Journal of Pharmacovigilance and Drug Research

April- June 2022
JPADR, 2022; 3(2): 27-33.
DOI: 10.53411/jpadr.2022.3.2.6



RESEARCH ARTICLE

Journal home page: www.jpadr.com

Knowledge, attitude and practice towards adverse drug events reporting among graduating health science students of college of health sciences, Addis Ababa University, Ethiopia

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ARTICLE INFO

Received 16 March 2022;
Revised 24 April 2022;
Accepted 19 May 2022.

Keywords:
KAP, ADE, pharmacy students, medical interns, Graduating students

ABSTRACT

OPEN ACCESS

Introduction: The knowledge, attitude, and practice of the health sciences students are crucial for their future monitoring and reporting of adverse drug events as professional responsibility.
Aim: To describe the knowledge, attitude, and practice of graduating medicine and pharmacy students at the College of Health Sciences, Addis Ababa, Ethiopia.
Method: This study was based on a cross-sectional study design. Data were collected through a structured and pilot-tested questionnaire. The data was entered and analyzed using SPSS version 20. The descriptive statistics such as frequency, mean, standard deviation, percentages computed, and the association between variables were conducted using Chi-square. The p-value of < 0.05 was taken as statistically significant.
Result: A total of 140 students were included in this study. The majority of the participants were medicine students 82 (58.6 %) and males 84 (60 %). Most of the respondents, 106 (75.7 %) knew the ADE reporting system, and 126 (98.6 %) drug safety monitoring is important. However, about half of the students 65 (46.4 %) were not aware of the national ADE reporting system. During clerkships 57 (40.7 %) participants encountered at least once ADE, but only 23 (16.4%) of them had reported it. Graduating pharmacy students have better knowledge on "pharmacovigilance" (84.5 % Vs 43.9 %, $p < 0.001$) but medicine students were better at reporting the encountered ADE (22.0 % Vs 8.6 %, $p = 0.04$).
Conclusion: The graduating medical interns and pharmacy students have a positive attitude towards ADEs. However, they have a low level of knowledge and practice about voluntary adverse drug events reporting.

An official publication of Global Pharmacovigilance Society.

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Available online 1 June 2022

Introduction

Adverse drug events (ADEs) are medication-related injuries that can be caused by preventable medication errors or non-preventable adverse drug reactions (ADR) (Becker, 2004). As ADEs are a common cause of illness, disability, and even death in the health care system, they must be addressed (Arabyat *et al*., 2020). ADRs account for 6.7 % of hospital admissions, with 0.32 % being fatal (Davies *et al*., 2009). Furthermore, approximately 10 % – 20 % of inpatients will have at least one ADR during their hospital stay (Schatz and Weber, 2015). Therefore, a pharmacovigilance system to monitor the safety of medications is critical for identifying and preventing unexpected harm from medications.

The pharmacovigilance systemis 'the science and activity relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible medicine-related problems' (WHO, 2004). Pharmacovigilance plays an important role in the rational use of medicines by providing information about ADRs in the general population (EFDA, 2020; WHO, 2004).

The uppermost priority of the health care professional responsibilities is ensuring patient safety by reporting suspected ADEs spontaneously and voluntarily. These reports signal potentially serious, previously unknown safety problems with marketed drugs. The national pharmacovigilance system depends on these reports of ADRs from health care professionals. However, under-reporting is the major shortcoming of spontaneous reporting both in developing and developed countries. It is estimated that only 6–10 % of all ADRs are reported (John *et al*., 2012; Lopez-Gonzalez *et al*., 2009).

The key determinant factors for voluntary reporting of ADEs by health care professionals are knowledge, access to local ADE reporting systems, clinical skills in detecting an ADR, and attitude toward reporting ADRs. Several studies reported that the knowledge and attitudes of health professionals are strongly related to reporting of ADRs (Mulatu and Worku, 2014). In Ethiopia, the national spontaneous ADR reporting system was established in 2002 through the ADR monitoring division of the Food, Medicine, and Health care Administration and Control Authority (formerly Drug Administration and control authority). This national reporting center developed a yellow card reporting scheme and made it available throughout all the health facilities. Following the third national pharmacovigilance guideline developed in 2014, the ADR reporting form was revised to include reports of medication error and its name was changed to FMHACA's adverse drug event reporting form (FMHACA, 2014)and the recent national directive on pharmacovigilance was developed (EFDA, 2020). However, ADR reporting is often overlooked by healthcare professionals in Ethiopia. For instance, only 250 ADR reports were sent to the center in five years since its establishment. This was an alarmingly low rate of the report generated by the spontaneous ADR reporting system (Ermias *et al.*, 2011).

There are only a few studies conducted on ADR reporting in Ethiopia. Most of these studies assessed the KAP of health care providers working in public health facilities. To our knowledge, there is no study conducted to determine the KAP of health science students towards ADE monitoring and reporting in Ethiopia. To promote the rational use of medicines and ensure patient safety; health care providers should be acquiring appropriate knowledge and attitude to report ADEs in their pre-service training. Therefore, this study aims to determine the knowledge, attitude, and practice of graduating class medical and Pharmacy students towards ADE reporting, Addis Ababa University, Ethiopia.

Method

Study Setting and Study Design

This study was conducted in Addis Ababa University, College of Health Sciences, Addis Ababa, Ethiopia. The College of health sciences is comprised of four schools and Tikur Anbessa Specialized Hospital as a teaching hospital. The study was conducted among graduating medicine and pharmacy students of the college. Both medical interns and graduating clinically oriented pharmacy students have passed through clinical attachments at Tikur Anbessa Specialized Hospital during their stay in school. Besides, the students may also attach to other general hospitals located in Addis Ababa and have a chance of encountering ADEs.

A cross-sectional study design was conducted from April 15 - June 01, 2019 to assess the knowledge, attitude, and practice of adverse drug event reporting among medical interns and graduating pharmacy students of Addis Ababa University, College of health science.

Source and Study Population

The source population is all health science students in the College of Health Science, Addis Ababa University. The study population includes all graduating class medical (medical interns) and pharmacy students who are studying in the College of Health Science.

Inclusion and exclusion criteria

All graduating pharmacy and medical students were eligible for the study and all students willing and interested to participate in the study were included in the study.

Data Collection Techniques

Data was collected by using a self-administered questionnaire that contains questions on knowledge, attitude, and practices towards ADE reporting. The questionnaire contained 20 items; 9 items to assess knowledge, 8 items to assess attitude, and 3 items to assess the practice of graduating students towards ADE reporting. The questionnaire was distributed to all medicine and

pharmacy graduating students after describing the purpose of the study. Then students return filled questionnaires within a day.

Data Processing and Analysis

The data were checked for completeness and consistency. Then data were categorized, coded, and entered using SPSS version 20 software. The independent variables like age, gender, the field of study, and the dependent variable (KAP) were analyzed for descriptive statistics using the same software. The analysis results were summarized in the form of tables. Chi-square test was used to test the presence of an association between the outcome variables and the explanatory variables and a P value of less than 0.05 was considered significant.

Ethical Consideration

The study was conducted after Ethical clearance was approved by the Ethical Review Committee of the School of Pharmacy, College of Health Science, Addis Ababa University. The research objectives were explained to participants, and verbal informed consent was secured from each participant. Furthermore, the confidentiality of participants was maintained by removing their identifiers from the questionnaire and keeping the filled data secure.

Result

The Demographic Characteristics of Participants

In this study, a total of 140 graduating medical and pharmacy students were included. The majority of participants were medical interns 82 (58.6 %), males 84 (60 %), and within the age range of 20-25 years 97 (69.2 %). The mean age of participants was 24.98 (SD, 2.19) years. The demographic characteristic of participants is described in **Table 1.**

Table 1: **Demographic characteristic of participants (N=140)**

Characteristics		Frequency (%)
Age (in years)	20-25	97 (69.2)
	25-30	39 (27.9)
	>30	4 (2.8)
Gender	Male	84 (60)
	Female	56 (40)
Profession	Medical interns	82 (58.6)
	Graduating Pharmacists	58 (41.4)

The Knowledge Graduating Medical and Pharmacy Students towards ADE Reporting

Among the respondents, three fourth 106 (75.7 %) participants; of whom 56 (68.3 %)medicine and 50 (86.2 %) pharmacy graduating students were aware of ADE reporting. However, about half 65 (46.4 %) of respondents were not aware of the national ADE reporting system. Pharmacy students claimed more awareness of the term "pharmacovigilance" (84.5 % Vs 43.9 %, $p \leq 0.01$), and that ADRs differ from side effects (94.8 % Vs 68.3 %, p = 0.00) than medical interns.

Regarding the response of participants for the open-ended question, 'What is ADEs?' less than half 60 (43 %) answered correctly, 51 (36.4 %) answered incorrectly, and 25 (17.9 %) did not provide a response. Similarly, the responses respondents on a question "what is the difference between ADEs and side effects?", 57 (40.7 %) were correct, 57 (40.7%) were wrong and 26 (18.6 %) were incomplete. The pharmacy students better defined ADE (69 % Vs 22 %, P = 0.001), and differentiated ADEs and side effects (69 % Vs 20.7 %, p = 0.00) correctly than medical interns. **Table 2** shows the knowledge of participants towards the ADE reporting.

Table 2. The knowledge of graduation medicine and pharmacy students towards ADE reporting, AAU, College of Health Sciences, Ethiopia

Question	Interns (n = 82)		Pharmacy (n = 58)		Pearson's X^2	
	Yes	No	Yes	No		P-value
Have you been thought about ADE reporting?	56 (68.3 %)	26 (31.7 %)	50 (86.2 %)	8 (13.8 %)	2.20	0.14
Do you think that ADR is the same as with side effect?	26 (31.7 %)	56 (68.3 %)	3 (5.2 %)	55 (94.8 %)	14.31	0.00

Do you know the term pharmacovigilance?	36 (43.9 %)	46 (56.1 %)	49 (84.5 %)	9 (15.5 %)	19.02	0.00
Do you know the national ADE reporting system?	36 (43.9 %)	46 (56.1 %)	34 (58.6 %)	24 (41.4 %)	1.37	0.24
Do you know the availability of ADE reporting form?	38 (46.3 %)	44 (53.7 %)	37 (63.8 %)	21 (36.2 %)	3.91	0.048
Do you think that ADEs are well documented at the time a medicine is marketed?	33 (40.2 %)	49 (59.8 %)	22 (37.9 %)	36 (43.9 %)	0.59	0.44

The Attitude of graduating medical and Pharmacy Students towards ADE Reporting

Most of the students agreed that ADEs should be reported spontaneously 126 (90 %) and it is the duty of health care professionals 136 (97.1 %). However, about 61 (42.9 %) of them consider reporting ADEs creates an additional workload on health workers. There is no significant difference in attitude among medical interns and graduating pharmacy students except that pharmacy students better disagree with the statement "Only ADE of prescription-only drugs need to be reported" (72.4 % Vs 39.0 %, p = 0.002). The attitude of students towards ADE reporting is presented in **Table 3.**

Table 3: The Attitude of graduating medicine and pharmacy students towards ADE reporting, AAU, college of health sciences

Statement	Graduating pharmacy students (N=58), n (%)			Medical Interns (N=82), n (%)			Chi-square	P value
	Agree	Neutral	Disagree	Agree	Neutral	Disagree		
ADE should be reported spontaneously at regular time	48 (82.7)	7 (12.1)	3 (5.2)	78 (95.1)	3 (3.7)	1 (1.2)	6.76	0.149
Reporting ADE is part of duty of health professionals	56 (96.6)	1 (1.7)	1 (1.7)	80 (97.6)	2 (2.4)	0 (0)	1.57	0.66
Monitoring drug safety is important for the patient	55 (94.8)	3 (5.2)	0	82 (100)	0	0 (0)	4.38	0.112
Monitoring drug safety is important for the health care system	56 (96.6)	2 (3.4)	0	81 (98.8)	1 (1.2)	0 (0)	0.82	0.665
Reporting drug safety is important for the public	53 (91.4)	5 (8.6)	0	76 (92.7)	4 (4.9)	2 (2.4)	2.17	0.538
Only ADE of prescription drugs need to be reported	8 (13.8)	8 (13.8)	42 (72.4)	33 (40.2)	17 (20.7)	32 (39.0)	16.52	0.002
There is a need to be sure that an ADR is related to the drug before reporting	38 (65.5)	12 (20.7)	8 (13.8)	58 (70.7)	16 (19.5)	8 (9.8)	2.73	0.604
Reporting creates additional work load health workers	20 (34.5)	7 (12.1)	31 (54.5)	41 (50)	14 (17.1)	27 (32.9)	6.53	0.163

The Practice of graduating Medical and Graduating Pharmacy Students

Of the total participants, 57 students have encountered a patient with ADE during their clinical practice however only 23 (16.4 %) of them reported. Concerning the profession, 34 (41.5 %) of medical and 23 (39.7 %) of pharmacy students have encountered ADE. Regarding the reporting of encountered ADEs, medical students were better than pharmacy students (22.0 % Vs. 8.6 %; p = 0.03).

Discussion

This study described the knowledge, attitude, and practice of graduating medicine and pharmacy students since pre-service training is paramount in future practice. Our study revealed that three-four of participants were aware of ADE reporting but only 42.9 % corrected define ADE. Besides, 60.7 % were aware of pharmacovigilance about half 46.4 % of respondents were not aware of the national ADE reporting system of pharmacovigilance. Similarly, a study in Nigeria reported close to three-quarters of the health workers were aware of pharmacovigilance but only 5 % provided the correct comprehensive definition of ADE (Adisa and Omitogun, 2019)

In our study majority, 75.7 % of participants replied that they were taught about ADE reporting in classes. This finding is higher than the findings of a national study in Ethiopia on physicians and pharmacists that reported 44 % of respondents recalling being thought about ADE reporting in classes (DACA, 2009). It is also in contrast with findings that 65 % of the participant does not feel that there are adequately trained (Zewde, 2020) and 78.4 % of doctors report no pre-service training on ADR reporting systems (Nadew *et al.*, 2020). This variation may be due to the short recall time for students or the difference in curriculums they were trained in.

Our study revealed that 39.5 % of graduating medicine and pharmacy students believe that ADEs were well documented at the time a drug is marketed. Similarly, other studies reported that 32.2 % (Gidey *et al*., 2020) and 30.3 % of health care providers think that all ADRs are known before a medicine is marketed (DACA, 2009). This wrong assumption that all ADRs were documented before medicines were marketed may contribute to a low level of ADEs reporting in clinical practice by health care providers.

Our study found that 20.7 % replied ADR was the same as with side effects. This finding is lower than the study conducted in TASH Addis Ababa that reported only 53.5 % of health care providers were able to differentiate side effects from ADEs. However, WHO recommended that to retain the term side effect for minor effects which are related to the pharmacological properties of the drug (WHO, 2004)

Our study revealed that about half, 46.4 % of graduating medicine and pharmacy were not aware of the availability of a national ADE reporting system. Besides, only half of the participants were aware of the ADE reporting form. Similarly, a study by Kefale et al., reported that only 36.6 % of health care providers were aware of the existence of a national ADE monitoring system in Ethiopia (Kefale *et al*., 2017). A study in Jordan also reported that 46.1 % of hospitals and 31.5 % of community pharmacists were aware of the availability of a national pharmacovigilance center (Suyagh *et al.*, 2015). Another study in Ethiopia reported a sizeable, 57.1 % participants have no awareness regarding the presence of ADE reporting form (Mulatu and Worku, 2014). Not knowing the existence of the ADR reporting system could major reason for underreporting of ADR practice in Ethiopia.

This study showed that only 42.9 % of students define correctly ADE. This finding is better than the report by Alemu and Biru that reported 8.7 % of health care providers correctly defined ADR study (Hindoliya and Chitapure, 2019). However, it is lower than the finding in India that revealed 66.3 % of physicians correctly defined ADR (Siddeshwara *et al*., 2016). This may be due to variation in depth of attention given to medication safety and ADE monitoring and reporting in the medicine and pharmacy curriculums.

This study showed the majority of 92.9 %participants have a positive attitude towards ADE reporting and they believe that it is a professional responsibility to report ADEs. Most of the students believe that monitoring of ADR is important for the public 85.7 %, and the health care system, 98.57 %. However, more than two-third 69.3 % of the respondents think that they need to be sure that ADE is related to the drug before reporting. This is almost similar to the study conducted in Ethiopia where more than 95 % of the respondents agreed that ADR should be reported and believe reporting is a professional responsibility(DACA, 2009; Ermias *et al*., 2011; Mulatu and Worku, 2014). A similar study in Pakistan also reported majority 94.5 % of the respondents considered reporting ADR should be made compulsory and 84 % accepted reporting ADR as their professional role (Nisa *et al*., 2018).

In this study, 40 % of the study participants agreed that reporting ADEs may create an additional workload on health care workers. Of those who agreed reporting may increase the workload for health care workers, the majority 71.9 % were medical students, this result is almost similar to the study conducted 34.7 %, of the respondents, replied that reporting creates additional workload on health care workers (DACA, 2009).

Of the total participants, 40.7 % have encountered a patient with ADE at least once in their clinical practice attachment. Among these, the majority 59.6 % were medical interns. However, in this study, only 40.4 % of them reported ADEs to the authorized body. More than two-third, 78.2 %, of the reported ADEs were reported by medical interns. This finding is higher than from the study done by DACA (15.1 % by physicians and 12.5 % by pharmacists) and in the

Amhara region of Ethiopia,101 (16.2 %) of the reporting was done by physicians (Mulatu and Worku, 2014). Similar findings from Gujarat, India showed medical students have a better attitude toward reporting ADRs but have a lack of knowledge and poor practices of ADRs (Upadhyaya *et al*., 2015). Another study from India revealed that there was a wide gap between the ADR experienced in professional practice (71 %) and ADR reported (23 %) (Hindoliya and Chitapure, 2019).

Conclusion and Recommendation

The knowledge and awareness of graduating medicine and pharmacy students on the availability of a national ADE monitoring system and reporting forms were low. However, the students had believed that monitoring and reporting of ADE are important for the public and health care system. Similarly, the practice of reporting encountered ADE was below half. Therefore, creating awareness on pharmacovigilance in the pre-service training for health students is vital to creating the foundation for healthcare professionals to be diligent in monitoring and reporting ADE. The promotion of the national pharmacovigilance system should be delivered to health students and healthcare professionals to enhance spontaneous reporting. The schools of medicine and pharmacy should consider incorporating pharmacovigilance topics in their pre-service training curriculum to equip the graduates with appropriate knowledge and attitude to reporting ADE.

Acronyms

ADE	Adverse drug event
ADR	Adverse drug reaction
DACA	Drug Administration and Control authority
FMHACA	Food, drug and healthcare administration and control authority
KAP	Knowledge, Attitude and practice
WHO	World Health Organization

Conflict of interest

The authors declare that they have no conflicts of interest.

Funding statement

No funding was received for this work.

Authors' contributions

MF conceived the idea, supervised the design, data collection, write up research, and prepared the manuscript, HM, designed and conducted data collection; analyzed and interpreted the results, MG analyzed data and prepared the manuscript for publication.

Acknowledgments

The authors gratefully acknowledge all participants of the study participants.

Data availability

The datasets supporting the conclusions of the study will be available on request from the first author.

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