

# Predictors of nurses reporting practice related to adverse drug reaction 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 Nurses. Objective: to assess predictors of Nurses' practice related to adverse drug reaction reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia. Method: 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. A total number of 214 Nurses involved in this study. Self-administered pre-tested questionnaire was used. Stratified random sampling technique was used to select study participants. Bivariate analysis and multivariable logistic regression analyses were employed for identifying not reporting practice regarding adverse drug reaction. Results: Mean age of the respondents 21.8 years (SD = 7.01). One hundred twenty two (57.0%) of the respondents were females, 152(71.7%) participants' level of education were bachelor of Nurse. The participants mean of experience were 1.64 (SD = 4.7) years. Participants who took training/seminar on Pharmacovigilance had 0.29 times more likely to have adequate knowledge (AOR = 0.29, 95% CI = 0.226– 0.004, P=0.001) Conclusions and recommendation: Even though most Nurses had encountered adverse drug reaction, most of them were not reporting regarding adverse drug reaction. So Food, Medicine, Health Care Administration and Control Authority of Ethiopia should prepare training and continual education related to adverse drug reaction reporting for Nurses.

**Keywords:** Factor, Practice, Pharmacovigilance, Ethiopia

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## 1. Introduction

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).

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 (2).

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 (3).

A study in USA revealed that 108,000 Americans died in hospitals from adverse reactions to Food and drug authority of America-approved drugs properly administered by licensed medical professionals. In the same year, 2.2 million Americans had adverse reactions to Food and drug authority of America-approved drugs (4).

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 adverse drug reactions are 7<sup>th</sup> most common cause of death (5).

A study conducted in South Africa of secondary hospital 6.3% of medical admissions were due to an adverse drug reaction, which is similar to proportions found in developed countries (6).

The burden of incidence of adverse drug reactions 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 (7). Due to: It is known that different classes of adverse events might be displayed when drugs are exposed to different environmental and genetic influences (8). 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 (9).

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 (10).

In two Swedish studies, underreporting rates ranging from 86 to 100%, have been demonstrated (11-12). 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% (13).

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 (14). In Namibia, average of 126 adverse drug reaction cases per million populations was reported between 2007 and 2012. In Ethiopia, a total of 249 adverse drug reaction cases were reported between 2002 and 2007. An average of 0.5 adverse drug reaction 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) (15).

Although 225 (52.25%) of Health care providers had encounter with an adverse drug reaction in their practice during the last 12 months, only 34 (14.6%) had reported to DACA (16). 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 (17). Another study done in Ethiopia showed that the most frequently reasons for not reporting adverse drug reactions were the adverse drug reaction was not serious, the adverse drug reaction was already known, uncertainty concerning the causal relationship between the adverse drug reaction and the drug, forgetting to report the adverse drug reaction and lack of time (16).

The present study identified independent predictors for not reporting practice with respect to adverse drug reactions. It may also sensitize policy makers, planners, health care providers, professional associations and Food, Medicine, Health Administration and control authority and others interested bodies in promoting good health need

specific, concrete information in order to develop effective programs to tackle adverse drug reaction under reporting. The findings of this study will be used to help improve and continuity of adverse drug reaction reporting by fully functionalizing and well equipping drug information center.

Above all findings of this study will be used to help appropriate adverse drug reaction reporting in the health system by identifying different barriers and indicating mechanisms to overcome those barriers.

## 2. Participants' and Methods

### 2.1. Study Setting and Period

This study was conducted from March 11, 2013 to April 12, 2013 at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital. Felegehiwot Referral Hospital and University of Gondar Teaching Hospital 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 Nurses, 189 Nurses and 23 Pharmacy professionals) and 654 health professionals (130 Nurses, 461 Nurses and 63 Pharmacy professionals) in Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, 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, Bahirdar 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.

### 2.2. Study Design and Data Collection

Hospital based cross-sectional study design was used to relate sociodemographic characteristics respondents, adverse drug reaction reporting system, health institution and training on pharmacovigilance predictors of Nurses reporting practice related to adverse drug reaction for this study among stratified proportional random sampling technique sampled 214. For this study data were collected by a self-administered questionnaire and collected within a maximum of 7 days and focuses on demographic characteristics and responses of Nurses to the reporting practice related questions.

### 2.3. Participant Eligibility Criteria

To exclude bias, study participants 214 Nurses (43 Nurses, 152 Nurses and 21 Pharmacy professionals) in (Felegehiwot Referral Hospital) and University of Gondar Teaching Hospital Nurses willing to participate, signing the

written informed consent and working at (Felegehiwot Referral Hospital) and University of Gondar Teaching Hospital were involved. Based on the inclusion criteria and stratified sampling technique, out of 654 Nurses, 214 were included in the study by considering confidence level of 95% with margin of error 5%, and response rate of 100%.

**2.4. Measures and Operational Definitions**

Independent variables and outcomes measures are defined as follow.

**2.5. Socio-Demographic and Other Factors**

Socio-demographic variables, such as age, sex, experience, profession, and level of education and other factors adverse drug reaction reporting system, and training on pharmacovigilance

Nurses regard to adverse drug reaction reporting system were responded as to Head of the pharmacy department, to Food, Medicine, and Health Care Administration and control authority, to hospital Drug and Therapeutic committee. Participants whether working at (Felegehiwot Referral Hospital) and University of Gondar Teaching Hospital selected in the category of respondent space. Nurses were asked participated in training related to adverse drug reaction reporting and /or pharmacovigilance.

**2.6. Nurses’ Practice Regarding Adverse Drug Reaction Reporting**

For the assessment of reporting practice about adverse drug reaction, health professional practices were measured by whether they reported the encountered adverse drug reaction or not reported.

For the purpose of this study the following terms were defined below:

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 working at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital.

Practice- answering practice related questions on adverse drug reaction i.e. identifying by the Nurses whether encountered, documented, reported adverse drug reactions. (17).

Reporting - The process of providing adverse drug reaction information by filling in the adverse drug reaction form appropriately and forwarding the same to the drug and therapeutic committee or Food, Medicine, Health Administration and control authority.

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

**2.7. Data Analysis**

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. Binary logistic regression was used to determine for not reporting practice of the encountered adverse drug reaction. Odds ratio was used to determine significance and 95% confidence interval was calculated. Those variables in multivariate analysis with a P value <0.05 were used independent predictors for not reporting practice of adverse drug reaction.

**2.8. Ethical Considerations**

Ethical clearance and approval of the study was obtained from Institutional review board of Jimma University. Subsequent permission was granted from the authorities of University of Gondar Teaching Hospital. In addition each participant was asked a written consent before data collection. Participation of Nurses, 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 Hospital. The right of participants to withdraw was respected and names were not mentioned.

**3. Results**

**3.1. Demographic Characteristics of Nurses**

A total number of 214 Nurses’ filled and all returned the questionnaire within the stipulated time frame.

As can be seen on table 1, mean age of the respondents 21.8 years (SD = 7.01). A total of 122(57.0%) of the respondents were females, 152 (71.0%) participants’ level of education were bachelor of Nurse. The participants mean of experience were 1.64 (SD = 4.7) years.

**Table 1.** Socio-demographic characteristics of respondents at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

| Demographic characteristics(n=214) |  | Frequency | Percentage |
|------------------------------------|--|-----------|------------|
| Age                                | 18-25                                  | 37        | 17.3       |
|                                    | 26-35                                  | 102       | 47.7       |
|                                    | 36-45                                  | 75        | 35.0       |
| Sex                                | Male                                   | 92        | 43.0       |
|                                    | Female                                 | 122       | 57.0       |
| Institution                        | Felegehiwot Referral Hospital          | 62        | 29.0       |
|                                    | University of Gondar Teaching Hospital | 152       | 71.0       |
| Level of education                 | Nurse ,degree                          | 152       | 71.0       |
|                                    | Diploma ,Nurse                         | 62        | 29.0       |
| Experience                         | 0-5years                               | 103       | 48.1       |
|                                    | 6-10years                              | 88        | 41.1       |
|                                    | 10-15 years                            | 19        | 8.9        |
|                                    | >/= 16 years                           | 4         | 1.9        |

### 3.2. Nurses' Practice Related Questions on Adverse Drug Reaction Reporting

Even if 209(97.7%) of the Nurses stated that they had experienced adverse drug reactions during the last 12 months in patients, only 13 (6.4%) of them recorded the adverse drug reaction that encountered on the patient clinical follow up chart and only 5 (2.3%) Nurses were reported an adverse drug reaction that encountered during the last 12 months. Out of 5 (2.3%) reported adverse drug reaction, 2(0.9%)participants sent to Food, Medicine, Health Administration and control authority of Ethiopia (Table.2).

**Table 2.** Nurses practice related questions on adverse drug reaction at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

| Variable  | Frequency (n=214) | Percentage |
|---|-------------------|------------|
| Have you seen any patient experiencing an adverse drug reaction during your practice in last 12 months? |                   |            |
| Yes   | 209               | 97.7       |
| No  | 5                 | 2.3        |
| Have you recorded the adverse drug reaction you encountered on the patient clinical follow up chart?    |                   |            |
| Yes   | 13                | 6.1        |
| No  | 201               | 93.9       |
| Do you report an adverse drug reaction that you encountered in the last 12 months?                      |                   |            |
| Yes   | 5                 | 2.3        |
| No  | 209               | 97.7       |
| If the answer is YES, to which organization   |                   |            |
| Hospital drug and therapeutic committee   | 1                 | 0.5        |
| Food, Medicine, Health Administration and control authority   | 2                 | 0.9        |
| Ministry of Health  | 1                 | 0.5        |
| All of the above  | 1                 | 0.5        |

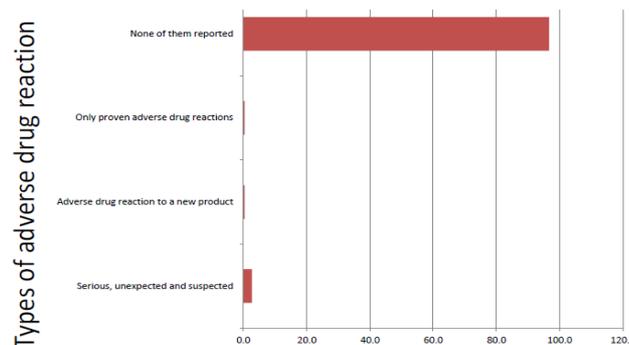
**Table 3.** Availability and accessibility of reporting format at your hospital at Felege-Hiwot referral Hospital and Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

| Variable  | Frequency (n=214) | Percentage |
|---|-------------------|------------|
| Do you usually give advice to your patients on possible adverse effects of drugs you prescribed, dispensed or administered? |                   |            |
| Yes   | 30                | 14.0       |
| No  | 184               | 86.0       |
| Is adverse drug reaction reporting form available and accessible at your hospital?  |                   |            |
| Yes   | 59                | 27.6       |
| No  | 155               | 72.4       |
| 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  | 77                | 36.0       |
| Some times  | 26                | 12.1       |
| Always a shortage   | 3                 | 1.4        |
| Not at the right place  | 49                | 22.9       |

Only30 (14.0%) Nurses were usually given advice to their patients on possible adverse effects of drugs during prescribed, dispensed or administered. One hundred fifty five (72.4%) agreed that adverse drug reaction reporting

form is not available at their job place. Seventy seven (36.0%) participants were not seen adverse drug reaction reporting format in their hospitals. Forty four (22.95%) agreed that adverse drug reaction reporting form is not available at their job place (Table 3).

Among the participants that reported adverse drug reaction, 5(6.3%) agreed that serious, unexpected and suspected types of adverse drug reactions usually were reported (Figure 1).



Percentage

**Figure 1.** Types of adverse drug reactions are usually reported at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia 2013.

Two hundred fourteen (97.2%) Nurses were not participated in any seminar/training that includes topic on adverse drug reaction monitoring or pharmacovigilance during their practice (Table 4).

**Table 4.** Participated in any seminar or training which includes topic on adverse drug reaction monitoring or pharmacovigilance at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

| Variable | Frequency | Percentage |
|----------|-----------|------------|
| Yes      | 6         | 2.8        |
| No       | 208       | 97.2       |
| Total    | 214       | 100.0      |

One hundred six (49.5%) participants stated that proper training and 61(28.5%) continuing education should be provided to Nurses for adverse drug reaction reporting. The rest participants stated important in improving adverse drug reaction reporting were listed in table 5.

**Table 5.** 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=214) | Percentage |
|--------------------------------|------------------|------------|
| Training                       | 106              | 49.5       |
| Incentives                     | 15               | 7.0        |
| Feedback to reporters          | 9                | 4.2        |
| Preparing drug safety leaflets | 23               | 10.7       |
| Continuing education           | 61               | 28.5       |

### 3.3. Predictors of Participants' Reporting Practice regarding Adverse Drug Reaction

Nurses' practice of reporting of adverse drug reaction was assessed for its association with socio-demographic variables. Out of 214 participants, 209 (97.7%) were not reporting the encountered adverse drug reaction.

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.

Bivariate analysis in the binary logistic regression model showed that institution, participation training on adverse drug reaction or pharmacovigilance and experience was candidate for multivariate logistic analysis. However, other

factors such as age, level of education, sex, and to whom you report the encountered adverse drug reaction weren't candidate for multivariate logistic analysis.

Accordingly, in the multivariate logistic analysis participation training on adverse drug reaction or pharmacovigilance was retained as significant factor for not reporting the encountered adverse drug reaction towards (Table 6).

Crude odds ratio results not listed in table 3, due to from categories of age, level of education, sex, and to whom you report the encountered adverse drug reaction zero values for not reporting the encountered adverse drug reaction and/or for reporting Participants who took training/seminar on pharmacovigilance had 0.29 times more likely to have adequate knowledge (AOR = 0.29, 95% CI = 0.226– 0.004, P=0.001)(Table 6).

**Table 6.** Binary and multivariable logistic regression model predicting the association of between practice of reporting and demographic ,and different variables at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013.

| Variables                              | Nurses practice of reporting the encountered adverse drug reaction (n=214) |                    | COR (95%CI)         | AOR (95%CI) | P     |
|--|--|--------------------|---------------------|-------------|-------|
|  | Not reporting<br>N (%)   | reporting<br>N (%) |                     |             |       |
| Institution                            |  |                    |                     |             |       |
| Felegehiwot Referral Hospital          | 58(93.5%)  | 4(6.5%)            | 0.096(0.877-0.011)  |             |       |
| University of Gondar Teaching Hospital | 151(99.3%)   | 5(0.7%)            | 1                   |             |       |
| Experience (years)                     |  |                    |                     |             |       |
| 0-5                                    | 100(97.1%)   | 3(2.9%)            |                     |             |       |
| 6-10                                   | 87(98.9%)  | 1(1.1%)            | 11.11(40.587-0.878) |             |       |
| 11-15                                  | 19(100.0%)   | 0(0.0%)            | 1                   |             |       |
| >=16                                   | 3(75.0%)   | 1(25.0%)           |                     |             |       |
| Participated in training               |  |                    |                     |             |       |
| Yes                                    | 4(66.7%)   | 2 (0.0%)           | 0.29(0.226-0.004)   |             | 0.001 |
| No                                     | 205 (98.6%)  | 3(1.4%)            | 1                   |             |       |

### 3.4. Reasons for Not Reporting

**Table 7.** Possible reason/s that contribute/s for not reporting the encountered adverse drug reaction at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

| Possible reason/s   | Frequency (n=214) | Percentage |
|---|-------------------|------------|
| Only safe drugs are available in the market                         | 21                | 10.8       |
| Reporting does not influence the treatment scheme                   | 6                 | 2.8        |
| Reporting could show ignorance                                      | 7                 | 3.3        |
| Busy schedule   | 99                | 46.3       |
| I don't know to whom to report                                      | 6                 | 2.8        |
| Reporting format not available                                      | 42                | 19.6       |
| Lack of incentives  | 15                | 7.0        |
| I thought I am not the right person to report adverse drug reaction | 8                 | 3.7        |
| Lack of response  | 8                 | 3.7        |
| Others  | 2                 | 1.0        |

The practitioners were allowed to select more than one reason for not reporting in the study questionnaire in this

study. All Nurses cited one or the other reason for not reporting. A total of 10 responses were obtained from 216Nurses. Various causes of not reporting of adverse drug reactions cited by the practitioners include: reporting does not influence the treatment scheme 6(2.8%), busy schedule 99(46.3%), don't know whom to report 6(2.8%), I thought I am not the right person to report adverse drug reaction8(3.7%), reporting format not available 42(19.6%),reporting could show ignorance 7(3.3%). Two (1.0%) respondents cited other reasons for not reporting which included combination of paired answered (Table 7).

## 4. Discussion

In clinical practice, 209(97.7%) of Nurses in the current study had experienced adverse drug reactions in patients during the last 12 months. But, only 5(2.3%) of those who diagnosed adverse drug reactions reported them to reporting centers. The considerable numbers of Nurses in the present study never reported an adverse drug reaction that is comparable with other studies (18-20).

Only 6(2.8%) Nurses 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 adverse drug reaction reports(18). 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(21). Some studies that takes placed at Iran (22),India (23) , China (24),India (25)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 Nurses, the unavailability of tools for reporting, low utilization and poor feedback on adverse drug reaction surveillance reports, lack of appropriate guidelines on pharmacovigilance and not continuous training given by Food, Medicine, Health Administration and control authority .

Even if majority of the Nurses 209(97.7%) stated that they had encountered adverse drug reactions during the last 12 months, but none 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. Study done in South west Ethiopia (17) and Ethiopia (26), respondents encountered patients with adverse drug reactions 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(17). A study in Texas, America 67.9% of pharmacists indicated that they had never reported adverse drug reactions during their career, but only 6.6% pharmacists had reported any adverse drug reactions in the previous 12 months(27). One study in Turkish also showed that 65% of the Nurses encountered patients with adverse drug reactions in the last 12 months and 7% of them actually reported it to National pharmacovigilance center in their country (28). In a survey done at England, out of 280 participants 39% of the hospital pharmacists did not report the encountered adverse drug reaction(29).

Only30(14.0%) Nurses were usually given 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 adverse drug reactions (17). A study conducted in Ethiopia 32.7% of respondents usually gives advice to their patients

concerning the possible occurrence of adverse effects (26).

One hundred fifty five (72.4%) participants agreed that adverse drug reaction reporting form is not available at their job place. Seventy seven (36.0%) and 49(22.9%) of participants were not seen adverse drug reaction reporting format in their hospitals and not available at the right place respectively. Unavailability of adverse drug reactions reporting forms and adverse drug reaction guidelines in hospitals considerably influenced the practice of adverse drug reactions reporting. Adverse drug reaction 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 Nurses are not adequately equipped with necessary guidelines and tools to guide and facilitate professionals in monitoring and reporting of adverse drug reactions at their working places. A study conducted in Ethiopia 68.8% respondents were accepted that reporting form is not available adequately (26). 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 Nurses enrolled in a survey in China (24).

Participants agreed that serious, unexpected and suspected types of adverse drug reactions usually were be reported. These are as the same as other studies' results(29-32).We found only one study in that the idea of reporting all kind of adverse drug reactions was more often selected by pharmacist than reporting only serious and unexpected reactions(28).Although there are many studies(33-39),208(97.2%) Nurses 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 (26).

One hundred six (49.5%) participants stated that proper training and 61 (20.6%) continuing education on pharmacovigilance should be provided to Nurses for adverse drug reaction reporting. It is a known fact that information regarding adverse drug reactions changes on a daily basis and hence the need for constant updating of the knowledge of Nurses 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(20),and Figueras (18), recommend including "pharmacovigilance" as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program.

In our study, the contributed factors for not reporting adverse drug reaction by the Nurses were does not influence the treatment scheme, busy schedule, don't know whom to report, I thought I am not the right person to report adverse drug reaction, reporting format not available, reporting could show ignorance. Under-reporting of adverse drug reactions is a worldwide phenomenon and this

has been established from previous studies (40-43). A study conducted by Toklu. HZ in Istanbul similar to the above mentioned reasons(28).

In order to address some of the determinants of not reporting of adverse drug reactions found in this study, include: reporting does not influence the treatment scheme 6(2.8%), busy schedule 99(46.3%), don't know whom to report 6(2.8%), I thought I am not the right person to report adverse drug reaction 8(3.7%), reporting format not available 42(19.6%), reporting could show ignorance 7(3.3%). 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 adverse drug reaction due to the workload of clinical practitioners was detected as the most important reason to adverse drug reaction underreporting(19). Other causes of not reporting in that study were lack of information about the spontaneous reporting system, unavailability of yellow cards, doubt of adverse drug reaction causality assessment and lack of patient confidentiality(33). Other reasons for not reporting of an adverse drug reaction 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 adverse drug reactions 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 adverse drug reaction reporting. These included is through training 106(49.5%). Several studies also agreed (24, 29, 44-46), continuing education on pharmacovigilance 61(28.5%), incentives 15(7.0%) studies supported were (19, 47). 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 adverse drug reaction reporting should be a fundamental responsibility of health care workers and, therefore, it should be understood as such. Improving adverse drug reaction 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 reporters 2(2.5%) argued with (33), (95.74%) medical professionals expect feedback from adverse drug reaction monitoring centers(48). Feedback from adverse drug reaction monitoring centers about the causality and severity of adverse drug reactions reported by Nurses would also encourage them to continue reporting(48). Some workers 1(1.3%) have suggested the use of financial incentives as a tool to stimulate reporting of adverse drug reactions. Studies in India also showed that, giving incentives improved adverse drug reaction reporting(24, 33, 48),(49), and preparing drug safety leaflets 4(4.9%) studies showed (24, 33).

Although this study has strength like high response rate,

questionnaire was pretested, it has some limitations; since the study is a cross-sectional, and it has a limitation to formulate a casual association, as to how and when the associations are established.

## 5. Conclusion

All Nurses not reported the already encountered adverse drug reaction in the past 12 months. This could delay signal detection of adverse drug reaction. So preparing trainings and continual education on pharmacovigilance will increase reporting of adverse drug reaction. Only safe drugs are available in the market was identified as one of the major reason that hinders reporting of Nurses.

## Recommendations

Based on the study findings the following recommendations are forwarded: prepare training for Nurses, making adverse drug reaction reporting mandatory for Nurses, assign at least one focal person in each hospital that he/she organizes adverse drug reaction reporting.

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