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KNOWLEDGE AND PERCEPTION TOWARDS PHARMACOVIGILANCE AND ADVERSE DRUG REPORTING AMONG PHARMACY AND NURSING STUDENTS IN AL JOUF UNIVERSITY

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ABSTRACT

Pharmacovigilance is one of the building blocks of health education in the community, which includes prevention of side effects of drugs or their complications caused by either the misuse of the dosage during the treatment period or the frequent use without medical consultation. Many international bodies and organizations, including the World Health Organization (WHO), are interested in this concept, formulating it on the basis of scientific basis for reporting, evaluation, prevention and early detection of drug side effects. The aim of this study was to determine the level of ADR's Knowledge and Perceptions of Pharmacovigilance and adverse drug reactions (ADRs) reporting between pharmacy students and medical students of Aljouf university. This is descriptive cross-sectional surveys which determine the Knowledge and Perceptions of Pharmacovigilance of pharmacy students and medical students of Aljouf University that was conducted from March - April 2017. Design of a structured questionnaire was administered as regards pharmacovigilance and ADRs reporting process. The mean knowledge score of pharmacovigilance and ADR reporting for the overall study sample was 2.99 (SD=0.44) with a scoring range from 0 to 9. Findings of the current study had demonstrated that there is insufficient knowledge level among pharmacy and nursing students regarding pharmacovigilance and ADRs reporting systems. Investigating the pharmacy and nursing students' perceptions toward ADRs reporting had demonstrated that they are having positive perceptions about reporting ADRs. Study concluded that there is insufficient knowledge level among pharmacy and nursing students regarding pharmacovigilance and ADRs reporting systems and a positive perception towards ADRs. Study recommends the necessity of an educational intervention plan that aims to increase the undergraduate healthcare workers knowledge and perceptions towards pharmacovigilance and ADRs reporting system.

KEYWORDS: ***Pharmacovigilance, Adverse Drug Reactions, Perceptions, Nursing, Knowledge.***

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INTRODUCTION

According to the "World Health Organization" (WHO), Pharmacovigilance (PV) is defined as ''the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem".[1] Pharmacovigilance aims at enhancing patient safety by assessing the risk-benefit profile of medicines. While medications have caused and will continue to cause harm to a number of people's lives alongside many benefits.[2] To assure the safety of medications is a crucial matter that requires to be gained for each member of the community, but unfortunately, this thing is highly ignored in several developing countries.[3]. Alongside the various benefits obtained by various drugs, adverse drug reactions (ADRs) are reported as one of the most harm causing agents to individuals' lives. They have a significant adverse impact on health care systems as they negatively affect the patient care process. These negative impacts include elevated morbidity and mortality rates, increased incidence of hospitalization, increased economic burden, and death.[4] ADRs are divided often into type A and type B. Type A is defined as "reactions represent an extension of the drug's therapeutic effect." On the other hand, type B reactions are unpredictable, occurring only in susceptible individuals. Other types of ADRs are classified as type C reactions or "continuing" reactions, which lasts for a relatively long period, type D reactions, or "delayed" reactions, which appear sometime after the administration of a specific drug, and type E or end-of-use reactions are linked with the withdrawal of a medicine.[5] Improving the levels of awareness regarding ADRs is considered to be an important step in providing and obtaining safe drug therapy use, especially for medications with significant low therapeutic index such as anticonvulsants, cardio active drugs, antineoplastic drugs, antiasthmatic drugs, immunosuppressant, antidepressant drugs, antibiotics, antiretroviral drugs and antimycobacterial drugs. Furthermore, disease-modifying antirheumatic drugs, such as Methotrexate and Sulfasalazine, can only be safely administered if they are monitored thoroughly. [6] The global awareness in monitoring, detecting and reporting ADRs has been reported to have increased significantly in the last few decades, especially after the thalidomide disaster of 1961. This was done by setting up a framework of an effective pharmacovigilance system. The involvement of pharmacy students in pharmacovigilance and ADRs reporting has remarkably enriched the amount of documented ADRs[7].And through nurses' position as drug administrators who are responsible for recording vital signs and symptoms of the patients; they play an increasingly important role in detection of suspected ADRs and are now contributing to a significant amount of ADR reporting. Thus, pharmacy and nursing students as future experts need to be well trained on how to identify prevent and report ADRs.

Objectives of the study

Knowledge, attitudes and practices of pharmacovigilance and adverse drug reactions reporting had been examined among pharmacists working in secondary and tertiary government hospitals in Kuwait city by Alsaleh *et al* (2016)[5]. Study included the distribution of a researcher developed 25 items self-reported questionnaire over 342 participants. Results of the study showed that hospital pharmacists in Kuwait city had good knowledge level and positive attitudes toward pharmacovigilance and ADR reporting. Study recommended the necessity of a targeted educational interventions and a well-defined policy for ADR reporting. In 2008, Toklu and Uysal [8] had performed a survey study to investigate the knowledge and attitudes of community pharmacists towards pharmacovigilance and ADRs in Kadikoy district of Istanbul, Turkey. The study sample was composed of 219 community pharmacists, and the study tool was a face to face questionnaire. The study findings showed that only 17.2% of the pharmacists had any knowledge about pharmacovigilance. Moreover, 65% of the pharmacists stated that patients reported an ADR to them during the previous twelve months and 7% actually reported on ADR to the national pharmacovigilance center. To analyze the community pharmacists' knowledge and perceived barriers to ADRs reporting system in Alahsa region, KSA. Khan (2013) [9] had performed a cross-sectional study by distributing a self-administered questionnaire over a sample of 70 community pharmacists. The results of the study had shown that 90% of the study participants were not aware of the ADR reporting system in Saudi Arabia, as well as 8% of them were unable to differentiate between the right and wrong definition of ADRs, and 84% of the pharmacists had stated that the patients often report adverse events. Several studies have reported evidence regarding the level of knowledge and perception of pharmacy and nursing students about pharmacovigilance and ADRs[8, 10]. Pharmacy and nursing students in the Kingdom of

Saudi Arabia are supposed to possess enough knowledge regarding pharmacovigilance and ADRs, and they have to hold specific significant perceptions toward the same topic. Current study aims to investigate and measure the level of knowledge among pharmacy and nursing students in Al-Jouf University (JU) towards the pharmacovigilance and ADRs.

METHODS

Study Design

A cross sectional descriptive study, including 303 Saudi adult university students enrolled in Al-Jouf University, northern of Saudi Arabia and of the age range between 19 to 23 years, characterized by enrolling in pharmacy or nursing colleges in Al-Jouf University (JU). The study population is represented by the male and female students in the pharmacy or nursing colleges in Al-Jouf University.

Sample selection criteria

1. Study participants should be students in the colleges of pharmacy or nursing in Al-Jouf University.
2. Age of participants is within the range of 19 to 23 years.
3. Voluntary participation in the ongoing study.

Setting

The study was conducted in the pharmacy or nursing colleges in Al-Jouf University, covering male and female students achieving the previously mentioned characteristics and enrolled in the pharmacy or nursing academic programs

Sample Size, Selection of Sample and Data Collection

Random sampling was performed to get the study sample. Data will be collected using a semi-structured questionnaire (Appendix A) Socio-demographic factors data will be collected using a semi-structured questionnaire.

Ethical Approval

The study was performed under the institutional research and ethics committee. The ethical approval number (JURE-1712/2018).

Part I

Questionnaire

Gender

Male □
Female □

Age

20-22 □
22-24 □

College

Pharmacy □
Nursing □

Academic level

Fourth □
Fifth □
Sixth □
Seventh □
Eighth □

Part II

Students' knowledge regarding pharmacovigilance and ADRs reporting

Item	Yes	No
I have an idea of how to report ADRs to the relevant authorities in Saudia	□	□
Students can perform adverse drug reactions reporting during their clerkship	□	□
The topic of pharmacovigilance is well covered in my curriculum	□	□
Reporting of known ADRs makes significant contribution to the reporting system	□	□
I know the different classifications of ADR	□	□
Hypersensitivity reactions are related to ADR	□	□
There is a difference between ADR and adverse event	□	□
I know the different types of hypersensitivity reactions	□	□
I know what Post-Marketing Surveillance is	□	□
I know how Causality Assessment of ADR is done in Saudia.	□	□

Part III
Beliefs and perceptions of students towards ADRs reporting

Item	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
ADR reporting should be made compulsory for healthcare professionals.	□	□	□	□	□
Information on how to report ADRs should be taught to students.	□	□	□	□	□
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	□	□	□	□	□
Healthcare is one of the most important professions to report adverse drug reactions.	□	□	□	□	□
Serious and unexpected reactions that are not fatal or life-threatening during clinical trials must be reported	□	□	□	□	□
The purposes of ADR spontaneous reporting system to measure the incidence of ADR	□	□	□	□	□
Any ADR (serious or non-serious) should be reported spontaneously	□	□	□	□	□
Reason for not reporting a suspected ADRs due to the uncertainty of its association with drug	□	□	□	□	□
Patients should be counseled about ADR every time their medications are dispensed	□	□	□	□	□
Female patients should be asked if she is pregnant when dispensing medications to them	□	□	□	□	□

STATISTICAL ANALYSIS

Data regarding knowledge and perception towards pharmacovigilance and Adverse Drug Reporting (ADR) had been collected by measuring the participants' knowledge and perceptions using the study tool. Data analysis was performed after the coding process using SPSS 24.0 software; both univariate and multivariate analysis were utilized in the study. Frequencies, percentages, mean scores, standard deviations, and correlation coefficients were calculated for study variables.

Study instrument
The survey questionnaire had been composed of three parts:

Part one
Demographic data section consists of questions investigating the participants' demographic background such as: Gender, Age, state of origin, Nationality, college and level of study.

Part Two
Ten closed ended questions investigating the participants' knowledge regarding pharmacovigilance and ADR. Provided choices were two likert scale options (Yes =1 or No = 0), which imposes a scoring system for the knowledge items as: 0-4: no/ little knowledge, 5-9: sufficient knowledge

Part Three
Ten closed ended questions investigating the participants' Perception towards Pharmacovigilance and ADR. The questions were framed into a 5-point Likert-scale format (5 = strongly agree, 4 = agree, 3 = neutral, 2 disagree, and 1 = strongly disagree).

Reliability
Reliability of tool had been done using Cronbach's Alpha calculation.

Validity
The content validity of the research tool for its completeness and clarity had been maintained through a literature review and consultation with concerned advisor (or expert).

Ethics and Human Subjects Issues
- Formal approval had been obtained from the concerned authorities.
- Informed verbal consent had been obtained from

the female students before giving the questionnaire.
- Confidentiality had been maintained throughout the study and will be maintained later.

RESULTS

Demographic characteristics of the study participants

Data presented in table (1) show the demographic characteristics of the study participants. Study sample distribution according to age had indicated that participants ranging in age between 22 and 24 had constituted the majority of the sample by a percentage equals to 78.9%, while the lowest represented category was for participants exceeding 24 years old which constituted 6.2%. Study sample distribution according to gender had shown that about two thirds (65.3%) were females, while male participants had constituted 34.7% of the total study sample count. Distributing the study participants according to their college had indicated that 62% of them were pharmacy students, and 38% were nursing students. Moreover, the distribution of the study sample according to their academic level has shown that the 8th level students were the highest represented category (38.3%), followed by the 7th level students which constituted 31% of the total study sample. The lowest represented category was fourth level students who accounted 4.3% (Table 1).

Table 1
Demographic characteristics of the study participants

Variable	Frequency	Percentage
Gender		
Male	105	34.7%
Female	198	65.3%
Age		
20 – 22	45	14.9%
22 – 24	239	78.9%
More than 24	19	6.2%
College		
Pharmacy	188	62%
Nursing	115	38%
Academic level		
Fourth	13	4.3%
Fifth	29	9.6%
Sixth	51	16.8%
Seventh	94	31%
Eighth	116	38.3%

Students' knowledge regarding pharmacovigilance and ADRs reporting

The mean knowledge score of pharmacovigilance and ADR reporting for the overall study sample was 2.99 (SD=0.44) with a scoring range from 0 to 9. Highest knowledgeable aspects of pharmacovigilance and ADR reporting were represented in that students had responded positively to that reporting of known ADRs makes a significant contribution to the reporting system (95.4%), followed by their knowledge about different types of hypersensitivity (90.4%), and knowing what post-marketing surveillance is (84.5%). (Table 2)

Table 2
Study sample responses towards the knowledge items in the study instrument

Item	Yes (%)	No (%)
I have an idea of how to report ADRs to the relevant authorities in Saudia	98 (32.3%)	205 (67.7%)
Students can perform adverse drug reactions reporting during their clerkship	104 (34.3%)	199 (65.7%)

The topic of pharmacovigilance is well covered in my curriculum	76 (25.1%)	227 (74.9%)
Reporting of known ADRs makes significant contribution to the reporting system.	289 (95.4%)	14 (4.6%)
I know the different classifications of ADR	117 (38.6%)	186 (61.4%)
Hypersensitivity reactions are related to ADR	241 (79.5%)	62 (20.5%)
There is a difference between ADR and adverse event	164 (54.1%)	139 (45.9%)
I know the different types of hypersensitivity reactions	274 (90.4%)	29 (9.6%)
I know what Post-Marketing Surveillance is	256 (84.5%)	47 (15.5%)
I know how Causality Assessment of ADR is done in Saudia.	63 (20.8%)	240 (79.2%)

Factors affecting knowledge score among pharmacy and nursing students had been investigated (Table 3). Despite the little knowledge for both categories, pharmacy students showed a significantly better knowledge of pharmacovigilance and ADRs reporting system than nursing students (3.81±0.39 and 2.97±0.71, respectively, p>0.005). Moreover, the results showed that a higher knowledge score was obtained among students in the 8th academic level. Finally, there were no significant statistical differences in the pharmacovigilance and ADRs reporting that is referred to gender variable (P=0.316) (Table 3).

Table 3
Factors affecting knowledge of pharmacovigilance and ADRs reporting score among study participants

Factor	Knowledge score Mean±SD	*P*-value*
Gender		
Female (n=228)	3.07±0.51	
Male (n=75)	2.91±0.36	0.316
College		
Pharmacy	3.81±0.39	
Nursing	2.97±0.71	>0.005
Level of study		
Fourth	3.01±0.69	
Fifth	3.19±0.39	>0.005
Sixth	4.07±0.77	
Seventh	5.61±0.51	
Eighth	5.83±0.88	

**** Significnce level at α≤0.05***

Beliefs and perceptions of students towards ADRs reporting

Results shown in table (4) indicate the student's perceptions toward ADRs reporting. It is obvious that 92.1% of the students strongly agreed that female patients should be asked if she is pregnant when dispensing medications to them and 85.1% reported that any ADRs (serious or non-serious) should be reported spontaneously. Moreover, 82.8% of the students strongly recommended that ADR reporting should be made compulsory for healthcare professionals, and 75.6% of them had strongly indicated that serious and unexpected reactions that are not fatal or life-threatening during clinical trials must be reported (Table 4).

Table 4
Response rate regarding Beliefs and perceptions of students towards ADRs reporting

Item	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly disagree N (%)
ADR reporting should be made	251(82.8%)	21(6.9%)	11(3.6%)	13(4.3%)	7(2.3%)

compulsory for healthcare professionals.					
Information on how to report ADRs should be taught to students.	213(70.3%)	61(20.1%)	6(1.99%)	9(2.97%)	14(4.6%)
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	12(3.96%)	30(9.9%)	13(4.3%)	85(28%)	163(53.8%)
Healthcare is one of the most important professions to report adverse drug reactions.	189(53.8%)	37(12.2%)	9(2.97%)	18(5.9%)	50(16.5%)
Serious and unexpected reactions that are not fatal or life-threatening during clinical trials must be reported	229(75.6%)	61(20.1%)	3(0.99%)	7(2.3%)	3(0.99%)
The purposes of ADR spontaneous reporting system to measure the incidence of ADR	190(62.7%)	43(14.2%)	16(5.3%)	19(4.9%)	35(11.6%)
Any ADR (serious or non-serious) should be reported spontaneously	258(85.1%)	18(5.9%)	3(0.99%)	14(4.6%)	10(3.3%)
Reason for not reporting a suspected ADRs due to the uncertainty of its association with drug	176(58%)	41(13.5%)	16(5.3%)	51(16.8%)	19(6.3%)
Patients should be counseled about ADR every time their medications are dispensed	181(59.7%)	56(18.4%)	6(1.98%)	29(9.6%)	31(10.2%)
Female patients should be asked if she is pregnant when dispensing medications to them	279(92.1%)	14(4.6%)	8(2.6%)	1(0.33%)	1(0.33%)

Mean and standard deviation scores of the students perceptions towards ADRs reporting has shown that the total score was 38.04, which indicates a positive perception of the students toward ADRs reporting.(Table 5)

Table 5
Mean and standard deviation scores for Beliefs and perceptions of students towards ADRs reporting

Item	Mean	Standard deviation
ADR reporting should be made compulsory for healthcare professionals.	3.99	0.55
Information on how to report ADRs should be taught to students.	3.72	0.71
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	1.03	0.51
Healthcare is one of the most important professions to report adverse drug reactions.	3.72	0.48
Serious and unexpected reactions that are not fatal or life-threatening during clinical trials must be reported	4.81	0.39
The purposes of ADR spontaneous reporting system to measure the incidence of ADR	4.31	0.59
Any ADR (serious or non-serious) should be reported spontaneously	4.29	0.73
Reason for not reporting a suspected ADRs due to the uncertainty of its association with drug	3.87	0.66
Patients should be counseled about ADR every time their medications are dispensed	3.39	0.68
Female patients should be asked if she is pregnant when dispensing medications to them	4.91	0.63
Total score	**38.04**	

DISCUSSION

The main aim of the current study was to evaluate and assess the knowledge and perceptions of pharmacy and nursing students toward pharmacovigilance and ADRs reporting. Several previous studies had reported that there is a lack of ADR reporting among pharmacists and healthcare workers (Sweis and Wong, 2000; Toklu and Uysal, 2008). Findings of the current study had demonstrated that there is insufficient knowledge level among pharmacy and nursing students regarding pharmacovigilance and ADRs reporting systems. Results of the current study are consistent with Toklu and Uysal's (2008) study which reported insufficient knowledge level among pharmacists regarding pharmacovigilance. Moreover, findings are consistent with the findings of Abu Farha *et al* (2015) study outcomes which reported insufficient knowledge regarding pharmacovigilance and ADRs reporting. On the other hand, findings of the ongoing study are inconsistent with Alshakka *et al* (2016) [10] study findings which indicated a relatively good level of knowledge of pharmacovigilance and ADRs reporting among physicians and nurses. Despite the insufficient knowledge level of pharmacovigilance and ADRs reporting, pharmacy students showed a relatively higher knowledge score than nursing students. Results could be referred to that pharmacy students are more involved in the study and identification of potential ADRs. Investigating the pharmacy and nursing students' perceptions toward ADRs reporting had demonstrated that they are having positive perceptions regarding reporting ADRs, especially in the case of a patient who is a pregnant female. These findings are in accordance with the findings of other previous studies[8]. Moreover, findings are in accordance with Vessal *et al* (2009) who reported that the uncertainty of the association of the ADR to the drug is a reason for not reporting the ADRs. As the knowledge level and the perceptions are modifiable variables, an educational intervention could significantly change their values, so it would be advantageous to set an educational intervention plan that aims to increase the undergraduate healthcare workers' knowledge and perceptions towards pharmacovigilance and ADRs reporting system. Educational intervention could take many forms, such as including pharmacovigilance and ADRs as a core topic in the undergraduate study plan or holding training programs, workshops, and special courses.

CONCLUSION

The study concluded that there is insufficient knowledge level among pharmacy and nursing students regarding pharmacovigilance and ADRs reporting systems and positive perception towards ADRs. The study recommends the necessity of an educational intervention plan that aims to increase the undergraduate healthcare workers knowledge and perceptions towards pharmacovigilance and ADRs reporting system. These results are significant as it might constitute the basis of an awareness campaign that might be carried out to increase medical students' knowledge level regarding pharmacovigilance and ADRs reporting systems. These results had revealed better scores in the level of the medical students' knowledge compared to regional and local studies.

LIMITATIONS OF THE STUDY

The study has a narrow scope on a number of dimensions:

1. The study is confined to the viewpoint of pharmacy and nursing students. The findings of the study could not be applicable to other healthcare providing professions or specializations.
2. The current cross-sectional study took place in the context of a single university and must be expanded to other educational or health institutions to harvest more accurate and generalizable results.

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AUTHORS CONTRIBUTION STATEMENT

Dr. Odai Magableh had conceptualized and gathered data with regard to this work. Miss Ghaida Al-Hamed was responsible for reviewing the literature and took part in data collection and the analysis procedure. All authors designed the manuscript and participated equally in formulating the methodology and writing the results section.

CONFLICT OF INTEREST

Conflict of interest declared none.

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