



Factors Influencing Awareness of Drug Store Personnel about Pharmacovigilance

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Authors' contributions

This work was carried out in collaboration among all authors. Authors HS, MTB, SI and AJ designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author SNNS, SS, SWS, AH, MK and US managed the analyses of the study. Author SS and MUS managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Pharmacovigilance is an essential process when dealing with the medicines. It is one of the basic roles of community pharmacist. This role is not found in practice. Due to lacking this role, monitoring of adverse drug reactions and awareness to report them is missed in the society. However, no significant data has been published to exhibit the role of community pharmacists in

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Pharmacovigilance. This study was aimed to help in stowing the pharmacist role, in community Pharmacovigilance of Pakistan, to give awareness not only to community pharmacists but to regulatory authorities to establish policies regarding ADRs. A cross-sectional study was conducted through a pre-validated questionnaire. This study was conducted in 16 Districts of Sindh Province of Pakistan. 368 pharmacies/ medical stores responded to the self administered questionnaire. The results showed dependence of Awareness to the Pharmacovigilance upon Professional Status, Education of Participants and Experience of study population in pharmacies/ medical stores.

Keywords: Pharmacovigilance; community pharmacy; regulatory; ADRs; public health.

1. INTRODUCTION

In Pakistan, principally the health facility is covered by two sectors; Public Health Care Sector and Private Health Care Sector. Public hospitals are contributed to 25% and the rest 75% is covered by private sectors. In Pakistan Doctor to patient ratio is not sufficient and is reported as 1:1300 and nurse to population ratio is 1:3568 which is quite alarming [1]. Public health delivery system acts as an incorporated health composite which is organizationally supervised at district level. It comprises of Primary and Secondary Health System. The Primary Health system comprises of Basic Health Units (BHUs) and Rural Health Centers (RHCs). On the other hand the secondary health care comprising of first/second referral services offering acute, inpatient ambulatory care is provided at Tehsil/Taluka headquarter hospitals (THQ) and District headquarter hospitals (DHQs) which are assisted by teaching hospitals. Doctors, traditional healers, pharmacists, drug vendors, nurses along with shopkeepers, unqualified practitioners and laboratory technician comprise the private health care system. Out of total spending on health care the private spending in Pakistan is estimated to be 70% out of which 98% expense is borne by the households [2]. The majority of the population in Pakistan is using health facilities by paying from their pocket. Only 27% of the total population is using free health services and these include government servants and armed persons [3]. Pakistan is one among 57 countries that has a severe shortage of health care workers including doctors, nurses, auxiliary staff, paramedic staff and managerial staff [4].

Drugs are chemicals that react to external stimuli such as microbial agents, humidity, heat, light, and dust. In many cases, such reactions can lead to physical modifications including discoloration of the drug product. In many other cases, the reaction may influence the drug more fatally resulting in the decrease or elimination of

its efficiency and/or potency [5]. Dispensing of drugs after the order is produced, is then processed by pharmacist or a pharmacy technician and then finally dispensed by a pharmacist [6].

Pharmacovigilance (PV) is reporting of ADRs, which may cause increase in hospital stay. All drugs can produce ADRs, but not all patients develop the same level and type of ADRs [7-9]. Pharmacovigilance is one of the basic roles of community pharmacist. This role is not found in practice. Due to lacking this role, monitoring of adverse drug reactions and awareness to report them is missed in the society. However, no significant data has been published to exhibit the role of community pharmacists (CP) in Pharmacovigilance [10-13]. The knowledge and practice of CP is thought to be insufficient, which may lead to lack of awareness in society concerning the reporting of adverse drug reactions [14-15]. This study was aimed to help in stowing the pharmacist role, in community Pharmacovigilance of Pakistan, to give awareness not only to community pharmacists but to regulatory authorities to establish policies regarding ADRs. This study was also designed to help the community pharmacist to provide a tool to improve knowledge regarding the Pharmacovigilance (PV) and to serve as an indicator for practicing clinical care within Pakistan.

2. METHODOLOGY

500 community pharmacies/ medical stores from 16 districts of Sindh Province of Pakistan were approached after selection using simple random sampling technique using the list of Community Pharmacies/Medical Stores of Sindh. After getting the written informed consent and fulfilling the inclusion criteria, 368 community pharmacies/ medical stores were included in the study. Only those Community Pharmacies / Medical Stores were included in the study, which had a valid Pharmacy Drug Sale License and were registered with Health Department,

Government of Sindh. A pre-validated questionnaire was furnished to the participants after having their written consent. An assurance was given to all participants that all information provided would be completely confidential and that the results would be incognito presented.

3. RESULTS AND DISCUSSION

The demographic characteristics of participants showed that 97.8% of the personnel at drug stores were male (Table 1). It was also found that most of the participants working at Pharmacies/ Medical Stores were in between 28 to 47 years of age (Table 2). Again it was found that two third of the participants were non-pharmacists while only 31% were pharmacists. Table 3 shows that 69% of the Pharmacies/ Medical Stores were lacking the service of pharmacist as qualified person to deal with dispensing of medicines. Table 4 shows that 58.1% were having education till 12th grade only. 10.5% were having graduate and above level of education but were not amongst the pharmacists. Only 31.3% of the personnel working at Pharmacies/ medical stores were pharmacy graduates or masters in pharmacy. Table 5 exhibits that 12% of the study population was based on less than 2 years of experience. Most of the participants of the study population were having 6-19 years of experience at pharmacies/ medical stores (33.4%). It was found that only 18.5% of the population was aware of the

terminology of Pharmacovigilance (PV), while 81.5% were unaware of PV (Table 6). Table 7a shows Chi-Square Test for Dependence of Awareness upon Professional Status. Pearson Chi-Square value was 1.306 with p-value less than 0.05, which shows that the results were significant and acceptance of alternate hypothesis, which showed that there was significant association between awareness of PV and Professional Status of the participants of the study. Table 7b shows Phi Coefficient and Cramer's V values that exhibited moderate association between the two variables. Table 8a shows Chi-Square Test for Dependence of Awareness upon Experience of Participants in Pharmacies/ Medical Stores. Pearson Chi-Square value was 69.065 with p-value less than 0.05, which shows that the results were significant and acceptance of alternate hypothesis, which showed that there was significant association between awareness of PV and Professional Status of the participants of the study. Table 8b shows Phi Coefficient and Cramer's V values as 0.433, which exhibits that there was a very strong association between the two variables. Table 9a shows Chi-Square Test for Dependence of Awareness upon Education Level of the Participants. Pearson Chi-Square value was 27.326 with p-value less than 0.05, which shows that the results were significant and acceptance of alternate hypothesis, which showed that there was significant association

Table 1. Gender of the participants

	Frequency	Percent
Male	360	97.8
Female	8	2.2
Total	368	100.0

Table 2. Age range of the participants

Age Range	Frequency	Percent
18-27 years	58	15.8
28-37 years	97	26.4
38-47 years	153	41.6
48-57 years	53	14.4
58-67 years	5	1.4
Above 67 years	2	0.5
Total	368	100.0

Table 3. Professional status of the participants

Professional Status	Frequency	Percent
Pharmacist	114	31.0
Non-pharmacist	254	69.0
Total	368	100.0

between awareness of PV and Professional Status of the participants of the study. Table 9b shows Phi Coefficient and Cramer's V values as 0.272, which exhibits that there was a moderately strong association between the two variables.

Table 4. Educational level of the personnel at pharmacy/ medical stores

Qualification		Frequency n (%)	
Less than Graduation	Matriculation	105 (28.5%)	214 (58.1%)
	Compounder (Matriculation)	4(1.1%)	
	Intermediate	105(28.5%)	
Graduation and Above (Other than Pharmacy)	B.A	4(%)	39 (10.5%)
	B.Com	2(0.5%)	
	B. Sc	31(8.4%)	
	M. Sc	2(0.5%)	
Graduation and above (Pharmacy)	B. Pharmacy	74(20.1%)	115 (31.3%)
	Pharm. D	30(8.2%)	
	Masters Degree in Pharmacy	11(3.0%)	
Total		368 (100%)	

Table 5. Experience of personnel at pharmacy and medical stores

Experience (Years)	Frequency	Percent
Less than 2	44	12.0
3-5	42	11.4
6-10	123	33.4
11-15	71	19.3
16-20	44	12.0
21-30	9	2.4
Above 30	35	9.5
Total	368	100.0

Table 6. Awareness of the participants regarding the terminology of pharmacovigilance

Awareness Level	Frequency	Percent
Correctly Defined the PV	68	18.5
No Awareness with the Terminology of PV	300	81.5
Total	368	100.0

Table 7a. Dependence of PV awareness upon professional status by chi-square statistics

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.306 ^a	1	0.0253		
Continuity Correction ^b	0.995	1	0.0318		
Likelihood Ratio	1.276	1	0.0259		
Fisher's Exact Test				0.250	0.159
N of Valid Cases	368				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 21.07.
b. Computed only for a 2x2 table

Table 7b. Dependence of PV awareness upon professional status by phi and Cramer's v statistics

Symmetric Measures ^a			
		Value	Approx. Sig.
Nominal by Nominal	Phi	0.060	0.253
	Cramer's V	0.060	0.253
N of Valid Cases		368	

a. Correlation statistics are available for numeric data only.

Table 8a. Dependence of PV awareness upon drug store experience by chi-square statistics

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	69.065 ^a	6	0.000
Likelihood Ratio	66.012	6	0.000
N of Valid Cases	368		

a. 1 cells (7.1%) have expected count less than 5. The minimum expected count is 1.66.

Table 8b. Dependence of PV awareness upon drug store experience by phi and Cramer's V statistics

Symmetric Measures^a			
		Value	Approx. Sig.
Nominal by Nominal	Phi	0.433	0.000
	Cramer's V	0.433	0.000
N of Valid Cases		368	

a. Correlation statistics are available for numeric data only.

Table 9a. Dependence of PV awareness upon education level by chi-square statistics

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	27.326 ^a	9	0.001
Likelihood Ratio	28.772	9	0.001
N of Valid Cases	368		

a. 9 cells (45.0%) have expected count less than 5. The minimum expected count is .37.

Table 9b. Dependence of PV awareness upon education level by chi-square statistics phi and Cramer's V

Symmetric Measures^a			
		Value	Approx. Sig.
Nominal by Nominal	Phi	0.272	0.001
	Cramer's V	0.272	0.001
N of Valid Cases		368	

a. Correlation statistics are available for numeric data only.

4. CONCLUSION

It was concluded that Medical Stores/ Pharmacies, where qualified person as Pharmacist was present, the awareness of Pharmacovigilance was found. However the awareness level was found to be dependent upon Education, experience and professional status.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

Ethical approval was obtained from Ethics Review Committee (ERC) of Ziauddin University. A written informed consent form was also taken from each of the participants.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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