

# Nurses knowledge related to adverse drug reaction reporting and associated factors at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia

**Abewa Adimasu**

College of Medical and Health sciences, Debremarkos, Ethiopia

**Email address:**

gebretsadek@yahoo.com

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**Abstract:** Background: Even though some adverse drug reactions are minor and can be resolved quickly, some can cause permanent disability or death. Inadequate knowledge of adverse drug reactions by Nurses is a common problem of any pharmacovigilance programs. Objective: The objective of this study is to assess predictors of Nurses knowledge related to adverse drug reaction reporting at Felegehiwot Referral Hospital and University of Gondar Teaching Hospital, Northwest Ethiopia. Methods - Hospital based cross sectional study was conducted 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 inadequate knowledge regarding adverse drug reaction reporting. 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. One hundred one (99.0%) participants had inadequate knowledge on how to report adverse drug reaction and Nurses who categorized in the age of 26-35 years was 10.4 times more likely inadequate knowledge (AOR = 10.4, 95% CI = 86.423 - 1.251, P=0.030). Conclusions and recommendation: Nurses were inadequate knowledge on adverse drug reaction reporting. 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:** Predictor, Knowledge, 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).

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 (2).

A study in United States of America 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(3). In the same year, 2.2 million Americans had adverse reactions to food and drug authority of America-approved drugs (3).

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 (4).

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 (5). Studies have shown that the Ethiopian population has a distinct genetic makeup compared to Caucasian, Oriental or other Black populations that results in a higher probability of getting adverse drug reaction (6).

The finding of the studies performed at China (7), Northern India (8) and Italy (9) showed healthcare professionals' knowledge on adverse drug reaction reporting was very low. A study done in Ethiopia showed that 137 (26.6%) participants had adequately answered knowledge determining questions (10). A study conducted in Southwest of Ethiopia showed that 19 (23.17%) respondents had adequate knowledge on adverse drug reaction reporting (10). According to the available data, no study has assessed Nurses' knowledge related to adverse drug reaction reporting and associated factors in the study areas. So, the present study would determine the level of Nurses' knowledge and identify dependent predictors for inadequate knowledge towards adverse drug reaction reporting. Therefore, this study will be used to help appropriate adverse drug reaction reporting in the health system.

## 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. Finote Selam 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 Physicians, 189 Nurses and 23 Pharmacy professionals) and 654 health professionals (130 Physicians, 461 Nurses and 63 Pharmacy professionals) in Finote Selam 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 of 284 beds. It has 275 technical and 187 administrative staffs.

The University of Gondar Teaching Hospital has the only referral teaching hospital providing 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 of respondents, adverse drug reaction reporting system and training on pharmacovigilance predictors of Nurses' knowledge related

to adverse drug reaction reporting for this study among stratified proportional random sampling technique sampled 214. The structured questionnaire is compiled and adapted from different literatures and by considering the local situation. 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 knowledge related questions.

### 2.3. Participant Eligibility Criteria

To exclude bias, study participants for study 214 Nurses (62 and 152 in Finote Selam hospital and University of Gondar Teaching Hospital respectively). Nurses willing to participate, signing the written informed consent and working at Finote Selam Hospital and University of Gondar Teaching Hospital were involved. Based on the inclusion criteria and stratified sampling technique, out of 650 health professionals, 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 follows.

#### 2.4.1. Socio-Demographic and other Factors

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

Nurses regarding 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 working at Finote Selam hospital and University of Gondar Teaching Hospital selected in the category of respondent space. Nurses were asked to participate in training related to adverse drug reaction reporting and/or pharmacovigilance.

#### 2.4.2. Nurses Knowledge Regarding Adverse Drug Reaction Reporting

For the assessment of knowledge about adverse drug reaction reporting, already prepared 6 structured questions. Each correct question corresponded to 1 point, and incorrect one is 0. There was a total of 6 points for the 6 questions. For the purpose of this study, respondents were considered to have adequate knowledge if they scored  $\geq 5$  out of 6. They were considered to have inadequate knowledge if they scored below 5 out of 6.

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 Finote Selam hospital and University of Gondar Teaching

Hospital.

Knowledge-the ability of Nurses to give response on adverse drug reaction, adverse drug reaction reporting and reporting system related questions.

### 2.5. 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 inadequate knowledge. 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 inadequate knowledge of adverse drug reaction reporting.

### 2.6. 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 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 Health Professionals

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

**Table 1.** Socio-demographic characteristics of respondents at Felege-Hiwot 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	Finote selam 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
	0-5years	103	48.1
Experience	6-10years	88	41.1
	10-15 years	19	8.9
	>/= 16 years	4	1.9

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.

As presented in table 2, Even if 212(99.1%) participants knew the term adverse drug reaction, only 32(25.0%) respondents know how to report adverse drug reactions. most of participants i.e. 120(56.1%) and 37(17.35%) responded for possible factor (s) that may predispose(s) a patient to adverse drug reaction were dispensing error and Non adherence to drug regimen, respectively.

Only 46(21.5%) respondents were knowledgeable about the term pharmacovigilance. One hundred sixty eight (78.5%) of Nurses weren't believe all the drugs available in the market are safe. More than half participant weren't seen drug reaction reporting format of Ethiopia and thought that adverse drug reaction is the same as with side effect. More participants responded that adverse drug reactions should be reported only when they are serious and life threatening. Pharmacy Personnels were primarily responsible to remind and follow up patients about adverse drug reaction of drugs. One hundred fifty two (57.0%) Nurses were responded that head of the pharmacy department for whom you report the encountered adverse drug reaction. Food, Medicine, Health Administration and control authority was regulatory body is responsible for monitoring of adverse drug reactions answered by 183(85.5%), and only 20 (9.3%) participants answered that this system created awareness of adverse drug reaction reporting in you. More participants worried about legal problems while they think of adverse drug reaction reporting. A standard text book was their source of information about adverse drug reaction 140 (65.4%).

### 3.2. Knowledge of Nurses Regarding Adverse Drug Reaction Reporting

Out of 214 participants, 14 (25.7%) had adequate knowledge on adverse drug reaction reporting, while significant proportion of health professionals, 200 (74.3%) had inadequate knowledge on adverse drug reaction reporting. Bivariate analysis in the binary logistic regression model showed that level of age was candidate for multivariate logistic analysis. However, other factors such as sex, experience, level of education, institution, participation training on adverse drug reaction or pharmacovigilance and to whom you report the encountered adverse drug reaction weren't candidate for multivariate logistic analysis.

Crude odds ratio results not listed in table 3, due to from categories of level of education, experience and to whom you report the encountered adverse drug reaction zero values adequate knowledge and/or inadequate knowledge (Table 3).

**Table 2.** Participants Knowledge related questions on adverse drug reaction reporting of respondents at Felege-Hiwot referral Hospital and University of Gondar Teaching Hospital, North west Ethiopia, 2013

Variables		Frequency	Percentage
Do you know the term adverse drug reaction?	Yes	212	99.1
	No	2	.9
What possible factor (s) do you think predispose(s) a patient to adverse drug reaction?	Dispensing error	120	56.1
	Over dose	25	11.7
	Prescription error	9	4.2
	Life style of the patient	18	8.4
	Non adherence to drug regimen	37	17.3
	All of the above	4	1.9
	None of the above	1	.5
Do you know the term Pharmacovigilance?	Yes	46	21.5
	No	168	78.5
Do you believe all the drugs available in the market are safe?	Yes	49	22.9
	No	165	77.1
Have you seen adverse drug reaction reporting format of Ethiopia?	Yes	70	32.7
	No	144	67.3
Do you think that adverse drug reaction is the same as with side effect?	Yes	65	30.4
	No	149	69.6
	Serious and life threatening	149	69.6
Adverse drug reactions should be reported only when they are	Severe and cause disability	35	16.4
	Mild and cause less inconvenience	15	7.0
	All of the above	15	7.0
	None of the above	149	69.6
Which products are usually reported or adverse drug reaction?	Prescription drugs	168	78.5
	Over-the-counter drugs	16	7.5
	Medical device	1	.5
	All the above	29	13.6
Who do you think is primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given?	Pharmacy Personnels	152	71.0
	Physicians	3	1.4
	Nurses	1	.5
	All of the above	58	27.1
Do you know how to report adverse drug reactions?	Yes	32	15.0
	No	182	85.0
To whom you report the encountered adverse drug reaction?	To Head of the pharmacy	152	71.0
	To Food, Medicine, and Health Care Administration and control authority	22	10.3
	To hospital Drug and Therapeutic committee	21	9.8
	All of the above	19	8.9
	Food, Medicine, Health Administration and control authority	183	85.5
In Ethiopia, which regulatory body is responsible for monitoring of adverse drug reactions reporting?	Ethiopian pharmaceutical association	1	.5
	Federal ministry of health	18	8.4
	Pharmaceutical fund and supply agency	8	3.7
	All of the above	4	1.9
Has this system created awareness of adverse drug reaction reporting in you?	Yes	20	9.3
	No	194	90.7
Do you worry about legal problems while you think of adverse drug reaction reporting?	Yes	116	54.2
	No	98	45.8
	National drug formulary and Standard Treatment Guideline	54	25.2
What is your source of information about adverse drug reaction?	Standard text books	140	65.4
	Notes from the training	6	2.8
	Internet	8	3.2
	Drug information centers	6	2.8
	Telephone	45	21.0
Which method would you prefer to send adverse drug reaction reporting?	Internet	138	64.5
	Post	28	13.1
	I don't know	3	1.4

Accordingly, in the multivariate logistic analysis age was retained as significant factor for inadequate knowledge towards adverse drug reaction reporting i.e age categorized as

26-35 years was 10.4 times more likely inadequate knowledge AOR = 10.4, 95% CI = 86.423 - 1.251, P=0.030 (Table 3).

**Table 3.** 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.

Variables	Nurses Knowledge of adverse drug reaction reporting (n=214)				
	Inadequate Knowledge	adequate Knowledge	COR (95%CI)	AOR (95%CI)	P
	N (%)	N (%)			
Age (year)					
18-25	31(83.8%)	6(16.2%)	0.53(1.714 - 0.651)		0.03
26-35	101(99.0%)	1(0.9%)	10.4(86.423 - 1.251)	10.4(86.423 - 1.251)	
36-45	74(91.4%)	7(8.6%)	1	1	
Sex					
Male	86(93.5%)	6(6.7%)	1.06(3.006-0.337)		
Female	114(93.4%)	8(6.6%)	1		
Level of education					
Nurse ,Degree	152(100.0%)	0(0.0%)			
Diploma Nurse	48(77.4%)	14(22.6%)			
Name of Institution					
Finote selam hospital	55(88.7%)	7(11.3%)	2.63(7.862-0.884)		
University of Gondar Teaching Hospital	145(95.4%)	7(4.6%)	1		
To whom you report					
To pharmacy head To Food, Medicine, Health Administration and control authority	152(100.0%)	0(0.0%)			
To hospital drug and therapeutic authority	16(72.7%)	6(27.3%)			
To hospital drug and therapeutic authority	13(61.9%)	8 (39.1%)			
All of the above	16(100.0%)	0 (0.0%)			
I don't know	3(100.0%)	0 (0.0%)			
Experience (years)					
0-5	97(89.7%)	6(5.8%)			
6-10	80(90.9%)	8(9.1%)			
10-15	19(100.0%)	0(0.0%)			
>= 16	4(100.0%)	0(0.0%)			
Participated in training					
Yes	5(83.3%)	1(16.7%)	0.333(3.067-0.36)		
No	195 (93.8%)	13(6.2%)	1		

## 4. Discussion

In the present study several important findings were obtained and only 14 (25.7%) 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(11). Limited knowledge of adverse drug reaction reporting may reduce the number of reports submitted to Food, Medicine, Health Administration and control authority 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 adverse drug reactions. The results of this study suggest that greater effort is needed to improve adverse drug reaction reporting among Nurses 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 200(74.73%) of the participants have been identified using multiple logistic regression analysis. Age was independent predictor for inadequate knowledge.

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 10.4 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 adverse drug reactions reporting than those aged below 50 years(12). Differently to this finding, a study in Texas, America the lack of knowledge was found to be more acute among older (>38 years) pharmacists (13). Studies that takes place at China(7), Northern India(8) and Italy(9) had inadequate knowledge on adverse drug reaction reporting. This however contradicts the findings as reported at UK(14), Nigeria(15), and Australia(16).

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 adverse drug reactions reporting forms influenced the practice towards adverse drug reactions reporting among health professionals. Two

hundred twelve (99.1%) of participants were aware of the term “adverse drug reactions”, but only 46(21.5%) respondents aware of the term “pharmacovigilance.” Studies in South West Ethiopia(11) and Ethiopia(10) of the respondent knew the term pharmacovigilance (19.51%) and 45.3% respectively. One hundred sixty eight (78.5%) Nurses stated that all drugs available in the market are not safe, but only 32(25.0%) indicated that they do not know how to report adverse drug reactions. A study from Italy reported that doctors had little information concerning adverse drug reactions and adverse drug reaction reporting systems (17). Of 214 the participants, more than half participant did not know the format in which adverse drug reactions are reported, in congruence with a study in south west Ethiopia 25.61% Nurses knew the availability of adverse drug reaction reporting format(11). This might be due to inadequate promotion of reporting form and weak regulatory body contact with the health facilities in general and the Nurses in particular. More than half participants, 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 adverse drug reaction was different from side effect(11). 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(18). This might lack of adequate information regarding adverse drug reaction in the curricula and/ or trainings.

One hundred twenty (56.1%) 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 Nurses are more familiar with (39.03%) of them replied that dispensing error was the primary factor predisposing to adverse drug reactions. This might be due to the fact that dispensers are the expected Nurses 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(11). Thirty seven (17.35%) of them also believed that drug non adherence to the drug regimen was the primary factor predisposing adverse drug reactions. From this, we can understand that respondents had inadequate knowledge on factor (s) that may predispose(s) a patient to adverse drug reaction.

One hundred forty nine (69.6%) participants stated that serious and life threatening reactions should be reported. A research conducted in Dar Es Salaam respondents, majority(60.3%) agreed that reporting is necessary for serious adverse drug reactions(12). A study in Texas, America 43.3% of the pharmacists thought that all adverse drug events, regardless of severity, should be reported to food and drug authority of America(13). On the contrary, a study done in Portugal on serious adverse drug reactions should not be reported (19).

One hundred sixty eight (78.5%) Nurses believed that all prescription drugs, should usually reported for adverse drug

reaction. A study conducted in Ethiopia 24% of the responders believed that only adverse drug reaction of the prescription drugs need to be reported whereas most of them don't think so (69%) (20).

One hundred fifty two (57.0%) agreed that pharmacy personnels were primarily responsible to remind and follow up patients about adverse drug reaction of drugs they are given. A study in Ethiopia 15.3% providers response believe that it is the responsibility of the pharmacist/druggist (20).

One hundred fifty two (57.0%) participants agreed that the encountered adverse drug reaction would be reported to head of the pharmacy department. A study conducted in south West Ethiopia (46.34 %) of the respondents believed that adverse drug reaction should be reported to drug administration and control authority (30.49%) to drug and therapeutic authority, and 19% to the pharmacy department of the respective health facilities(11). It is obviously known that among the major activities of head of the pharmacy department, drug and therapeutic authority and Food, Medicine, Health Administration and control authority was monitoring adverse drug reaction in the health facilities.

One hundred eighty three (85.5%) 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 only 194 (80.7%) Nurses 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 Nurses in particular. One study in south west Ethiopia showed that 183(85.5%) of the Nurses knew the availability of national adverse drug reaction reporting system(11). A study done in Lagos, Nigeria on perception of doctors to adverse drug reaction reporting showed that 40.4% of the respondent knew about existence of National Pharmacovigilance center in their country (8, 21).

One hundred sixteen (54.2%) participants admitted that they were worried about legal problems while adverse drug reaction reporting. Equivalently 46.49% doctors in Hyderabad, India admitted that they were worried about legal problems while adverse drug reaction reporting(22).

One hundred forty (65.4%) respondents stated that standard text book was their source of information for adverse drug reaction reporting. More than half, 138(64.5%) 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 adverse drug reactions information on drugs (11).

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

Vast majority of respondents had inadequate knowledge might lead to not reporting the encountered adverse drug reaction. This could delay signal detection of adverse drug reaction. So it requires urgent attention for enhanced safety of the patients and society at large.

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