

Pharmacovigilance Knowledge and Perceptions Among Pharmacy, Medical and Nurse Students in University of Duhok

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Abstract

Objective: To assess pharmacy, medical and nurse students' knowledge of and perceptions about pharmacovigilance and reporting of adverse drug reactions (ADRs) at University of Duhok (UOD). **Methods:** A cross-sectional study was conducted from November 1, 2017, through January 1, 2018 using a validated self-administered questionnaire delivered to a sample of 202 students at Colleges in UOD. **Results:** About 42% of students indicated that they had taken courses on the concept of pharmacovigilance during their current curriculum. The mean score for knowledge about pharmacovigilance and ADR reporting was 6.98. There was a significant difference in the mean scores for knowledge about pharmacovigilance across the Colleges. About 38.6% of the respondents believed that students are competent and capable of reporting ADRs during their clerkships. The majority (67.6%) of respondents perceived that students should be taught how to report ADRs. **Conclusion:** The results of this study demonstrate that the majority of students in public universities have insufficient knowledge about pharmacovigilance and ADR reporting.

Key words: Pharmacovigilance, Knowledge, Perception, Iraq

INTRODUCTION

Morbidity and mortality of patients increase due to Adverse Drug Reactions (ADRs) in community settings and hospitals. About 5% to 20% of hospital admissions cause by ADRs.^[1,2] The roles of health care providers (HCPs) concern with prescription, monitoring, choice of drugs, and many other health activities that includes many ideas of such pharmaceutical care as ensuring the safe and effective use of pharmaceutical drugs, improving patient satisfaction and quality of life, improving economic outcomes, and preventing ADRs and medication errors.^[3-5] HCPs can play an important role in both pharmacovigilance activities and ADR reporting.^[6]

ADRs more likely to be detect by HCPs, in both community settings and hospitals.^[6,7] HCPs should be very vigilant in detect and resolve drug-related problems, education and counsel patients on effective use of drug therapy.^[8] Because the HCPs have an important responsibility in monitoring the ongoing safety of medicines and approach to the information as part of their professional practice, they play an effective role in ADR reporting.^[9,10] Community HCPs consider the main source of ADR reports, because they formulate competent opinions and directly communicate with patients for information about ADRs.^[11] Significant increase in the number of authenticated ADRs is achieved by participation of HCP students.^[12]

Iraq- Kurdistan region established its own pharmacovigilance system in 2011. Kurdistan Medical Control Agency (KMCA) - Pharmacovigilance center is part of the Kurdistan Ministry of Health oversees and has run the pharmacovigilance program since that time. The number of ADR reports received from healthcare professionals by KMCA-PV reached 2 in 2011. However, according to WHO recommendations for the optimal National Pharmacovigilance Centre, this number is considered very low. The Iraqi

and Kurdistan pharmacovigilance system, like most others around the world, suffers from underreporting of ADRs by healthcare professionals.^[13] There is a lack of information about the reasons behind this underreporting by healthcare professionals in general and community pharmacists in particular, and few studies have explored this issue in Iraq- Kurdistan region.^[13-15]

Previous studies clarify that HCPs are crucial players in ADR monitoring and reporting. Really, the most HCPs are insensible or not knowledgeable about the guidelines and rules used by their respective countries' drug regulatory bodies responsible for estimating ADRs.^[16-17] Therefore, HCPs practitioners, students need more training on how to report ADR.

Few studies have been conducted to estimate students' knowledge and manner about ADR reporting.^[3,12,18] The current study aim is to evaluate the perceptions of and knowledge about pharmacovigilance and ADR reporting among Medical, Pharmacy and nurse students at university of Duhok.

MATERIALS AND METHODS

The initial draft of the survey questionnaire was developed using information from the literature about ADR reporting among healthcare professionals.^[19-23] Permission to approach the students and to conduct the study was obtained from the respective deans of the pharmacy college, medical college, and Nurse College, in University of Duhok. A total of 25 survey items organized into 3 sections were included. The first section consisted of 4 questions about student demographics and general information, such as age, gender, and current college, and 2 questions about whether the students had previously taken any course related to pharmacovigilance and whether they had been told to what the term "adverse drug reaction" refers.

The second section included elements designed to measure knowledge about pharmacovigilance and ADR reporting. Students were asked to select the correct answer from multiple-choice response options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum score obtainable was 10 and the minimum was 0.

The third section of the survey included 10 items designed to evaluate the perceptions of pharmacy students, medical students, and nurse students toward pharmacovigilance activities and ADR reporting. The questions were framed into a 5-point Likert-scale format (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, and 5 = strongly disagree). In order to avoid acquiescence, affirmation, or agreement bias, both positively- and negatively-worded items were included within each section.^[2-4]

Three pharmacy lecturers with experience in drug-use research and ADR reporting studies were asked to evaluate the relevance, clarity, and conciseness of the items included in the questionnaire. The observations and comments of the lecturers were taken into account. In order to test the validity and reliability of the survey form, the revised questionnaire was pilot-tested by administering it to a sample of 25 pharmacy students who did not participate in the main study. The overall Cronbach's alpha value was 0.73, and it is acceptable Cronbach's Value.^[25-35]

The sampling frame included (fifth year, fourth year) pharmacy students, (fifth year) medical students, (fourth year) nurse students who were enrolled full-time at university during the study period. The number of enrolled students during the study period was obtained from the respective lecturer coordinators in each college. The study was conducted for a period of 2 months from November 1, 2017, through January 1, 2018.

Students were informed about the objectives of the survey by means of an explanatory letter attached to the survey questionnaire that was distributed to all participants. The students received the survey questionnaire through the respective lecturer coordinators at each college.

Anonymity and confidentiality were ensured. Consent for participation was implied by the completion and return of the survey instrument. Descriptive statistical analyses such as frequencies and percentages were used to represent the respondents' demographic information. When appropriate, student t tests were performed by comparing the means of 2 continuous variables and One-way ANOVA with Post Hoc Tukey HSD (honestly significant difference). A post hoc analysis has been used for multiple comparisons in order to detect the existence of differences between pair-wise groups. The relationship between the categorical data was examined with the chi-square test.²⁵ Fisher Exact test is preferred over the chi-square test for skewed data if 25% or more of the cells in the table have expected frequencies of less than 5, or if any expected frequency is less than 1, as in this survey.²⁶⁻²⁸ For these survey data, SPSS software version 20 was used to estimate Fisher's exact P values because the data set was large and normal exact computations require a great amount of computer time and memory.

RESULTS

By the end of the 2-month study period, approximately all of final-year medical students had responded to the survey, yielding 202 usable survey instruments. One hundred twenty-eight of them (63.4%) were female, and 85 (42%) indicated having previously taken formal courses on pharmacovigilance. During their medical education, almost all respondents had been told what the term "adverse drug reactions" meant. Responses and demographic characteristics of the respondents are presented in Table 1. The knowledge of pharmacovigilance and ADR reporting among medical

Table 1: Interrelation of the Knowledge Score of Final-Year medical Students with their Demographic Characteristics (n=202).

Demographic	Mean(SD)	P
Gender Male (n=74) Female(n=128)	5.77 ± 1.54 5.4 ± 1.7	0.532 ^a
Pharmacovigilance course Yes(n=85)No(n=117)	5.88 ± 1.63 4.83 ± 1.64	0.01 ^{**}
Colleges 5 th Pharmacy (n=51) 4 th Pharmacy (n=44) 5 th Medicine (n=52) 4 th Nursing (n=55)	6.98 ± 1.64 6.15 ± 1.46 5.21 ± 1.45 4.82 ± 1.59	0.001 ^{*b>}

students was assessed by asking 10 questions with true/false options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum score obtainable was 10 and the minimum was 0. The mean knowledge score of pharmacovigilance and ADR reporting for the final-year medical students was 6.98. There was no significant difference in the mean score of the knowledge domain by gender (P = 0.532), but there was a significant difference in the mean score of pharmacovigilance concept knowledge current college attended (P > 0.001).

There also was a significant difference in the mean scores of pharmacovigilance knowledge between those who had taken a related course and those who had not (P = 0.01). There was a significant association between colleges group and those taking a course related to pharmacovigilance (P = 0.027) however, most of those who claimed to have taken a course related to pharmacovigilance were from college. There was association between those taking a course related to pharmacovigilance and gender (P = 0.013).

The mean scores of knowledge among medical students classified according to their demographic characteristics are shown in Table 1. Almost all respondents (n = 100, 49.5%) correctly identified as the body that regulates ADR reporting in IRAQ-Kurdistan.

Most students who responded (86.1%) incorrectly noted that an ADR related to a particular drug should be confirmed before it is reported. Approximately most (68.8%) respondents knew the minimum information required for the submission of an initial ADR report. A portion of the students (21.8%) failed to recognize the consequences of serious ADRs. Table 2 shows the responses to questions related to knowledge of the final-year medical students.

Approximately more than half of the students (n=143,70%) either agreed or strongly agreed that the pharmacovigilance concept should be included as a core topic in pharmacy education. There was a significant difference (P=0.034) in response to this question among students who had taken a pharmacovigilance course. Approximately one-third (31.4%) of the respondents either agreed or strongly agreed that the topic of pharmacovigilance is well-covered in their college curriculum. There was non-significant difference in response to this statement by students who had taken a pharmacovigilance course (P = 0.337). Only (n = 45) of these students indicated that they did not have any idea how to report an ADR. There was non-significant difference (P=0.381) in response to this statement between students at different college.

Students were asked whether they were capable of ADR reporting during their clerkships. Less than half (n=78, 38.6%) of the students either agreed or strongly agreed with the question. There was non-significant difference

Table 2: Final-Year medical Students Who Responded Correctly to Knowledge Questions on Adverse Drug Reactions.

Survey Item	Correct answer no.%
1) Pharmacoepidemiology	181(89.6)
2) Pharmacovigilance is the process of	126(62.4)
3) Which is the following regulatory body in IRAQ_Kurdistan region that regulates ADR	100(49.5)
4) Which of the following terms refers to the definition: "Any noxious, unintended, and undesired effect of a drug, which occur at doses used in humans for prophylaxis, diagnosis or therapy"?	81(40.1)
5) It is necessary to confirm that an ADR is related to a particular drug before reporting it.	28(13.9)
6) What is the consequence of serious ADR?	158(78.2)
7) The minimum information required for the submission of an initial ADR report?	139(68.8)
8) Adverse drug reaction related to the following products should be reported:	133(65.8)
9) Type A ADR	103(51)
10) Type B ADR	71(35.1)

($P = 0.163$) in responses to this question, according to where the students were currently enrolled.

About one-thirds of the students strongly disagreed or disagreed that reporting of known ADRs made any significant contribution to the reporting system, and around 20% ($n = 41$) agreed. Significant differences were found in college ($P = 0.008$).

Students were asked whether they believed that, with their current knowledge, they were well-prepared to report any ADR in their future practice. Approximately one-third ($n = 63$, 31.2%) of the students either strongly agreed or agreed with this statement. A significant difference was noted among responses from the students according to their current college ($p = 0.006$). Students were asked whether they perceived a health care provider as one of the most important healthcare professionals to report ADR. Approximately more than Half ($n = 121$, 59.7%) of the students either strongly agreed or agreed with this statement, and 20.8% ($n = 42$) either disagreed or strongly disagreed. A significant difference ($P = 0.009$) was found in responses according to the college of enrollment. To explore awareness of students about ADR reporting guidelines, they were asked whether serious and unexpected reactions that were neither fatal or life-threatening during clinical trials had to be reported. Nearly 30.4% ($n = 62$) of the students either agreed or strongly agreed with this statement, leaving 53.3% ($n = 131$) who disagreed. Most ($n = 20$, 16.3%) of the students who strongly agreed or agreed with the question statement were from university number 5. Only 7% ($n = 18$) of the students who indicated that they had previously taken a course related to pharmacovigilance either strongly agreed or agreed with this statement.

DISCUSSION

This is the first study in Kurdistan region-Iraq that evaluates the knowledge and perception of public university students toward pharmacovigilance and ADR reporting.

In the present study, an overall response rate of 79.9% was recorded. The number of students who participated in this study was relatively small considering the number of students currently enrolled in Iraqi colleges. Therefore, these results may not necessarily be extrapolated to all students.

This figure can be regarded as extremely high, especially when compared with those of other studies on the same topic carried out among pharmacy, nurse^[3,12,18] or medical students.^[36,37] The response rate is within the accepted range for survey research intended to represent colleges.^[38,39] In order to maximize the response rate and minimize response bias, the questionnaire was administered personally to students by the researchers at the respective colleges.^[40,41]

Because this study was conducted with final-year students in 3 colleges in University of Duhok that were accessible to the researcher, the findings may not be confidently extrapolated to the students in other public universities.

It was also unknown which colleges' curricula offered subjects related to pharmacovigilance. It would be logical to extend this type of study to other universities in Iraq to obtain more generalizable results.

During the study period, there was a lack of data regarding which colleges' curricula offered courses related to pharmacovigilance and ADR reporting. All the 3 colleges were selected for the study sample. There were 255 final-year students enrolled in these colleges. Our findings confirmed previous reports indicating that a deficiency in knowledge and perceptions about pharmacovigilance and ADR reporting is accountable for ADR underreporting in both developed and developing countries.^[3,14,42]

Although two-thirds of the students expressed a positive attitude toward pharmacovigilance and ADR issues, this survey revealed they were only moderately aware of and knowledgeable about pharmacovigilance.

The training that undergraduate students receive may be improperly delivered or otherwise insufficient to adequately prepare them for the task of ADR monitoring and reporting in their future careers.

This is not surprising, considering that only about 42% of the students indicated that they had taken a pharmacovigilance course. By promoting an ADR reporting culture among these professionals, the problem of underreporting could be reduced.^[43]

Unfortunately, only a few students were able to correctly answer questions relating to Iraqi ADR reporting guidelines, suggesting that this topic is either not covered sufficiently or not covered at all in the curricula of the study institutes. The current survey clearly shows that the majority of the students, regardless of which university they attend, do not understand the concept of pharmacovigilance. Educational training programs, however, can clarify and enhance the knowledge of healthcare professionals regarding ADR reporting requirements.^[44-46]

About 14% of the students correctly answered the survey question related to uncertainty about the causal relationship between the suspected ADR and the drug being a barrier to ADR reporting. This finding is consistent with those of similar reports about healthcare professionals elsewhere.^[47]

About 65% of the respondents believed that ADRs associated with herbal products should be reported. The responses to this question show that students do not know the requirements for reporting ADRs associated with herbal medication, which further suggests a lack of education about pharmacovigilance and ADR reporting guidelines.

The study results showed that attending courses on pharmacovigilance and ADR reporting was associated with an increase in students' level of knowledge and awareness about ADR reporting ($P = 0.01$). There also

Table 3: Perception About Pharmacovigilance Activities and ADR Reporting Among Final-Year medical students.

Survey Item	Strongly disagree,No%	Disagree,No%	Neutral ,No%	Agree,No%	Strongly Agree, No%	College	Gender	PV Course
1.Pharmacovigilance should be include as a core topic in collage education	12(54)	5(2.47)	42(20.7)	79(39)	64(31)	0.002	0.527	0.034
2. I believe that the topic of pharmacovigilance is well covered in my college curriculum	25(12)	68(33.7)	45(22)	47(23)	17(8.4)	0.002	0.507	0.337
3. I do not have any idea of how to report ADR to the relevant authorities in IRAQ	10(5)	35(17)	53(26)	56(27.7)	48(23.7)	0.381	0.247	0.328
4. students can perform adverse drug reactions reporting during their clerkship	17(8.4)	41(20)	66(32.7)	56(27.7)	22(10.9)	0.168	0.522	0.721
5. ADR reporting should be made compulsory for all health care provider	5(2.47)	17(8.4)	30(14.8)	90(44.8)	60(29.7)	0.06	0.255	0.105
6. Information on how to report ADR should be taught to students	3(1.48)	26(12.8)	36(17.8)	71(35)	66(32.6)	0.112	0.121	0.06
7. Reporting of known ADR makes no significant contribution to the reporting system	28(13.9)	67(33)	47(23)	41(20)	19(9.4)	0.008	0.55	0.196
8. With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	20(9.9)	60(29.7)	59(29%)	46(22.8)	17(8.4)	0.006	0.616	0.163
9. I believe a health care provider is one of the most important Healthcare professionals to report adverse drug reactions	8(4)	34(16.8)	39(19.3)	62(30.7)	59(29)	0.009	0.495	0.155
10. I believe serious and unexpected reactions that are not fatal or lifethreatening during clinical trials must not be reported	47(23.3)	61(30)	32(15.8)	43(21)	19(9.4)	0.001	0.407	0.166

was a significant difference in the mean total score of knowledge about pharmacovigilance according to which college the student attended. This finding may be explained by the differences and diversity in the curricula of the colleges in UOD or by students having been exposed to the practice of ADR reporting in the hospitals where they were trained. These weaknesses can be addressed by intensive training and workshops on pharmacovigilance and the structure of the ADR reporting system in this country.^[48] Knowledge, skills, and positive perceptions regarding pharmacovigilance and ADR reporting activities can be cultivated during undergraduate education and service training.

Beliefs regarding pharmacovigilance and ADR reporting activities in UOD were explored by asking students to respond to 5 statements using a 5-point Likert scale. The majority of the students agreed with the statement that pharmacovigilance should be included as a core topic in education. This indicated their positive perception of the importance of pharmacovigilance. This statement was significantly associated with the variable of whether

the student had previously taken a pharmacovigilance course. This finding is similar to that of previous reports involving healthcare professionals.^[44]

The majority of students (67%) agreed that there is a need to teach and provide pharmacy students with information on pharmacovigilance and how to report ADRs. Meeting this need will require colleges to provide education and training programs on ADR reporting to prepare students for performing their responsibilities as healthcare providers.

Health care provider who receives more education and training on ADR reporting are more likely to report ADRs. The majority of students (80%) believed that serious and unexpected ADRs, including those that are neither fatal nor life threatening, must be reported. The responses to this statement were significantly associated with colleges ($P < 0.001$) and are consistent with the results of previous studies involving pharmacists and other healthcare professionals.^[10]

CONCLUSION

This study shows that universities provide inadequate information about pharmacovigilance and ADR reporting in their undergraduate curricula, suggesting that a customized and comprehensive curriculum related to pharmacovigilance should be designed and implemented in pharmacy faculties and schools.

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CONFLICT OF INTEREST

We would like to declare that there was no conflict of interest in conducting this research.

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