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PHARMACOVIGILANCE AND ADVERSE DRUG REPORTING SYSTEM;

AWARENESS IN PAKISTAN: PHARMACY STUDENTS AND PROFESSIONALS APPROACH AND FACTS

Dr. Huma Ali[1], Dr. Farya Zafar[2], Dr. Safila Naveed[3], Dr. Shabana N. Shah[4], Saba A. Baloch[5], Ghazala Raza Naqvi[6], Shehla Siddiqui[7]

1. B.Pharm, M.Phil, Ph.D
Associate Professor
Department of Pharmaceutics
Faculty of Pharmacy,
Ziauddin University, Karachi,
Pakistan
2. B.Pharm, M.Phil, Ph.D
Associate Professor
Department of Pharmaceutics
Faculty of Pharmacy,
Ziauddin University, Karachi,
Pakistan
3. B.Pharm, M.Phil, Ph.D
Associate Professor
Faculty of Pharmacy,
Jinnah University for Women,
Karachi, Pakistan
4. B.Pharm, M.Phil, Ph.D
Martin Dow Pvt Ltd.
5. Pharm D, M.Phil (Scholar)
Senior Lecturer
Department of Pharmacy Practice
Faculty of Pharmacy,
Ziauddin University, Karachi,
Pakistan
6. Assistant Professor
Faculty of Pharmacy,
Federal Urdu University, Karachi,
Pakistan
7. Senior Lecturer
Faculty of Pharmacy,
Ziauddin University, Karachi,
Pakistan

Correspondence Address:
Huma Ali
Faculty of Pharmacy,
Ziauddin University,
Karachi, Pakistan
humaali80@live.com

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ABSTRACT: This study was conducted to assess the pharmacy students and graduate knowledge and awareness about pharmacovigilance & adverse drug reporting (ADR) system in Karachi, Pakistan. **Objectives:** This study was designed to identify the trends, perception and approaches of pharmacy students and graduate towards current scenarios of pharmacovigilance and ADR contextual to our setting. **Study Design:** It was cross sectional, qualitative study. **Setting:** Pharmacy final year students and fresh graduates of two public and two private sector universities were included in the study. **Period:** Data was collected between January to August, 2015. **Method:** Relevant information was collected using questionnaire with 18 open ended and 7 close ended questions. 400 final year participants and 150 fresh graduates were incorporated in this survey. SPSS 20.0 was used to analyze the results and Percent, frequencies and mean scores were calculated for various outcomes. **Results:** Response rate of final year students and fresh graduates was found (97%, n = 388) and (88%, n= 132) respectively. Students level of awareness about pharmacovigilance was found (54%, n =216) in final year students while little higher rates were observed (78%, n=110) in graduates. Concept of pharmacovigilance gained through pharmacy curriculum was calculated 45% rated by final year students. The pharmacovigilance knowledge mean score was found to be 2.368.5 and 2.886.3 for final year students and fresh graduates respectively. 58% total respondents were aware with relationship between the drug and the ADR. **Conclusion:** The results of this study demonstrate that pharmacy students of final year in public and private sector universities of Pakistan are aware with some basic knowledge of ADRs and pharmacovigilance, but it is a need of time to incorporate more contents of such aspects in curriculum with some practical exposure that how to report ADRs.

Keywords: pharmacovigilance, adverse drug reporting, pharmacy curriculum

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INTRODUCTION

Adverse drug effects have been a major prevailing element of indisposition, fatality and poor economic end result.[1,2] The knowledge and undertakings executed to identify, evaluate, apprehend and avert adverse drug effects or any other drug related problem is defined as pharmacovigilance.[3,4] As pharmacovigilance and post marketing surveillance are used interchangeably; therefore, maintaining pharmacovigilance of new drug is imperative. It is also mandatory to identify and prevent adverse drug effects as early as possible for the welfare of the patients at a legit cost. The foundation of pharmacovigilance is reporting of ADRs by health professionals during the initial evaluation of a drug.[5,6]

The role of a pharmacist has been unbarred from preparation and dispensing of prescribe drugs to different particulars of patient care. Some of these roles include ADRs reporting, improving health of patients, and improving economic outcomes.[1,7] Pharmacists are better equipped to practice pharmacovigilance by presenting quality reports.[8]

Pharmacist are better able to play their part in pharmacovigilance when they are better educated at their graduate levels about the knowledge concerning the process, procedure, and importance of ADE reporting.[9] Numerous studies have pointed out pharmacists play a crucial role in ADR monitoring and reporting, despite that it has been observed over and over again that still pharmacists lack the awareness and knowledge about the protocols and guidelines used by their corresponding countries, drug regulatory authorities responsible for evaluating ADRs.[10-12] The instructors at Pharm.D institutes must provide ample knowledge and practical skills to their students on pharmacovigilance to better prepare them in terms of patients and drug safety.[13]

RATIONALE OF STUDY

Small numbers of reports have been published in past few years in Pakistan related to pharmacovigilance and adverse drug reporting scenarios. There is unevenness in scope and quality of these studies. Nevertheless, enough information still needs to be accumulated from large series of studies, to permit analyses of data regarding these important issues. The current study will focus on these elements at various levels. Results of this study can be used for educative purposes both in the professional settings and academia to develop proper standards of practices contextual to our settings.

METHODS

Study Design

The design of this qualitative study was observational, and cross-sectional.

Settings

This study was designed to collect information about pharmacovigilance perception and awareness of ADR reporting system in Karachi Pakistan. Several public and private sector pharmacy institutes are located in Karachi. Beside that high number of graduating pharmacist are working in different capacities in various healthcare setups. As pharmacovigilance and adverse drug event monitoring is vital concern nowadays, this study was planned with the objective to assess the approaches and facts related to pharmacovigilance in selected cohorts of final year and graduated (professional) students of different universities.

Study Duration

Study was conducted between January to August, 2015.

Study Population

Population of the study comprised of two cohorts. One is of enrolled pharmacy final year students, while other included professionals or graduates working in various healthcare facilities.

Study Tool and Data Collection

Data was collected using well-constructed questionnaire containing 18 open ended and 7 close ended questions. Reliability of survey was calculated by determining the Cronbach's alpha value (0.809). It was calculated by administering the same questionnaire to another group of respondents who did not actually participated in the study.

SELECTION OF SAMPLE

Inclusion and Exclusion Criteria

Only final year students of different pharmacy school were incorporated. Pharmacy graduates involved in healthcare setups as clinical and hospital pharmacist, in marketing and regulatory sections of pharmaceuticals and other specialized pharmacy services personnel's were included.

Students of first to fourth year were not recruited in this study.

Sample Size

Sample size of study comprised of 400 students from final year while 150 graduates (professionals)

from different healthcare settings and academia. Informed consent of each participant was collected with questionnaire.

DATA VARIABLES

Demographic information of participant is summarized in Table-I. In this survey based questionnaire respondent's gravity of knowledge regarding pharmacovigilance, its significance, adverse drug reaction, monitoring and reporting system was assessed using multiple choice options. The subsequent section incorporated elements premeditated to evaluate facts about pharmacovigilance knowledge and ADR reporting. Respondents were asked to choose the accurate response from multiple-choice response options. While non-comparative scaling technique is used to evaluate the perception of respondents. Staple scale was used for rating, composed of five comparative statements (the higher the number, the more accurately the term describes the object), (Table-II). Concord bias of beliefs was prevented by incorporating the bipolar words where needed. Results were analyzed using descriptive statistical approach.

QUALITY PLEDGE OF DATA

Study tool was elucidated in detail before application. In order to defend the exactness (accuracy) of outcomes, all questionnaires were filled under direction of the evaluators and reviewed and checked carefully before they collected.

DATA ANAYLYSIS

SPSS 20.0 was used to analyze the results and percent, frequencies and mean scores were calculated for various outcomes.

RESULTS

Pharmacy schools students of final year from public and private sector universities were incorporated in this study. Fresh graduates of pharmacy were also included in this study. The demographic facts of study participants are presented in Table-I. Data was collected between January to August, 2015 using well-structured questionnaire with 18 open ended and 7 close ended questions. SPSS 20.0 was used to analyze the results and Percent, frequencies and mean scores were calculated for various outcomes. Response rate of final year students and fresh graduates were calculated and found 97% (n = 388) and 88% (n= 132) respectively. Students altitude and perception about pharmacovigilance awareness was found to be 54% (n =216) in final year students while little higher rates were observed (78%, n=110) in graduates. The mean score for awareness about pharmacovigilance and ADR in both cohorts is summarized in Table-II. Knowledge associated queries and proportion of correct statements are presented in Table-III. Pearson correlation was used to assess the association among training and reporting of ADR (Table IV-V). Figure-I showed the participants response toward pharmacovigilance course.

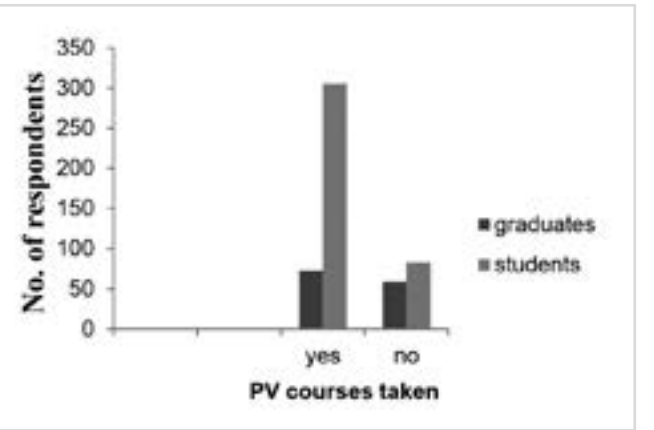

Figure-1. Response of respondents towards pharmacovigilance course

DISCUSSION

Adverse drug reactions (ADRs) are widespread reasons of high morbidity and associated mortality in healthcare facilities, and accounts for 5-20% hospital admittance.[14-15] The Role of pharmacists is vital in identification and management of ADR and effective execution of pharmacovigilance agenda. Such activities can widely be used in hospital setups due to the direct access to the relevant information and materials essential to report ADRs.[16] In past few year participation and training of pharmacy students towards ADR and its protocol of reporting has resulted in amplified documented literature of ADRs[17-19] This study was conducted with the objective to determine the

Sex	Fresh Graduate (N=132)		Final Year Students (N=388)	
	Total number	%	Total number	%
Male	43	32.5	133	34.2
Female	89	67.4	255	65.7

Table-I. Demographic presentation of respondents (n=520)

Final year students (n=388)		Fresh graduates (n=132)		P1 (n=120)	
score	Frequency	score	Frequency	score	Frequency
1	129	1	18	1	34
2	114	2	32	2	22
3	47	3	41	3	17
4	69	4	29	4	29
5	29	5	12	5	18
Mean Score = 2.368.55		Mean Score = 2.886.36		Mean Score =2.791.66	
P2 (n=120)		P3 (n=74)		P4 (n=74)	
score	Frequency	score	Frequency	score	Frequency
1	43	1	19	1	27
2	14	2	12	2	07
3	29	3	23	3	16
4	18	4	15	4	13
5	16	5	05	5	11
Mean Score = 2.583.33		Mean Score = 2.662.16		Mean Score = 2.648.64	

Table-II. Attitude/perception of respondents about pharmacovigilance and adverse drug reaction reporting

Note:P1 &P2: Public Sector Universities : P3&P4 : Private Sector Universities
Score: 1=poor, 2=inadequate, 3=fair, 4=good, 5=excellent

Questionnaire Statements	Fresh graduate answered appropriately (n=132)		Final year students answered appropriately (n=388)	
	No.	%	No.	%
Description of Pharmacovigilance	119	90.15	294	75.7
regulatory body in Pakistan responsible to control ADR and pharmacovigilance	98	74.2	189	48.72
Definitional aspects of ADR	107	81.0	315	81.1
Types of ADR	102	77.2	304	78.3
Sequencing of ADR	89	67.4	176	45.3
Interrelation of ADR with drug	96	72.7	279	71.9
Protocol of ADR reporting	91	68.9	182	46.9
Knowledge regarding existing pharmacovigilance program in Pakistan	104	78.7	235	60.5
Perception towards ADR reporting	128	96.9	313	80.9
Extent of contents coverage of pharmacovigilance and ADR	106	80.3	354	91.2
Knowledge about ADR preventive strategies	87	65.9	149	38.4
Have you ever attended any conference/training/ workshop for ADR	53	40.1	104	26.8
belief to institute ADR and pharmacovigilance centers	109	82.5	309	89.6

Table-III. Responses of Final year students and fresh graduates towards pharmacovigilance and ADR

Count		ADR Training		Total	Ever reported ADR		Total
		Yes	No		Yes	No	
Respondents	Male	15	28	43	11	32	43
	Female	38	51	89	15	74	89
Total		53	79	132	26	106	132

Table-IV. Detail of respondents included to calculate the association among training and reporting of ADR.

Parameters	ADR Training				Ever reported ADR			
	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Value	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	0.736	0.391			1.396	0.237		
Continuity Correction	0.447	0.504			0.899	0.343		
Likelihood Ratio	0.743	0.389			1.353	0.245		
Fisher's Exact Test			0.451	0.253			0.251	0.171
Linear-by-Linear Association	0.731	0.393			1.386	0.239		
McNemar Test			0.268[a]				0.019[a]	
N of Valid Cases	132				132			

Table-V. Association among guidance of pharmacovigilance and adverse drug reaction reporting

Binomial distribution used.

pharmacy students and graduate knowledge and level of awareness about pharmacovigilance & adverse drug reporting (ADR) system in Karachi, Pakistan.

Most of the respondents were in support of effective System of ADR reporting. There was a common perception of majority of the respondent that courses of pharmacovigilance should be taught in detailed at various level of pharmacy curriculum. Few of the respondents from fresh graduate group (n=45, 34%) have also emphasized that credit hours of these course contents need to be increased. Response of respondents either they were taught or not the pharmacovigilance course was shown in Figure-1. 82.5% practicing graduates were agreed with the statement that monitoring and reporting centers of ADR must be customary in each health care setup. Regarding the protocol of ADR reporting, only 42.4% participants were aware with methodology and time frame of reporting system. During this study different factors were also investigated to improve the ADR reporting system, amongst them respondents from both cohorts stated that poor perception towards ADR reporting accounts 48.9%, no compensation 41.5%, time constraint 34.8%, and lack of training to detect ADR 29.4% (Table-III).

Students level of awareness about pharmacovigilance was found 54% (n =216) in final year students while little higher rates were observed (78%, n=110) in graduates. Concept of pharmacovigilance gained through pharmacy curriculum was calculated 45% reported by the final year students. The pharmacovigilance knowledge mean score was found to be 2.368.5 and 2.886.3 for final year students and fresh graduates respectively (Table-II). Most of the respondents had shown positive perception towards the importance of pharmacovigilance.

In this study about 90.15% and 81% fresh graduate and 75.7% &81.1% enrolled students answered appropriately regarding basic concepts of pharmacovigilance and ADR. Significant proportion of participant considered ADR reporting as professional responsibility. Awareness regarding regulatory setup responsible for ADR reporting and pharmacovigilance is significantly high in fresh graduate cohort in comparison to

final year students (74.2% *vs.* 48.72%). Relevant training by attending conferences, workshops, sessions or seminars on these subjects was comparatively low in both cohorts (40.1 *vs.* 26.8) (Table-III). Pearson's correlation coefficient was applied to determine the association among the pharmacovigilance training and frequency of ADR reporting. (n = 132 (professional graduate group), $P < 0.01$). An average and constructive association was observed (Table-IV-V). In another study it was reported that ineffective ADR reporting may be due to in appropriate training, lack of knowledge towards ADR reporting format and procedures and ignorance of the regulations.[14] Implementation of unified and standard sets of practice was enforced by most of the study respondents. From various study outcomes an inclination in pharmacist perception and approach towards pharmacovigilance and ADR reporting is also observed.[20-23]

As this study indicated the constructive correlation between pharmacovigilance guidance and ADR reporting systems (Table-V), it is now need of time to signify the monitoring of adverse events, and enforce an effective system of reporting to improve the drug safety. A consolidated team work with individuals from various levels of expertise like academia, healthcare setups, industries and regulatory agencies is strongly recommended to undertake such activities. Regular training of professionals in the area of pharmacovigilance and ADR reporting may also improve the situation. Patient counseling regarding self-reporting can also play important role along with the availability of necessary forms and resources.

CONCLUSIONS

In conclusion, current study illustrated the moderate level of awareness in student cohort in comparison to the fresh graduates who have shown superior acquaintance and approach. A common consensus towards the necessity of ADR was observed among all respondents. However it is strongly recommended to signify and clarify the pharmacovigilance and its related aspects at various levels of pharmacy education, and also in healthcare facilities through instructive training sessions. Since there are higher complexities associated with ADR like increased mortality and morbidity, which necessitates the estimation and reporting of these undesirable events. Such studies may be used as an eye opener to set priorities and to develop effective tools for the drug monitoring and sophisticated clinical judgment support systems, which interns contributed to enhance clinical success rates of treatments and can improve patient's safety.

CONFLICT OF INTEREST

No conflict of interest.

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“Nothing worth having comes easy.”

Unknown

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Dr. Huma Ali	Concept, Designing and writing of article	
2	Dr. Farya Zafar	Method section / questionnaire	
3	Dr. Safila Naveed	Data collection / compilation	
4	Dr. Shabana N. Shah	Data collection / compilation	
5	Saba A. Baloch	Data collection / compilation	
6	Ghazala Raza Naqvi	Data collection / compilation	
7	Shehla Siddiqui	Statistical evalustion	