

Research Article

**Knowledge, Attitude and Practice towards Pharmacovigilance and Adverse Drug Reaction Reporting among Pharmacy Students in Basra University, Iraq****Adheed Khalid Sharrad*, Haydar F.AL-Tukmagi, Ghassan Salah Ahmed**

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ABSTRACT

Safe use of medications is an important requirement in today's world. One of the most important areas in the field of Pharmacovigilance (PV) is the studies involving the post-marketing safety issues regarding the Adverse Drug Reactions (ADRs). The current study was meant to evaluate the knowledge, attitude and practice towards reporting of ADR and pharmacovigilance among final year students studying in the college of pharmacy at a public university in Basra. This questionnaire was tested and made error-free prior to using. This questionnaire contained ten knowledge-based questions, five attitude related questions and two questions which were related to the practices used towards the ADRs. The participants were interviewed and data was collected. Concerning the results of this study, A total of 83 respondents participated in the study. The mean knowledge score of pharmacovigilance and ADR reporting for the final year pharmacy students was 6.26 + 1.56. In general, the participants had a good attitude towards ADRs. Most of the participants of the survey, i.e., 96.3% (80), did not attend in any ADR workshop or training course. Most of the participants of the survey, i.e., 95.1% (79), did not have any idea about ADR reporting process. It was concluded from the results that the Pharmacovigilance plays an important role in safe and effective use of drugs in a situation which arises after the marketing and sales of drugs. Regarding the research, the pharmacy students displayed relatively modest knowledge and positive attitude but inadequate practice regarding ADRs and pharmacovigilance. There is a requirement for continuous learning strategy for the pharmacists.

Keywords: Pharmacovigilance, Adverse Drug Reactions, post-marketing safety issues.**INTRODUCTION**

Safe use of medications is an important requirement in today's world. The most vital parts in the field of Pharmacovigilance (PV) is the reports concerning the post-marketing safety issues about the Adverse Drug Reactions (ADRs). According to WHO, PV can be defined as "the science and the activities with respect to the assessment, detection, understanding and the prevention of the harmful results or any adverse drug-related issues"¹. The ADR reports are the core resource of the data available in PV². WHO defines ADR as "any type of response caused by a drug, that is unintentional, noxious and takes place at the drug doses which are used for diagnosing, prophylaxis, or treatment of a disease or due to the medications for the physiological functions"³. Christopher, et al. confirmed that pharmacists have a sound awareness and are helpful in using the Yellow Card spontaneous ADR system for reporting. However, training and education are important in retaining and growth of ADR reporting by pharmacists⁴. The less amount of ADR reporting is a global problem of major concern. As in majority of the pharmacovigilance system all over the world, the Iraqi system for pharmacovigilance also experiences the issue of ADR under-reporting. The major drawbacks of the pharmacovigilance programme are the lack of knowledge among health experts regarding pharmacovigilance, and under-reporting⁵. Several studies associated with knowledge, attitudes, perception or practice (KAP) concerning pharmacovigilance activity

among pharmacy or medicine students in various universities have been recorded in various nations⁶⁻⁸. The efficiency and success of any system for pharmacovigilance depends largely on the participation of all healthcare experts, and thus pharmacists and physicians are important healthcare experts responsible for the activities regarding pharmacovigilance and ADR reporting throughout their practice and also to raise awareness among public pharmacovigilance. Investigations indicate that insufficient knowledge and need for awareness about reporting of ADR among healthcare experts as well as attitudes is related to a high amount of under-reporting⁹⁻¹⁴. Gavaza and Bui found that pharmacy students had solid intentions and positive attitudes towards reporting of ADR, but they had insufficient knowledge of the manner of reporting serious ADRs¹⁵. There is a necessity for continuous learning initiatives for the physicians, nurses and the pharmacists. Hajebi, et al. determined that it is essential to offer constant ADR related learning programs until a point is reached when voluntary reporting of ADRs become usual and habitual as far as the nursing staff is concerned.

The current study was meant to assess the KAP towards reporting of ADR and pharmacovigilance among final year students studying in the college of pharmacy at a public university in Basra.

METHODOLOGY

Analytical study conducted at University of Basra, College of Pharmacy, during Feb – July 2017, to evaluate knowledge, attitude and practice (KAP) in pharmacy student. All the final year pharmacy students in Basra were participated in the study. The questionnaire was adapted from the previously published articles and modified according to the need of the present study^{8, 16-17}. A total of 20 survey items, classified into four groups, were developed. The first part consisted of two demographic questions: age and gender. In the second part, items were pooled under the heading of 'knowledge of participants regarding ADR and pharmacovigilance. This section included ten questions which asked the students to select the correct answer. The third part includes five items each designed to evaluate the pharmacy students' attitude. Questions were framed in a

four-point Likert scale format (1 = 'strongly agree'; 2 = 'agree; 3= 'disagree' and 4 = 'strongly disagree'). This type of scale was chosen because its construction is relatively simple and the explanation of results is easy¹⁸. The fourth part of questionnaire consist of three items to assess the participants' practice (practice related questions designed to be fit for students).The questionnaire was validated by Three lecturers of clinical pharmacy from Basra University¹⁹. This questionnaire was tested and made error-free prior to using²⁰⁻²¹. The Cronbach's alpha was calculated as 0.70 which is considering to be acceptable in exploratory research²¹.

RESULTS

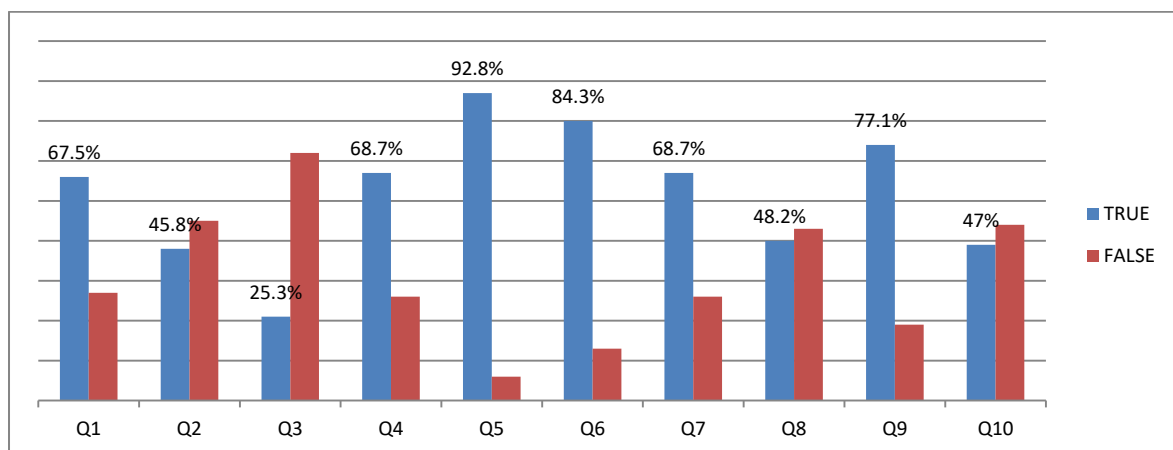
The total 83 (79.8%) participants provided their response. The demographic details are tabulated in (Table. 1).

Table 1: Gender of the Respondent

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	female	53	63.9	63.9	63.9
	male	30	36.1	36.1	100.0
	Total	83	100.0	100.0	

The knowledge of the participants regarding the pharmacovigilance and ADR reporting was assessed by asking ten questions with true/false options. A score of 1 was given for each correct answer and 0 score for each wrong answer. The highest score obtainable was 10 and

the lowest was 0. The mean knowledge score for the participants was 6.26 + 1.56. (Figure 1). There were no a statistically significant difference ($p=0.359$) in the mean score between males and females (table 2).



Five questions were designed to investigate participants' attitude toward ADRs reporting and pharmacovigilance (table 3). In general, the respondents had a good attitude towards ADRs. Nearly 91.6% ($n=76$) of students were agreed that ADR reporting will be decreased health system costs and 93.3% ($n=75$) of them believed that all health care professionals should be actively report ADRs. Around 79.5% ($n=66$) participants agreed that "ADR monitoring centre should be established in every hospital." while 75.9% ($n=63$) believed that

Pharmacovigilance should be taught to all health care students during their curriculum. However, most of the respondents 96.4% ($n=80$) fixed that the Educational programs have positive effects on ADRs reporting.

Around 96.3% (80) respondents did not attend in any ADR workshop or training course. While 78.3% (65) respondents said No to the question "Have you anytime read any article on prevention of ADRs". Also, 95.1% (79) respondents said Yes to the question "I do not have any idea about ADR reporting process" (Table 4).

Table 2: Responses to knowledge questions by final year pharmacy students/gender

Question	Answer	number	Gender	
			male	female
1- Pharmacovigilance is the study that relates to:	correct	56	20	36
	incorrect	27	10	17
2-The functions of Pharmacovigilance are:	correct	38	10	28
	incorrect	45	20	25
3-Pharmacovigilance includes:	correct	21	8	13
	incorrect	62	22	40
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'?	correct	57	24	33
	incorrect	26	6	20
5- It is necessary to confirm that ADR is related to a particular drug before reporting it	correct	77	28	49
	incorrect	6	2	4
6- What is the consequence of serious ADR	correct	70	26	44
	incorrect	13	4	9
7- The minimum information required for the submission of an initial ADR report:	correct	57	24	33
	incorrect	26	6	20
8-Adverse drug reaction related to the following products should be reported:	correct	40	15	25
	incorrect	43	15	28
9- Type A ADR:	correct	64	24	40
	incorrect	19	6	13
10- Type B ADR :	correct	39	11	28
	incorrect	44	19	25

Table 3: Pharmacy students' attitude about Adverse Drug Reactions reporting.

S.No	Questions	Strongly disagree (%)	Disagree (%)	Agree (%)	Strongly agree (%)
1	ADRs reporting will be increased health system costs	5 (16)	2 (2.4)	38 (45.8)	38 (45.8)
2	ADRs reporting are a duty of all health care professionals.	0	8 (9.6)	51 (61.4)	24 (28.9)
3	ADR monitoring centre should be established in every hospital.	6 (7.2)	11(13.3)	58 (69.9)	8 (9.6)
4	Pharmacovigilance should be taught to all health care students during their curriculum.	2 (2.4)	18 (21.8)	41 (49.4)	22 (26.5)
5	Educational programs have positive effects on ADRs reporting	0	3 (3.6)	35 (42.2)	45 (54.2)

Table4: Student's attitude about the practice

S.No.	Questions	Yes (%)	No (%)
1	Do you attend in any ADR workshop or training course	3(3.7)	80 (96.3)
2	Have you anytime read any article on prevention of ADRs.	18(21.7)	65(78.3)
3	I do not have any idea about ADR reporting process	79 (95.1)	4(4.9)

DISCUSSION

As far as we are concerned, this research is the primary of its type, accomplished in Iraq/Basra area, which evaluates the KAP of the subject of pharmacovigilance and

reporting of adverse drug reactions (ADRs) among final year pharmacy students studying in the public university of Basra.



Pharmacists could be an important factor in ADRs reporting, since they are close to patient both in hospitals and communities and have excellent knowledge about adverse reactions of drugs; so it is reasonable to engage them more in reporting of ADRs. Our extensive pursuit of the literature showed a shortage in the papers that focus on the pharmacovigilance idea among students of pharmacy. On this basis, the aim of this research was to assess the level of awareness, attitude and the practice regarding pharmacovigilance topics and ADR reporting process among pharmacy students in the University of Basra. As this research was only carried out on final year students of pharmacy in one public college of pharmacy, i.e. Basra University, easily available to the researcher, the results may not be assertively extrapolated to the similar other pharmacy students in different public universities .

Our results show that pharmacy students have reasonable knowledge and positive attitudes about ADRs but the habit of detecting and reporting ADRs were found to be at the minimum level. Results of a related KAP research in India show that pharmacy students had superior knowledge but terrible attitude and habits concerning activities of ADRs monitoring and reporting¹⁶ ,while KAP research in Iran demonstrates that 70% of candidates had potential knowledge and approach towards ADRs but the customs of detecting and reporting ADRs were at the minimum level⁽¹⁷⁾ .

Elkalmi, et al. researched on the last year pharmacy students' awareness about pharmacovigilance and ADRs and established that most of the final-year students in Malaysian public universities have inadequate knowledge regarding pharmacovigilance and reporting process of ADR⁽⁸⁾ .Comparable KAP research conducted in Pakistan proved that participants had superior knowledge, awareness and insight towards pharmacovigilance and reporting process of ADR compared to medical students. As prospective health care experts, they are supposed to have sound awareness, positive attitude and insight towards pharmacovigilance activities⁽²²⁾ The lack in the practice of reporting of ADR can be resolved in upcoming years only if all students and healthcare experts are aware of the significance of reporting, the reporting structure, and their responsibility to report ADRs⁽²³⁾ .Other research conducted by Rajiah et al. in a private-run medical University in Kuala Lumpur, Malaysia to evaluate the awareness and perception towards ADR reporting showed that the students of pharmacy had sufficient understanding and there are noteworthy differences in opinion among the students on reporting of ADRs⁽²⁴⁾ .

In Nigeria, an analysis among college pharmacy students on reporting of ADR and other pharmacovigilance endeavours showed lack of knowledge in the particular fields which were ascribed to the need of pharmacovigilance topics in the curricula; eventually, lack of awareness may lead to under-reporting⁽²⁵⁾ .Similar results were noticed in the study carried out by Raza and

Jamal, where both students in medical and pharmacy college showed lower KAP scores on the whole; both showed poor knowledge scores pointing out that intervention is necessary to improve understanding of future professionals at college level. However, among students, pharmacy students displayed better knowledge grades in comparison to medical students. Despite poor knowledge, both pharmacy and medical students displayed better attitude regarding pharmacovigilance. These findings encourage the need for interventions to enhance the knowledge of both medical and pharmacy students⁽²⁶⁾ .The outcomes of this analysis also may offer a chance for forthcoming research keen on curricular development and teaching of subjects such as pharmacovigilance and ADR reporting where false conceptions exist.

Limitations

The drawback of the research is that the number of participants who were involved in this study was comparatively small considering the amount of students currently registered in various pharmacy colleges in Iraq. Thus, generalizing this study's results to apply to all of Iraq's pharmacy students should be done carefully.

CONCLUSION

Pharmacovigilance is a subject combined of various endeavours which are exclusively planned to improve patient care, by preventing ADRs related to usage of drugs and assure drug safety and consistency of drug use. Pharmacovigilance plays an important role in harmless and effective use of drugs in a situation which arises after the marketing and sales of drugs. Thus, pharmacovigilance should be a branch of every healthcare setup. Regarding the research, the pharmacy students displayed relatively modest knowledge and positive attitude but inadequate practice regarding ADRs and pharmacovigilance. There is a requirement for continuous learning strategy for the pharmacists. The exclusion of pharmacovigilance and ADR reporting in the curriculum of pharmacy is probably attributed to lack of knowledge of pharmacy students on reporting of ADR and other pharmacovigilance activities, and a lack of specialized educational programs can cause lack of pharmacovigilance practice or can be a cause for under-reporting or no reporting at all. As future pharmacy experts, pharmacy students have to be well versed in pharmacovigilance activities to decrease the incidents of low reporting of ADR. In addition, the role of the professional pharmacist as a member of the healthcare group and in direct patient care is not present in Iraq, which will be a primary test for the graduating pharmacist. It is a requirement of time that a dedicated pharmacovigilance centre with dedicated members should be developed for the supervision of ADRs and for ensuring safety of drugs use.



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