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Knowledge, Attitude, Practices, and Barriers of Pharmacovigilance among Healthcare Workers: A Cross-sectional Survey from Lahore, Pakistan

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Knowledge, Attitude, Practices, and Barriers of Pharmacovigilance among Healthcare Workers: A Cross-sectional Survey from Lahore, Pakistan

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Abstract

Background: Adverse drug reactions (ADRs) are associated with increased length of hospital stay, permanent disability and even death.

Objectives: The purpose of this study was to assess knowledge, attitude, practice (KAP), and barriers related to Pharmacovigilance (PV) among Pakistani healthcare workers (HCWs).

Methods: A cross-sectional study was conducted in the second largest metropolitan city (Lahore) of Pakistan during a period of 4 months (June–September 2018). A self-administered questionnaire was used to collect data from the doctors, pharmacists, and nurses from 8 tertiary care hospitals, recruited via convenient sampling. All data were analyzed in SPSS version 21.

Results: A total of 363 participants (125 doctors, 83 pharmacists and 155 nurses) were recruited. The median [inter-quartile range (IQR)] knowledge score was 6 (3), with 44.6, 41.9, and 13.5% of participants having poor (score < 6), moderate (score 6–9), and good (score ≥ 10) PV related knowledge, respectively. Additionally, the median (IQR) attitude and practice score were 7 (3) and 4 (2), respectively [good attitudes 24.8% (score ≥ 8); good practices 33.9% (score ≥ 5)]. Pharmacist were found to have significantly better KAP related to PV than others ($p < 0.001$). Moreover, male HCWs had substantially better KAP than females.

Conclusion: Although pharmacist have better KAP scores than other HCWs, yet overall KAP of PV among study participants were inadequate. Thus, continuous training and teaching programs should be conducted to improve awareness and to promote ADR reporting.

Keywords: Knowledge, Barriers, Adverse drug reactions, Pakistan, Pharmacovigilance

1. Introduction

A drug is a peculiar entity having both therapeutics as well as unwanted or adverse effects. Adverse drug reaction (ADR) is defined as

any response to a drug which is noxious and unintended that occurs at doses normally used in patients for prophylaxis, diagnosis, treatment, or modification of physiological function [1]. ADRs are not only associated with increased length of

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hospital stay and economic burden but may also lead to serious consequences like congenital anomaly, permanent disability, life threatening conditions and death [2,3].

The incidence of emergency hospitalization due to ADRs ranges 0.2–41.3% globally, among them 28.9% are preventable [4]. In US, 15% of hospital admissions are due to ADRs. The quality assurance and medicine safety team of WHO is continuously promoting safe use of drug [5]. Pharmacovigilance (PV) 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” [6]. Timely identification and management of ADRs can prevent serious drug-related adverse events. Although medical professionals are responsible for reporting ADRs, often times they are not able to do it efficiently either due to lack of time or the inability to identify and report ADRs which results in under reporting of ADRs [7,8].

There was no established PV center in Pakistan until 2011. In 2012, the Supreme Court of Pakistan issued an order to the government to establish an independent drug regulatory authority after the incidence at Punjab Institute of Cardiology that resulted in more than 200 deaths and hospitalization of 1000 people that was related to adulteration in locally manufactured drugs [7]. Thus, Drug Regularity Authority of Pakistan (DRAP) was established in 2012 to monitor drug related practices in Pakistan. The country's first PV center also established in DRAP where HCWs could report ADRs. In 2018, Government of the Punjab took an excellent initiative with the development of ‘Pharmacovigilance wing’ for online reporting of ADRs occurring throughout the health facilities in Province, Punjab. Since HCWs knowledge, attitudes, and practices (KAP) related to ADRs are the key predictors for the efficient working of the PV system. The current study was carried out to estimate the knowledge, attitude, practice, and barriers of PV in Lahore, the capital of province Punjab, Pakistan.

2. Methods

2.1. Participants and study settings

A descriptive cross-sectional study was carried out among HCWs (medical doctors, nurses, and pharmacists) in Lahore which is the second largest metropolitan city of Pakistan. Data were gathered from 9 public, and 2 private tertiary care hospitals (Lahore General Hospital, King Edward Medical University/Mayo Hospital, Punjab Institute of

Cardiology, Services Hospital, Children Hospital, Shaikh Zaid hospital, Doctors hospital, Shoukat Khanum Memorial Cancer Hospital, and Mid City hospital) between June–September 2018. A convenient sampling strategy was used to recruit HCWs providing services in the aforementioned hospitals. Investigators approached HCWs and briefed them about the purpose and nature of the study. Those who were willing to participate were enrolled and the study questionnaires (hard copies) were administered.

2.2. Ethical consideration

Ethical approval of the current study was acquired from the Human Research Ethics Committee of Punjab University College of Pharmacy, University of the Punjab, Lahore, Pakistan. A verbal informed consent was obtained from every volunteer prior to the administration of study instrument. Moreover, participants’ were guaranteed of the confidentiality of their responses.

2.3. Sample size estimation

We calculated the sample size by using the proportional formula of OpenEpi (<https://www.openepi.com/SampleSize/SSPropor.htm>) by assuming the population size of 100,000 and anticipated frequency of 50%. The maximum required sample size was 384 HCWs at confidence interval 95%.

2.4. Data collection instrument

A self-administered questionnaire was developed to measure the knowledge, attitudes, practices, and barriers of ADR reporting from published literature [9–15]. The content validation of the questionnaire were performed by a panel of experts from Punjab University College of Pharmacy, University of the Punjab, Lahore, Pakistan. Minor revisions were recommended by the expert panel in order to improve clarity and understanding of some of the questions. After revising the questionnaire in light of the panel's recommendations, it was pilot tested among 10 HCWs who reported that all items and their response options were comprehensible and relevant to PV/ADRs.

The final questionnaire was comprised of five sections (Appendix). Section-I had six items to collect demographic data. Section-II had 12-items regarding knowledge of PV and 1-item to enquire the source of information regarding ADRs. Knowledge score was computed by giving one point for

every right response and zero point for every wrong response. Knowledge score ranged from 0 to 12; participants were classified as having poor, moderate and good knowledge if their score was <6, 6–9 and >9, respectively. Section-III had 10-items to evaluate the attitude of HCW towards PV. Attitude score was computed by giving one point for every right response and zero point for every wrong response. Attitude score ranged from 0 to 10; participants with scores ≥ 8 were considered to have positive attitude toward pharmacovigilance. Section-IV had 7-items to assess practices-related to PV. Practice score was computed by giving one point for every good practice and zero point for every puny practice. Practice score ranged from 0 to 7; participants with scores ≥ 5 were considered to have better practice-related to pharmacovigilance. Section-V had 6 questions regarding the barriers of ADR reporting.

2.5. Statistical analysis

All data were entered and analyzed in SPSS version 21 for Windows. Continuous and categorical variables were expressed as median (interquartile range) and number (percentage), respectively. Mann–Whitney U and Kruskal–Wallis H tests were used to assess the significant ($p < 0.05$) difference of knowledge, attitude, and practices among demographic variables.

3. Results

3.1. Participants' characteristics

A total of 524 individuals were approached, of them, 363 gave consent and filled-out study instruments, with a response rate of 69.3% (125 medical doctors, 83 pharmacists, and 155 nurses). Demographics of the study sample are shown in Table 1. The median age of study participants was 28 years, with a preponderance of females (68.9%).

3.2. Knowledge of pharmacovigilance

Reponses to knowledge items regarding ADR are presented in Table 2. In this study, 57% of the participants' knew what Pharmacovigilance was and 62.8% knew its purpose. Moreover, 62% chose the correct definition of ADRs and 43.8% knew the right classification of ADRs. Interestingly, majority of Pakistani health professionals did not know where to report ADRs after identification. The median (IQR) of overall knowledge was 6 (3), with 44.6%, 41.9%, and 13.5% of the study participants having

Table 1. Demographic details of participants.

Variables	N (%)
Age (years)	
≤ 25	87 (24.0)
26–30	141 (38.8)
31–35	80 (22.0)
≥ 36	55 (15.2)
Gender	
Male	113 (31.1)
Female	250 (68.9)
Profession	
Doctors	125 (34.4)
Hospital Pharmacists	83 (22.9)
Nurses	155 (42.7)
Designations	
Doctors	
Assistant professor	5 (4.0)
Registrar	5 (4.0)
PGR/medial officer	79 (63.2)
House officer	36 (28.8)
Pharmacist	
Senior pharmacist	18 (21.7)
Pharmacist	65 (78.3)
Nurses	
Head nurse	26 (16.5)
Staff/charge nurse	129 (83.5)
Work experience (years)	
≤ 1	71 (19.6)
>1-3	119 (32.8)
>3-5	45 (12.5)
>5-9	82 (22.6)
≥ 10	46 (12.7)

poor, moderate, and good ADR knowledge, respectively. There was a significant difference of ADR knowledge score among study participants ($p < 0.001$), with pharmacist having better knowledge scores than doctors as well as nurses (Table 3). Moreover, male HCWs had significantly higher knowledge scores than females. Majority of the participants reported that they were getting ADRs-related information from multiple sources namely textbooks, medical journals, drug information websites, medical representatives and seminars/conferences.

3.3. Attitude of health professionals towards pharmacovigilance

Participants' attitude toward PV are shown in Table 4. Majority of the participants (51%) stated that ADRs reporting was very time consuming whereas 54.7% stated that reporting of a just one ADR would make no substantial contribution to ADR reporting scheme. Moreover, 54.9% stated that the identity of HCWs who report ADRs should be kept confidential. The median (IQR) attitude score was 7 (3), with 28.4% HCWs having good attitudes

Table 2. Respondents' knowledge regarding pharmacovigilance.

Item	N (%)
1. Which of the following correctly defines Pharmacovigilance?	
A. The science and activities of detecting, assessing, understanding and preventing adverse effects or any other drug-related problems*	207 (57.0)
B. The science of detecting the type and incidence of adverse drugs reactions (ADRs) after a drug is marketed	81 (22.3)
C. The process of improving the safety of drugs	27 (7.4)
D. The science of monitoring ADRs happening in a Hospital	32 (8.8)
E. Do not know	16 (4.4)
2. Which of the following correctly describes the purpose of Pharmacovigilance?	
A. To enhance patient care and patient safety in relation to use of medicines*	228 (62.8)
B. To identify predisposing factors of ADRs	44 (12.1)
C. To identify unknown ADRs	29 (8.0)
D. To calculate incidence of ADRs	25 (6.9)
E. Do not know	37 (10.2)
3. Which of the following accurately defines an ADR?	
A. Any noxious or undesired effect of a drug occurring at normal doses, during normal use*	225 (62.0)
B. Adverse health outcomes associated with inappropriate drug use	66 (18.2)
C. Harm resulting from the use of substandard/counterfeit drugs	26 (7.2)
D. Harm caused by drug overdose	34 (9.4)
E. Adverse outcomes associated with drug impurity	8 (2.2)
F. Health problems associated with drug use	4 (1.1)
G. Do not know	—
4. What types of ADRs should be reported?	
A. All serious ADRs	112 (30.9)
B. ADRs related to herbal and non-allopathic drugs	21 (5.8)
C. ADRs to new drugs	18 (5.0)
D. ADRs to vaccines	15 (4.1)
E. Unknown ADRs of old drugs	20 (5.5)
F. All of the above*	177 (48.8)
5. Which of the following is the extended Rawlins–Thompson Classification of ADRs?	
A. Type A, B, C, D, E and F*	159 (43.8)
B. Type 1, 2, 3, 4, 5, 6 and 7	25 (6.9)
C. Known, unknown and common, uncommon	46 (12.7)
D. Reversible and irreversible	36 (9.9)
E. Do not know	97 (26.7)
6. Which of the following is major risk factor for ADRs occurrence?	
A. Arthritis	30 (8.3)
B. Renal failure*	132 (36.4)
C. Visual impairment	16 (4.4)
D. All of the above	95 (26.2)
E. Do not know	90 (24.8)
7. Side effects like headache, fever and vomiting should not be reported.	
A. Strongly agree	60 (16.5)
B. Agree	86 (23.7)
C. Neutral	44 (12.1)
D. Disagree*	114 (31.4)
E. Strongly disagree*	59 (16.3)
8. Are you aware of any formal reporting system available in other countries?	
A. Yes*	231 (63.6)
B. No	132 (36.4)
9. Are you aware of any drug that has been banned in the world due to its ADRs?	
A. Yes*	273 (75.2)
B. No	90 (24.8)
10. Where is the “WHO Collaborating Center for International Drug Monitoring” located?	
A. Sweden*	114 (31.4)
B. Germany	28 (7.7)
C. United States of America	93 (25.6)
D. United Kingdom	36 (9.9)
E. Do not know	92 (25.3)
11. Which of the following is the WHO online database for reporting ADRs?	
A. ADR advisory committee	77 (21.2)
B. Med safe	42 (11.6)

(continued on next page)

Table 2. (continued)

Item	N (%)
C. VigiBase*	61 (16.8)
D. Med watch	62 (17.1)
E. Do not know	121 (33.3)
12. Which of the following is the ADR reporting organization in Pakistan?	
A. Pakistan Medical and Dental Association	48 (13.2)
B. Drug Regularity Authority of Pakistan*	97 (26.7)
C. National Institute of Health	81 (22.3)
D. No center for reporting	11 (3.0)
E. Do not know	126 (34.7)

*Right answer; ADR-adverse drug reaction; WHO-World Health Organization.

(attitude score $\geq 75\%$). Pharmacists had significantly ($P < 0.001$) more positive attitudes toward ADRs reporting than doctors, and nurses (Table 3). Furthermore, male HCWs had significantly better attitude scores than females ($p < 0.001$).

3.4. Practices-related to pharmacovigilance

Pakistani HCWs practices-related to PV are shown in Table 5. A wide majority (81%) of study participants reported that they have identified ADRs; however, approximately 61% of HCWs stated that they have reported the ADRs. Interestingly, only 39% of study participants stated that they were well trained in detection, reporting, and managing

ADRs. Additionally, only 35.5% indicated of reporting all ADRs, not just serious or life threatening ones. Around 45% of study participants admitted of not mentioning ADRs on patient records. Median (IQR) of overall ADRs-related practice score was 4 (2), with 33.9% HCWs having good PV practices. As shown in Table 3, pharmacists displayed significantly better practices-related to Pharmacovigilance than other HCWs.

3.5. Barriers of pharmacovigilance

Reasons of ADRs under-reporting are shown in Table 6. Around 53% of study participants agreed that ADRs under-reporting was due to the belief

Table 3. Comparison of knowledge, attitude and practice scores among demographic variables.

Variables	Sub-categories	Knowledge score (Mean rank)	Attitude score (Mean rank)	Practice score (Mean rank)
Age	≤ 25	187.07	196.94	186.20
	26–30	184.46	181.55	190.67
	31–35	179.34	168.31	172.81
	≥ 36	171.53	176.43	166.51
	P-value	0.826	0.333	0.389
Gender	Male	223.05	213.45	204.14
	Female	163.44	167.00	171.99
	P-value	<0.001	<0.001	0.006
Occupation	Medical doctors	202.24	198.94	181.14
	Pharmacist	255.06	231.57	218.57
	Nurses	126.55	140.74	163.11
	P-value	<0.001	<0.001	<0.001
Work experience (years)	≤ 1	186.06	198.79	177.67
	>1–3	196.37	184.71	190.63
	>3–5	167.92	207.27	188.10
	>5–9	160.60	158.28	163.50
	≥ 10	190.49	163.08	193.38
	P-value	0.136	0.031	0.365
Post-hoc analysis with Bonferroni correction				
Occupation	Medical doctors	90.24	95.25	96.79
	Pharmacists	125.98	117.07	116.11
	P-value	<0.001	0.008	0.021
	Medical doctors	166.18	175.00	147.36
	Nurses	112.67	119.05	134.97
	P-value	<0.001	<0.001	0.196
	Pharmacists	171.08	156.51	144.45
	Nurses	91.88	99.68	106.14
	P-value	<0.001	<0.001	<0.001

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Table 3. (continued)

Variables	Sub-categories	Knowledge score (Mean rank)	Attitude score (Mean rank)	Practice score (Mean rank)
Work experience (years)	≤1	—	99.56	—
	>1-3		92.32	
	P-value		0.370	
	≤1		56.96	
	>3-5		59.62	
	P-value		0.669	
	≤1		85.69	
	>5-9		68.65	
	P-value		0.015	
	≤1		63.07	
	≥10		51.54	
	P-value		0.065	
	>1-3		80.03	
	>3-5		89.02	
	P-value		0.270	
	>1-3		106.90	
	>5-9		92.44	
	P-value		0.078	
	>1-3		85.46	
	≥10		76.63	
	P-value		0.278	
	>3-5		75.73	
	>5-9		57.56	
	P-value		0.006	
	>3-5		51.89	
	≥10		40.24	
	P-value		0.031	
	>5-9		64.13	
	≥10		65.16	
	P-value		0.876	

Table 4. Respondents' attitudes towards pharmacovigilance.

Statement N (%)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. ADRs should promptly be reported to the Pharmacovigilance center	8 (2.2)	30 (8.3)	19 (5.2)	185 (51.0)	121 (33.3)
2. ADR reporting should be made mandatory	12 (3.3)	27 (7.4)	36 (9.9)	137 (37.7)	151 (41.6)
3. ADR reporting is our professional obligation.	7 (1.9)	26 (7.2)	53 (14.6)	172 (47.4)	105 (28.9)
4. ADR reporting increases patient safety	7 (1.9)	16 (4.4)	34 (9.4)	158 (43.5)	148 (40.8)
5. ADR reporting is time consuming	30 (8.3)	69 (19.0)	79 (21.8)	122 (33.6)	63 (17.4)
6. ADR reporting form is too complex to fill.	10 (2.8)	43 (11.8)	103 (28.4)	152 (41.9)	55 (15.2)
7. Are you willing to implement ADRs reporting in your practice?	7 (1.9)	13 (3.6)	21 (5.8)	172 (47.4)	150 (41.3)
8. I believe that reporting of only one case makes no significant contribution to the ADR reporting scheme.	28 (7.7)	104 (28.7)	65 (17.9)	122 (33.6)	44 (21.1)
9. Identity of healthcare worker reporting the ADR must be kept confidential.	18 (5.0)	66 (18.2)	80 (22.0)	140 (38.6)	59 (16.3)
10. Pharmacovigilance should be taught in detail to Healthcare workers.	9 (2.5)	28 (7.7)	24 (6.6)	141 (38.8)	161 (44.4)

that all marketed drugs were safe as they have undergone rigorous safety and efficacy trials, 67.3% stated that it was due to the uncertainty whether the ADR was due to a particular drug, and 67.7% agreed that it was because of shortage of time.

4. Discussion

The awareness of ADR and possible barriers in their reporting were examined in the current study.

Although majority of the study participants were aware regarding the correct definition of the pharmacovigilance as well as the purpose of this but 73.3% of the participants were unaware of the location of PV centers in Pakistan. Similar findings have been reported in Kingdom of Saudi Arabia and India where 60.6%, and 55.5% did not know exact location of PV centers in their countries [2,15]. In our study, knowledge of study participants regarding

Table 5. Practices-related to pharmacovigilance.

Statement N (%)	Disagree	Neutral	Agree
1. Have you ever identified an ADR in any patient?	44 (12.1)	25 (6.9)	294 (81)
2. Have you ever reported an ADR?	95 (26.2)	46 (12.7)	222 (61.1)
3. I have been well trained to detect, report and control ADR.	143 (39.4)	79 (21.8)	141 (38.9)
4. I am following approaches in preventing ADRs during my practice/prevented ADRs during my practice.	75 (20.6)	66 (18.2)	222 (61.2)
5. I only report severe or life threatening ADRs.	129 (35.5)	75 (20.7)	159 (43.8)
6. I mention the ADRs on patients' medical record.	68 (18.7)	94 (25.9)	201 (55.4)
7. I have done ADRs reporting at least once in the past 1 year.	127 (35.0)	54 (14.9)	182 (50.1)

Table 6. Reasons for under reporting of ADRs.

Statement N (%)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. ADR reporting system is not incorporated because of financial issues.	20 (5.5)	53 (14.8)	72 (19.8)	137 (37.7)	81 (22.3)
2. ADR reporting system not incorporated because of limited awareness of the health care professionals.	15 (4.1)	26 (7.2)	35 (9.6)	200 (55.1)	87 (24.0)
3. Fatal ADRs are mostly not reported because usually general public do not allow conducting postmortem studies.	9 (2.5)	67 (18.5)	48 (13.2)	161 (44.4)	78 (21.5)
4. ADRs are not reported because of the belief that all marketed drugs are safe.	15 (4.1)	75 (20.7)	80 (22.0)	110 (30.3)	83 (22.9)
5. ADRs are not reported because of uncertainty that ADR occurred due to drug administered.	22 (6.1)	40 (11.0)	57 (15.7)	173 (47.7)	71 (19.6)
6. ADRs are not reported because of shortage of time	22 (6.1)	58 (16.0)	37 (10.2)	158 (43.5)	88 (24.2)

the WHO online database for ADR reporting was very low as only 16.8% participants knew about it. Furthermore, the location of international center of ADR monitoring was also poor (31%). By contrast, Gupta et al. [15] reported that more than 41% HCW knew about the international ADR monitoring center. Spontaneous reporting by the HCW about the ADR is the most commonly employed method of ADR monitoring in Pakistan. Therefore, the knowledge about the regional ADR monitoring center is of great value. In the current study, only 26.7% HCWs knew where to report ADR in Pakistan which was significantly higher than the findings of Palaian et al. [16] who reported that 41% of Nepali HCWs knew about the their ADRs reporting center.

After detection of ADRs by the HCWs, it must immediately be reported to the regional ADRs monitoring center. In this study, majority (84%) of the HCWs believed that all ADR should promptly be reported to the National Pharmacovigilance Center. These findings were comparable to the results of Alsaleh and colleagues [14]. It was encouraging to see that majority (88.7%) of our HCWs were willing to implement PV practice in their health facilities. Additionally, they also believed that PV should be taught in detail to all HCWs, and 76.3% HCWs considered PV activities as professional obligation which was in contrast to the study conducted among nurses in United Arab Emirates

reporting that around 41% considered PV activities as professional obligation [8]. Deplorably, 51% of our study participants considered ADRs reporting as a very time consuming task which was similar to findings of an earlier study [17]. Around 55% of participants in the present study reported that the identity of ADR should be kept hidden which was significantly higher to the findings of a previous study (18.2%) including Nigerian physicians [18].

All in all, the knowledge, attitude and practices of PV/ADR were found to be insufficient among our study population which was comparable to the findings of earlier studies from Pakistan [9,10], Malaysia [11], Turkey [19] and South Africa [20]. We found out that pharmacists had better knowledge, attitude and practices scores than doctors and nurses. This can be due to receiving comprehensive pharmacology and clinical pharmacy education during in-school pharmacy education; as PV, medication errors, drug-related problems, and ADR detection, reporting and causality assessment are taught extensively in Doctor of Pharmacy program in Pakistan. Similar to our findings, O'Callaghan et al. also reported that hospital pharmacists had the most experience and highest mean knowledge scores related to ADR reporting than other health professionals [20]. The findings of Tew et al. also revealed better awareness of PV and ADR reporting among pharmacists than doctors [11].

Surprisingly, a little more than one third of the study participants believed that reporting of only one ADR would not make a significant contribution to the overall ADRs reporting scheme. These findings were in contrast to the study conducted in south eastern European region [17]. Around 40% of our HCWs stated that they were well trained in detection, reporting, and prevention of ADR which was in contrast to a previous study conducted in Karachi where half of the pharmacist enrolled in the study were trained in PV activities [10]. More than half of the HCWs believe that all marketed drugs were safe and they could not cause severe ADR. In contrast, Belton reported a very low percentage of European HCWs who believed all marketed drugs were completely safe [19].

This study had some limitations. As the study was conducted in health care institutes of just the Lahore city, our results and conclusions drawn cannot be generalized to overall HCWs population of Pakistan. Another significant limitation is the use of convenience sampling which is known to be associated with over- or under-representation of the population and selection bias. Additionally, even though the questions used in the study questionnaire were derived from the previously validated instruments, we did not perform complete reliability analysis on the questionnaire and only determined the face and content validity. We recommend nationally representative studies to determine ADR reporting practices as well as barriers associated with ADR reporting.

The results of our study have the following important implications for future practice.

- Pharmacovigilance should be taught in detail to all HCWs during in-school education.
- Continuous teaching and training programs need to be conducted in hospitals to train HCWs where and how to report ADR in Pakistan [20,21].
- Educational trainings alone do not necessarily result in adequate PV practices/ADRs reporting unless there is a blame-free environment in hospitals where HCWs are able to report medication errors as well as ADRs without fear of adverse career-related consequences. Therefore, the concept of “safety culture” should also be promoted [14].
- Incentives should be offered to the HCWs for regular reporting of ADRs [9].
- There is a very high deficit of qualified and skilled HCWs in Pakistan [22]. Therefore, health regulators should take steps necessary to increase the strength of doctors, nurses and

pharmacists in Pakistani healthcare settings [23]. This may help decrease the excessive work-load and improve patient care as well as ADR reporting.

5. Conclusions

Overall, Pakistani health professionals have inadequate information regarding PV. This study highlights the areas (what, how, and where to report ADRs in Pakistan) that required improvement in order to improve patient care by efficient PV. Therefore, robust and multidimensional approach (hands-on training, lectures, e-learning modules, PV workshop, conferences) should be employed to address them.

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Conflict of interest

None declared.

Appendix.

The aim of this study is to estimate healthcare workers' knowledge, attitude and practices related to Pharmacovigilance. This study is strictly for research purpose and all data given will be treated with utmost confidentiality.

Please answer the following questions.

Age _____ years

Gender: A) Male B) Female

Profession: A) Doctor B) Pharmacist C)

Nurse

Designation: _____

Name of hospital: _____

Work experience: _____ years

1. Which of the following correctly defines Pharmacovigilance?

- The science and activities of detecting, assessing, understanding and preventing adverse effects or any other drug-related problems
- The science of detecting the type and incidence of adverse drugs reactions (ADRs) after a drug is marketed
- The process of improving the safety of drugs
- The science of monitoring ADRs happening in a Hospital
- Do not know

2. Which of the following correctly describes the purpose of Pharmacovigilance?

- A. To enhance patient care and patient safety in relation to use of medicines
- B. To identify predisposing factors of ADRs
- C. To identify unknown ADRs
- D. To calculate incidence of ADRs E. Do not know

3. Which of the following accurately defines an ADR?

- A. Any noxious or undesired effect of a drug occurring at normal doses, during normal use
- B. Adverse health outcomes associated with inappropriate drug use
- C. Harm resulting from the use of substandard/ counterfeit drugs
- D. Harm caused by drug overdose
- E. Adverse outcomes associated with drug impurity
- F. Health problems associated with drug use
- G. Do not know

4. What types of ADRs should be reported?

- A. All serious ADRs
- B. ADRs related to herbal and non-allopathic drugs
- C. ADRs to new drugs
- D. ADRs to vaccines
- E. Unknown ADRs of old drugs
- F. All of the above

5. Which of the following is the extended Rawlins–Thompson Classification of ADRs?

- A. Type A, B, C, D, E and F
- B. Type 1, 2, 3, 4, 5, 6 and 7
- C. Known, unknown and common, uncommon
- D. Reversible and irreversible E. Do not know

6. Which of the following is major risk factor for ADRs occurrence?

- A. Arthritis
- B. Renal failure
- C. Visual impairment
- D. All of the above
- E. Do not know

7. Side effects like headache, fever and vomiting should not be reported.

- A. Strongly agree
- B. Agree
- C. Neutral
- D. Disagree

E. Strongly disagree

8. Are you aware of any formal reporting system available in other countries?

- A. Yes
- B. No

9. Are you aware of any drug that has been banned in the world due to its ADRs?

- A. Yes
- B. No

10. Where the “WHO Collaborating Center for International Drug Monitoring” is located?

- A. Sweden
- B. Germany
- C. United States of America
- D. United Kingdom
- E. Do not know

11. Which of the following is the WHO online database for reporting ADRs?

- A. ADR advisory committee
- B. Med safe
- C. Vigibase
- D. Med watch
- E. Do not know

12. Which of the following is the ADR reporting organization in Pakistan?

- A. Pakistan Medical and Dental Association
- B. Drug Regularity Authority of Pakistan
- C. National Institute of Health
- D. No center for reporting
- E. Do not know

13. Sources of information regarding ADRs to new drugs?

- A. Textbooks
- B. Journals
- C. Internet
- D. Medical representatives
- E. Seminars/conferences
- F. Direct mail brochures
- G. All of the above

14. ADRs should promptly be reported to the Pharmacovigilance center

- A) Strongly agree B) Agree C) Neutral
- D) Disagree E) Strongly disagree

15. ADR reporting should be made mandatory
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
16. ADR reporting is our professional obligation.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
17. ADR reporting increases patient safety
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
18. ADR reporting is time consuming
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
19. ADR reporting form is too complex to fill.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
20. Are you willing to implement ADRs reporting in your practice?
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
21. I believe that reporting of only one case makes no significant contribution to the ADR reporting scheme.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
22. Identity of healthcare worker reporting the ADR must be kept confidential.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
23. Pharmacovigilance should be taught in detail to Healthcare workers.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
24. Have you ever identified an ADR in any patient?
A) Agree B) Neutral C) Disagree
25. Have you ever reported an ADR?
A) Agree B) Neutral C) Disagree
26. I have been well trained to detect, report and control ADR.
A) Agree B) Neutral C) Disagree
27. I am following approaches in preventing ADRs during my practice/prevented ADRs during my practice.
A) Agree B) Neutral C) Disagree
28. I only report severe or life threatening ADRs.
A) Agree B) Neutral C) Disagree
29. I mention the ADRs on patients' record.
A) Agree B) Neutral C) Disagree
30. I have done ADRs reporting at least once in the past 1 year.
A) Agree B) Neutral C) Disagree
31. ADR reporting system is not incorporated because of financial issues.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
32. ADR reporting system not incorporated because of limited awareness of the health care professionals.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
33. Fatal ADRs are mostly not reported because usually general public do not allow conducting postmortem studies.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
34. ADRs are not reported because of the belief that all marketed drugs are safe.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
35. ADRs are not reported because of uncertainty that ADR occurred due to drug administered.
A) Strongly agree B) Agree C) Neutral D) Disagree E) Strongly disagree
36. ADRs are not reported because of shortage of time

A) Strongly agree B) Agree C) Neutral
D) Disagree E) Strongly disagree

Other reasons for the under-reporting of ADRs:

Thank you for participating in our study.

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