



Emerging need of Pharmacovigilance: Perspectives of future pharmacist in Pakistan

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Research Article

Please cite this paper as Sadia Shakeel*¹, Wajiha Iffat¹, Fakhshena Anjum¹, Rabia Bushra², Sadaf Ibrahim³, Shajya Shafiq¹, Emerging need of Pharmacovigilance: Perspectives of future pharmacist in Pakistan. IJPTP, 2014, 5(2), 966-9.

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Abstract

Objectives: The present study was aimed to evaluate the knowledge, attitude and perception of senior pharmacy students towards pharmacovigilance and reporting of adverse drug reactions.

Method: This cross sectional study was conducted from Feb till July 2013 by adopting a pre validated questionnaire distributed to senior pharmacy students (fourth and final year) at different private and public sector universities of Karachi. Four hundred and thirty one students responded to the study survey. Descriptive statistics were used to demonstrate students' demographic information and their response to the questionnaire items. Chi square test was applied to evaluate the association of gender, institution and academic year of students with their response.

Result: Pharmacy undergraduate students in Karachi, Pakistan showed positive attitudes towards pharmacovigilance and ADR reporting. They recognized the role of pharmaceutical companies and ministry of health in ADR reporting and agreed that the ADR reporting system in Pakistan needs further development.

Conclusion: It is concluded that pharmacy students were motivated to practice pharmacovigilance during their clerkship as well as professional career. A nationwide survey including all pharmacy institutions of Pakistan would provide further evidence.

Keywords: ADR reporting, Pharmacovigilance, KAP, Pharmacy students, Pakistan

Introduction

Drug is inimitable human creation whose number is increasing with the passage of time. It is evident that the rational use of medicines (RUM) improves quality of health services. Therefore safety, efficacy and quality are the utmost criteria which are considered globally for the registration of any drug. However, irrational use of these drugs can be life threatening and may be the reason of serious adverse drug reactions (ADRs) which are the major health problems considered worldwide. The status of public health is majorly affected by consequences of ADRs. ADRs related morbidity and mortality are very common reasons of patient hospitalization because all the drugs have adverse effects, even if consumed appropriately. Near about 5-20% of hospital admissions are due to ADRs^[1, 2]. It imposes a considerable fiscal burden on the health care systems of society^[3, 4]. Pharmacovigilance has now become centre of attention by regulatory bodies, considering it as a fundamental component of pharmaceutical care to ensure patient safety. Spontaneous reporting of health care professionals can contribute significantly to successful pharmacovigilance^[5, 6]. Pharmacists being the drug expert are more likely to detect ADRs as compared to other healthcare professionals^[7, 8]. Pharmacists may be the first to be contacted by patients and have access to the information necessary to report ADRs. They should have the expertise and skills to prevent, identify, and resolve drug-related problems and counsel patients on rational use of drug^[9-11]. There is an increase in the number of documented ADR with contribution of pharmacy students in ADR reporting. Therefore, pharmacist can play a crucial role in both ADR reporting and pharmacovigilance activities^[8]. Studies have also revealed the significant role of pharmacists in ADR monitoring and reporting. Majority of pharmacists were unacquainted about the guidelines used by their respective countries' drug regulatory bodies responsible for assessing ADRs^[12, 13].

Pharmacovigilance is still in its formative years in Pakistan. This may be due to ignorance, lack of awareness by healthcare professionals and lack of training about drug safety monitoring that leads to



insufficient data of local population and reliance on the data collected in other countries. The prospective pharmacy practitioners need to be well trained on how to recognize, prevent, and report ADR. Few studies have been conducted to evaluate pharmacy students' knowledge and attitudes about ADR reporting^[14]. Therefore, the present study was conducted with the aim to evaluate the knowledge, attitude and perception of imminent pharmacist regarding pharmacovigilance and ADR reporting.

Material and Method

Study design and setting:

This cross sectional study was conducted from Feb till July 2013 by adopting a pre validated questionnaire distributed to senior pharmacy students (fourth and final year) in different private and public sector universities of Karachi. We did not have any earlier estimation regarding the knowledge and perception of pharmacy students towards pharmacovigilance in Pakistan. Therefore we assumed the KAP prevalence to be 50% and calculated the required sample for our survey with an allowable error of 5% and 95% confidence limits. Four hundred and thirty one fourth and fifth professional pharmacy undergraduate students were selected by convenience sampling method. Students were motivated to respond to given questionnaire on spot. The questionnaires were consequently collected for further analysis.

Ethical Approval:

Each institution's head of department was informed prior to initiate the study and the ethical approval was taken from them. Students' participating in the study were briefed about the rationale of the study and were assured about the secrecy of their personal information and responses.

Data Collection:

A pre validated questionnaire used in other researches was adopted and modified^[15, 16]. The questionnaire was structured to obtain the demographics of the students, information about their knowledge and attitude towards ADR reporting and their levels of education and training on ADR reporting. A pretested KAP questionnaire comprising of 27 questions (knowledge 11, attitude 10, and perception 6) was administered to participants.

Statistical analysis

The filled questionnaires were analyzed by using SPSS 20.0. Descriptive statistics were used to demonstrate students' demographic information and their response to the questionnaire items. Chi square test was applied to evaluate the association of gender, institution and academic year of students with their response. A p value < 0.05 was considered as significant.

Results

Out of 550 survey questionnaires, only 431 were returned back in useable form. Hence the response rate was 78.36%. Table 1 showed the demographic of the study population. The study population comprised of 82.6% females and 17.4% males.

Table 1: Characteristics of study population

S.No	Characteristics	Number (Percentages)
1	Gender	
	Male	75(17.4%)
	Female	356(82.6%)
2	Academic year	
	Fourth year	161 (37.4%)
	Final year	270 (62.6%)
3	Institute	
	Private	190 (44.1%)
	Public sector	241 (55.9%)

More than 55% of the participants belonged to the public sector university. More than 60% of the participants were final year pharmacy students whereas 37.4% were fourth year pharmacy students. Responses of the students regarding their knowledge are recorded in Table 2.

Table 2: Knowledge of students towards ADRs and pharmacovigilance

S.No	Opinion	Yes	No	Don't know
1	Pharmacovigilance	270(62.64)	121(28.07)	40(9.28)
2	Adverse drug reactions	424(98.37)	6(1.39)	1(0.23)
3	Different types of ADR	414(96.05)	9(2.08)	8(1.85)
4	Role of pharmaceutical company and ministry of health	387(89.79)	16(3.71)	28(6.49)
5	DRAP form	193(44.77)	119(27.61)	119(27.61)
6	Need for improvement	382(88.63)	14(3.24)	35(8.12)

The study revealed that 98.37% of the students have the knowledge of ADRs, 96.05% knows the different types of ADRS, 89.79% of the students understand the role of pharmaceutical companies and ministry of health in ADR reporting. Majority of the students 88.63% agreed that the ADR reporting system in Pakistan needs further improvement. On the other hand, only 44.77% of the respondents have information about the availability DRAP form for reporting of ADR.

Students' response for the purpose of reporting ADR is illustrated in Fig.1. It showed that 73.55% of the respondents considered the purpose of reporting ADR is to identify safe drugs, calculate incidence of ADR, identify predisposing factors to ADR, identify



Table 3: Attitude of students towards ADRs and pharmacovigilance

S.No	Opinion	Yes	No	Don't know
1	Know where to report ADR	227(52.66)	154(35.73)	50(11.60)
2	Know how to report ADR	215(49.88)	172(39.90)	44(10.20)
3	Difficult for you to decide whether or not an ADR has occurred	237(54.98)	163(37.81)	31(7.19)
4	Confidently discuss the ADR with other colleagues	318(73.78)	87(20.18)	26(6.03)
5	Reporting of only one ADR makes no significant contribution to the ADR Reporting system	141(32.71)	230(53.36)	60(13.92)

previously unrecognized ADR and patient safety. Attitude of pharmacy students to report ADR is illustrated in Table 3. Approximately 74% of the students have the confidence to discuss ADR with their colleagues. 52.66% and 49.88% of the students know where to report and how to report ADRs respectively. Only 32.71% considered that reporting of a single ADR makes no significant contribution to the ADR reporting system. Whereas 54.98% of the students find it difficult to decide whether an ADR has occurred or not.

Table 4: Perception of students towards ADRs and pharmacovigilance

S.No	Opinion	Yes	No	Don't know
1	Pharmacovigilance should be included as a core topic in pharmacy education	304(70.53)	39(9.04)	88(20.41)
2	Pharmacovigilance is well covered in my pharmacy curriculum	148(34.33)	192(44.54)	91(21.11)
3	Can report adverse drug reactions during their clerkship	288(66.82)	84(19.48)	59(13.68)
4	ADR reporting should be made compulsory for pharmacists.	373(86.54)	34(7.88)	24(5.56)
5	I am very well prepared to report any ADRs notice in my future practice.	224(51.97)	138(32.01)	67(15.54)

Table 5: Influence of gender, institution and academic year of students on their response.

S.No	Opinion	χ^2	Sig.*
1	Gender Vs Different types of ADR	7.102	0.029
2	Gender Vs Existence of DRAP form	6.839	0.033
3	Gender Vs Know where to report ADR	7.048	0.029
4	Gender Vs Pharmacovigilance should be included as a core topic in pharmacy education	7.736	0.021
5	Year of study Vs Pharmacovigilance	12.798	0.002
6	Year of study Vs Different types of ADR	6.422	0.04
7	Year of study Vs Reporting of only one ADR makes no significant contribution to the ADR Reporting system	7.667	0.022
8	Institute Vs Pharmacovigilance	14.97	0.001

Note: In the table-5 value of sig. < 0.05 considered as significant

Perception of students towards ADRs and pharmacovigilance is recorded in Table 4. It showed

that 86.54% of the respondents considered that adverse drug reporting must be obligatory for pharmacy students. Only 34.33 % agreed that pharmacovigilance is well covered in my pharmacy curriculum and 70.53% of the participants emphasized that pharmacovigilance should be included as a core topic in pharmacy education. The most reliable source of information from student's point of view is recorded in Fig.2. Textbooks (27.61%), journals (24.82%) and internet (15.31%) were considered as the most reliable source of

information. Table 5 summarizes the influence of gender, institution and academic year of students on their response.

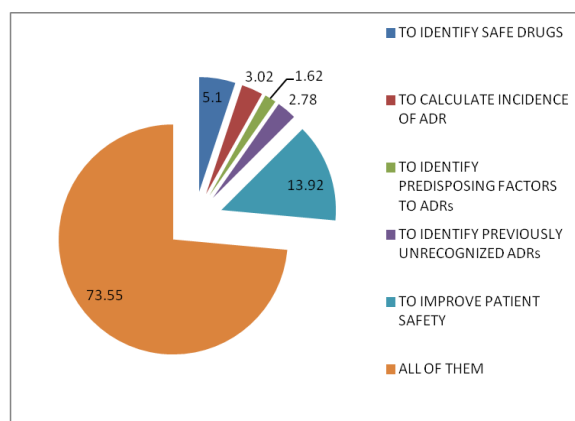


Fig 1. Purpose of reporting ADR from students' point of view

Discussion

An increased rate of morbidity and mortality are associated with ADRs [1, 2]. ADRs were considered to be the 4th to the 6th largest causes of death in the United States and were responsible for about 0.3% -



10 % hospital admission in some countries^[1]. To triumph over this issue, national pharmacovigilance systems have been established in many countries around the world. ADR reporting is the cornerstone of pharmacovigilance system considered globally. Pharmacists occupy a fundamental position in drug safety by contributing to the prevention, identification, documentation and reporting of ADRs^[12]. Studies have shown that pharmacist can play a significant role in the reporting system^[4]. Our study showed similar results that 58.9% considered pharmacist to be the most competent healthcare professional to report ADRs. The present study revealed that 98.37% of the pharmacy students have the knowledge of ADRs, 96.05% knows the different types of ADRs. It reflects the sound knowledge and understanding of prospective pharmacist regarding ADRs. 89.79% of the students understand the role of pharmaceutical company and ministry of health in ADR reporting. Only 44.77% of the respondents have information about the availability DRAP form for reporting of ADR. Majority of the students 88.63% agreed that the ADR reporting system in Pakistan needs further improvement. This evidently highlights that the prospective pharmacist realized the necessity for the enhanced awareness as well as implementation of the rules and regulation to improve the quality of life of Pakistani population. There is great need of time that pharmaceutical companies, regulatory bodies and ministry of health of Pakistan strive together for the betterment of society by maintaining safety profiles of the drugs. The knowledge and perception of pharmacists pertaining to pharmacovigilance had major impact on the practice of pharmacovigilance. So if pharmacists are trained, there would be a positive drive towards increase in reporting and thereby would help in maintaining the safety profiles of drugs^[17]. Approximately 74% of the students have the confidence to discuss ADR with their colleagues. 52.66% and 49.88% of the pharmacy students know where to report and how to report ADRs respectively. Underreporting of ADRs is a widespread observable fact in spontaneous post marketing surveillance programs. Underreporting may be impediment in signal detection and cause underestimation of the size of a problem. Correcting the underreporting scenario is complex as the extent is unidentified and inconsistent^[18]. It is an alarming condition that 54.98% of the pharmacy students find it difficult to decide whether an ADR has occurred or not. In another study^[19, 20], 32.3% and 36.4% respectively agreed that level of clinical knowledge makes it difficult to decide whether or not an adverse drug reaction has occurred. Our study indicates the higher percentage of deciding about the ADR occurrence as compared to studies conducted in other countries. Major obstacles to reporting also include reluctance to report reactions about which a degree of uncertainty exists. Education and training have a significant influence on ADR reporting and should be continued and re-enforced in order to improve ADR reporting by pharmacists.^[19] The perception of pharmacy students towards ADR and pharmacovigilance indicates student's eagerness to enhance their awareness about pharmacovigilance and ADR reporting. Only 34.33 % agreed that pharmacovigilance is well covered in my pharmacy

curriculum and 70.53% of the participants emphasized that pharmacovigilance should be included as a core topic in pharmacy education. Research has shown that pharmacists who receive more education and training on ADR reporting are more likely to report ADRs^[11]. The prospective pharmacist signifies the extensive incorporation of pharmacovigilance and ADR in the clinical pharmacology and therapeutics curricula of medical schools^[21]. 66.82% respondents agreed that they can report adverse drug reactions during their clerkship. More than 50% of the participants considered themselves well prepared to report any adverse drug reporting in their future practice. About 86.54% of the prospective pharmacists considered that ADR reporting should be made compulsory for the pharmacist. The results are far better than the study conducted in India^[17, 22].

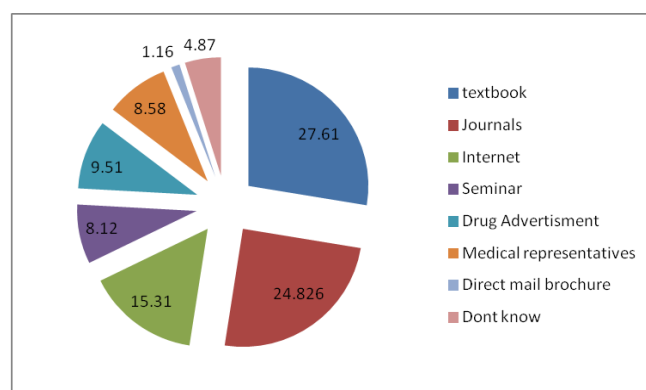


Fig 2. Most reliable source of ADR from students' point of view

To the best of our knowledge, this is the first study that evaluates the knowledge and perception of pharmacy students toward pharmacovigilance and ADRs reporting in Pakistan. The present study revealed a positive attitude and perception of pharmacy students towards ADR reporting and pharmacovigilance. The students realize the importance of pharmacist being health care professional to report ADR which is a good indication for providing pharmaceutical care as it is revealed that the effective participation of the pharmacy students has led to increase in number of ADR-reporting^[14]. Several studies have shown that Adverse drug reaction reporting can be improved by providing appropriate education^[23, 24], spending further time with patients, creating more knowledge^[25], informing how to report adverse drug reactions to senior pharmacy students, making reporting system simple, and acknowledging the receipt of the report and participation of the pharmacists in ward rounds^[26].



Conclusion

It is concluded that pharmacy students were motivated to practice pharmacovigilance during their clerkship as well as professional career. Incessant monitoring on ADRs of drugs and appropriate documentation of the drug safety data is needed to generate high-quality treatment outcomes. Being the future healthcare professionals, pharmacy students should be meticulously involved in pharmacovigilance activities through their interactions with both prescribers and patients during the clerkship. They should be adequately train for the task of ADR monitoring and reporting in their future careers which will ultimately set a concrete foundation in healthcare system of Pakistan.

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

Not commissioned; externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.