Health professionals outside the government system should also report adverse reactions. These would include, among others, nongovernmental organizations and charitable health facilities (3). According to the FMHACA guideline all health providers in the country are required to report ADRs (37, 40).

Any suspected ADR should be reported as soon as possible. Delay in reporting will make reporting inaccurate and unreliable. If possible, health professionals should report while the patient is still in the health facility, this will give a reporter a chance to clear any ambiguity by re-questioning or examining the patient (9).

Knowledge on ADR reporting was not rated the same among health professionals who participated on this kind of study worldwide. The finding of the studies performed at China (12),Northern India (13) and Italy (14) shows that the level of knowledge among the health professionals on ADR reporting was rated to be very low when compared to other countries like UK (4) , Nigeria (15) and Australia (16).

A study conducted in Ethiopia shows that level of knowledge among the healthcare professionals on ADR reporting was at satisfactory level 50.6% (42).

2.2. Attitudes of health professionals regarding ADR reporting

The attitude of health professionals was not the same towards ADR reporting. Some were having a positive attitude (4, 12, 16) while others were having a negative one (17-18).

Lee *et al*. (1994) in Hong Kong reported that, most of the pharmacists agreed that ADR reporting is necessary even though a smaller proportion have done so (43). Other positive attitudes were observed among the pharmacists at UK (17) and Britain (22).

It was reported in a study conducted in New Zealand that 5.7% of CARM reports were submitted by pharmacists compared with about 70% of ADR reports submitted to the MEDWATCH program in the US by pharmacists (17).

Studies were showing positive attitude of physicians (21, 43), while A negative attitude was observed on the doctors at Nigeria (15) , Germany (44) and Canada (45) towards ADR reporting.

2.3. Practices of health professionals regarding ADR report

At the global level, the WHO programme for international drug monitoring at the Uppsala Monitoring Centre in Geneva collates ADR reports via the national pharmacovigillance centers of the 106 member countries. When the latest reporting statistics were presented in Uppsala Registered 53 last April, the total of 6 million reports in VigiBase had just been passed, and it seems that it will not be long until the next milestone 7 million case reports will be reached. As of 19th of September 2011, the total number of active ICSRs in VigiBase was 6,755,430. When we see reporting rates and country distribution for many years, New Zealand has been the top country in terms of reporting rate per million inhabitants and year. However, Singapore has now taken the lead. New Zealand is runner-up for the top position and the USA is currently in third place. This indicates that only few countries from the developing countries are reporting ADR to the Uppsala Monitoring Centre (41).The main reasons why some of the developing countries are not reporting ADRs to Uppsala Monitoring Centre are lack of resources, infrastructure, and expertise. Thus, although access to medicines is increasing in developing countries, there is a danger that their risk benefit profiles in indigenous populations will not be fully monitored and acted upon (30).

The findings of many conducted studies have shown that majority of the health professionals were having knowledge on how to diagnose ADRs. A challenge on those studies was that majority of the participants reported to have not send ADR to reporting centers due to lack of knowledge on where to send those reports (4, 12, 14, 19).

Studies proved that majority of the doctors at China, Italy and Nigeria have ever diagnosed an ADR in their profession (12, 19, 21) respectively. Lee at.et found in a study conducted at China that 62% of the doctors had encountered an ADR that was not reported at all. These findings are similar to a study that was performed at India whereby 43% of the participants were having awareness

The findings of a study conducted at Iran (47) were that 70% of the nurses had never encountered an ADR when compared to a similar study in China (12),were 85% of nurses had encountered with an ADR before.

Various authors (16, 18, 43) reported in their studies that pharmacists were having little knowledge on how to report and on the kind of reaction that need to be reported. The very same findings were noticed in Hong Kong (43) and Turkey (18), whereby majority of the pharmacists were not even aware of any ADR reporting system in their area.

According to the findings of the studies (4, 12, 21, 48), health professionals mentioned different reasons for not reporting the encountered ADR.

2.4 Reasons for not reporting

The most identified contributed factors for not reporting doctors from reporting were the accessibility of the ADR forms and lack of information on how to report (24). The other influencing factors that were identified in a conducted study at Nigeria were a lack of motivation because of poor feedback on reported cases, unavailability of address or telephone(15). Various authors (49-50) found that majority of the pharmacists were not reporting because they assumed that an ADR was already known. Nurses put not reporting due to not having enough time to report (24).

Different authors (4, 12, 15, 20) came up with different recommendations or conclusions on how to avoid not reporting of ADRs by health professionals. They recommended; training (12, 21-22, 51), centralizing ADR reporting activities (20, 49, 52), incentives (20, 25), feedback (4),drug safety leaflets (4, 12).

2. Conceptual frame work

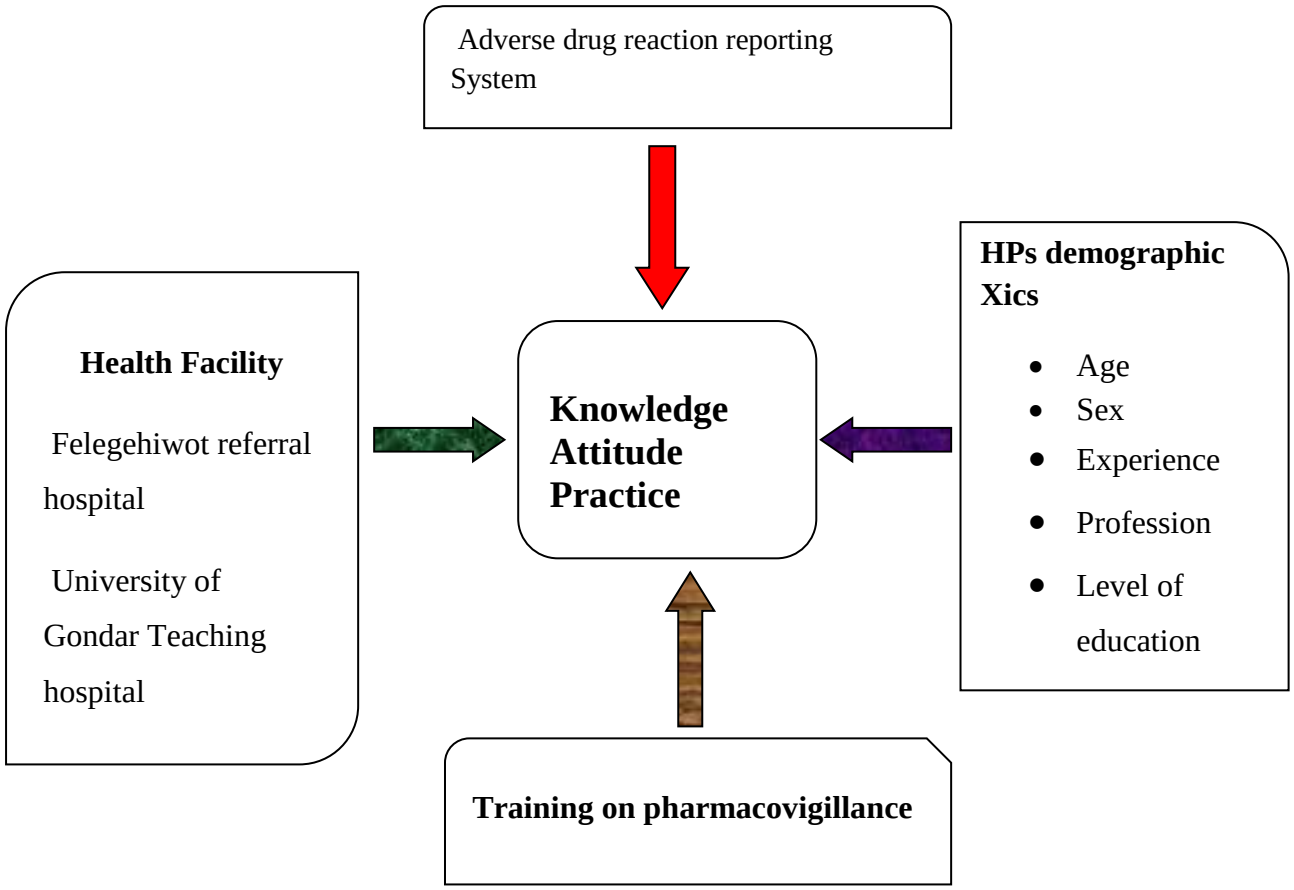

Figure.1: Factors that might affect health professionals knowledge, attitude, and practice towards adverse drug reaction reporting at Felege-Hiwot Referral Hospital and University of Gondar Teaching Hospital, North West Ethiopia 2013.

3. Significance of the study

Involvement of all health professionals' is vital in improving underreporting. Active ADR monitoring without the involvement of nurses is unlikely to achieve its purpose in Ethiopia. They are one of the key players in the health care system. Most of the health facilities in Ethiopia are staffed with nurses. The fact that nurses spend most of their time with patients is an asset in monitoring ADRs: this put them in a strategic position to detect ADRs (37).

According to the available data, no study has assessed predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting in these study areas. So, the present study would determine level of health professionals' knowledge, attitude and practice towards adverse drug reaction reporting.

In addition, the present study identified independent predictors for inadequate knowledge, and not reporting practice with respect to ADRs so that suitable interventions may be planned in future in order to improve the reporting culture.

It may also sensitize policy makers, planners, health care providers, professional associations and FMHACA and others interested bodies in promoting good health need specific, concrete information in order to develop effective programs to tackle ADR under reporting, in such a way that ADR reporting will be improved.

The findings of this study will be used to help improve and continuity of ADR reporting by fully functionalizing and well equipping drug information center.

Above all findings of this study will be used to help appropriate ADR reporting in the health system by identifying different barriers and indicating mechanisms to overcome those barriers. Therefore it will be used as a base line for further studies in the future at regional and national level.

4. Objectives of the study

4.1General objective

- To assess predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting at Felege-Hiwot Referral Hospital and University of Gondar Teaching Hospital**,** Northwest Ethiopia.

4.2 Specific objectives

- To measure health professionals knowledge towards adverse drug reaction reporting
- To measure health professionals attitudes regarding adverse drug reaction reporting
- To assess health professionals reporting practices on adverse drug reaction
- To identify reasons for not reporting
- To identify predictors of inadequate knowledge, negative attitude and not reporting

5. Participants and Methods

5.1 Study Area and period

This study was conducted from March 11, 2013 to April 12, 2013 at Felegehiwot Referral Hospital (FRH) and University of Gondar Teaching Hospital (UoGTH). FRH and UoGTH are located in Bahirdar and Gondar, North West of Ethiopia, respectively.

BahirDar and Gondar are located in Amhara region approximately 565 km and 724 km, located in the North West of Ethiopia away from Addis Ababa respectively.

According to the available data, there are 244 health professionals (32 Physicians, 189 Nurses and 23 Pharmacy professionals) and 654 health professionals (130 Physicians, 461 Nurses and 63 Pharmacy professionals) in FRH and UoGTH, respectively.

Felegehiwot Referral Hospital is one of the regional referral hospitals in North Eastern part of Ethiopia. It serves for people of East and West Gojjam, Bahir Dar liyu and Awi, and its surroundings, south Gondar zones. The hospital has a total 284 beds. It has 275 technical and 187 administrative staffs.

The University of Gondar Teaching Hospital has the only referral teaching hospital provides health in Amhara region services with 466 beds for inpatient at five wards and 14 outpatient wards and more than 672 health professionals.

5.2 Study design

Hospital based cross-sectional study design was used.

5.3 Population

5.3.1 Source population

All health professionals who were working at FRH and UoGTH

5.3.2 Study population

The study population for this study was sampled from HPs working at FRH and UoGTH.

5.3.3 Inclusion and exclusion criteria

5.3.3.1 Inclusion criteria

Health professionals willing to participate in the study and working at FRH and UoGTH

5.3.3.2 Exclusion criteria

Health professionals working at FRH and UoGTH who refused to participate in the study were excluded.

5.4 Sample size determination

5.4.1 Quantitative method

Considering knowledge of health care providers on the term adverse drug reaction on age category of 41-up to 45 years old to be (p=0.5) (32).

Taking attitudes of health professionals agreement on the statement of regarding "reporting creates additional work load" to be (p=0.5) (33).

Taking the prevalence of adverse drug reactions of the health professionals had usually give advice in their practice during the last 12 months to be (p=0.5) (33)

The sample size to be used in the survey will be calculated as follows with 95% confidence level ($Z_{\alpha/2}$ =1.96) and taking 5% standard of error (δ=0.05)

$$n = (Z^2\alpha/2)\frac{P(1-P)}{\delta 2}$$

$$n = \frac{(1.96)^2 \text{ x}0.5\ (1\text{-}0.5)}{(0.05)^2}$$

n=384.16 ~384

Where n is the minimum sample size, $Z_{\alpha/2}$ the reliability coefficient at 95% i.e. 1.96. P is to assess health professionals' knowledge, attitude, and practice towards adverse drug reaction reporting at Felege-Hiwot Referral Hospital (FRH) and University of Gondar Teaching Hospital (UoGTH)**.** P is taken as 50% to calculate the maximum sample size. Taking 5% (δ=0.05) for precision, the minimum sample size becomes 384.16~384.

Using the correction formula to estimate final sample size (nf) from a finite target population (N):

$$nf = \frac{ni}{1 + \frac{ni}{N}}$$

Where **nf** is the final corrected sample size for the study, ***n*i** is the minimum sample size determined and **N** is the number of target population. According to the human resource department data there are 898 health professionals (162 Physicians, 650 Nurses and 86 Pharmacy professionals) currently working at FRH and UoGTH, N is equal to 898.

From the above data there are 244 health professionals (32 Physicians, 189 Nurses and 23 Pharmacy professionals) and 654 health professionals (130 Physicians, 461 Nurses and 63 Pharmacy personnels) in FRH and UoGTH respectively.

$$nf = \frac{384}{1+384/898}$$

$$nf = \frac{384x898}{898+384} = \frac{344,832}{1282} = 268.9 \sim 269$$

The final corrected sample size was 269 by substituting in the formula. Adding 10% for non response rate (0.1X269=26.9~27), the final sample included in the study was 296.

From this we can calculate, from this we can calculate, Proportionate allocation for each stratum (Physicians, Nurses and Pharmacy personnels): using the following formula:

$$n_j = \frac{n}{N} N_j$$

- Where, **j** = 1, 2, ..., k where, k is the number of strata and **nj** is sample size of the **j**th stratum **Nj** is population size of the **j**th stratum **n** = n1 + n2 + ...+n_k is the total sample size **N** = N1 + N2 + ...+N_k is the total population size

Breaking down this sample size to proportion of the sample size by the number of respective profession available in the hospitals:

For Physicians, n (Physicians) = $\frac{162x296}{898}$ =53.4 ~54

For Nurses, n (nurse) = $\frac{650x296}{898}$ =214.25~214

For Pharmacy personnels, n (Pharmacy personnels) = $\frac{86x296}{898}$

=28.34~28

Total numbers of Physicians are 54, Nurses are 214 and 28 are Pharmacy personnels that was included in the study areas.

To allocate the numbers of each health professionals in their institutions,

A. Number of Health professionals involved in UoGTH

Numbers of Physicians was involved in the study= $\frac{130x54}{162}$ =43.3~43

Numbers of Nurses was involved in the study = $\frac{461 \text{ x } 214}{650}$ =151.8 ~152

Numbers of Pharmacy personnels was involved in the study = $\frac{63 \times 28}{86}$ =20.5~21

B. Number of Health professionals involved in FRH

Numbers of Physicians was involved in the study = $\frac{32 \times 54}{162}$ =10.67~11

Numbers of Nurses was involved in the study = $\frac{189X\ 214}{650}$ =62.22~62

.

Numbers of Pharmacy personnels was involved in the study = $\frac{23X28}{86}$

=7.48~7

So, out of this in FRH 80 study samples (11 Physicians, 62 Nurses and 7 Pharmacy personnels) and UoGTH 216 study samples (43 Physicians, 152 Nurses and 21 Pharmacy personnels) were taken.

5.4.2 Qualitative method

In the present study, a total of 6 health professionals in Felegehiwot referral hospital were interviewed. By nomination, a participant number of two participants were selected for each profession. From pharmacy personnels, one clinical in-service trained pharmacist and one drug information service provider pharmacist. For physicians, one was from Tuberculosis/leprosy clinic and one was from ART clinic. For Nurses, one was from Tuberculosis/leprosy clinic and one from ART clinic. The discussion was conducted in their hospital by principal investigator.

5.5 Sampling technique

- For quantitative study, stratified proportional random sampling technique was used.
- For qualitative study, judgment sampling technique was used.

5.6 Measurement and variables

5.6 .1 Measurement

We determined the knowledge about adverse drug reaction reporting using 6 questions out of 16 questions. Each correctly answered question corresponded to 1 point, and there was a total of 6 points for the 6 questions. Respondents were considered having adequate knowledge if they scored greater or equal to 5 out of 6 (33). They were considered to have inadequate knowledge if they scored below 5 out of 6 (33). The health professionals' attitudes were measured using sixteen rated items on a five -point likert scale as strongly agree, agree, disagree , Neutral and strongly disagree. Using the five-point scale for sixteen questions we arbitrarily set the maximum score for each respondent at 80 and the minimum at 16. We decided that a high score (more than 50%) was indicative of positive attitude while a low score (less than or equal to 50%) was indicative of a negative attitude (33). The health professional practices were measured by whether they reported the encountered ADR or not reported.

5.6.2 Variables

5.6.2.1 Independent variables

- Age
- Sex
- Profession
- Level of education
- Health facility
- Experience
- Adverse drug reaction reporting system
- Training on pharmacovigillance

5.6.2.2 Dependent variables

- Knowledge, Attitude and Practice towards adverse drug reaction reporting

5.7 Data collection technique and instrument

For quantitative study, data were collected by a self administered questionnaire that was developed and given for comment. The structured questionnaire is compiled and adapted questions from different literatures and by considering the local situation (13, 18, 32, 33, 46, 47, 69, 74). The first and the second part of the questionnaire focus on demographic characteristics and were containing responses of HPs to the knowledge related questions respectively.

The third part contained health professionals' attitudes toward the ADR reporting. The fourth part dealt with responses of health professionals' practice toward the ADR reporting. Four data collectors (druggists) were requested to distribute and collect a questionnaire to the participants. The data collectors distributed questionnaire attached to a consent form (appendix 1) to the health professional that are willing to participate in the study. Participation was voluntary and no incentive was given to the participants.

Questionnaires were directly distributed to medical doctors, to nurses and to pharmacy personnels through data collectors. A maximum time frame of one week was allowed for the collection of the anonymously filled forms. There was no deliberate plan to exclude any particular class. The absence of any physicians, nurses and pharmacy personnels in the analysis was due to their not returning the questionnaire within the stipulated time.

For qualitative data collection, the interviews focused on the following issues: Describing a problem in greater detail, deciding if an intervention is feasible, targeting the intervention, defining specific intervention messages, and deciding format and style of intervention. Data were collected by using tape recording. Interviewed health professionals were allowed to give multiple answers, in order to get the maximum possible responses and no limits of answers were kept. All the practitioners cited one or more reason not reporting. They were also given freedom to express additional views on the topics discussed at the end of each interview session. Participants were informed about the purpose of the study, which was not to audit their practice but to understand their perceptions of the problems of spontaneous ADRs reporting and ways to improve the current system in place.

5.8. Definition of terms

Adverse events - any unfavorable medical occurrence that in coincidence may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with the treatment

Member countries - countries which comply with the criteria for, and have joined the WHO Programme for International Drug Monitoring

Poly-pharmacy - is a concomitant use of more than one drug, sometimes prescribed by different practitioners.

Prescription Only Medicine – are medicinal product available to the public only on prescription.

Rational drug use - an ideal of therapeutic practice in which drugs are prescribed and used in exact accordance with the best understanding of their appropriateness for the indication and the particular patient, and of their benefit, harm effectiveness and risk.

Regulatory authority - the legal authority in any country with the responsibility of regulating all matters relating to drugs

Serious adverse events - any untoward medical occurrence that at any dose: results in death, is life-threatening requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage.

Side effect - refers to any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug.

Signal - reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Spontaneous reporting - is the voluntary reporting of an adverse reaction by a physician, pharmacist and other health professionals or a patient with the main

objective being able to provide signals about potentially serious, previously unknown safety problems with marketed drugs.

Under reporting - Adverse drug reaction not identifying by the health professionals whether encountered, documented or reported per population.

Unexpected adverse reaction - an adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

5.9 Operational definitions

Adequate Knowledge - respondents were considered to have adequate knowledge if they scored greater than or equal to 5 out of 6 (33).

Attitude – the way of thinking to which ADR reporting should be reported to and an intention to report ADR in the future.

Health professionals - are professionals who involved in diagnosis, prevention and treatment of diseases that includes Physicians, Nurses and Pharmacy personnels.

Inadequate Knowledgeable - respondents were considered to have inadequate knowledge if they scored under 5 out of 6 (33).

Knowledge - the ability of health professionals to give response on ADR, ADR reporting and reporting system related questions.

Negative attitude - if respondents scoring $\leq$ 50% of answering attitude related questions (33).

Nurse - a person trained to care for the sick or infirm, especially in a hospital consists of clinical nurse, dentists, midwife nurse, physiotherapy nurse, Anesthetics nurse, Health officers and Ophthalmology nurse.

Pharmacy personnel - professionally qualified in drugs that include pharmacists, and diploma pharmacy.

Physician - is practitioner of medicine in different departments of hospital.

Positive attitude - if respondents scoring more than 50% of answering attitude related questions (33).

Practice - answering practice related questions on adverse drug reaction i.e. identifying by the health professionals whether encountered, documented, reported ADRs. (33).

Reporting - The process of providing ADR information by filling in the ADR form appropriately and forwarding the same to the DTC or FMHACA.

Reporter - is a health professional who reports adverse drug reaction on the ADR form.

5.10 Data collection procedures

Data were collected using self-administered questionnaire. Therefore data for this cross sectional study needs a time frame of maximum one week was allowed for the collection of the anonymously filled forms.

For depth interview, response was recorded and not taken from each interviewee during at the time of discussion and text note.

5.11 Data processing, analysis, interpretation and presentation

The collected quantitative data were coded, cleared and checked for completeness, then entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 20.0 statistical software. The descriptive statistic was performed on demographic characteristics, knowledge, attitude and practice of adverse drug reaction reporting, including percentage and frequency. Binary logistic regression was used to determine the associations between independent and dependent variables. Odds ratio was used to determine significance and 95% confidence interval was calculated. Those variables with a P value $\leq$ 0.25 level in bivariate analysis was candidate for multivariate analysis i.e. entered into backward stepwise multivariable logistic regression model. Those variables in multivariate analysis with a P value < 0.05 were used independent predictors for inadequate knowledge, negative attitude and not reporting of adverse drug reaction. Results were presented as numbers with percentages or graphic presentations for categorical variables.

Each interview session, which lasted for about 28.50 – 42.00 minute, was conducted at a place where and time convenient for the participants, all of interviewed in the premises where the health professionals practiced. Since guidelines of in-depth interview questionnaire were prepared in English, the qualitative data was transcribed from English to Amharic language. The interviews were all taped recorded and transcribed verbatim. The researcher then listened to the tapes to verify the accuracy of transcripts; the transcripts generated from the tapes were independently read carefully, categorized and summarized by thematic areas (thematic framework analysis) and manually analysed the transcripts line by line for relevant content and interviews revealed three major themes: familiarity with the ADR reporting and reporting system (familiarity with the ADR reporting system, Familiarity with the ADR reporting form), attitudes and behaviours towards ADR reporting, and the possibility of coming across ADRs in daily practice (perceived barriers to ADRs reporting, access to the ADR reporting form, complexity of the ADR reporting process and suggestions to improve the ADR reporting) of the health professionals towards ADR reporting.

5.12 Data quality management

To assure the quality of the data great emphasis was given in designing data collection instrument for its simplicity and understandability. The data collection instrument format was developed in English and checked by different individuals for its accuracy and desired results.

For administering the structured questionnaire four data collectors and one supervisor were recruited. All the data collectors and the supervisor were Pharmacy personnels. The principal investigator was training data collectors for one day about the objective, relevance of the study, confidentiality, respondent's right, and informed consent. They were given an orientation on the protocol and specific details concerning participation in the study.

For depth interview the principal investigator facilitated the discussion based on already designed guideline questionner and control to protect participant's redundancy of answering and prevent out of discussion objective until saturation points reached. All the practitioners cited one or more reason for not reporting. They were also given freedom to express additional views on the topics discussed at the end of each interview session. Participants were informed about the purpose of the study, which was not to audit their practice but to understand their perceptions of the problems of spontaneous ADRs reporting and ways to improve the current system in place.

Pre-test was conducted three days before the actual data collection to assess the understandability and applicability of the instrument in the study areas. Pre-test was done on 15 participants at UoGTH. Participants in the pretest were not included in final sample. Based on the findings, amendments and arrangements were be made on the instrument.

The principal investigator and a supervisor also closely supervised the field activity on a daily basis. At the end of each data collection day the principal investigator was checked the completeness of filled questionnaires and whether recorded information makes sense to ensure the quality of the data collected.

Besides this, the principal investigator was carefully entered and thoroughly clears the data before the commencement of the analysis.

5.13 Ethical Consideration

Ethical clearance and approval of the study was obtained from Institutional review board of Jimma University, College of Public Health and Medical Sciences before starting the actual data collection. Subsequent permission was granted from the authorities of FRH and UoGTH. In addition Physicians, Pharmacy Personnels and Nurses of FRH and UoGTH was approached and asked about the feasibility of the study at the Hospitals.

Participation of Physicians, Pharmacy Personnels and Nurses in this study was entirely voluntary and confidential and private information was protected. Study subjects were assured that non participation didn't affect their work activities at the Hospitals. Each participant was asked a written consent before data collection. The right of participants to withdraw was respected and names were not mentioned.

5.14 Dissemination and Utilization of Results

After data were analyzed, conclusions and recommendations were made. The results of the study will be submitted to the Department of Pharmacy, College of Public Health and Medical Science (Jimma University), Felegehiwot Referral Hospital, University of Gondar Teaching Hospital, Federal FMHACA, Bahirdar special zone Health Desk, Bahirdar branch FMHACA ,Ethiopian pharmaceutical association and Amhara Regional State Health Bureau. The result was presented during thesis defence, as a partial fulfillment of Master of Science in Clinical Pharmacy. Finally, attempts will be made to present the results on scientific conferences, different meetings, workshops and to publish the results of the study on local as well as international journal.

6. Result

A total number of 296 health professionals' filled and all returned the questionnaire within the stipulated time frame.

6.1 Demographic characteristics of respondents

As can be seen on table 2, mean age of the respondents 33 years (SD = 5.609). A total of 144(48.6%) of the respondents were males. In their profession were nurses 214(72.3%), Physician 54(18.2%) and pharmacy personnels 28(9.5%). and 216(73%). 152(51.4%) participants were bachelor Nurses. 216(73%) of participants were from University of Gondar Teaching Hospital. The participants mean of experience were 5.66(SD = 3.491) years.

Table 2: Socio demographic characteristics of respondents at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Demographic characteristics(n=296)		Frequency	Percentage
Age	18-25	45	15.2
	26-35	147	49.7
	36-45	104	35.1
Sex	Male	144	48.6
	Female	152	51.4
Profession	Physician	54	18.2
	Nurse	214	72.3
	Pharmacy Personnel	28	9.5
Level of education	Specialist	44	14.9
	General practitioner	10	3.4
	Pharmacist ,degree	22	7.4
	Nurse ,degree	152	51.4
	Diploma ,pharmacy	6	2.0
	Diploma, nurse	62	20.9
Institution	FRH	80	27.0
	UoGTH	216	73.0
Experience	0-5years	139	47.0
	6-10years	127	42.9
	11-15years	26	8.8
	>/=16years	4	1.4

6.2 Knowledge of health professionals regarding ADR report

6.2.1. Participants Knowledge related questions on adverse drug reaction reporting

As presented in table 3, most of participants i.e. 141(47.6%) and 46(15.5%) responded for possible factor (s) that may predispose(s) a patient to adverse drug reaction were dispensing error and non adherence to the drug regimen, respectively. This finding was also supported by the qualitative finding. For example, the indepth-interviewees said *"overdose and prescribing error."*

Table 3: Responses of health professionals on possible factor (s) that may predispose(s) a patient to adverse drug reaction at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Possible factor (s)	Frequency	Percentage
Dispensing error	141	47.6
Over dose	42	14.2
Prescription error	13	4.4
Life style of the patient	24	8.1
Non adherence to the drug regimen	46	15.5
All of the above	29	9.8
None of the above	1	0.3
Total	296	100.0

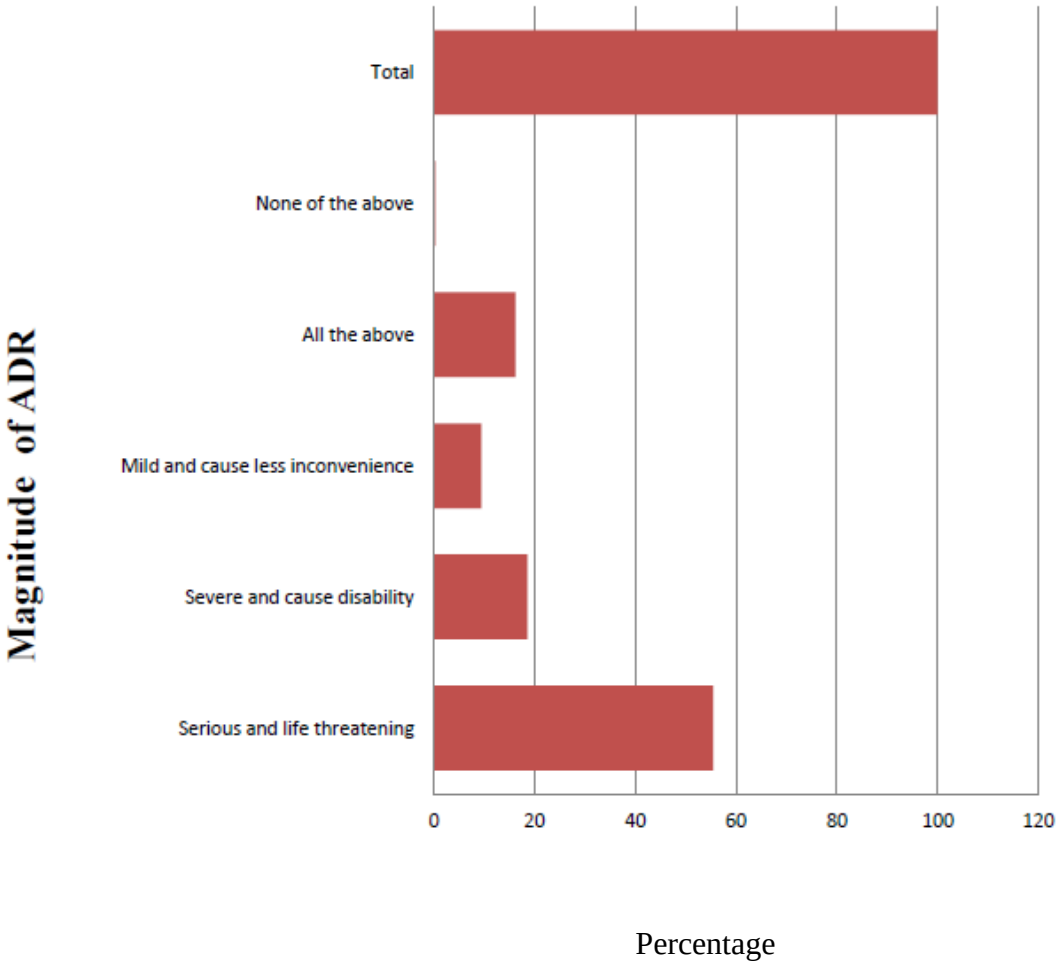

Figure 2: Adverse drug reactions should be reported only when they are**:** at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North West Ethiopia, 2013.

Fig 2, presents the summary of the healthcare professionals level of knowledge on the kind of reactions that have to be reported. More than half (55.4%) of the participants mention that serious and life threatening reactions should be reported.

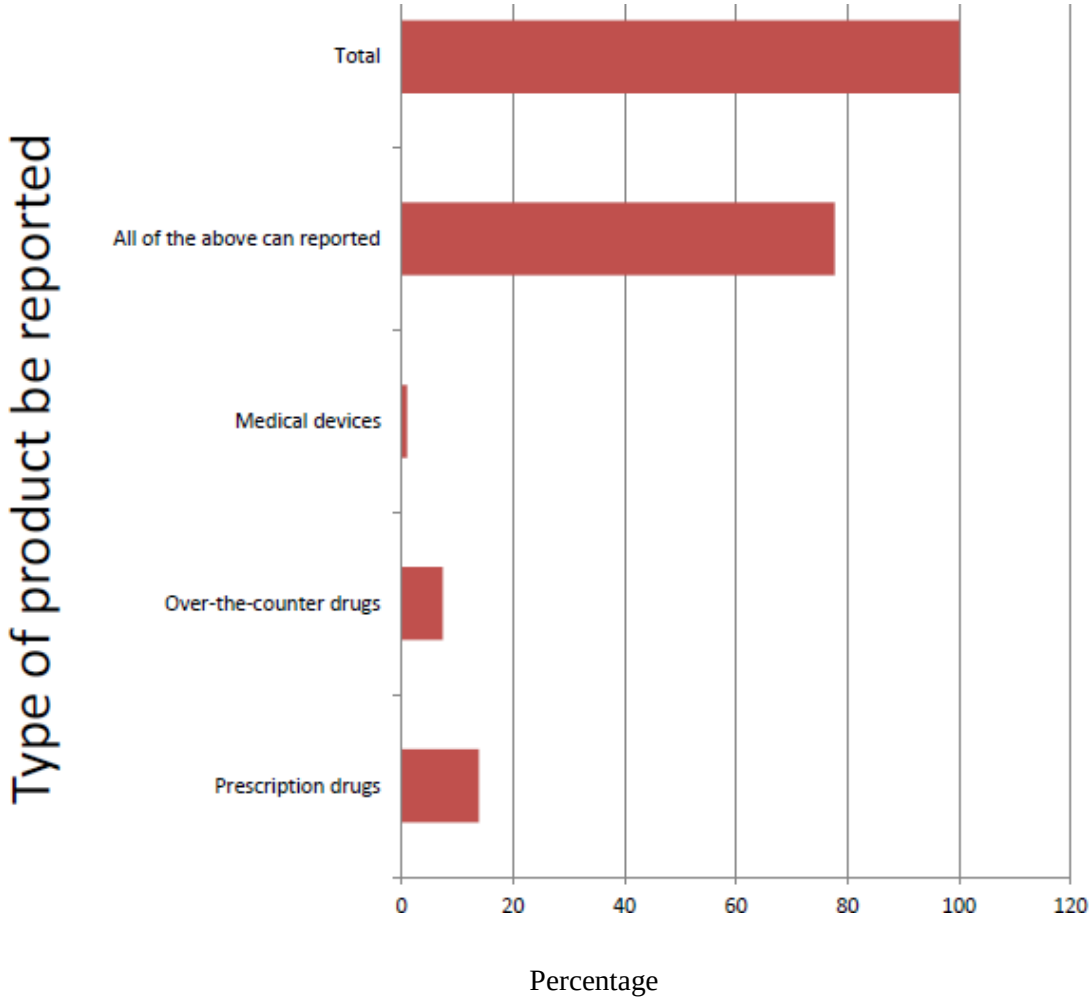

Figure 3**:** Products are usually reported for adverse drug reaction at Felege-Hiwot referral Hospital and University of Teaching Hospital, North West Ethiopia2013. More than 77% Participants' knowledge on products usually reported for adverse drug reaction would be prescription drugs, over-the-counter drugs and medical devices.

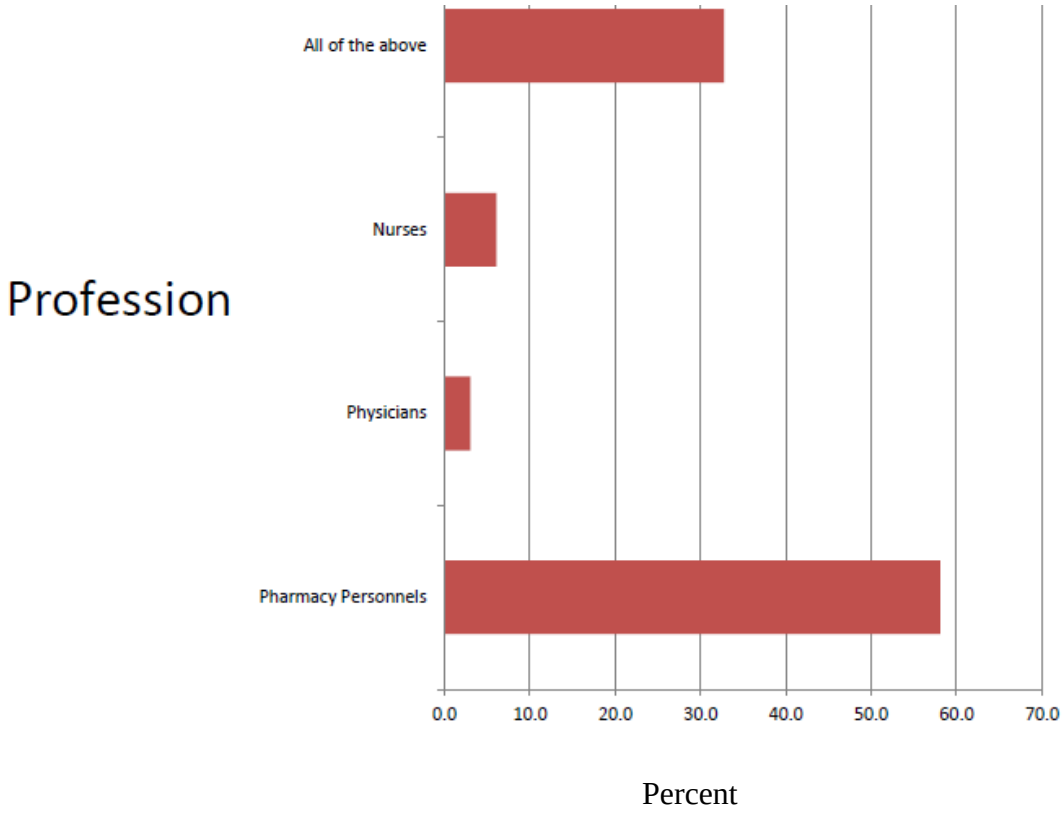

Figure 4: Primarily responsible professional/s to remind and follow up patients about adverse drug reaction of drugs they are given at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia 2013.

From fig 4; more than half participants (58.1%) agreed that Pharmacy personnels were primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given. This finding was also supported by the qualitative finding. For example, the indepth-interviewees said *"exactly pharmacists, because after prescribed patients returned to me and asked how I can use the drug you prescribed."* 97(32.8%) of participants agreed that Pharmacy personnels, Physicians and Nurses were all health professionals primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given.

It is clearly seen from table 4 out of the total of 296 participants, 163 (55.1%) agreed that the encountered adverse drug reaction would be reported to head of the pharmacy department.

Table 4: Adverse drug reporting system at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Organization	Frequency	Percentage
To Head of the pharmacy department	163	55.1
Food, Medicine, Health Care Administration and control authority	39	13.2
To hospital Drug and Therapeutic committee	40	13.5
All of the above	48	16.2
I don't know	6	2.0
Total	296	100.0

Even though most of participants knew the regulatory body responsible for monitoring of ADRs i.e. FMHACA, 255 (86.1%) health professionals agreed that, Food, Medicine, Health Care Administration and control authority definitely has not created awareness on ADR reporting (Table.5). This finding was also supported by the qualitative finding. For example, the indepth-interviewees said *"I do not know what the proper channel to report ADR is in Hospital and actually, personally I don't know how to report, through which medium. Which form? How to report? "*

Table 5: Regulatory body responsible for monitoring of adverse drug reactions in Ethiopia identified by health professionals at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Regulatory body	Frequency	Percentage
Food, Medicine, Health Administration and control Authority	238	80.4
Ethiopian pharmaceutical association	3	1.0
Federal ministry of health	30	10.1
Pharmaceutical fund and supply agency	3	1.0
All of the above	16	5.4
I don't know	6	2.0
Is this system created awareness on adverse drug reaction reporting for you?		
Yes	41	13.9
No	255	86.1

From a total number of 296 participants, 171 (57.8%) admitted that they were worried about legal problems while ADR reporting. Sources of information about ADRs used by the health professionals were summarized in table 6.

Table 6: Worry about legal problems while you think of ADR reporting at FRH and UoGTH, North west Ethiopia, 2013

Worry about legal problems while reporting adverse drug reaction	Frequency	Percentage
Yes	171	57.8
No	125	42.2
Total	296	100.0

165(55.7%) of the respondents' standard text books were their sources of information about adverse drug reactions (Table 7). This finding was also supported by the qualitative finding.

Standard text book, Pharmacopeias, training manuals (SIV)

Internet, Standard text book (SIV)

Standard text book (TIV)

Internet, journals, Standard text book (FIV)

Internet, Standard text book (FFIV)

Leaflets, drug magazines', journals (SSIV)

Table 7: The Source/s of information for health professionals about adverse drug reaction at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Source	Frequency	Percentage
National drug formulary and Standard Treatment Guideline	67	22.6
Standard text books	165	55.7
Notes from the training	8	2.7
Internet	28	9.5
Drug information centers	17	5.7
Journals	2	0.7
National drug formulary and Standard Treatment Guideline, & Standard text books	4	1.4
Standard text books and Notes from the training	2	0.7
Internet and Journals	3	1.0
Total	296	100.0

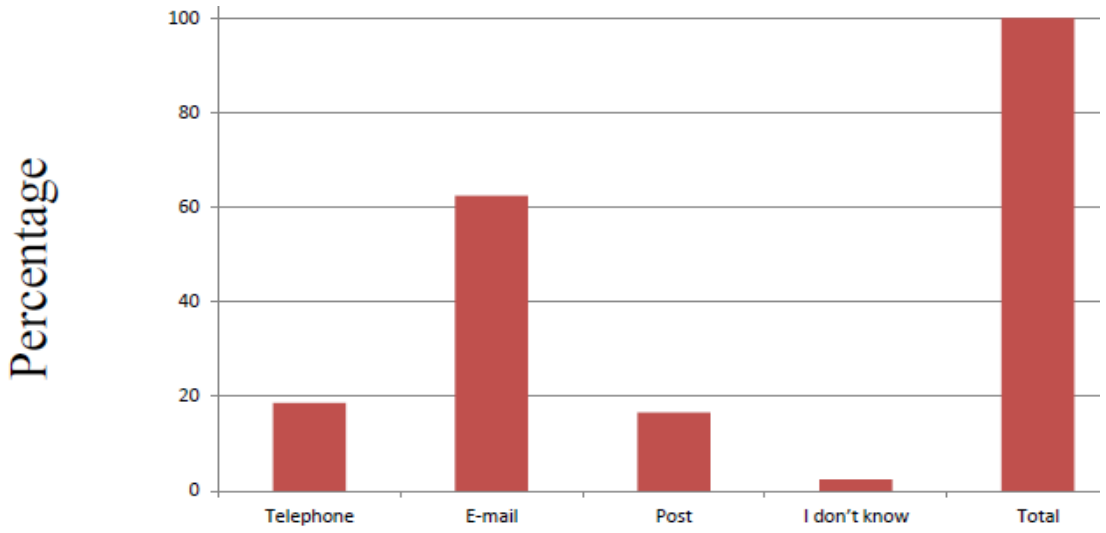

Figure 5: The preferred method to report adverse drug reaction at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia 2013

181(62.5%) participants preferred e-mail as their method to send adverse drug reaction reporting (Fig 5).

6.2.2 Variables associated with knowledge of respondents on ADR

Table 8, provides the information on the knowledge of health professionals regarding ADR reporting. 291(98.3%) health professionals were aware of the term "adverse drug reactions.", but 223(75.3%) respondents were not aware of the term pharmacovigillance." This finding was also supported by the qualitative finding. For example, the indepth-interviewees *"I think I saw this term before during my undergrad, but seriously I forget the meaning already and Vigilance . . . vigilance!!* Pharmacovigilance I don't know the meaning" 231(78.0%) of respondents stated that all drugs available in the market are not safe, but 242 (81.8%) of the respondents indicated that they do not know how to report ADRs. Two hundred nine (70.6%) of the participants did not know the format in which ADRs are reported. This finding was also supported by the qualitative finding 'm*ajority of the respondents replied negatively on familiarity with the ADR reporting form.'* Two hundred twenty two (75.7%) participants think that adverse drug reaction is the same as with side effect.

Table 8: Knowledge determining variables of respondents on ADR reporting at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Variable	Frequency (n=296)	Percentage
Do you know the term adverse drug reaction?		
Yes	291	98.3
No	5	1.7
Do you know the term pharmacovigillance?		
Yes	73	24.7
No	223	75.3
Do you believe all the drugs available in the market are safe?		
Yes	65	22.0
No	231	78.0
Have you seen adverse drug reaction reporting format of Ethiopia?		
Yes	87	29.4
No	209	70.6
Do you think that adverse drug reaction is the same as with side effect?		
Yes	72	24.3
No	224	75.7
Do you know how to report adverse drug reactions?		
Yes	54	18.2
No	242	81.8

6.2.3 Predictors of knowledge on ADR reporting

Health professionals' knowledge on ADR reporting was assessed for its association with socio-demographic variables. Out of 296 participants, 20 (6.76%) had adequate knowledge on ADR reporting, while significant proportion of health professionals, 276 (83.24%) had inadequate knowledge on ADR reporting. Bivariate analysis in the binary logistic regression model showed that age, profession, institution, and participation in seminar or trainings on pharmacovigilance or ADR reporting were candidate for multivariate logistic analysis. However, other factors such as sex, level of education, experience and to whom you report the encountered ADR were not

candidate for inadequate knowledge towards ADR reporting. Crude odds ratio from categories of profession, level of education, experience and to whom you report the encountered adverse drug reaction zero values inadequate knowledge and/or inadequate knowledge (Table 9).

Adjusted multivariable logistic analysis was performed to identify independent predictors of inadequate knowledge towards adverse drug reaction reporting among health professionals. For the purpose of this analysis, variables identified with p-value, $\leq$ 0.25 on the bivariate analysis were candidate for multivariable analysis. Accordingly, knowledge of adverse drug reaction reporting was more likely to have inadequate in the age category of those 26-35 years (AOR = 4.945, 95% CI = 20.965–1.166, P=0.030), participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance (AOR = 8.098, 95% CI = 36.408– 1.801, P=0.006).This analysis indicated that participants with the age category of 26-35 years were 4.945 times more likely inadequate knowledge towards adverse drug reaction reporting as compared to those who were in the age category of 36-45.Participants who were not participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance were 8.098 times more likely to have inadequate knowledge towards adverse drug reaction reporting as compared to those who were participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance. However, profession, and institution were not retained as a significant factor with inadequate knowledge towards adverse drug reaction reporting in the multivariate analysis (Table 9).

Table 9: Binary and multivariable logistic regression model predicting the association of between knowledge and different variables at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

		Health professionals knowledge on ADR reporting (n=296)				
		Inadequate knowledge	Adequate knowledge	**COR (95%CI)**	**AOR (95%CI)**	**P**
Variables		**N (%)**	**N (%)**			
Age (year)						
	18-25	38(84.4%)	7 (15.6%)	0.39(0.130 - 1.19) *		
	26-35	141(95.9%)	6(4.1%)	1.696(0.553- 5.201)	4.945(1.166,20.965)	0.030 **
	36-45	97(93.3%)	7(6.7%)	1	1	
Sex						
	Male	136(94.4%)	8(5.6%)	1.457 (0.578- 3.675)		
	Female	140(92.1%)	12(7.9%)	1		
Institution						
	FRH	71(88.8%)	9(11.2%)	0.423 (0.168, 1.064) *	0.583 (1.773– 0.191)	0.341
	UoGTH	205(94.9%)	11(5.1%)	1	**1**	
Participated in seminar or training						
	Yes	15(71.4%)	6(28.6%)	1	1	
	No	261(94.9%)	14(5.1%)	7.457(22.153-2.510)	8.0989(36.408– 1.801)	0.006 ***

*= candidate for multivariate analysis

**= statistically significant

**= statistically highly significant

6.3 Attitudes of health professionals regarding adverse drug reaction reporting

6.3.1 Attitudes of health professionals regarding ADR reporting in level of agreement

The respondents were asked to indicate their agreement or disagreement on a four point Likert scale from ‘strongly agree’ to ‘strongly disagree’ and their response was summarized as follows in table 10. 182(61.5%) health professionals agreed that adverse drug reactions should be reported spontaneously on regular bases, reporting adverse drug reaction is part of duty of health professionals 157(53.0%), reporting drug safety is important for the public 170(57.4%), reporting adverse drug reaction is part of health care activity 230(77.7%), reporting adverse drug reactions improves quality of patient care 159(53.7%), reporting creates additional work load 172(58.1%), confidentiality should be maintained while adverse drug reaction reporting 176(59.5%), and sending feedback to adverse drug reaction reporters increases adverse drug reaction reporting 181(61.1%), while other participants strongly agreed on reporting drug safety is important for the health care system 153(51.7%), adequate training is important in adverse drug reaction reporting 211(71.3%), and preparing educational programmes on pharmacovigillance increases adverse drug reaction reporting 152(51.4%). This finding was also supported by the qualitative finding, “m*ajority of the discussant expressed their willingness to report”*.

Respondents were disagreed on statements stated that only adverse drug reaction that cause persistent disability should be reported 166(56.1%), one report of adverse drug reaction makes no difference 184(62.2%), and that there is a need to be sure that adverse drug reaction is related to the drug before reporting 117(39.5%). Others strongly disagreed, only adverse drug reaction of prescription drugs need to be reported 165(55.7%), and reporting is not useful to the patient 155(52.4%) (Table10).

Table 10: Participants attitude towards adverse drug reactions reporting (percentage) at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013 (n=296).

Statements	Level of agreement			
	SA	A	D	SD
	N (%)	N (%)	N (%)	**N (%)**
Adverse drug reactions should be reported spontaneously at regular base	70 (23.6)	182 (61.5)	38 (12.8)	6 (2.0)
Reporting adverse drug reaction is part of duty of health professionals	105(35.5)	157(53.0)	29(9.8)	5(1.7)
Reporting drug safety is important for the public	121(40.9)	170(57.4)	3(1.0)	2(0.7)
Reporting drug safety is important for the health care system	153(51.7)	136(45.9)	5(1.7)	2(0.7)
There is a need to be sure that ADR is related to the drug before reporting	19(6.4)	44(14.9)	117(39.5)	116(39.2)
Only ADR of prescription drugs need to be reported	5(1.7)	7(2.4)	119(40.2)	165(55.7)
Only adverse drug reaction that cause persistent disability should be reported	15(5.1)	15(5.1)	166(56.1)	100(33.8)
Reporting ADR is part of health care activity	59(19.9)	230(77.7)	3(1.0)	4(1.4)
Reporting ADRs improves quality of patient care	130(43.9)	159(53.7)	3(1.0)	4(1.4)
One report of ADR makes no difference	4(1.4)	18(6.1)	184(62.2)	90(30.4)
Reporting is not useful to the patient	8(2.7)	9(3.0)	124(41.9)	155(52.4)
Reporting creates additional work load	68(23.0)	172(58.1)	18(6.1)	38(12.8)
Adequate training is important in ADR reporting	211(71.3)	79(26.7)	2(0.7)	4(1.4)
Confidentiality should be maintained while adverse drug reaction reporting	112(37.8)	176(59.5)	1(0.3)	7(2.4)
Sending feedback to reporters increases adverse drug reaction reporting	113(38.2)	181(61.1)	1(0.3)	1(0.3)
Preparing educational programmes on pharmacovigillance increases ADR reporting	152(51.4)	140(47.3)	3(1.0)	1(0.3)

Note: - SA – strongly agree A – agree

SD – strongly disagree D – disagree

6.3.2 Predictors of attitudes regarding ADR reporting

Health professionals' attitude on ADR reporting was assessed for its association with socio-demographic variables. Out of 296 participants, 292 (98.6%) had a positive attitude towards ADR reporting with respective sociodemographic characteristics. Bivariate analysis in the binary logistic regression model showed that profession, level of education, experience and participation in seminar or trainings on pharmacovigilance or adverse drug reaction reporting was candidate for multivariate logistic analysis. However, other factors such as age, sex, institution and to whom you report the encountered adverse drug reaction did not candidate for negative attitude towards ADR reporting. Crude odds ratio results not listed in table 12, due to from categories of age, profession, level of education, institution, experience and to whom you report the encountered adverse drug reaction zero values positive attitude and/or negative attitude (Table 11).

Adjusted multivariable logistic analysis was performed to identify independent predictors of health professionals' negative attitude towards adverse drug reaction reporting. For the purpose of this analysis, variables identified with p-value, ≤ 0.25 by bivariate analysis were candidate for multivariate analysis. Accordingly, in the multivariate logistic analysis profession, level of education, experience and participation in seminar or trainings on pharmacovigilance or adverse drug reaction reporting were not retained as significant factor for negative attitude towards adverse drug reaction reporting (Table 11).

Table 11: Binary and multivariable logistic regression model predicting the association of between attitude and different variables at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

	Health professionals attitude on ADR reporting (n=296)				
	Negative attitude	**Positive attitude**	**COR (95%CI)**	**AOR (95%CI)**	P
Variables	**N (%)**	**N (%)**			
Sex					
Male	1(0.7%)	143(99.3%)	0.347(0.036, 3.378)		
Female	3(2.0%)	149(98.0%)	1		
Participated in seminar or training					
Yes	2 (9.5%)	19(90.5%)	1		
No	2 (0.7%)	273(99.3%)	0.070 (0.522, 0.009)*		

*= candidate for multivariate analysis

6.4. Health professionals reporting practice towards ADR

6.4.1 Health professionals practice related questions on ADR reporting

Even if 279(94.3%) of the physicians stated that they had experienced ADRs during the last 12 months in patients, but only 19(6.4%) recorded the adverse drug reaction that encountered on the patient clinical follow up chart and only 10 (3.4%) health professionals were reported an adverse drug reaction that encountered during the last 12 months. This finding was also supported by the qualitative finding. For instance, the indepth-interviewees said*" did come across ADR, but not reported."* Out of 10(3.4%) reported adverse drug reaction, 5(1.5%) participants sent to Food, Medicine, Health Administration and control authority of Ethiopia (Table12).

Table 12: Health professionals practice related questions on adverse drug reaction at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

Variable	Frequency (n=296)	Percentage
Have you seen any patient experiencing an adverse drug reaction during your practice in last 12 months?		
Yes	279	94.3
No	17	5.3
Have you recorded the adverse drug reaction you encountered on the patient clinical follow up chart?		
Yes	19	6.4
No	277	93.6
Do you report an adverse drug reaction that you encountered in the last 12 months?		
Yes	10	3.4
No	286	96.6
If the answer is YES, to which organization		
Hospital DTC	3	0.9
FMHACA	5	1.5
Ministry of Health	1	0.3
All of the above	1	0.3

Only 56(18.9%) health professionals were usually give advice to their patients on possible adverse effects of drugs during prescribed, dispensed or administered. 209 (70.6%) agreed that ADR reporting form is not available at their job place. Most participants were not seen adverse drug reaction reporting format in their hospitals.209 (70.6%) agreed that ADR reporting form is not available at their job place (Table 13). This finding was also supported by the qualitative finding. For example, the indepth-interviewees said "d*id not see reporting format."*

Table 13: Availability and accessibility of reporting format at your hospital at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Variable	Frequency (n=296)	Percentage
Do you usually give advice to your patients on possible adverse effects of drugs you prescribed, dispensed or administered?		
Yes	56	18.9
No	240	81.1
Is adverse drug reaction reporting form available and accessible at your hospital?		
Yes	87	29.4
No	209	70.6
If the answer is No, how often the reporting format is not available at your hospital		
I haven't seen adverse drug reaction reporting format in this hospital	101	34.1
Some times	37	12.5
Always a shortage	12	4.4
Not at the right place	56	19.3
Not at the right time	3	1.0

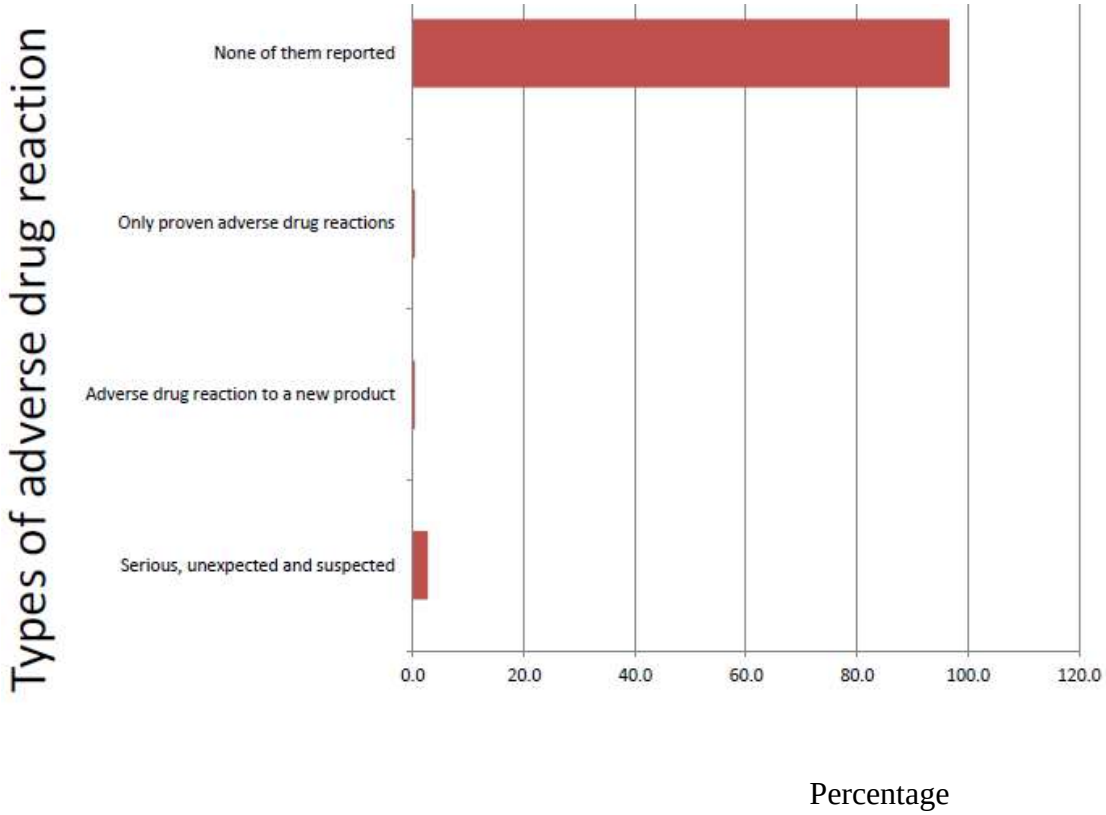

Figure 6**:** Types of adverse drug reactions are usually reported at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia 2013.

Among the participants that reported ADR, 8(2.7%) agreed that serious, unexpected and suspected types of adverse drug reactions usually were reported (Figure 6).

275(92.9%) health professionals were not participated in any seminar/training that includes topic on adverse drug reaction monitoring or Pharmacovigilance during their practice (Table 14).

Table 14: Participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

Variable	Frequency	Percentage
Yes	21	7.1
No	275	92.9
Total	296	100.0

152 (51.4%) participants stated that proper training and 61 (20.6%) continuing education on pharmacovigillance should be provided to health professionals for ADR reporting. The rest participants stated important in improving adverse drug reaction reporting were listed in table 15.This finding was also supported by the qualitative finding.

F1IV replied as *"Incorporation of pharmacovigilance into pre- and postgraduate continuing education programs"*

Involve private health organizations in ADR reporting and preparing training, continual education continuously including media, feed back to reporters, giving orientations for health providers reporting as part of work (SIV).

Providing training and continual education on pharmacovigilance for health professionals and ADR drop boxes should be introduced at strategic sites in hospitals (TIV).

Responsible body should periodically collect ADR forms and involving administrative officials, and NGOs supporting financial in training and continual education (FRIV).

ADR reporting should be included in health professionals job descriptions and Put ADR reporting as one criteria point for institutions ranks which under control of both ministry of health and education (FFIV).

Assign at least one focal person in each hospital that organizes ADR reporting and to functionalize control overall work of DTC (SSIV).

Table 15: Actions suggested for improving adverse drug reaction reporting at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Variable	Frequency (n=296)	Percentage
Training	152	51.4
Incentives	15	5.1
Feedback to reporters	9	3.0
Preparing drug safety leaflets	23	7.8
Continuing education	61	20.6
Training, incentives	9	3.0
Training, feedback to reporters	1	0.3
Training, preparing drug safety leaflets	10	3.4
Training, continuing education on	3	1.0
Incentives, continuing education	4	1.4
Incentives, feedback to reporters	1	0.3
*	2	0.7
**	5	1.7
***	1	0.3

*****= Training, incentives, feedback to reporters

******= Training, incentives, feedback to reporters, preparing drug safety leaflets

*****=** Training, incentives, feedback to reporters, preparing drug safety leaflets, continuing education

6.4.2 Predictors of participants reporting practice regarding ADR

Health professionals' practice of reporting of ADR was assessed for its association with socio-demographic variables. Out of 296 participants, 286 (96.6%) were not reporting the encountered ADR with respective sociodemographic characteristics. Bivariate analysis in the binary logistic regression model showed that sex, profession, level of education, experience, to whom you report the encountered adverse drug reaction, and participation in seminar or trainings on pharmacovigilance or adverse drug reaction reporting were candidate for multivariate logistic analysis. However, age, and institution did not candidate for not reporting regarding ADR (Table 16).

Adjusted multivariable logistic analysis was performed to identify independent predictors for not reporting the encountered adverse drug reaction. For the purpose of this analysis, variables identified with p-value, ≤ 0.25 by bivariate analysis were candidate for multivariate analysis. Accordingly, in the multivariate logistic analysis reporting practice of the adverse drug reaction was participated in any seminar or trained (AOR = 18.465, 95% CI = (99.292-3.434), P=0.001).This analysis indicated that among participants who were not participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance were 18.465 times more likely not to report the encountered adverse drug reaction as compared to those who were participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance. However, sex, profession, level of education, experience, and to whom you report the encountered adverse drug reaction were not retained as a significant factor for not reporting practice towards adverse drug reaction in the multivariate analysis. Crude odds ratio from categories of level of education, and experience were zero values in reporting practice of health professionals (Table 16).

Table 16: Binary and multivariable logistic regression model predicting the association of between practice of reporting and demographic ,and different variables at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

	Health professionals practice of reporting the encountered ADR (n=296)				
	Not reporting	**reporting**	**COR (95%CI)**	**AOR (95%CI)**	**P**
Variables	**N (%)**	**N (%)**			
Age (year)					
18-25	42(93.3%)	3(6.7%)	0.416(0.081, 2.144)		
26-35	143(97.3%)	4(2.7%)	1.062(0.233, 4.848)		
36-45	101(97.1%)	3(2.9%)	1		
Sex					
Male	141(97.9%)	3(2.1%)	2.269(0.575, 8.949)*	2.835 (14.299– 0. .562)	
Female	145(95.4%)	7(4.6%)	1	**1**	
Profession					
Physician	51(94.4%)	3(5.6%)	1.308(0.206, 8.321)	0.999 (15.724– 0.040)	0.110
Nurse	209(97.7%)	5(2.3%)	3.215(0.593, 17.421)*	2.12 (33.630– 0.143)	0.061
Pharmacy Personnel	26(92.9%)	2(7.1%)	1	1	
Institution					
FRH	76(95.0%)	4(5.0%)	0.543(0.149, 1.976)		
UoGTH	210(97.2%))	6(2.8%)	1		
To whom you report					
To pharmacy head	160(98.2%)	3(1.8%)	10.667(0.937, 121.395)*	1.065 (28.460– 0.040)	0.976
To FMHACA	38(97.4%)	1(2.6%)	7.600(0.408, 141.540)*	0.922 (39.208– 0.022)	0.966
To hospital DTC	38 (95%)	2 (5.0%)	3.800(0.289, 49.908)	0.489 (13.359– 0.018)	0.672
All of the above	45 (93.8%)	3 (6.2%)	3.000(0.260, 34.575)	0.972 (23.807– 0.040)	0.986
I don't know	5(83.3%)	1 (16.7%)	1		
Participated in training					
Yes	17 (81.0%)	4(19.0%)	1	1	
No	269 (97.8%)	6(2.2%)	10.549 (40.969-2.716)*	18.465 (99.292-3.434)	0.001**

*= candidate for multivariate analysis **= statistically highly significant

6.5. Reasons for not reporting

The practitioners were allowed to select more than one reason for not reporting in the study questionnaire in this study. All health professionals cited one or the other reason for not reporting. A total of 16 responses were obtained from 296 health professionals. Various causes of not reporting of ADRs cited by the practitioners include: only safe drugs are available on the market 1(0.3%); reporting does not influence the treatment scheme 6(2.0%), busy schedule 181(61.1%), lack of incentives 15(5.1%), don't know whom to report 6(2.0%), I thought I am not the right person to report adverse drug reaction 8(2.7%), Lack of response regarding the outcome of the report 8(2.7%), reporting could show ignorance 7(2.4%). 22(7.4%) respondents cited other reasons for not reporting which included combination of paired answered (Table 17). This finding was also supported by the qualitative finding. For example, the indepth-interviewee reason out *"unavailability of time for reporting ADR."*

Table 17: Possible reason/s that contribute/s for not reporting the encountered adverse drug reaction at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Possible reason/s	**Frequency (n=296)**	**Percentage**
Only safe drugs are available in the market	1	0.3
Reporting does not influence the treatment scheme	6	2.0
Reporting could show ignorance	7	2.4
Busy schedule	181	61.1
I don't know to whom to report	6	2.0
Reporting format not available	42	14.2
Lack of incentives	15	5.1
I thought I am not the right person to report ADR	8	2.7
Lack of response	8	2.7
Others*	22	7.4

* includes Insufficient clinical knowledge to identify adverse drug reaction & I thought I am not the right person to report adverse drug reaction I thought I am not the right person to report adverse drug reaction I thought I am not the right person to report adverse drug reaction, only safe drugs are available in the market & reporting could show ignorance, reporting does not influence the treatment scheme & Thinking one report doesn't make any difference, busy schedule & lack of incentives, busy schedule & I thought I am not the right person to report adverse drug reaction, busy schedule & lack of response regarding the outcome of the report, and busy schedule & The reporting process is long.

7. Discussion

7.1 Knowledge of health professionals on ADR reporting

In the present study several important findings were obtained and with only 20(16.8%) of participants were adequate knowledge which is in congruence with the study in selected health facilities of Jimma zone, south west Ethiopia 23.17% had adequate knowledge (33). Limited knowledge of ADR reporting may reduce the number of reports submitted to FMHACA by health professionals, which in turn could delay the identification of drug hazards and reduce the likelihood of warnings being generated about unexpected and uncommon ADRs. The results of this study suggest that greater effort is needed to improve adverse drug reaction reporting among health professionals worked at Felege-Hiwot Referral Hospital and University of Gondar Teaching Hospital. The questions of what predicts inadequate knowledge on adverse drug reaction reporting has not been answered rationally in study area. In the present study, the possible factors related to inadequate knowledge on adverse drug reaction reporting among 276(93.2%) of the participants have been identified using multiple logistic regression analysis. The results showed that age of the participants, and participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance were independent predictors of inadequate knowledge on adverse drug reaction reporting.

The present study showed that age of the participants was a significantly associated with knowledge and identified as one of the independent predictor of inadequate knowledge. Participants with the age category of 26-35 years were 4.945 times more likely inadequate knowledge towards adverse drug reaction reporting as compared to those who were in the age category of 36-45. Why this factor was associated with inadequate knowledge is unclear, probably this age groups of health professionals could be busy life schedule and/or less interaction with patients. Similarly research that agreed to this finding that conducted in Dar Es Salaam, Tanzania Community Pharmacy Dispensers aged 50 years and above were more knowledgeable about ADRs reporting than those aged below 50 years(53). Differently to this finding, a study in Texas, America the lack of knowledge was found to be more acute among older (>38 years) pharmacists (54). Studies that takes placed at China(12), Northern

India(13) and Italy(14) had inadequate knowledge on ADR reporting. This however contradicts the findings as reported at UK(4), Nigeria(15), and Australia(16).

Only 7.1% health professionals were participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance during their experience and it was significantly associated knowledge and was identified as one of the independent predictors of inadequate in the present study. Participants who were not participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance were 8.098 times more likely inadequate knowledge towards adverse drug reaction reporting as compared to those who were participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance. A study conducted in Dar Es Salaam, Tanzania respondents, who had attended continuous pharmaceutical education 20.8% had more knowledge on ADRs reporting than those who had not attended (53). This result was similar to the studies that takes placed at Iran and India (12, 55) supported that, more than half participants were knowledgeable who took training on pharmacovigillance. Possible reasons could be the undergraduate training in pharmacovigilance and medicine risk perceptions may be either insufficient or improperly delivered to prepare the health professionals for the task of ADR monitoring and reporting in their future career, training participants not selected appropriately and contents of training not adequate, lack of budget to prepare training, lack of appropriate guidelines on pharmacovigilance and not continuous training given by FMHACA.

Lack of knowledge on what is to be reported, who should report, when to report, how to report where to report, together with unavailability of ADRs reporting forms influenced the practice towards ADRs reporting among health professionals. 291(93.3%) of participants were aware of the term “adverse drug reactions”, but 223(75.3%) respondents not aware of the term “pharmacovigillance.” Studies in South West Ethiopia (33) and Ethiopia (32) of the respondent knew the term pharmacovigilance (19.51%) and 45.3% respectively. Vast majority of respondents 231(78.0%) stated that all drugs available in the market are not, but majority of the respondents 242(81.8%) indicated that they do not know how to report ADRs. A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems (56). Of 296 the participants, 209(70.6%) did not know the format in which ADRs are reported, in congruence with a study in south west

Ethiopia 25.61% health professionals knew the availability of ADR reporting format(33). This might be due to inadequate promotion of reporting form and weak regulatory body contact with the health facilities in general and the health professionals in particular. More than three –fourth participants, 224(75.7%) think that adverse drug reaction is the same as with side effect, but opposite of a study in South West Ethiopia 79.27% of participants said that ADR was different from side effect(33). According to WHO recommendation , 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(57). This might lack of adequate information regarding ADR in the curricula and/ or trainings.

Most of participants i.e. 141(47.6%) responded for possible factor (s) that may predispose(s) a patient to adverse drug reaction were dispensing error. These results showed that south west of Ethiopia health professionals are more familiar with (39.03%) of them replied that dispensing error was the primary factor predisposing to ADRs. This might be due to the fact that dispensers are the expected health professionals to know more about drug properties including their adverse effects than other professionals and as a result they are expected to remind the patients about drugs than other health professionals(33). Forty-six (15.5%) of them also believed that drug non adherence to the drug regimen was the primary factor predisposing ADRs. From this, we can understand that respondents had inadequate knowledge on factor (s) that may predispose(s) a patient to adverse drug reaction.

More than half (55.4%) of the participants mention that serious and life threatening reactions should be reported. A research conducted in Dar Es Salaam, Tanzania respondents, majority (60.3%) agreed that reporting is necessary for serious ADRs (53). A study in Texas, America 43.3% of the pharmacists thought that all ADEs, regardless of severity, should be reported to FDA (54).On the contrary, a study done in Portugal non serious ADRs should not be reported (58).

Two hundred thirty (77.7%) health professionals believed that all prescription drugs, over-the-counter drugs, and medical devices should usually reported for adverse drug reaction. A study conducted in Ethiopia 24% of the responders believed that only

ADR of prescription drugs need to be reported whereas most of them don't think so (69%) (42).

Two hundred thirty (58.1%) agreed that pharmacy personnels were primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given, while 97(32.8%) were agreed all health professionals. A study in Ethiopia 15.3% providers response believe that it is the responsibility of the pharmacist/druggist and (67.2%) said it is the physician who is responsible (42).

One hundred sixty three (55.1%), 40(13.5%) and 39(13.2%) participants agreed that the encountered adverse drug reaction would be reported to head of the pharmacy department, to hospital DTC and FMHACA respectively. A study conducted in south West Ethiopia (46.34 %) of the respondents believed that ADR should be reported to DACA (30.49%) to DTC, and 19% to the pharmacy department of the respective health facilities (33). In Saudi Arabia a study done showed that 19% of the respondents considered the pharmacy department is responsible for receiving and reporting ADR results (8.54%) (11). It is obviously known that among the major activities of head of the pharmacy department, DTC and FMHACA were monitoring ADR in the health facilities.

Two hundred thirty eight (80.4%) participants knew the regulatory body responsible for monitoring of adverse drug reactions i.e. Food, Medicine, Health Administration and control authority of Ethiopia. This might be due to adequate promotion on widened responsibilities in addition to drug monitoring. But 255 (86.1%) health professionals agreed that, this sector definitely not created awareness on adverse drug reaction reporting. This might be due to inadequate promotion of reporting system and weak regulatory body contact with the health facilities in general and the health professionals in particular. One study in south west Ethiopia showed that 23.17% of the health professionals knew the availability of national ADR reporting system(33). A study done in Lagos, Nigeria on perception of doctors to ADR reporting showed that 40.4% of the respondent knew about existence of National Pharmacovigilance center in their country (13, 21).

From a total number of 296 participants, 171 (57.8%) admitted that they were worried about legal problems while ADR reporting. Equivalently 46.49% doctors in Hyderabad, India admitted that they were worried about legal problems while ADR reporting(59).

Respondents' of 165(55.7%) and 67(22.6%) in this study were obtained their information on ADRs were from standard text books, and national drug formulary and standard treatment guideline respectively, because probably majority of them had these references in their respective health facility. More than half, (62.5%) participants preferred E-mail as their method to send adverse drug reaction reporting. A study done in South West Ethiopia 78.05% used National Drug Formulary and Standard Treatment Guidelines as sources of information on ADRs and other information on drugs (33). A study in Saudi Arabia showed that 13.2% of the respondents read about ADRs of drugs from standard text books (60).

7.2 Attitudes of health professionals regarding ADR reporting

The health professionals involved in the study strongly felt that it was their professional obligation to report ADRs. This is particularly true as physicians, nurses and pharmacists increasingly collaborate in providing management of medication therapy through the use of primary health care as a part of their professional practices.

Despite of the inadequate knowledge and practices of reporting exhibited by the health professionals for this study areas, revealed that majority 292(93.3%) of participants had positive attitude towards ADRs reporting. So, it is the responsibility of the pharmacovigilance centre (FMHACA) to maintain this positive attitude of the health professionals by informing them about the importance of reporting and the newly updates on pharmacovigilance. Probably, positive attitude towards ADRs reporting signifies that HPs are willing and eager to learn and practice towards ADRs reporting and those they are adequately equipped and facilitated. This result is in line with a study done in South West Ethiopia, 27 (75.00%) participants had positive attitude towards ADR reporting. These results are very similar to figures reported for community pharmacists in Holland(61),Tanzania(53) and United Kingdom (62), but different from the study at New Zealand, were negative attitude was observed among pharmacists (17). Another positive attitude which was in line with the current study was noted among the doctors in Nigeria (21). Differently, in other countries like

Canada (45), Nigeria (15) and Germany (44). The finding of the studies conducted at Australia (4), Iran (47) and UK (63) also showed that nurses had a positive attitude towards ADR reporting because they felt that all ADRs are valuable and should be reported.

The results obtained from multivariate logistic regression analysis of the present study revealed that no significant association of attitude and profession, institution, and participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance i.e., they were not independent predictors of negative attitude on adverse drug reaction reporting. Similarly a research done Ethiopia also attitude insignificant to any demographic characteristics(42), but studies done at Nepal (56),India (64) showed attitude was significantly associated to training i.e. More participants had positive attitude towards adverse drug reaction reporting post intervention than pre intervention.

Two hundred fifty two (85.1%) of health professionals agreed that adverse drug reactions should be reported spontaneously at regular base. A study in South West of Ethiopia 53.66% health professionals agreed that the importance of spontaneous regular reporting of ADRs. A study in Netherlands revealed that 55% of community pharmacists said that before reporting they needed to be convinced of the causality between the drug and adverse reaction(65). A study in Saudi Arabia showed that 96% of hospital pharmacists mentioned that they must be sure of causality between drug and adverse drug reaction before reporting and in Netherlands 82% said that reporting should be as inherent part of pharmaceutical care(60, 65).

Among 296 health professionals, 262 (88.5%) respondents agreed that ADR reporting is part of duty of them but in contrary 274 (92.6%), and 279 (94.3%) disagreed that one report of ADR makes no difference and reporting is not useful for the specific patient respectively. A study conducted in Ethiopia almost all health providers agree towards the fact that an ADR should be reported (96%) and it is part of the professional duty of a health professional (95%). A study done in British showed that 49.8% of the surveyed population felt that ADR reporting should be compulsory and another study which was done in Saudi Arabia showed that 98.3% of the respondents considered the reporting of ADR to be integrated to their professional duties. A study done in Ethiopia 80.3% participants agreed that one report makes no difference (42).A

study in South West of Ethiopia 57.31% respondents agreed that ADR reporting is part of duty of them but in contrary 56.10% and 57.31% disagreed that one report of ADR makes no difference and reporting is not useful for the specific patient respectively (33). A study in British showed that 2.0% of the surveyed professionals felt that one report of ADR made no difference, which was much lower than this study area (66).

Two hundred ninety one (98.3%), 289(97.6%), and 289(97.6%) agreed that reporting ADR are important for the public, health care system and patient respectively; but 233(78.7%) complain that there should be a need to be sure that ADR is related to the drug before reporting. A study done in Ethiopia participants agreed on the idea that monitoring an ADR is important for the public (96%), for the patient (95%), and for the health care system 96% (42). A study in South West Ethiopia showed 71.95%, 70.73% and 73.17% agreed that reporting ADR are important for the public, health care system and patient respectively; but majority of them 85.37% complain that there should be a need to be sure that ADR is related to the drug before reporting (33).

Respondents disagreed on statements stated that only adverse drug reaction that cause persistent disability should be reported 266 (89.9%). A study done in Ethiopia showed that most of the participants (86%) disagreed on the statement that said "only adverse drug reaction that cause persistent disability should be reported" (42).The statement that dealt "there is a need to be sure that adverse drug reaction is related to the drug before reporting" disagreed upon by the majority of the participants 233(78.7%).In addition 284(95.9%) of participants also disagreed on the statement dealt "only adverse drug reaction of prescription drugs need to be reported."

Two hundred forty (81.1%) health professionals agreed on the statement of "reporting creates additional work load." A study which was done in Ethiopia showed that 34.7% participants agreed reporting creates an additional workload (42). Two hundred eighty eight (97.3%) of respondents agreed that confidentiality should be maintained while adverse drug reaction reporting. A study conducted in Ethiopia showed that reporting ADR is breach of patient confidentiality 75.6% (42).A study done in Hyderabad, India (65.95%) respondents feel that patient confidentiality should be maintained while ADR reporting(55).

Two hundred ninety four (99.3 %) of health professionals agreed that sending feedback to adverse drug reaction reporters would increase adverse drug reaction reporting**.** A study in Saudi Arabia showed that, almost all respondents acknowledged the importance of ADR reporting(60).

Participants agreed that adequate training, and preparing continues educational programmes on pharmacovigillance were increased adverse drug reaction reporting with respective value of 290(98.0%) and 292(98.6%). Different studies at Nigeria (20), China (11), Britain (21), and UK (23) showed that adequate training increased ADR reporting.

7.3 Practices of health professionals towards ADR reporting

In clinical practice, 279(94.3%) of health professionals in the current study had experienced ADRs in patients during the last 12 months. However, 10 (3.4%) of those who diagnosed ADRs reported them to reporting centers. The considerable numbers of health professionals in the present study never reported an ADR that is comparable with other studies (14, 25, 67).

Only 21(7.1%) health professionals had participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance during their experience was significantly associated with practice in the present study. This analysis indicated that among participants who were not participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance were 18.465 times more likely not to report the encountered adverse drug reaction as compared to those who were participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance. Similarly, in Portugal, a cluster-randomized controlled trial involving an education intervention resulted in a 10-fold increase in the number of ADR reports(67). A study in Rhode Island agree with this result provided that physicians with education on the reporting system increased 17-fold than before intervention was done(68). Some studies that takes placed at Iran (55),India (69) , China (12) ,India (64) also showed that participated in training health professionals resulted in improvement of adverse drug reaction reporting. Possible reasons could be poor quality of training of HPs, the unavailability of tools for reporting, low utilization and

poor feedback on ADR surveillance reports, lack of appropriate guidelines on pharmacovigilance and not continuous training given by FMHACA.

Even if majority of the health professionals 279(94.3%) stated that they had encountered ADRs during the last 12 months, but only 19(6.4%) and 10(3.4%) of participants were recorded the adverse drug reaction that encountered on the patient clinical follow up chart and reported an adverse drug reaction that encountered during the last 12 months respectively. Out of 10(3.4%) health professionals that were reported, 5(1.5%) and 3(0.9%) respectively sent to FMHACA and hospital DTC. Study done in South west Ethiopia (33) and Ethiopia (42).Out of the 296 respondents encountered patients with ADRs in the last 12 months, 15.85% and 56.25% respectively, none of them and 14.6% actually recorded in the patient follow up chart and reported it to the concerned body(33). A study in Texas, America 67.9% of pharmacists indicated that they had never reported ADRs during their career, but only 6.6% pharmacists had reported any ADRs in the previous 12 months(54). One study in Turkish also showed that 65% of the health professionals encountered patients with ADRs in the last 12 months and 7% of them actually reported it to National pharmacovigilance center in their country (18). In a survey done at England, out of 280 participants 39% of the hospital pharmacists did not report the encountered ADR (22).

Only 55(18.9%) health professionals were usually give advice to their patients on possible adverse reaction of drugs during prescribed, dispensed or administered. Probably, because of they were busy or have no time and just don’t give it enough attention for unknown reasons. In South West of Ethiopia 24.39% of the respondents said that they usually gave advice for their patients, and 32.93% of them replied that they never advice their patients on ADRs (33). A study conducted in Ethiopia 32.7% of respondents usually gives advice to their patients concerning the possible occurrence of adverse effects (42).

Two hundred nine (70.6%) participants agreed that ADR reporting form is not available at their job place. 101(34.1%) and 56(19.3%) of participants were not seen adverse drug reaction reporting format in their hospitals and not available at the right place respectively. Unavailability of ADRs reporting forms and ADR guidelines in hospitals considerably influenced the practice of ADRs reporting. ADR reporting

guidelines should be made available in the form of booklets and posters at conspicuous locations in health care facilities to serve as a constant reminder. The study revealed that Health professionals are not adequately equipped with necessary guidelines and tools to guide and facilitate professionals in monitoring and reporting of ADRs at their working places. A study conducted in Ethiopia 68.8% respondents were accepted that reporting form is not available adequately (42). In a survey done by the European pharmacovigilance research group on members of the European Union, it was mentioned as one of the reasons that discourage reporting and this same fact was found to be a reason in 60.4% of health professionals enrolled in a survey in China (12).

Among the participants that reported ADR, 8 (2.7%) agreed that serious, unexpected and suspected types of adverse drug reactions usually were reported. These are as the same as other studies' results (16, 22, 70-71). We found only one study in that the idea of reporting all kind of ADRs was more often selected by pharmacist than reporting only serious and unexpected reactions (18)**.** Although there are many studies (4, 51, 72-76), 275(92.9%) health professionals were not participated in any seminar/training that includes topic on adverse drug reaction monitoring or pharmacovigilance during their practice. A study conducted in Ethiopia 74% of respondents had never participated in any seminar (42).

One hundred fifty two (51.4%) participants stated that proper training and 61 (20.6%) continuing education on pharmacovigillance should be provided to health professionals for ADR reporting. It is a known fact that information regarding ADRs changes on a daily basis and hence the need for constant updating of the knowledge of health professionals in this area. This should be in addition to regular sensitization of all health care workers on the importance of pharmacovigilance in the quest to decrease morbidity and mortality among the population. Based on the finding of Cosentino(14),and Figueras (67), recommend including "pharmacovigilance" as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program.

7.4 Reasons for not reporting

In our study, the contributed factors for not reporting ADR by the health professionals were busy schedule 181(61.1%), unavailability of the reporting format 42(14.2%), and lack of incentives 15(5.1%). Under-reporting of ADRs is a worldwide phenomenon and this has been established from previous studies (77-80). A study conducted by Toklu. HZ in Istanbul similar to the above mentioned reasons (18).

In order to address some of the determinants of not reporting of ADRs found in this study, include: only safe drugs are available on the market (0.3%); reporting does not influence the treatment scheme (2.0%), I don't know whom to report (2.0%), I thought I am not the right person to report adverse drug reaction (2.7%), Lack of response regarding the outcome of the report (2.7%), reporting could show ignorance (2.4%). Results of a study performed in a tertiary teaching hospital in Barcelona/ Spain are similar to our study, and lack of time to report an ADR due to the workload of clinical practitioners was detected as the most important reason to ADR underreporting(25). Other causes of not reporting in that study were lack of information about the spontaneous reporting system, unavailability of yellow cards, doubt of ADR causality assessment and lack of patient confidentiality(4). Other reasons for not reporting of an ADR in other studies were diagnosed as uncertain association, lack of incentives, too well known to report, yellow card unavailability, lack of time and not knowing how to report (65-70). Availability of appropriate guidelines and reporting forms was expected to provide proper guidance and procedures to be followed by professionals during reporting of ADRs including how to fill in the details of yellow forms, which would have greatly facilitated the pharmacovigilance exercises in Ethiopia.

Several measures were suggested to improve ADR reporting. These included is through training 51.4% several studies also agreed (12, 21-24), continuing education on pharmacovigillance 20.6%, incentives 5.1% studies supported were (20, 25). Apart from the fact that the use of incentives have not been widely accepted and practiced, it raises the possibility of over-reporting by some health care workers in a bid to obtain financial rewards. This should not be supported because ADR reporting should be a fundamental responsibility of health care workers and, therefore, it should be understood as such. Improving ADR reporting, apart from reducing the incidence of

adverse drug reactions in clinical practice, will also lead to a reduction in health care costs., feedback to reporters3.0% argued with (4), (95.74%) medical professionals expect feedback from ADR monitoring centers(59). Feedback from ADR monitoring centers about the causality and severity of ADRs reported by physicians would also encourage them to continue reporting(59). Some workers (3.0%) have suggested the use of financial incentives as a tool to stimulate reporting of ADRs(59). A study in India also showed that, giving incentives improved ADR reporting(81), and preparing drug safety leaflets 7.8% studies showed (4, 12).

7.6 Strength of the study

- high response rate
- Questionnaire was pretested
- Qualitative study done

7.7 Limitation of the study

- Since the study is a cross-sectional, it has a limitation to formulate a casual association, as to how and when the associations are established.
- The study did not determine association between knowledge, attitude, and practice ADR reporting by health professionals.

8. Conclusion

Vast majority of respondents had inadequate knowledge might lead to not reporting the encountered adverse drug reaction.

Most participants had positive attitude. Therefore FMHACA should use this opportunity in order to increase reporting.

More than ninety percent of health professionals not reported the already encountered adverse drug reaction in the past 12 months. This could delay signal detection of adverse drug reaction. So it requires urgent attention not only to improve the rate of spontaneous reporting, but also for enhanced safety of the patients and society at large.

Age and participation in training on pharmacovigilance were independent predictors of inadequate knowledge. Participation in training on pharmacovigilance was also independent predictors of not reporting practice. So preparing trainings and continual education on pharmacovigilance will increase reporting of adverse drug reaction.

Busy schedule was identified as one of the major reason that hinder reporting of health professionals.

9. Recommendations

Based on the study findings the following recommendations are forwarded:

Ministry Of Health

- Providing a separate space for ADR reporting in patient chart.
- Involve private health organizations in ADR reporting.

Ministry Of Education

- Incorporation of pharmacovigilance into pre- and postgraduate continuing education programs

Food, Medicine, Health Care Administration and Control Authority

- The FMHACA should periodically collect ADR forms from hospitals.
- Prepare training for health professionals

Regional Health bureau, Hospital administrative bodies, Health service providers

- Making ADR reporting mandatory for health professionals.
- Assign at least one focal person in each hospital that he/she organizes ADR reporting.
- Active involvement of the administrative staff in spontaneous reporting of ADR will go a long way in improving the reporting rates
- Each hospital should functionalize local DTC 'Pharmacovigilance Unit' for disbursement and collection of ADR reporting forms.
- ADR drop boxes should be introduced at strategic sites in hospitals.
- Put ADR reporting as one criteria point for institutions ranks which under control of both ministry of health and education.
- ADR reporting should be included in health professionals job descriptions

Other relevant bodies

- NGO which works in this area should prioritize and support ADE reporting education and training for health professionals and administrative bodies to increase ADR reporting.

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Annexes

Health professionals' sheet

Name of the principal investigator: Abewa Adimasu Gugissa

Name of study area: Felege-hiwot Referral Hospital and University of Gondar Teaching Hospital

Research budget covered by: Jimma University

Research objective: predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting at Felege-hiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia.

Significance of the study: The study will be used to help the public in general, to identify factors not reporting that played on public health decisions and come up with initiatives to improve reporting of adverse drug reaction (ADR) among health professionals' and the policy makers in particular will be the beneficiaries of this study as areas of possible interventions will be obtained from to improve the adverse drug reaction (ADR) reporting and monitoring.

Study procedure: The data collectors will disseminate questioner to study participants using questions after obtaining consent from the health professionals. Then data will be collected after filling the questioner. On selected participant's depth interview will be done by using prepared guideline questioner.

Risks: No risks except the time that health professionals spend during questioner filling.

Participant right: Health professionals have a right to stop participates in the study, or to skip any question that he/she does not want to answer.

Beneficial: The study is beneficial for patients and health facility quality service delivery for future activities.

Incentives: You will not be provided any specific incentive for taking part in the research other than acknowledgment.

Confidentialities: The study result will not include health professionals name and address.

Agreement: Health professionals are expected to be fully voluntary to participate in the study.

Whom to contact: If you have any kind of inconveniencies about the study, you can contact the following individuals:

- Mr. Nezif Hussein, Clinical Pharmacist, Head Department of Pharmacy, Jimma University (advisor of the study)
    - Tel: 0911185351 or 0471111979
    - email: nezifad@gmail.com
- Mr. Abewa Admasu (principal investigator)
    - Tel: 0919130037
    - Email: gebretsadek@yahoo.com //abewa2005@gmail.com

Self administered questionnaire Consent form for participants

Dear Participants

Name of principal investigator: - Abewa Admasu Gugissa (Jimma University).

I am inviting you to participate in a research project to predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia.

Along with this letter is a questionnaire that asks a variety of questions knowledge, attitude and practices towards adverse drug reaction (ADR) reporting among health professionals. I am asking you to look over the questionnaire and, if you choose to do so, complete it and give it back to me. Your correct answer to the questions can make the study achieve its goals. You are kindly requested to respond genuinely and voluntary with patience. Return questioner within a week. The results of this project will be useful in determining predictors for inadequate knowledge, negative attitude, and for not reporting of adverse drug reactions by healthcare professionals. Through your participation I hope to share my results by publishing them in a scientific journal.

I know risks to you if you decide to participate in this survey and I guarantee that your responses will not be identified with you personally. I promise not to share any information that identifies you with anyone. You should not put your name address on the questionnaire.

If you have any questions or concerns about completing the questionnaire or about being in this study, you may contact me at **0919130037**. Ethical clearance and approval of the study was obtained from institutional review board of Jimma University, College of Public Health and Medical Sciences before starting the actual data collection. Subsequent permission will be granted from the authorities of FRH and UoGTH.

1. I confirm that I understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is completely voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I agree to take part in the above study. I would like to confirm my agreement by signing.

Participants

Signature_____ date_____

Name of the data collector: _____

Signature_____date_____

Name of the principal investigator: _____

Signature_____date_____

Thank you

Identification number: _____

Questionnaire for the assessment of predictors of health professionals' knowledge, attitude, and practice related to adverse drug reaction reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North West Ethiopia

Please answer the following questions by encircle or tick in front of the answer number/s. For Questions 101 and 106 write your age and service year on the space provided.

I. Participants' demographic characteristics

101. Age .....in year.

102. Sex:

1. Male
2. Female

103. Profession:

1. Physician
2. Nurse
3. Pharmacy Personnel

104. W hat is your Level of education?

1. Specialist
2. General practitioner
3. Pharmacist, Doctor
4. Pharmacist ,Master
5. Pharmacist ,degree
6. Nurse, Doctor
7. Nurse, Master
8. Nurse ,degree
9. Diploma pharmacy
10. Diploma nurse

105. Name of Institution

1. Felegehiwot Referral Hospital
2. University of Gondar Teaching Hospital

106. Total Years of experience in your profession: …… in year.

II. Responses of the professionals to the knowledge related questions

Instructions: You are requested to give information to the best of your knowledge. Please mark encircle for the correct response.

107. Do you know the term adverse drug reaction?

1. Yes 2. No

108. What possible factor (s) do you think predispose(s) a patient to adverse drug reaction?

1. Dispensing error
2. Over dose
3. Prescription error
4. Life style of the patient
5. Non adherence to the drug regimen
6. All of the above
7. None of the above

109.Do you know the term pharmacovigillance?

1. Yes
2. No

110. Do you believe all the drugs available in the market are safe?

1. Yes
2. No

111 .Have you seen adverse drug reaction reporting format of Ethiopia?

1. Yes
2. No

112.Do you think that adverse drug reaction is the same as with side effect**?**

1. Yes 2.No

113.Adverse drug reactions should be reported only when they are

1. Serious and life threatening
2. Severe and cause disability
3. Mild and cause less inconvenience
4. All the above 5. None of the above
6. I don't know

114.Which products are usually reported for adverse drug reaction?

1. Prescription drugs

2. Over-the-counter (OTC) drugs
3. Medical devices
4. All of the above can reported

115. Who do you think is primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given?

1. Pharmacy Personnels
2. Physicians
3. Nurse
4. All of the above
5. I don't know

116. Do you know how to report adverse drug reactions?

1. Yes
2. No

117. To whom you report the encountered adverse drug reaction?

1. To Head of the pharmacy department
2. To Food, Medicine, and Health Care Administration and control authority (FMHACA)
3. To hospital Drug and Therapeutic committee
4. All of the above
5. I don't know

118 .In Ethiopia, which regulatory body is responsible for monitoring of adverse drug reactions reporting?

1. Food, Medicine, Health Administration and control authority (EFMHACA)
2. Ethiopian pharmaceutical association (EPA)
3. Federal ministry of health (MOH)
4. Pharmaceutical fund and supply agency (PFSA)
5. All of the above
6. I don't know

119 .Has this system created awareness of adverse drug reaction reporting in you?

1. Yes

2. No

120. Do you worry about legal problems while you think of adverse drug reaction reporting?

1. Yes
2. No

121. What is your source of information about adverse drug reaction? (possible to select more than one)

1. National drug formulary and Standard Treatment Guideline
2. Standard text books
3. Notes from the training
4. Internet
5. Drug information centers
6. Journals

122. Which method would you prefer to send adverse drug reaction reporting?

1. Telephone
2. E-mail
3. Post
4. I don't know

III. Responses of the professionals to the attitude related questions

No	Questions	SD (5)	D (4)	Neutral (3)	Agree (2)	SA (1)
123	Adverse drug reactions should be reported spontaneously at regular base					
124	Reporting adverse drug reaction is part of duty of Health professionals					
125	Reporting drug safety is important for the public					
126	Reporting drug safety is important for the health care system					
127	There is a need to be sure that adverse drug reaction is related to the drug before reporting					
128	Only adverse drug reaction of prescription drugs need to be reported					
129	Only adverse drug reaction that cause persistent disability should be reported					
130	Reporting adverse drug reaction is part of health care activity					
131	Reporting adverse drug reactions improves quality of patient care					
132	One report of adverse drug reaction makes no difference					
133	Reporting is not useful to the patient					
134	Reporting creates additional work load					
135	Adequate training is important in adverse drug reaction reporting					
136	Confidentiality should be maintained while adverse drug reaction reporting					
137	Sending feedback to adverse drug reaction reporters increases adverse drug reaction reporting					
138	Preparing educational programmes on pharmacovigillance increases adverse drug reaction reporting					

SD -strongly Disagree SA - strongly agree

Disagree – D

IV. Responses of the professionals to the practice related questions

139.Have you seen any patient experiencing an adverse drug reaction during your practice in last 12 months?

1. Yes
2. No

140. Do you usually give advice to your patients on possible adverse effects of drugs you prescribed, dispensed or administered?

1.Yes

2.No

141.Have you recorded the adverse drug reaction you encountered on the patient clinical follow up chart?

1.Yes

2.No

142. Is adverse drug reaction reporting form available and accessible at your hospital?

1. Yes
2. No

143.If the answer is No, how often the reporting format is not available at your hospital

1.I haven't seen adverse drug reaction reporting format in this hospital

2.Some times

3.Always a shortage

4.Not at the right place

5.Not at the right time

144.Do you report an adverse drug reaction that you encountered in the last 12 months?

1. Yes
2. No

145. If your answer is YES, where did you report that reaction?

1. Hospital drug and therapeutic committee
2. Food, Medicine, Health Administration and control authority
3. Ministry of Health
4. All of the above

146. If your answer "Yes" for question number 144, which types of adverse drug reactions are usually reported?

1. Serious, unexpected and suspected
2. Any adverse drug reaction of old drug
3. Adverse drug reaction to a new product
4. Only proven adverse drug reactions
5. Any adverse event
6. All of the above
7. None of the above
8. I don't know

147. Have you ever participated in any Seminar/Training which includes topic on adverse drug reaction monitoring or Pharmacovigilance?

1. Yes
2. No

148. Which of the following is/are important in about improving adverse drug reaction reporting? (you can select more than one answer)

1. Training
2. Incentives
3. Feedback to reporters
4. Preparing drug safety leaflets
5. Continuing education on pharmacovigillance

149. What is/are the possible reasons for not reporting the encountered adverse drug reaction you encountered during your practice? (You may select more than one option and please tick what is appropriate).

possible reasons for not reporting adverse drug reaction	✓
1.Insufficient clinical knowledge to identify adverse drug reaction	
2. Only safe drugs are available in the market.	
3.Reporting does not influence the treatment scheme	
4.Difficult to pin point suspected drug	
5.Reporting could show ignorance	
6.Busy schedule	
7.Thinking one report doesn't make any difference	
8.I don't know to whom to report	
9.Reporting format not available	
10.Lack of incentives	
11.I thought I am not the right person to report adverse drug reaction	
12.Lack of response regarding the outcome of the report	
13.The reporting process is long	

Thank You for your time!!!

Consent to participate in depth interview

You will be asked to participate in depth interview prepared by the principal investigator and during discussion if you allowed to record is up to you. The purpose of the group is to describing a problem in greater detailed, deciding if an intervention is feasible, targeting the intervention, defining specific intervention messages, and deciding format and style of intervention.

The information obtained in the depth interview will be used to help appropriate ADR report in health professionals and address barriers to be improved in reporting of ADRs.

You can choose whether to participate or not recording in the depth interview was based on your permission and you can stop at any time. Although the depth interview will not be tape recorded, your responses will remain anonymous and no names will be mentioned in the report.

There are no rights or wrong answers to the depth interview questions. I want to hear many different viewpoints and will like to hear from everyone. Responses made by all participants are kept confidential.

I understand this information and agree to participate fully under the conditions stated above:

Signed: _____

Date: _____

Indepth interview Confirmation Letter

April (?), 2013

Dear _____,

Thank you for your willingness to participate in depth interview. As discussed in phone, I would like to hear your ideas and opinions about knowledge, attitude and practices towards adverse drug reaction (ADR) reporting among health professionals at Felegehiwot Referral Hospital. You will be individually asked answer questions and answer what you know and feel. Your responses to the questions will be kept anonymous. No payment, during in the in depth interview. The date, time, and place will be on your hospital. Please look for signs to know your participation in the indepth interviewing.

Date……..

Time…….

Place……..

If you need directions to the in depth interview or will not be able to participate for any reason please call 0919130037. Otherwise I will look forward to get available you on time and place.

Sincerely,

Abewa Admasu

Questionnaire for qualitative study

Health professionals Depth interview Participant Demographics

1. Age (years): ____ Years
2. Your gender:
    1. Male
    2. Female
3. What is your profession?
    1. Pharmacist
    2. Physician
    3. Nurse
4. Level of education:
    1. Specialist
    2. General practitioner
    3. Pharmacist ,degree
    4. Nurse, Master
    5. Nurse ,degree
    6. Diploma pharmacy
    7. Diploma nurse
5. How long have you been in practice? ____ Years

Guide lines for Depth interview of health professionals

a. To Describe a Problem in Greater Detail

1. Do you know Pharmacovigilance?
2. Does adverse drug reaction (ADR) reporting among health professionals' practices vary greatly by location, health facility, or health provider?
3. Do deficits in adverse drug reaction (ADR) knowledge contribute to reporting problem practices?
4. What specific areas of knowledge are deficient: diagnostic procedures, prescribing, administering, dispensing, filling adverse drug reaction reporting format (yellow card) of etc.?
5. What are the potential obstacles not to report adverse drug reactions spontaneously at regular time in your understanding?
6. Solutions for overwhelming obstacles not to report spontaneously adverse drug reactions (ADRs)
7. What are the possible Error causes(s) and contributing factor(s) adverse drug reactions to occur?
8. What is your opinion on the availability of adverse drug reactions reporting format (Yellow card) in your facility?
9. Do you apply HMIS manual and Patient allergy card recording on patient card?
10. What looks like your recording system of patient allergy card and your documentation about patient profile?
11. What is your suggestion on contents, participants on training on pharmacovigillance?

b. To decide if an Intervention is Feasible

1. What is the communication like between patients and health professionals?
2. What is the communication like between Food, Medicine, and Health Care Administration and control authority (FMHACA) and/or To hospital Drug and Therapeutic committee (DTC), pharmacy department your facility and with other health professionals?

3. How often do patients express a preference for a certain drug or type of therapy problem (adverse drug reactions)?
4. How satisfied are patients with the care they received?
5. What specific aspects of care contribute to patient satisfaction?
6. How important is satisfying patients to health professionals?
7. Do health professionals try to educate patients about their illness or the drugs they prescribed, dispensed and administered?
8. Are there severe constraints in the work environment that would prevent health professionals from changing their attitude on adverse drug reaction reporting?
9. Are there proper drugs available at all times?
10. Are you interested in improving their practices of adverse drug reaction reporting?
11. Are the administrative authorities supportive of the types of changes proposed?

c. To Target the Intervention

1. Are there particular health professionals or departments (wards) with especially poor practices on adverse drug reaction reporting?
2. What is the relationship between an individual professional and the group in which he or she practices?
3. Are there features of the social, cultural, or behavioral context that could be used to influence the adverse drug reaction reporting practices of individual health workers or patients?
4. Are there particular people whose opinion is especially influential with health professionals?
5. Would it be possible to recruit these opinion leaders to assist in implementing the intervention?
6. Is it possible to reduce the general problem of interest to more specific behaviors or practices that it would be easier to change?

d. To Define Specific Intervention Messages

1. Can specific myths (A traditional story accepted as history; serves to explain the world view of a people) about practice be identified that it is possible to debunk (The exposure of falseness or pretensions) with scientific facts?
2. Are there specific areas of miscommunication between patients and health professionals that can be highlighted in an intervention?
3. What kinds of educational materials are available to health professional or patients in your working class or organization?
4. When health professional or patients have changed in the past, what was it that caused them to change?
5. How do health professionals or patients respond to prototype intervention materials?

e. To Decide Format and Style of Intervention

1. What sources of information do health professional use to learn about adverse drug reaction?
2. What educational programs have health professionals already attended?
3. What model of continuing education is most highly rated: group seminars? Workshops, visits by medical experts, etc.?
4. How often do health workers interact with drug pharmacy representatives?
5. Is information from drug companies considered to be biased?
6. Do health professionals have access to any unbiased sources of drug information?
7. Are there any ways for health professionals to review their practices on adverse drug reaction reporting? Regular utilization reports, practice audits, departmental reviews, etc.?
8. How do health professionals respond when given summaries of their own practices on adverse drug reaction reporting?

Thank You for your time!!!

Certificate

This is to certify that the thesis entitled **"**Health Professionals Knowledge, Attitude, and Practice towards Adverse Drug Reaction Reporting and identifying predictors at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia**"** was carried out by **Abewa Adimasu** under direct supervision the advisor(s) listed below. Further, the advisor(s) certify that this work has not been submitted in part or full in any University or Institution for any Degree or Diploma.

1. Name: _____Signature: _____ Date: _____

2. Name: _____Signature: _____ Date: _____

Declaration

I hereby declare that the work embodied in this thesis was carried out by me under direct supervision of Mr**. Nezif Hussien** Department of Pharmacy, College of Public Health and Medical Sciences, Jimma University and **Mr.Desta Hiko** Department of Epidemiology, College of Public Health and Medical Sciences, Jimma University. This work has not been submitted in part or full in any University or Institution for any Degree or Diploma. I further endorse that this work is the property of Jimma University and all rights in this regard are reserved with Jimma University.

Name: _____ Signature: _____