

## Original Research Article

# A Cross-Sectional Study on Knowledge and Perceptions of Pharmacovigilance among Pharmacy Students of Selected Tertiary Institutions in Jordan

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### Abstract

**Purpose:** To assess the perceptions and knowledge of pharmacovigilance and adverse drug reactions (ADRs) reporting among Bachelor of Pharmacy (BPharm) and Doctor of Pharmacy (PharmD) students of selected tertiary institutions in Jordan.

**Methods:** A cross-sectional study involving 434 pharmacy students from three different Jordanian universities was conducted from March - April 2014. During the study period, a validated structured questionnaire was administered to the participants to assess their knowledge and perceptions regarding pharmacovigilance and ADRs reporting process.

**Results:** Majority of the students had insufficient awareness and lack of knowledge of pharmacovigilance and ADRs reporting with a mean knowledge score of 4/10. PharmD students had better knowledge about pharmacovigilance and ADRs reporting system than the BPharm students (knowledge score of 5.4 versus 3.2, respectively;  $p < 0.001$ ). Also, higher knowledge scores were recorded for public university and fifth-year students ( $p < 0.001$ ). About two-thirds of the students expressed a positive attitude toward pharmacovigilance and ADRs issues and agreed that they would be willing to report ADRs during their clerkship programme.

**Conclusion:** BPharm and PharmD students have insufficient knowledge of the concept of pharmacovigilance and ADRs reporting. There is a need to incorporate pharmacovigilance into pharmacy curriculum in order to increase its awareness among pharmacy students as this will positively impact on their practice and enhance public health.

**Keywords:** Pharmacovigilance, Adverse drug reactions reporting, Pharmacy students, Knowledge, Perception, Awareness, Attitude

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## INTRODUCTION

The use of medicine is usually associated with harm that may range from mild to fatal adverse drug reactions (ADRs). About 5 to 20 % of hospital admissions are due to ADRs [1,2]. Fatal ADRs have been estimated to be a major cause of patient-related morbidity and mortality [3].

Accordingly, reporting of ADRs is considered to be crucial to maintain and achieve safe drug therapy in clinical practice [4].

Pharmacists as health care professionals working in a hospital or community pharmacy can play an essential role in both pharmacovigilance activities and ADRs reporting

[5], since they may be the first to be contacted by patients for information about ADRs [6] and have access to the information required to recognise and report ADRs [7,8]. Pharmacists are drug specialists who have the skills to avoid, identify, and resolve treatment-related problems and educate patients about their drug therapy [9]. However, there is a lack in the pharmacist's awareness or knowledge about the guidelines for assessing ADRs used by the drug regulatory bodies in their countries [10,11]. In addition, under-reporting of ADRs is the main inherent problem, in which reporting of serious ADRs is usually less than 10 % [4,7,12].

Elsewhere, the involvement of pharmacy students in pharmacovigilance and ADRs reporting has significantly increased the number of documented ADRs [13]. Thus, pharmacy students as future pharmacy experts need to be well trained on how to identify prevent and report ADRs [14].

Jordan established its own pharmacovigilance centre in January 2001. At present, only one study has assessed pharmacists' knowledge and attitudes toward ADRs reporting in hospital and community settings in Jordan [4]. In the study, pharmacists had positive attitudes toward pharmacovigilance despite their little experience with ADRs reporting and inadequate knowledge of the concept of pharmacovigilance [4]. The aim of this study, therefore, was to assess the perception and knowledge of pharmacy students of public and private universities in Jordan of pharmacovigilance and ADRs reporting.

## METHODS

### Study sites, design and participants

This was a cross-sectional study that involved Bachelor of Pharmacy (BPharm) and Doctor of Pharmacy (PharmD) students from three different Jordanian universities (one public and two private universities) in their last two years of study (fourth and fifth year for BPharm students and fifth and sixth year for PharmD students). The universities are located in two of the largest cities in Jordan; Amman and Zarqa. The study commenced in March 2014 and continued for two months.

A total of 630 questionnaires were distributed by the investigators to students. The questionnaires were handed to students at the beginning of different classes after obtaining the instructors' permission. The 434 completed questionnaires

were returned at the end of the class with a response rate of 66.7 %.

### Instrument

A questionnaire previously developed by our team was used in this survey [4]. The questionnaire included demographic data and was structured in two main sections which displayed the Knowledge and perceptions of students regarding pharmacovigilance and ADRs reporting process.

Demographic data included age, gender, type of study either pharmacy student or pharmD student, if they received any pharmacovigilance courses, name of university and year of study. Knowledge section included 10 questions to assess students' knowledge regarding the definition of pharmacovigilance and adverse drug reaction, and their knowledge about the reporting process in Jordan. For each correct answer the student was assigned a score of 1, and a final score out of 10 was calculated for each student to assess their knowledge level. So the knowledge score ranges from 10 (maximum score) to zero (lowest score).

The second section considered students' beliefs and perception, in which they were asked about their perceptions regarding the health care providers' responsibilities in reporting ADRs, why it is necessary to report ADRs and whether pharmacovigilance should be included as a core topic in the pharmacy curriculum.

### Data analysis

Data were analyzed using statistical package for social science version 19 (SPSS, Inc., Chicago, IL, USA). Students' answers were analyzed using a 5 - point Likert-type scale consisting of "strongly agree", "agree", "uncertain", "disagree", strongly disagree" and uncertain.

Descriptive analysis was done using mean and SD for continuous variables and percentage for qualitative variables. Independent sample t-test and one-way ANOVA were used to evaluate differences between groups for continuous variables, while Chi-square test was used for categorical variables.  $P < 0.05$  was considered statistically significant.

## RESULTS

### Demographic characteristics of study sample

The demographic details of the students included in the study are shown in Table 1. The mean age

of the students were approximately  $22.4 \pm (1.37)$  years. In this study, 274 (63.1 %) students were BPharm while 160 (36.9 %) were PharmD. Females accounted for 84.6 % (367) of the students.

### Students' knowledge regarding pharmacovigilance and ADR reporting

The mean knowledge score of pharmacovigilance and ADR reporting for the overall study sample was 4.0 (SD = 2.2) with a range from zero to 9.

Some of the students (106, 24.4%) defined 'pharmacovigilance' correctly while 62.4 % (n = 271) defined ADR correctly. More than 50 % of students were not aware of the presence of pharmacovigilance center in Jordan and they were not aware about the official standardized form for reporting ADRs and about the reporting process (Table 2).

Factors affecting knowledge score among Bpharm and PharmD students were assessed (Table 3). PharmD students showed a significantly better knowledge of pharmacovigilance and ADRs reporting system than BPharm students (mean score 5.4, 3.2 respectively;  $p < 0.001$ ). Also higher knowledge score was obtained among students from public university and fifth year students. There was no significant gender related difference in the students' mean score ( $p = 0.878$ ).

### Beliefs and perception of students towards ADRs reporting

Ninety five percent (n= 413) of the students believed that pharmacists have an important role in ADRs reporting process. The responsibility order was as follows: pharmacists (95.3 %, n = 513), physicians (94.1 %, n = 408), drug

companies (83.8 %, n = 364), patients (64.5 %, n = 280) and nurses (59.9 %, n = 258).

Responses to questions exploring the students' perceptions about pharmacovigilance and ADR reporting are shown in Table 4. Nearly 84.9 % (n = 360) of the students agreed that pharmacovigilance should be included as a core topic in pharmacy education and 73.2 % (n = 306) of the students strongly agreed that it should be made as a compulsory duty for pharmacists. About 84 % (n = 358) of the students believed that information on how to report ADRs should be taught to senior pharmacy students. Although only 39.6 % (n = 167) of the students are well prepared to report any ADRs in their future practice with their current knowledge. Sixty five percent (n = 277) of students agreed that they are willing to perform ADRs reporting during their clerkship.

**Table 1:** Demographic characteristic of the study sample (N = 434)

Variable	N (%)
Age (years; mean (SD))	22.4 (1.37)
Gender	
Female	367 (84.6)
Male	67 (15.4)
Type of study	
BPharm students	274 (63.1)
PharmD students	160 (36.9)
Level of study	
Fourth year	98 (22.6)
Fifth year	306 (70.5)
Sixth year	30 (6.9)
University	
1 (public)	254 (58.5)
2 (private)	156 (35.9)
3 (private)	24 (5.5)
Attended pharmacovigilance course	
Yes	114 (26.3)
No	320 (73.7)

**Table 2:** Assessment of students' knowledge of pharmacovigilance (PV) concept and policy

Question	Correct answer N (%)
1. Have you ever heard about the concept of PV?	173 (39.8)
2. What is the definition of PV?	106 (24.4)
3. What is the definition of adverse drug reaction?	271 (62.4)
4. In Jordan, are there legal provisions in the medicines act that provide for PV activities?	126 (29.0)
5. In Jordan, is there a PV centre?	102 (23.5)
6. In Jordan, is there an official standardized form for reporting adverse drug reactions?	194 (44.7)
7. Do you know from where can you get the ADR reporting form?	166 (38.2)
8. Do you know the period within which you should report a serious ADR experienced by a patient?	66 (15.2%)
9. To whom should you report the ADRs?	197 (45.4%)
10. It is necessary to confirm that an ADR is related to a particular drug before reporting it	342 (78.8%)

**Table 3:** Factors affecting knowledge of pharmacovigilance and ADR reporting score among pharmacy students

Factor	Knowledge score, Mean (SD)	P-value
Gender;		
Female (n=367)	4.0 (2.0)	0.878 <sup>a</sup>
Male (n=76)	4.0 (2.2)	
Type of study;		
Pharmacy students (n=274)	3.2 (1.7)	< 0.001 <sup>a *</sup>
PharmD students (n=160)	5.4 (2.3)	
Level of study;		
Fourth year (n=98)	3.3 (1.7)	< 0.001 <sup>b *</sup>
Fifth year (n=306)	4.3 (2.3)	
Sixth year (n=30)	3.0 (1.7)	
Current university		
1 (public) (n=254)	4.5 (2.4)	< 0.001 <sup>b *</sup>
2 (private) (n=156)	3.3 (1.6)	
3 (private) (n=24)	3.8 (1.7)	
Attended pharmacovigilance course		
Yes (n=114)	6.1 (1.9)	< 0.001 <sup>a *</sup>
No (n=320)	3.3 (1.8)	

a: independent sample t-test, b: one way ANOVA , \* statistically significant

About 61.2 % (n = 259) of participating students agreed that un-serious adverse reaction should be reported, also 60.4 % (n = 258) of students agreed that not only reactions for new products should be reported. Around 65.6 % (n = 279) supported the statement that serious and unexpected reactions that were neither fatal nor life-threatening during clinical trials had to be reported. Students also agreed that both well-known reactions and reactions not reported

previously for a particular drug should be reported (45.2 % (n = 191) and 67.8 % (n = 288) respectively).

Table 5 shows the perception of students toward the importance of reporting ADRs. It is obvious that almost the majority of them believed that reporting ADRs is an important duty of a pharmacist.

**Table 4:** Students' beliefs and perception towards ADR reporting

Statement	Agree N (%) <sup>*</sup>	Uncertain N (%) <sup>*</sup>	Disagree N (%) <sup>*</sup>
▪ Pharmacovigilance should be included as a core topic in pharmacy education.	360 (84.9)	53 (12.5)	11 (2.6)
▪ ADRs reporting should be made compulsory for pharmacists.	306 (73.2)	81 (19.7)	31 (7.4)
▪ I am willing to report ADRs during my clerkship.	277 (65.0)	104 (24.4)	45 (10.6)
▪ Information on how to report ADRs should be taught to senior pharmacy students.	358 (84.4)	47 (11.1)	19 (4.5)
▪ With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	167 (39.6)	120 (28.4)	135 (32.0)
▪ I believe that un-serious adverse reaction should be reported.	259 (61.2)	82 (19.4)	82 (19.4)
▪ I believe that only reactions for new products should be reported.	111 (26.0)	58 (13.6)	258 (60.4)
▪ I believe serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported.	92 (21.6)	54 (12.7)	279 (65.6)
▪ Reporting of well known ADRs makes no significant contribution to the reporting system.	153 (36.2)	79 (18.7)	191 (45.2)
▪ I believe that there is no need to report adverse reaction not reported before for a particular drug.	90 (21.2)	47 (11.1)	288 (67.8)

**Table 5:** Students' perception of the importance of ADR reporting

Purpose	Agree N (%)*	Uncertain N (%)*	Disagree N (%)*
1. To enable safe drugs to be identified.	402 (94.1)	20 (4.7)	5 (1.2)
2. To measure the incidence of ADRs.	392 (92.0)	30 (7.0)	4 (1.0)
3. To identify factors that might predispose to an ADR.	386 (91.0)	30 (7.1)	8 (1.9)
4. To identify previously unrecognized ADRs.	376 (89.1)	35 (8.3)	11 (2.6)
5. To compare ADRs for drugs in similar therapeutic classes.	358 (83.8)	57 (13.3)	12 (2.8)
6. To compare ADRs of the same drug from different drug companies.	351 (82.0)	52 (12.1)	25 (5.8)

## DISCUSSION

Spontaneous reporting of ADRs is an indication of pharmacovigilance awareness, because they are effective for distinguishing serious unexpected ADRs, medication errors, therapeutic inefficiency and disagreement in drug quality, besides its low cost. Despite the fact that practice of pharmacovigilance varies from country to country, the pharmacists' primary responsibility is the benevolence of each individual, so they are more likely to early detect ADRs than other healthcare professionals.

As future pharmacy practitioners, pharmacy students need to be well trained on how to recognize, prevent, and report ADRs, since the involvement of pharmacy students in ADRs reporting has led to a significant increase in the number of documented ADRs in a previous study [14]. Few studies have been carried out to evaluate pharmacy students' knowledge and attitudes toward ADRs reporting [14,15]. To the best of our knowledge, this is the first study in Jordan that evaluates the knowledge and perception of BPharm and PharmD students toward pharmacovigilance and ADR reporting.

Adverse drug reaction under reporting is a global reality evidenced by different recognized studies, which were carried out in different countries [4,12,15-20]. In these studies, where they found that a deficiency in knowledge and perceptions about pharmacovigilance and ADRs reporting is accountable for ADRs under reporting in both developed and developing countries [12,16,18-20]. In a different study, ignorance and insecurity were the main factors attributed to professionals' low knowledge about the activities of analysis of drug safety [21].

Our students' knowledge score was a little bit lower than that reported from pharmacy students of Malaysia (mean score 6.9/10) [14] and Philippines (mean score 3.52/5) [22]. This can be due to the weak media role in promoting the awareness about pharmacovigilance and lack of

workshops and seminars about ADRs reporting in the Jordanian universities.

The higher knowledge score among PharmD students compared to BPharm students was due to the fact that 51.9 % (n=) of them admitted that they have ever attended a workshop of pharmacovigilance among their educational courses compared to 11.3 % (n = 83) of BPharm students, and those students who attended the course were from the public university at the fifth year level.

Similar to the results from previous studies [4–6], a significant proportion of the study participants in the present study agreed that the pharmacist is one of the most important healthcare professionals to report ADRs.

Most of the study students expressed a positive attitude toward pharmacovigilance and ADRs issues and they agreed that they are willing to report ADRs during their clerkship. Attitude is conceivably modifiable variable exerting a strong influence on ADRs reporting [19], the greater the patient attitude the more positive influence on the overall ADRs reporting rate. This issue was proved previously by Granas *et al* in which they have shown that an educational program can significantly modify pharmacists' reporting-related attitudes and influence the ADRs reporting behaviour in a positive manner [12].

It would be advantageous to educate undergraduate pharmacy students about the importance of pharmacovigilance and ADRs reporting and encourage them to be involved in advocating ADRs reporting for both pharmacists and other healthcare professionals. By promoting a culture for ADRs reporting among healthcare professionals, the problem of under reporting could be reduced.

Most of students believed that serious and unexpected ADRs, including those that are neither fatal nor life threatening, must be reported. Students also agreed that both well-

known reactions and reactions not reported before for a particular drug should be reported (45.2 and 67.8 % respectively) which is consistent with the results of previous studies involving pharmacists and other healthcare professionals [4,6].

It was also found that the majority of students agreed that pharmacovigilance should be included as a core topic in pharmacy education. This indicated their positive perception of the importance of pharmacovigilance. This finding is similar to that of previous reports involving healthcare professionals [6,12]. To achieve better awareness about pharmacovigilance, more education and training programs on ADRs reporting are required in pharmacy faculties. Changhai *et al* showed that Pharmacists who receive more education and training on ADR reporting are more likely to report ADRs [7].

### Limitation of the study

There are some methodological weaknesses of this study since it was conducted among BPharm and PharmD students in only three schools of pharmacy in Jordan universities who were accessible to the researcher. Consequently, the findings should not be extrapolated to pharmacy students in other universities. It is necessary to extend this type of study to other universities in Jordan to obtain more generalizable results.

### CONCLUSION

The findings of this study underscore the urgent need for adjustment in the training curriculum to emphasize the role and responsibility of pharmacy students in pharmacovigilance practices, and to raise awareness toward ADRs reporting process.

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