Original Article

Impact of Educational Intervention for Improving Pharmacy Students' Knowledge of Pharmacovigilance and Adverse Drug Reactions Reporting

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ABSTRACT

Objective: Impact of Educational Intervention for Improving Pharmacy Students' Knowledge of Pharmacovigilance and Adverse Drug Reactions Reporting

Study Design: Descriptive / cross-sectional study

Place and Duration of Study: This study was conducted at the Department of Pharmacy, Lahore College of Pharmaceutical Sciences. Lahore in March 2018.

Materials and Methods: In this study, 133pharmacy students of both genders from fourth and final year classes having studied clinical pharmacy were included.. Institutional ethical committee approval was taken and the students were required to sign the informed consent. Survey using a pre-validated multiple choice questionnaire to assess the knowledge of pharmacovigilance and ADR reporting amongst the students was used before and after an educational intervention containing a power point lecture on the subject.

Results: 123 students returned the survey forms before and after the intervention. Student's age was ranging from 18 to 25 years. There were 50 male students and 73 female students, 42 had rural and 81 had urban back ground. The majority of the parents had a graduate degree. Overall score pre lecture showed a Mean of 7.55 ± 1.812and the score post lecture showed a Mean of 11.74 ± 2.353 with a P-value of 0.0001.

Conclusion: It is concluded that, the knowledge of pharmacovigilance and ADR reporting and awareness improved after the educational intervention. If regularly done on different forums and by different strategies this would improve the clinical practice of pharmacists by improving the ADR reporting process and culture.

Key Words: Pharmacovigilance; Adverse drug reaction; Pharmacists; Knowledge and awareness questionnaire; Educational intervention

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INTRODUCTION

Safety and Efficacy are the two outcomes followed after using a medicinal product or device. This is covered by Pharmacovigilance (PV) covering every aspect of the drug or device lifecycle. This begins during the preclinical phases I – III goes up to and beyond phase IV i.e. post marketing surveillance. This becomes the most important consideration for the healthcare. Article 21 of the constitution of the World Health Assembly requires the member states to adopt regulations concerning standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce'.

Since the disaster that occurred due to thalidomide in 1961 with use of the drug by pregnant mothers resulting in the birth of thousands of congenitally deformed infants, the first systematic international effort started to address the drug safety issues. The Sixteenth World Health Assembly (1963) adopted a resolution[1]that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and WHO technical report followed based on a consultation meeting held in 1971[2].

Pharmacovigilance is defined as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems'. Recently, its concerns have been widened to include: herbal, traditional and complementary medicine, blood products, biological, medical devices and vaccines[3– 5].

Clinical trials from phase I to III give limited information to regulatory authorities about the full

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safety profile. There is a lot of responsibility on healthcare workers to keep a close eye on these issues to prevent adverse events and itsincreased financial burden on hospitals[6].

With the importance pharmacovigilance has gained over the years, drug regulatory authorities have established national pharmacovigilance centers. There is a great need to improve further because of public expectations and the demands of modern public health[7].

Pakistan became an associated member many years ago and still has the same status. Recently the Pharmacy Services Directorate (which looks after Pharmacovigilance and Clinical research in Drug Regulatory Authority of Pakistan) has issued the Guidelines to be undertaken for performance of Pharmacovigilance Activities and also Med Vigilance Online Management System and is strengthening the whole process[8].

ADR reporting is the basis of any successful pharmacovigilance system. Identifying an ADR immediately and reporting it to the concerned pharmaceutical company and the national regulatory authority is the most important step. WHO defines ADRs as 'a response to a drug which is noxious and unintended, and which occurs at doses normally used in human for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'[9].

ADRs causes increase in mortality and morbidity and is related with increased financial loss[10].

Studies have shown that optimizing knowledge, attitude and practices (KAP) with regard to PV is important in formulating strategies to encourage ADR reporting[11].

Literature published examining KAP towards PV and ADR reporting among pharmacists was very low. Exploring causes of underreporting, shows that lack of knowledge and unfamiliarity of the reporting system were major discouraging factors for reporting ADRs[12-13].

MATERIALS AND METHODS

A cross-sectional descriptive study was conducted in Lahore College of Pharmaceutical Sciences. Fourth and final year students only willing to participate and having signed the informed consent were included. The questionnaire used was pre-validated and the whole process was given an approval by the college ethics review committee.

133 total students participated in the study. 66 students from fourth and 57 from final year completed and submitted the survey questionnaire. The demographic variables included characteristics like age, sex, residential status, parental educational status and usage of internet. The 16 multiple choice questions assessed the knowledge and awareness of pharmacovigilance and ADR reporting. Incorrect answer wasgiven"0" while the correct answer weremarked "1" for calculating the mean score.

The questionnaire was repeated after an educational intervention done by giving a presentation on pharmacovigilance, its definition, importance of ADR reporting and the process being followed by the national and international bodies. The overall percentage was calculated for both the classes on their responses for pre-lecture and post-lecture survey. Descriptive statistics for continuous variable was presented as Mean± SD and for categorical as proportion and percentage. Paired T-test was used to calculate the mean difference. Data was entered in SPSS version 24 and all statistical descriptive and analytical tests were done.

Objectives

1. To assess the knowledge and awareness regarding Pharmacovigilance and Adverse Drug Reaction Reporting amongst fourth and final year Pharmacy students.
2. To evaluate the effectiveness of an educational program for improving pharmacist knowledge of Pharmacovigilance and Adverse Drug Reaction reporting.

RESULTS

In this study 59.3% were females as compared to 40.7% males (Table 1) and 66% of participants' belonged to urban as compared to 34% from rural area. Majority of parents of the study population had done their graduation. (Table 2)

Correct response among the study participants regarding the healthcare professionals responsible for reporting ADRs in a hospital was 94 (76.4%) post-lecture as compared to 56 (45.5%) pre-lecture. Post-lecture 103(83.7%) gave the correct answer about the definition of Pharmacovigilance as compared to the pre-lecture response of 18(14.6%).

Important objective of Pharmacovigilance was correctly answered by 29(23.6%) prior to the lecture and after lecture correct response was 85(69.1%). Location of international center for ADRs monitoring was identified correctly by 85(69.1%) in post-lecture response as compared to 12(9.8%) in the initial response.

To the question on commonly used scale for assessment of causality of an ADR 114 (92.7%) werecorrect in their Post-lecture response as compared to 72(58.5%) pre-lecture. WHO online database for ADRs reporting was correctly marked by 96 (78%) after the lecture whereas only27(22%) could before. Rare ADRs can be identified in the following phase of clinical trial was correctly identified by 47(38.2%) after listening to the lecture as compared to 19(15.4%) pre-lecture. Regarding the importance of reporting ADRs correct answer was identified by 110 (89.4%) in the post-lecture response group as compared to 105(85.4%) pre-lecture.

Table No.1: Gender and region demographics

Demographics	Frequency	Percentage
Male	50	40.7
Female	73	59.3
Rural	42	34.1
Urban	81	65.9

Table No.2: Parent's education level

	Father		Mother	
Education Level	Frequency	%age	Frequency	%age
PG	13	10.6	9	7.3
Primary	13	10.6	19	15.4
Matric	32	26.0	28	22.8
Secondary	8	6.5	11	8.9
Under-graduate	19	15.4	18	14.6
Graduate	38	30.9	38	30.9

About which Regulatory body is responsible for monitoring ADRs in Pakistan correct post-lecture response was 112(91.1%) as compared to pre-lecture response of 66(53.7%).

The response about which Common method is used to monitor ADRs of new drugs once they are launched was given correctly in post-lecture group by 75(61%) as compared to 47(38.2%) pre-lecture. Regarding what type of ADRs is to be reported 118 (95.9%) in the post-lecture response gave correct answer in comparison to 105(85.4%). Regarding the knowledge of ADR reporting being a Professional obligation pre-lecture response was 90(73.2%) as compared to post-lecture response106(86.2). On the question which measures are to be taken when ADR is suspected students after the lecture responding correctly were 112(91.1%) as compared to 103(83.7%) pre-lecture . (Table 3).

Table No.3: Participant's response comparison

Characteristics	Answer	Pre-lecture response	Post-lecture response
The healthcare professionals responsible for reporting ADRs in a hospital	Incorrect	67(54.5%)	29(23.6%)
	Correct	56(45.5%)	94(76.4%)
Definition of Pharmacovigilance	Incorrect	105(85.4%)	20(16.3%)
	Correct	18(14.6%)	103(83.7%)
Important objective of Pharmacovigilance	Incorrect	94(76.4%)	38(30.9%)
	Correct	29(23.6%)	85(69.1%)
Location of international center for ADRs monitoring	Incorrect	111(90.2%)	38(30.9%)
	Correct	12(9.8%)	85(69.1%)
Commonly used scale for assessment of causality of an ADR	Incorrect	51(41.5%)	9(7.3%)
	Correct	72(58.5%)	114(92.7%)
WHO online database for ADRs reporting	Incorrect	96(78%)	27(22%)
	Correct	27(22%)	96(78%)
Rare ADRs can be identified in the following phase of clinical trial	Incorrect	104(84.6%)	76(61.8%)
	Correct	19(15.4%)	47(38.2%)
ADR and its causative drug	Incorrect	66(53.7%)	80(65%)
	Correct	57(46.3%)	43(35%)
Regarding classification of ADRs	Incorrect	18(14.6%)	13(10.6%)
	Correct	105(85.4%)	110(89.4%)
It is important to report ADRs because it leading to	Incorrect	27(22%)	18(14.6%)
	Correct	96(78%)	105(85.4%)
Regulatory body is responsible for monitoring ADRs in Pakistan	Incorrect	57(46.3%)	11(8.9%)
	Correct	66(53.7%)	112(91.1%)
Common method to monitor ADRs of new drugs once they are launched in the market	Incorrect	76(61.8%)	48(39%)
	Correct	47(38.2%)	75(61%)
Have you read any article on prevention of Adverse Drug Reaction?	Incorrect	87(70.7%)	84(68.3%)
	Correct	27(22%)	39(31.7%)
What type of ADRs to be reported?	Incorrect	18(14.6%)	5(4.1%)
	Correct	105(85.4%)	118(95.9%)
ADR reporting is a Professional obligation	Incorrect	33(26.8%)	17(13.8%)
	Correct	90(73.2%)	106(86.2)
Measures to be taken when ADR is suspected	Incorrect	20(16.3%)	11(8.9%)
	Correct	103(83.7%)	112(91.1%)

Table No.4: Comparison and correlation between responses

	Mean	Standard. Deviation	Correlation	Test Statistic (Paired T-test)	P-Value ((Paired T-test))
Overall Score (Pre)	7.55	1.812	0.41	-20.17	0.000

DISCUSSION

Safety of products being used by the doctors and dispensed by pharmacists depend on the effective pharmacovigilance system which depends on the reporting of Adverse Drug Reactions by the healthcare professionals to the regulatory authorities and individual pharmaceutical company marketing the product.

Drugs are endorsed to be marketed having adequate evidence that the product has an encouraging benefit-to-harm ratio. It is evident from systematic review that after approval of the product for general use the regulatory authorities take required action, including warnings on the label, letter to the prescribers for caution and in serious reactions withdrawal of marketing authorization depending on reported adverse drug reaction.[14].

Studies published from Pakistan and the region showed evidence that the knowledge, awareness and reporting of ADR is poor amongst the healthcare professionals including pharmacists[15 - 17].

Most of the studies have suggested that improvement in the basic knowledge of these healthcare professionals can be achieved by reviewing and improving the curriculum is the first step and then later on continued medical education in the shape of workshops and seminars should be regularly held to support their clinical function[18, 20].

Our study prior to the educational intervention showed that only one third knew about the HCPs responsible for reporting, one fourth knew the definition of pharmacovigilance, one third knew of the important objective of pharmacovigilance, only few students knew of the location of international center for ADR monitoring, half of them knew of the commonly used scale for assessment of causality of an ADR, one third knew about the WHO online database for ADR reporting, only half knew about the regulatory body responsible for monitoring ADR in Pakistan, very few knew about the types of ADR to be reported and only 11% new of the measures to be taken on suspicion of an ADR. Similar results were seen on other questions asked. The results shown in our study were similar to the results reported in the literature[21 - 22].

After the power point presentation on the subject explaining the definition and importance of PVand ADR reporting there was a significant improvement in the results of the post-KAP survey. Pharmacists who were trained regularly in their departments for PVand ADR reporting knew more the purpose of ADR forms and the system as reported in different studies[20, 23]. Our study also showed that educational intervention is an accepted means of improvement in knowledge of pharmacovigilance and ADR reporting. Our findings are similar to previously reported studies[24 -25].

CONCLUSION

ADR reporting is the main source of pharmacovigilance. Not only having information of pharmacovigilance system but actually reporting the adverse drug reactions to the regulatory authorities and the concerned manufacturer is essential. Drug Regulatory Authority of Pakistan is an Associate member of the WHO monitoring Center and has set up a system which is required to be followed. Punjab government has also established Punjab Drug Control Unit for pharmacovigilance and ADR reporting. These will also function properly if the pharmacists and HCPs have the knowledge and awareness of the system and are willing to report the adverse drug reactions. This can only be achieved if proper education on the subject is imparted during the education of healthcare professionals, but also establishing a system where constant reminders are given in shape of continuing education by workshops, seminars, newsletters and other similar programs.

Author's Contribution:

Concept & Design of Study:	Ahmad Atif Mirza
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