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Current Medical Research and Opinion

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/icmo20

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To cite this article: Muhammad Junaid Hassan Sharif, Muhammad Junaid Farrukh, Faiz Ullah Khan, Qasim Khan, Sardar Shabbir Ahmed, Rozina Kousar, Tawseef Ahmad, Syed Mobasher Ali Abid, Muhammad Ashfaq & Shujaat Ali Khan (2022): Exploring the factors and barriers of healthcare professionals in tertiary care hospitals toward pharmacovigilance: a multicenter study from Khyber Pakhtunkhwa, Pakistan, Current Medical Research and Opinion, DOI: 10.1080/03007995.2022.2042992

To link to this article: https://doi.org/10.1080/03007995.2022.2042992

CURRENT MEDICAL RESEARCH AND OPINION
https://doi.org/10.1080/03007995.2022.2042992
Article ST-0779.R1/2042992

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ORIGINAL ARTICLE

Exploring the factors and barriers of healthcare professionals in tertiary care hospitals toward pharmacovigilance: a multicenter study from Khyber Pakhtunkhwa, Pakistan

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ABSTRACT

Background: Spontaneous Adverse drug reactions (ADRs) reporting is a cornerstone for a successful pharmacovigilance program as under-reporting of ADRs remains a major issue around the globe. The current study aimed to assess the knowledge attitude and practices of health care professionals regarding pharmacovigilance along with barriers and factors to encourage ADR reporting at tertiary care hospitals of Khyber-Pakhtunkhwa, Pakistan.

Methods: A questionnaire-based cross-sectional survey was conducted, using the convenience sampling method to collect the data from doctors, nurses, and pharmacists working in seven tertiary care hospitals from seven districts of Khyber-Pakhtunkhwa province, Pakistan, between July 2019 and March 2020.

Results: During the study, a total of 830 questionnaires were distributed, out of which 669 were returned (response rate 80.6%). Overall, Healthcare professionals exhibited poor knowledge (79.5%) about ADR reporting and pharmacovigilance however, 73.5% of pharmacists were more knowledgeable as compared to 18.7% doctors and 13.8% nurses ($p < .001$). Moreover, poor reporting practices were displayed by 95.6% doctors, 94.4% nurses, 94.4 and 75.5% pharmacists ($p < .001$). However, the majority of healthcare professionals showed an overall positive attitude (94%) toward ADR reporting. The most frequently cited barriers were unavailability of reporting forms (92.5%), absence of a professional environment to discuss ADRs (82.5%), and lack of training (81.8%) whereas, most common factors to encourage ADR reporting were obligatory reporting (85.9%) and provision of ADR management guidelines and training (84.3%). A significant relation was found between the healthcare professionals and their professional status with the overall knowledge, attitude, and practice (KAP) scores ($p < .001$) whereas a medium, positive correlation was found between the knowledge and practice of pharmacovigilance and ADR reporting by the healthcare professionals ($r = 0.321$, $n = 669$, $p < .001$).

Conclusion: There is an overall lack of knowledge and poor reporting practices among health care professionals on ADR reporting and pharmacovigilance. Hence the study suggests that strategies should be devised by all the stakeholders to properly educate and train the healthcare professionals in this area to enhance overall patient safety and safe use of medicines.

ARTICLE HISTORY
Received 27 October 2021
Revised 27 January 2022
Accepted 9 February 2022

KEYWORDS
Knowledge; attitude; practice; pharmacovigilance; healthcare professionals; adverse drug reaction; medication safety

1. Introduction

Research and drug development have enhanced in modern times due to rigorous competition between pharmaceutical companies and increased demand for newer medications for various diseases. The current pandemic is a classic example in which several vaccines have been rolled out in a very short time. This in turn poses a global challenge to ensure medication safety, as adverse drug reactions to newer medications and biologicals are unknown and their identification is not possible without an effective pharmacovigilance system.

Adverse drug reactions (ADRs) are among the leading cause of death in the world with an increased patient disability, increased hospital admission, and length of stay[1,2]. It has significant financial implications on the health care system and also contributes toward fatality and reduces patient quality of life[3,4]. Among the total ADRs reported almost 1.34% are fatal with antineoplastic, neurological, and cardiovascular drugs being the major contributors. The history of pharmacovigilance dates back to the early '60s with the thalidomide disaster resulting in malformation of limbs in babies due to the drug thalidomide[5], which laid the foundation for the formation of ADR monitoring center by the World Health Organization (WHO) in 1971, which was later shifted to Uppsala, Sweden in 1978. The mechanism to evaluate ADR's

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is termed pharmacovigilance (PV) which is defined as "the science and the activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem" and aims at identifying and communicating medication-related hazards to the health care professional to enhance patient safety[6].

Spontaneous reporting of ADRs has been indicated as a cornerstone for a successful pharmacovigilance program by many worldwide studies, with significant contribution from health care professionals and patients in identifying and reporting ADRs, yet under-reporting has always been a major issue[7,8]. Reporting rates as low as 1–10% have also been reported[9,10], whereas a systematic review on the extent of underreporting to spontaneous ADR reporting systems indicated a median under-reporting rate of 94% along with a strong relationship between the knowledge and attitudes of health care professionals with their practice across 37 studies[11]. Sometimes under-reporting may be less important due to social networks and media coverage of some drug safety issues. Henceforth, to improve an ADR reporting system, it is crucial to comprehend the knowledge, attitude, and practices of various health care professionals[12].

Pharmacovigilance has grown and evolved in Asia due to the strict compliance requirements by the western world regulators to ensure public safety. Countries like China, Japan, and Korea have a robust PV system followed by India and Nepal who still have a developing system[13]. Pakistan is a lower-middle-income country (LMIC) with an estimated population of 3.285 billion and is ranked as the fifth most populous country in the world[14]. In terms of overall system performance, Pakistan's healthcare system currently ranks 154th out of 195 countries with only 3.2% of its GDP allocated for total health care expenditures[15]. As an LMIC, Pakistan struggles to maintain a proper healthcare system in terms of quality and accessibility. Pakistan established its national pharmacovigilance system under the Drug Regulatory Authority of Pakistan (DRAP) and became a full member of the WHO's Program for International Drug Monitoring (PIDM) in 2018, with still being in its early stages[2]. Since then, there is no published data available regarding ADR reporting from health care professionals to the national or regional pharmacovigilance centers. Whereas a communication gap exists between health care professionals and the drug regulatory authorities[12].

Very few KAP studies have been conducted previously in Pakistan on the current issue. A study from Islamabad revealed poor knowledge and reporting practice of physicians regarding ADR reporting[16] whereas a study from Lahore identified that very few reports are being sent to the national PV center[17]. Therefore, considering the scarcity of data on the pharmacovigilance knowledge and practices of healthcare professionals and its immediate importance in ensuring medication safety, the current first large scale study was designed, aiming to comprehensively assess the knowledge attitude and practices of doctors, nurses, and pharmacists, on pharmacovigilance and related activities along with barriers and associated factors to encourage ADR reporting, working in tertiary care hospitals of Khyber-Pakhtunkhwa province, Pakistan.

2. Methods

2.1. Methods

2.1.1. Study design

A descriptive cross-sectional survey was conducted among health care professionals (Doctors, Nurses, and Pharmacists) working at selected tertiary care government hospitals in the province of Khyber-Pakhtunkhwa (KP), Pakistan between July 2019 and March 2020.

2.1.2. Study site

Khyber Pakhtunkhwa is in the northwestern region of Pakistan and is one of the country's four administrative provinces with seven divisions and 26 districts with a total population of about 35.53 million. There are about 14 tertiary care hospitals (TCH) spread across seven divisions of KP[18]. A total of seven TCHs were selected for this study.

2.1.3. Study population

The study population included all the health care professionals, i.e. doctors nurses and pharmacists working as full-time employees in tertiary care hospitals of Khyber-Pakhtunkhwa (KP).

2.2. Inclusion and exclusion criteria

Full-time health care professionals, i.e. doctors, nurses, and pharmacists working at the TCH who gave their consent to participate were included in the study. Health care professionals performing only administrative duties and training as well who denied participating were excluded.

2.3. Variables

2.3.1. Outcome variables

- Overall knowledge, attitude, and practice of HCPs about Pharmacovigilance and ADR reporting

2.3.2. Independent variables

- Age, gender, professional status, years of experience

2.4. Sampling technique and sample size

The 14 TCHs are spread across seven divisions of KP namely Bannu, Dera Ismail Khan, Hazara, Kohat, Mardan, Malakand, and Peshawar. A total of seven TCHs was purposively selected, one from each division of KP, based on a high number of health care professionals working. In each TCH, convenience sampling of health care professionals working was done. The sample size was calculated using the Raosoft® online sample size calculator[19], based on the total number of registered doctors and nurses working in KP. Due to very few numbers registered pharmacists, all pharmacists working at the target hospitals were included. Thus when the estimated population was computed within the online calculator at 95% confidence interval, 5% margin of error, and 50% response rate, the sample size of 358 was required for

doctors and 350 for nurses. However including a 10% non-response rate a final sample size of 390 was required for doctors and 385 for nurses which were distributed proportionally to be collected from each tertiary care hospital.

2.5. Data collection tool and scoring system

A structured questionnaire was developed by an extensive review of the literature from studies with similar objectives[16,20–22]. The initial part included the sociodemographic information of respondents whereas there were three primary domains which included knowledge, attitude, and practice regarding pharmacovigilance, and two secondary domains covering barriers to ADR reporting and factors encouraging to report ADRs as follows:

a. Twelve statements were used to identify the knowledge about pharmacovigilance and responses were noted as yes, no and don't know with a total score of 12. Modified bloom's cut-off point was used for the categorization of the overall knowledge of participants. It was categorized as either good (score 10–12 points, 80–100%), moderate (score 6–9 points, 50–79%) or poor (score <6 points, <50%) knowledge.
b. Eight questions were used to assess the attitude toward pharmacovigilance with a total of 40 points. A 5-point Likert scale was used to grade responses relating to attitude with 1 point for Strongly disagree to 5 points for Strongly agree. Modified bloom's cut-off point was used for categorization of overall attitude as either positive (score 32–40 points; 80–100%), neutral (score 24–31 points; 60–79%) and negative (score <24 points; <60%).
c. Five questions were used to assess the practice having a total of 5 points whereas practice level was classified as poor (1–2 score; <60%), fair (3 scores; 60–80%), and good level (4–5 scores; 80–100%).
d. Eight questions were recorded the assess the barriers to ADR reporting whereas factors encouraging to report ADRs were recorded by five questions.

2.6. Pretest and validation of the instrument

Two experts in the discipline of social and administrative pharmacy reviewed the preliminary version of the questionnaire for content validity whereas clinical sensibility testing was carried out by reviewing the questionnaire to a panel of doctors nurses and pharmacists to assess the questions in terms of their clarity and understanding. The questionnaire was then simplified according to suggestions keeping in mind not to eliminate important constructs. Pilot testing was carried out on 40 participants for face validity whereas internal consistency of the questionnaire was measured by Cronbach's alpha which was 0.766 (~0.7), indicating homogeneity.

2.7. Ethical approval

Ethical approval was taken by the research and ethics committee at the department of pharmacy (No.PHM.E.th/CF-M10/17-0043), Comsats University Islamabad-Abbottabad Campus. Verbal consent was taken from participants who were willing to participate, and they were handed the questionnaires to fill and then returned.

2.8. Data collection procedure

Health care professionals were considerately approached in their respective TCHs during scheduled duty timings. Verbal informed consent was taken from every participant. The questionnaire was self-administered to the participants which took around 10–15 min to complete and were cross-checked for completeness before collection by the researcher.

2.9. Data analysis

The data from the questionnaires were checked for completeness, then sorted and entered into Statistical Package for the Social Sciences (SPSS) version 21 and edited for incorrectness. Data were summarized as frequencies and percentages for categorical variables and demographics. Association between HCPs and their knowledge, attitude, and practices as well as their KAP scores was done using Mann–Whitney and Kruskal Wallis tests, and a p-value <.05 was considered statistically significant.

3. Results

3.1. Demographic characteristics

The demographic data are displayed in Table 1. In the current study, a total of 830 questionnaires were distributed among doctors, nurses, and pharmacists in seven tertiary care hospitals of seven districts of KP. A response rate of 80.6% was

Table 1. Demographic characteristics.

Variables	Respondents response, n (%)*
Gender	
Male	279 (41.7)
Female	390 (58.3)
Healthcare professional	
Doctor	316 (47.2)
Nurse	304 (45.4)
Pharmacist	49 (7.3)
Age groups (years)	
20–30	432 (64.6)
31–40	191 (28.6)
≥41	46 (6.9)
Professional status	
House Officer	163 (24.4)
Medical Officer	124 (18.5)
Consultant	29 (4.3)
Staff Nurse	258 (38.6)
Head Nurse	46 (6.9)
Ward Pharmacist	19 (2.8)
Main store pharmacist	24 (3.6)
Chief Pharmacist	6 (0.9)
Experience (years)	
≤1	108 (16.1)
2–5	310 (46.3)
6–10	173 (25.9)
≥11	78 (11.7)

*The percentages were calculated in the total number of respondents, i.e. $n = 66$.

achieved, as 669 questionnaires were filled in properly and returned. Among the respondents, there were 47.2% were doctors ($n = 316$), 45.4% nurses ($n = 304$) and 7.3% pharmacists ($n = 49$). The majority (58.3%) of participants were females. Most of the participants (64.6%) were lying in age groups 20–30 years, followed by 31–40 years (28.6%). According to professional status, the majority of respondents were staff nurses (38.6%) followed by house officers (24.4%) and medical officers (18.5%). Most of the respondents had an experience of 2–5 years (46.3%) followed by 6–10 years (25.9%), $\leq$1 year (16.1%), and $\geq$11 years (11.7%).

3.2. Description of knowledge regarding pharmacovigilance and ADR reporting

Knowledge regarding pharmacovigilance and ADR reporting was assessed on 12 questions (Table 2). Among the respondents, only 18.5% were able to correctly identify the term pharmacovigilance, the majority being pharmacist 36.7% ($n = 18$), However, 68.9% ($n = 461$) healthcare professionals identified the term ADR correctly. Approximately 23.2% ($n = 155$) and 46.5% ($n = 311$) of respondents were able to identify types of ADRs and relate side effects, drug interactions, and allergic reactions as types of ADRs, respectively. Moreover, only 10.3% ($n = 69$) were able to identify the international ADR reporting and monitoring center whereas only 8.1% ($n = 54$) knew about the WHO online database for reporting ADRs. Few participants knew that a national or regional ADR reporting center exists in Pakistan 23.6% ($n = 158$) with the majority being pharmacists 42.9% ($n = 21$), whereas a very small proportion of respondents knew that an ADR reporting form exists in Pakistan 7.9% ($n = 53$). The majority of pharmacists 89.8% ($n = 44$), Doctors 63% ($n = 199$), and nurses 55.9% ($n = 170$) were able to identify that any serious event should be reported to the Drug

Table 2. Correct response of knowledge regarding pharmacovigilance.

Knowledge about pharmacovigilance	Category	Correct response *n* (%)*	*p*-Value**
Define pharmacovigilance	Doctor	63 (19.9)	<.001
	Nurse	43 (14.1)	
	Pharmacist	18 (36.7)	
	Overall response	124 (18.5)	
WHO has defined an Adverse drug reaction (ADR) "as any noxious unintended and undesired effects of a drug that occur at doses used for prevention, diagnosis or therapy"?	Doctor	236 (74.7)	<.001
	Nurse	177 (58.2)	
	Pharmacist	48 (98)	
	Overall response	461 (68.9)	
The Types of ADR are Type A, B, C, D, E, and F.	Doctor	73 (23.1)	<.001
	Nurse	58 (19.1)	
	Pharmacist	24 (49)	
	Overall response	155 (23.2)	
Side effects, drug interactions, allergic reactions are counted as ADR.	Doctor	161 (50.9)	.002
	Nurse	120 (39.5)	
	Pharmacist	30 (61.2)	
	Overall response	311 (46.5)	
Where is the international center for adverse drug reaction monitoring located?	Doctor	35 (11.1)	<.001
	Nurse	21 (6.9)	
	Pharmacist	13 (26.5)	
	Overall response	69 (10.3)	
Which one of the following is the WHO online database for reporting ADRs?	Doctor	27 (8.5)	<.001
	Nurse	12 (3.9)	
	Pharmacist	15 (30.6)	
	Overall response	54 (8.1)	
Does a national or regional/district ADR center linked to the DRAP (Drug Regulatory Authority of Pakistan) exist in Pakistan	Doctor	71 (22.5)	.004
	Nurse	66 (21.7)	
	Pharmacist	21 (42.9)	
	Overall response	158 (23.6)	
What procedure do companies adapt to monitor ADRs once launched into markets?	Doctor	155 (49.1)	<.001
	Nurse	89 (29.3)	
	Pharmacist	43 (87.8)	
	Overall response	287 (42.9)	
If a serious adverse drug event is observed, where should it be reported in Pakistan?	Doctor	199 (63)	<.001
	Nurse	170 (55.9)	
	Pharmacist	44 (89.8)	
	Overall response	413 (61.7)	
The healthcare professionals most responsible for reporting an ADR in hospital is?	Doctor	150 (47.5)	<.001
	Nurse	111 (36.5)	
	Pharmacist	20 (40.8)	
	Overall response	281 (42.1)	
Are there any ADRs reporting forms that exist in Pakistan?	Doctor	17 (5.4)	<.001
	Nurse	12 (3.9)	
	Pharmacist	24 (49)	
	Overall response	53 (7.9)	
Do you know how to report an ADR?	Doctor	29 (9.2)	<.001
	Nurse	19 (6.2)	
	Pharmacist	27 (55.1)	
	Overall response	75 (11.2)	

*The percentages were calculated from correct response within healthcare professionals.
**p-Value $\leq$.05 was considered statistically significant.

regulatory authority of Pakistan. Among the participants, 42.9% ($n = 287$) identified that companies used post-marketing surveillance to monitor the ADRs of existing medicines. Almost half of the participants 42.1% ($n = 281$), showed agreement that all the health care professionals were responsible to report an ADR. The majority of respondents 88.8% ($n = 594$), did not know how to report an ADR with almost,90.8% ($n = 289$) doctors followed by 93.8% ($n = 279$) nurses, in contrast to almost 55.1% ($n = 27$) pharmacists, who knew how to report an ADR.

3.3. Description of attitude regarding pharmacovigilance and ADR reporting

The attitude of participants is described in Table 3. Among the respondents, the majority strongly agreed that ADR reporting was necessary 79.1% ($n = 529$), that there should be an ADR monitoring center in every hospital 68.9% ($n = 461$), ADR must be related to a specific drug before reporting 61.4% ($n = 411$) and it contributes toward patient safety 60.1% ($n = 402$). Moreover, there was a strong agreement among 59.5% ($n = 398$) and 58% ($n = 388$), respondents that all ADRs for newly marketed drugs and of herbal/non-allopathic drugs should be reported, respectively. Further, 56.4% ($n = 377$) of respondents strongly agreed that ADR reporting should be compulsory whereas 52.6% ($n = 352$) accounted for it as their professional obligation.

3.4. Description of practice regarding pharmacovigilance and ADR reporting

The majority of respondents had experienced an ADR in their patients during their professional practice 80.9% ($n = 541$), whereas only 23.4% ($n = 72$) doctors and 22.7% ($n = 69$) had reported any ADR in the last 5 years in contrast to the pharmacist who reported a significant number of ADRs,71.4% ($n = 35$), p-value $<.001$. Moreover, 92.8% ($n = 621$) of respondents said that there is no regulatory body in their hospital to regulate ADR reporting, while 97% ($n = 649$) of respondents had never seen an ADR reporting form in their hospital. Most respondents 97.9% ($n = 655$), had never been trained to report an ADR (Table 4).

Majority respondents indicated that they would prefer to directly contact the ADR center to report an ADR 62.6% ($n = 419$), followed by 19.6% ($n = 131$) preferring email/website, 12.4% ($n = 83$) by telephone, 4.5% ($n = 30$) by post, and 0.9% ($n = 6$) choosing other methods (Figure 1).

3.5. Description of barriers and factors to encourage ADR reporting

Figure 2 shows the barriers to reporting ADRs. Most frequently cited barriers were unavailability of reporting forms 92.5% ($n = 619$), absence of professional environment to discuss ADRs, 82.5% ($n = 552$), lack of training, 81.8% ($n = 547$), not knowing

Table 3. Response of attitude regarding pharmacovigilance.

Questions	HCP-C	Response: *n* (%)					*p*-Value*
		SA	A	N	DA	SDA	
Adverse Drug Reaction (ADR) reporting is necessary	Doctor	256 (81)	59 (18.7)	–	1 (0.3)	–	.322
	Nurse	233 (76.6)	65 (21.4)	6 (2)	–	–	
	Pharmacist	40 (81.6)	9 (18.4)	–	–	–	
	Overall	529 (79.1)	133 (19.9)	6 (0.9)	1 (0.1)	–	
ADR reporting should be made compulsory	Doctor	186 (58.9)	126 (39.9)	3 (0.9)	1 (0.3)	–	**.020**
	Nurse	157 (51.6)	131 (43.1)	14 (4.6)	2 (0.7)	–	
	Pharmacist	34 (69.4)	13 (26.5)	2 (4.1)	–	–	
	Overall	377 (56.4)	270 (40.4)	19 (2.8)	3 (0.4)	–	
ADR reporting is a professional obligation for you	Doctor	169 (53.5)	108 (34.2)	36 (11.4)	3 (0.9)	–	.398
	Nurse	154 (50.7)	112 (36.8)	34 (11.2)	2 (0.7)	2 (0.7)	
	Pharmacist	29 (59.2)	17 (34.7)	3 (6.1)	–	–	
	Overall	352 (52.6)	237 (35.4)	73 (10.9)	5 (0.7)	2 (0.3)	
ADR reporting contributes to patient safety	Doctor	194 (61.4)	115 (36.4)	7 (2.2)	–	–	.056
	Nurse	173 (56.9)	107 (35.2)	16 (5.3)	7 (2.3)	1 (0.3)	
	Pharmacist	35 (71.4)	13 (26.5)	1 (2)	–	–	
	Overall	402 (60.1)	235 (35.1)	24 (3.6)	7 (1)	1 (0.1)	
All ADRs for newly marketed drugs should be reported	Doctor	192 (60.8)	109 (34.5)	13 (4.1)	2 (0.6)	–	.292
	Nurse	174 (57.2)	105 (34.5)	21 (6.9)	1 (0.3)	3 (1)	
	Pharmacist	32 (65.3)	16 (32.7)	1 (2)	–	–	
	Overall	398 (59.5)	230 (34.4)	35 (5.2)	3 (0.4)	3 (0.4)	
ADR of herbal and non-allopathic drugs should also be reported	Doctor	192 (60.8)	105 (33.2)	19 (6)	–	–	.229
	Nurse	169 (55.6)	105 (34.5)	22 (7.2)	6 (2)	2 (0.7)	
	Pharmacist	27 (55.1)	16 (32.7)	6 (12.2)	–	–	
	Overall	388 (58)	226 (33.8)	47 (7.0)	6 (0.9)	2 (0.3)	
It is necessary to be confirmed that an ADR is related to a specific drug before reporting	Doctor	199 (63)	103 (32.6)	11 (3.5)	1 (0.3)	2 (0.6)	.100
	Nurse	176 (57.9)	102 (33.6)	20 (6.6)	3 (1)	3 (1)	
	Pharmacist	36 (73.5)	8 (16.3)	3 (6.1)	2 (4.1)	–	
	Overall	411 (61.4)	213 (31.8)	34 (5.1)	6 (0.9)	5 (0.7)	
ADR monitoring center should be in every hospital	Doctor	224 (70.9)	85 (26.9)	7 (2.2)	–	–	**.023**
	Nurse	197 (64.8)	89 (29.3)	13 (4.3)	2 (0.7)	3 (1)	
	Pharmacist	40 (81.6)	8 (16.3)	1 (2)	–	–	
	Overall	461 (68.9)	182 (27.2)	21 (3.1)	2 (0.3)	3 (0.4)	

Abbreviations. SA, strongly agree; A, agree; N, neutral; DA, disagree; SDA, strongly disagree; HCP-C, healthcare professional category.
Bold represents significant values.
*p-Value $\leq .05$ was considered statistically significant.

Table 4. Response of practice regarding pharmacovigilance.

Practice about pharmacovigilance	HCP-C	Response: *n* (%)		*p*-Value*
		Yes	No	
Have you ever experienced adverse drug reactions in your patients during your professional practice?	Doctor	254 (80.4)	62 (19.6)	.9
	Nurse	248 (81.6)	56 (18.4)	
	Pharmacist	39 (79.6)	10 (20.4)	
	Overall response	541 (80.9)	128 (19.1)	
Have you ever reported any ADR among your patients in the last 5 years?	Doctor	72 (23.4)	242 (76.6)	<.001
	Nurse	69 (22.7)	235 (77.3)	
	Pharmacist	35 (71.4)	14 (28.6)	
	Overall response	178 (26.6)	491 (73.4)	
Is there any regulatory body that regulates ADR reporting in your hospital?	Doctor	18 (5.7)	298 (94.3)	.06
	Nurse	29 (9.5)	275 (90.5)	
	Pharmacist	1 (2)	48 (98)	
	Overall response	48 (7.2)	621 (92.8)	
Have you ever seen the ADR reporting form in your hospital?	Doctor	8 (2.5)	308 (97.5)	<.001
	Nurse	3 (1)	301 (99)	
	Pharmacist	9 (18.4)	40 (81.6)	
	Overall response	20 (3)	649 (97)	
Have you ever been trained on how to report ADRs?	Doctor	4 (1.3)	312 (98.7)	<.001
	Nurse	3 (1)	301 (99)	
	Pharmacist	7 (14.3)	42 (85.7)	
	Overall response	14 (2.1)	655 (97.9)	

Abbreviation. HCP-C, healthcare professional category.
*p-Value ≤.05 was considered statistically significant.

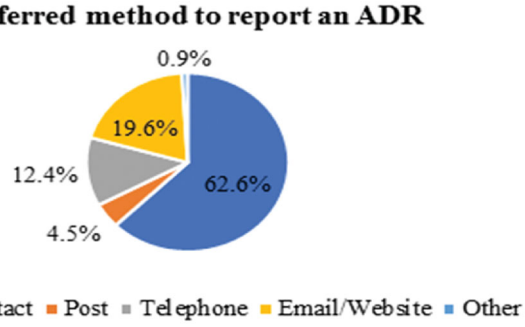

Figure 1. Methods to report ADRs by Health care professionals.

how to report 70.6% ($n = 472$) and not confident in identifying an ADR 65.2% ($n = 436$). Participants also recognized lack of motivation 51.4% ($n = 344$), and fear of legal liability 25.1% ($n = 168$) as barriers to reporting. A minority of respondents recognized reporting to be time-consuming 15.7% ($n = 105$).

Most common factors to encourage ADR reporting were obligatory reporting 85.9% ($n = 575$), provision of ADR management guidelines and training 84.3% ($n = 564$), simple reporting method 84.2% ($n = 563$), feedback from relevant authorities 82.2% ($n = 550$) and encouragement from hospital administration 81.8% ($n = 547$) (Figure 3).

3.6. Description of KAP scores and level

An overall median (IQR) knowledge score of 3 (2–5) was obtained with pharmacists obtaining a high score of 7 (5–8) as compared to doctors 4 (2–5) and nurses 3 (1–4). An overall median attitude score of 37 (34–40) was obtained followed by an overall median (IQR) practice score of 1 (1–2) (Table 5).

Among the respondents, the pharmacists were more knowledgeable 73.5% ($n = 36$) as compared with doctors 18.7% ($n = 59$) and nurses 13.8% ($n = 42$) $p < .001$. Majority respondents displayed an overall positive attitude, 94% ($n = 629$) had a positive attitude ($p < .05$). An overall poor practice was displayed by doctors 95.6% ($n = 302$) and nurses 94.4% ($n = 287$) followed by pharmacists 75.5% ($n = 37$) ($p < .001$) (Figure 4).

3.7. Association of total KAP scores of healthcare professionals with their demographics

A significant relation was found between the healthcare professional and their professional status with the overall KAP scores of the participants ($p < .001$). Similarly, significance was observed between age groups and experience with KAP scores ($p = .001$). No association was observed between gender and overall KAP scores ($p = .9$) (Table 6).

3.8. Correlation between knowledge, practice, and attitude of health care professionals

The correlation between the knowledge, practice, and attitude of health care professionals was analyzed by using spearman's correlation coefficient. The analysis shows that there was a medium, positive correlation between the knowledge and practice of pharmacovigilance and ADR reporting by the healthcare professionals ($r = 0.321$, $n = 669$, $p < .001$). All other correlations were non-significant.

4. Discussion

Adverse drug reactions are a significant contributor toward patient morbidity and mortality whereas effective pharmacovigilance activities help to reduce them[23]. Hence the knowledge of pharmacovigilance is very important for health care professionals for effective spontaneous ADR reporting because lack of knowledge might result in increased patient harm and overall cost of therapy. An overall response rate of 80.6% was achieved which is high as compared to previously

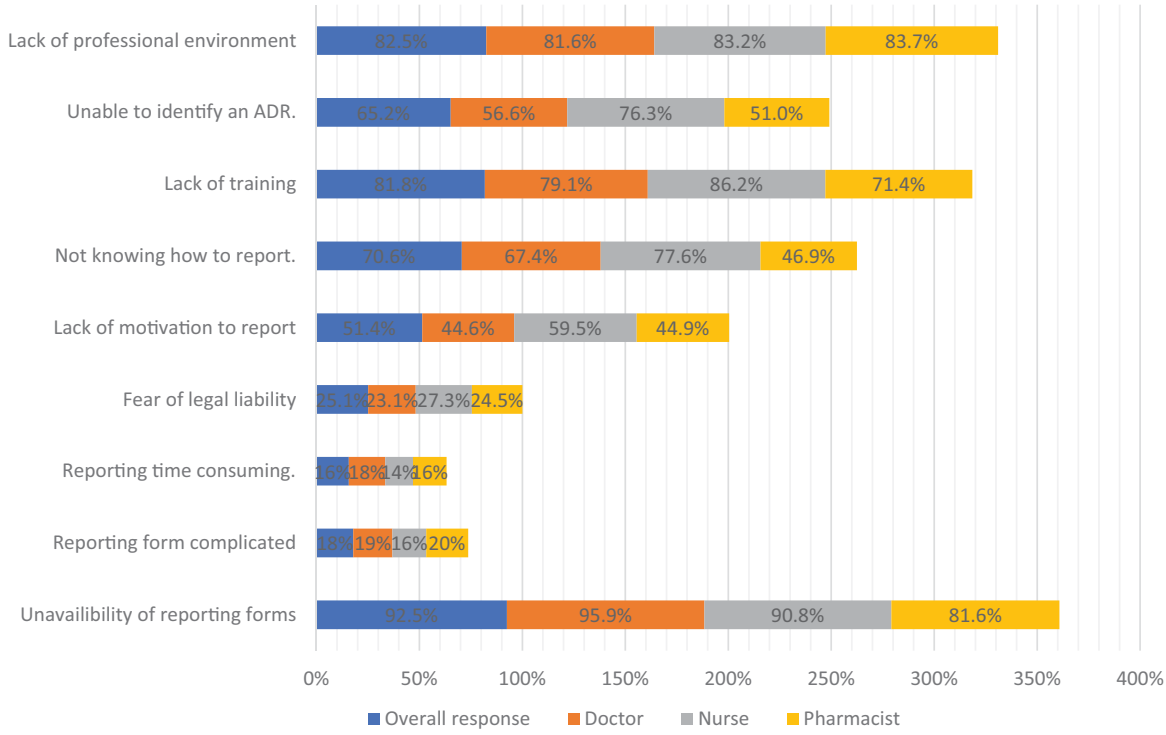

Figure 2. Barriers to ADRs reporting by Health care professionals.

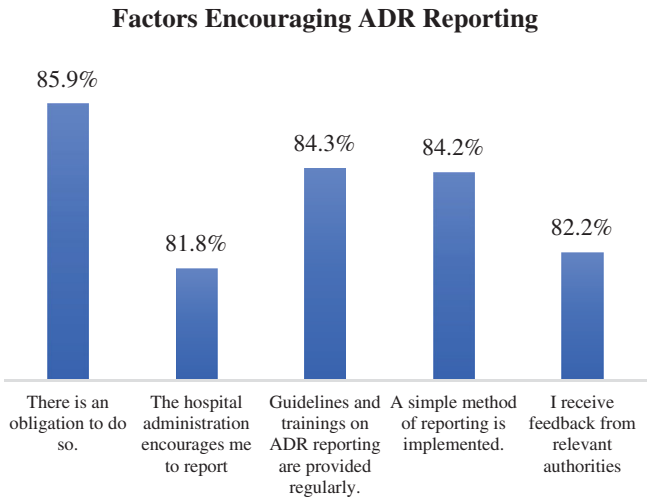

Figure 3. Factors to encourage ADR reporting by Health care professionals.

reported studies[18,24–26]. A face-to-face survey was utilized giving the researcher a control in overall quality and data control process as compared to electronic surveys or *via* mail or telephone which are rather difficult to gather data[27]. Key findings of the study included an overall poor knowledge and reporting practices of the healthcare professionals toward pharmacovigilance and ADR reporting. A positive correlation indicated that with increase in knowledge of the health care professional there is an improvement in the overall practice. However positive attitude was observed which is a positive sign to improve ADR reporting in the future. The study population had more females as compared to males due to the participation of nurses. As for age, professional status, and experience of participants, the majority were young, house officers and staff nurses and had experienced between 2 to 5 years. The number of pharmacists working in the public sector in Khyber-Pakhtunkhwa is still very low[28] hence all the available pharmacists working in tertiary care hospitals were included in this study.

Knowledge of ADR reporting plays a pivotal role in ensuring overall patient safety and safe use of medicine and requires contribution from all health care professionals. Our study revealed that healthcare professionals had overall poor knowledge (79.5%) on ADR reporting and pharmacovigilance activities with similar results being observed from a study in Pakistan and Nigeria with overall inadequate knowledge of health care professionals being 83.1%[16] and 75.4%[29].

Only a few participants (18.5%) were able to identify the term pharmacovigilance as reported in other studies as well where health care professionals had poor knowledge about pharmacovigilance[16,24,29,30]. Amongst the participants, pharmacists were able to define pharmacovigilance better (36.7%) as compared to doctors (19.9%) and nurses (14.1%). This is similar to findings by Hussain et al.[17] and Alemu et al.[29], where pharmacists had displayed a better understanding of pharmacovigilance as compared to other healthcare professionals. In contrast to these findings, all health care professionals were able to define the term ADR correctly (68.9%) amongst which majority were pharmacists (98%) followed by doctors (74.7) and nurses (58.2), as evident from some quantitative and qualitative studies where health care professionals had displayed an overall better understanding of the term ADR and medication safety[12,22,31,32]. A study from Lahore revealed similar findings where 91.8% of pharmacists had better knowledge about ADRs followed by 70.5% physicians and 60.4% nurses[17]. However, healthcare professionals were not able to recognize types of ADRs (76.8%). Possible reasons for the above findings might be that the term pharmacovigilance is relatively new to health care professionals in Pakistan hence they are unaware of it

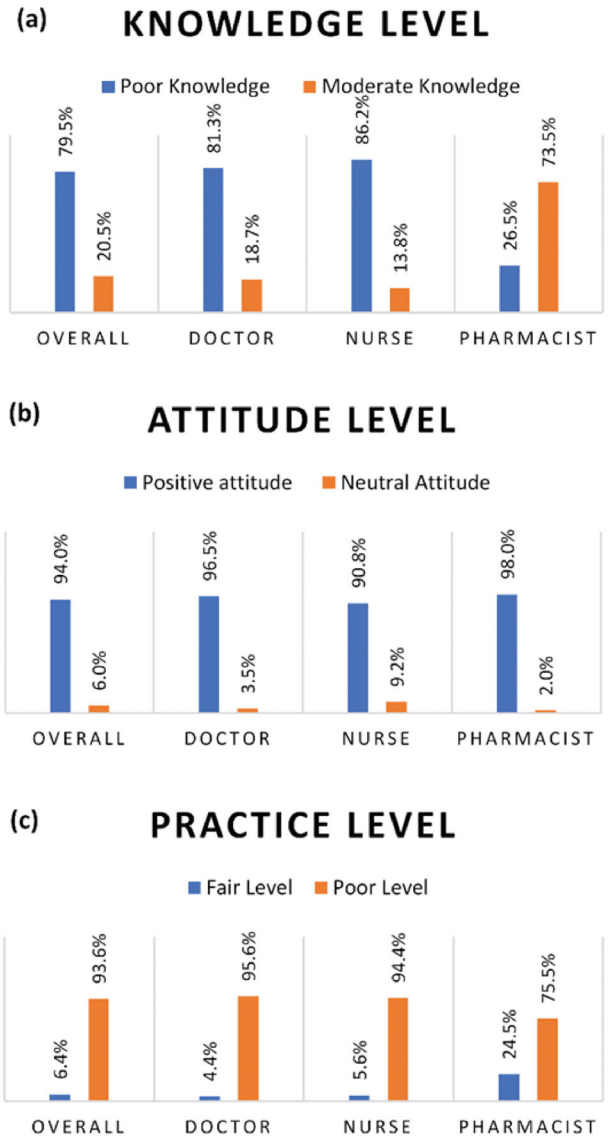

Figure 4. (a) Overall knowledge level of healthcare professionals. (b) Overall attitude level of healthcare professionals. (c) Overall practice level of healthcare professionals.

Table 5. Median (IQR) of the respondents KAP scores.

HCP	Median (IQR)			
	Knowledge	Attitude	Practice	Total Score
Doctor ($n = 316$)	4 (2–5)	37 (34–40)	1 (1–2)	42 (39–44)
Nurse ($n = 304$)	3 (1–4)	37 (33–40)	1 (1–2)	41 (38–43)
Pharmacist ($n = 49$)	7 (5–8)	38 (35–40)	2 (1–2)	46 (43–49)
Overall ($n = 669$)	3 (2–5)	37 (34–40)	1 (1–2)	41 (39–44)

Abbreviation. HCP-C, healthcare professional.

whereas pharmacists study medicines and their adverse effects in detail as part of their curriculum as compared to doctors and nurses, who do not study medicines extensively during their training, hence pharmacists can define ADR more properly as compared to other health care professionals[30,33]. Hence, this lack of knowledge might have serious implications on overall patient safety.

WHO International Pharmacovigilance center at Uppsala, Sweden, plays an important role in promoting patient safety by ensuring the safe use of medicines[6]. Moreover, national and regional pharmacovigilance centers present in

Table 6. Association of the total KAP scores with respondent's demographics.

Variables	Median (IQR)	*p*-Value*
Healthcare professional		
Doctor ($n = 316$)	42 (39–44)	<.001[a]
Nurse ($n = 304$)	41 (38–43)	
Pharmacist ($n = 49$)	46 (43–49)	
Gender		
Male ($n = 279$)	41 (39–44)	.9[b]
Female ($n = 390$)	41 (39–44)	
Age groups (years)		
20–30 ($n = 432$)	41 (39–44)	.001[a]
31–40 ($n = 191$)	42 (39–45)	
≥41 ($n = 46$)	44 (40–46)	
Professional status		
House officer ($n = 163$)	41 (39–43)	<.001[a]
Medical officer ($n = 124$)	42 (39–44)	
Consultant ($n = 29$)	45 (40–46)	
Staff nurse ($n = 258$)	41 (38–43)	
Head nurse ($n = 46$)	42 (39–46)	
Ward pharmacist ($n = 19$)	47 (43–49)	
Main store pharmacist ($n = 24$)	47 (45–49)	
Chief pharmacist ($n = 6$)	44 (41–46)	
Experience (years)		
≤1 ($n = 108$)	41 (39–44)	.01[a]
2–5 ($n = 310$)	42 (39–44)	
6–10 ($n = 173$)	41 (39–44)	
≥11 ($n = 78$)	43 (40–46)	

*p-Value ≤.05 was considered statistically significant.
[a]p-Value was calculated using the Kruskal Wallis test.
[b]p-Value was calculated using the Mann–Whitney U test.

developing countries linked to the international PV center are important for establishing a database to promote the safe and effective use of medicines and the knowledge of reporting centers is crucial for health care professionals[34].

Our study revealed that overall healthcare professionals had poor knowledge regarding ADR reporting centers and databases with only pharmacists having a better understanding of the international PV center (26.5%), national PV center (42.9%), and WHO online database for ADR reporting (30.6%) as compared to doctors and nurses. It is in agreement with other studies, where healthcare professionals lack the knowledge of PV reporting centers as well as did not know about databases for ADR reporting, with pharmacists having a better understanding as compared to other health care professionals[12,16,22,31,32,35]. However, most of the participants (61.7%) knew where to report a serious ADR with similar findings observed in studies from India (78.2%)[26] and Saudi Arabia (99.3%)[18] whereas other studies showed contrasting results where a majority of healthcare professionals did not have any idea where to report a serious event in their country[22,24,29,35]. This lack of awareness about reporting centers and databases indicates poor knowledge and pharmacovigilance practices by our healthcare professionals. It also adds to the fact that there is a visible communication gap between the drug regulatory authority activities and health care professionals[12].

Several studies pointed out that almost 70–80% of doctors, pharmacists, and nurses considered all health care professionals to be qualified to report ADRs[25,35,36] however, our study suggested contrasting results in which only 42.1% of participants considered all health care professionals equally important to report ADRs with similar findings from other studies as well[29,37]. Furthermore, only 33.9% of healthcare professionals agreed on pharmacists being the qualified

person to deal with ADR reporting and monitoring. Contrasting results were seen in similar studies from Lahore where physicians and nurses emphasized that being more trained in medication safety, pharmacists should deal with ADR monitoring within the hospital[32,38]. These are interesting findings, and this difference of opinion might be because Punjab has a better infrastructure on pharmacovigilance and many pharmacists working in hospitals as compared to Khyber-Pakhtunkhwa which has very few hospitals pharmacists working in the government sector. It might also reflect a lack of acceptance of the role of all health care professionals toward each other in Khyber-Pakhtunkhwa.

Similarly, concerning ADR reporting procedure, the majority of healthcare professionals (88.8%) did not know how to report an ADR nor had they seen any reporting form in their hospital (92.1%) which is in conjunction with previous studies where health care professionals had no idea about the reporting procedure and ADR forms[12,22,29,32,39]. These findings may be due to either absence or lack of implementation of local ADR reporting policies within the hospital and lack of training of health care professionals on ADR reporting and monitoring.

In the current survey, the overall attitude of health care professionals toward pharmacovigilance and ADR reporting was very positive (94%). A large percentage of health care professionals had a strong agreement that ADR reporting should be necessary, is a compulsion, is their professional obligation, and contributes toward patient safety. Furthermore, they also agreed that ADRs for newly marketed drugs, herbal and non-allopathic drugs must also be reported, and ADR reporting centers must be in every hospital which correlates with findings from previous studies[9,16,24,29,31,37,39,40]. However few studies from Punjab exhibited that healthcare professionals had associated their positive attitude to the quality of life of the patients, their job satisfaction, and assistance provided to them by the system to freely report ADRs[12,32]. This overall positive attitude might indicate a willingness of a paradigm shift of the health care professionals working in Khyber-Pakhtunkhwa, from product orientation toward patient safety and might act as a major determinant to improve the current poor pharmacovigilance practices in future.

In the present study, the practice of health care professionals toward ADR reporting was quite poor (93.6%). Most of the healthcare professionals encountered ADRs during their professional practice but only a few reported them to the relevant authority whereas the majority of them did not report ADRs at all. Amongst the participants, only pharmacists reported (71.4%) ADRs in the past five years followed by doctors (23.4%) and nurses (22.7%). It is similar to several studies where despite encountering an ADR and having knowledge on medication safety, health care professionals failed to report[12,16,17,26,31,32,37,40]. Almost majority of health care professionals (97.9%) reported that they have not received any formal training on ADR reporting further strengthening the reason for under-reporting of ADRs. These findings are similar to several studies where healthcare professionals failed to receive any training on ADR reporting and monitoring contributing to the under-reporting of ADRs[16,22,26,29,35,39]. The possible reasons for these findings might be that although healthcare professionals do encounter ADRs but are directed to report issues to their seniors who might not report due to fear of being accountable. Also, information might be passed to the relevant pharmaceutical companies or hospital administration, yet they don't fill out the forms and submit the report. It also reflects the lack of involvement of a pharmacist in pharmacovigilance-related activities[12,32,38]. This suggests that hospital management and regulatory authorities might not be contributing significantly to educating health care professionals on ADR monitoring and reporting. It indicates a possible administrative lapse and needs to be addressed by the regulatory authorities to ensure the safe use of medicines by the implementation of pharmacovigilance activities. Furthermore, this gap suggests the need for the introduction of training on ADR reporting of all health care professionals, as lack of training might be the reason for poor reporting practices by healthcare professionals.

In the current study, major barriers identified as obstacles in ADR reporting by the healthcare professionals included unavailability of reporting forms, absence of a professional environment to discuss ADRs, lack of training, absence of a proper reporting system, lack of confidence in identifying an ADR, and legal liability. Several studies from Lahore also reported similar results where healthcare professionals cited increased workload and lack of a proper system to report as major barriers in reporting ADRs. Moreover, lack of training and knowledge and fear of legal liability were also identified as barriers[12,32,38]. Furthermore, different studies from other countries have also reported similar findings but due to different cultural and medical practices and health care systems, the order in which these barriers are reported to differ from the current study[9,13,16,29,31,35,39,40]. The possible explanation of the above barriers might be that Pakistan remains well below the recommended WHO skilled health care professional density of a minimum 4.45 per 1000 population necessary to maintain the universal health coverage goals, with having only 1.45 professionals per 1000 population. Khyber-Pakhtunkhwa has an essential health professional's density of 1.15 per 1000 population. The estimated gap of physicians and specialists is estimated to be at 18,824 whereas the gap of nurses stands at around 141,792. A low pharmacist to population gap also exists with pharmacists' seats being vacant in many districts whereas a very low number is working in tertiary care hospitals. Furthermore, continuous professional education is also run at a suboptimal level so the health care professionals do not receive up-to-date knowledge regarding current practices and medication safety[28]. Hence this further adds to the workload of the healthcare professionals and refrains them from reporting ADRs. In contrast to this, western countries have established advanced guidance, reporting databases, and procedures to overall improve their pharmacovigilance systems[13].

Pharmacists have proven to prevent ADRs and reduce overall financial burden by effectively detecting and reporting

ADRs worldwide[41,42]. Pharmacist plays an important role in detecting and reporting ADRs and ensure medication safety. From being traditionally in drug dispensing role the role of a pharmacist has evolved over the past few decades to ensure safe use of medications and patient safety[43,44]. Moreover, clinical pharmacists work with patients and prescribers as part of pharmaceutical care and are trained to identify ADRs[42,45,46]. Hence all health care professionals should work in collaboration to strengthen the pharmacovigilance system.

The current study also reported the factors that would encourage health care professionals to report ADRs and found that the majority of respondents agreed that they would report ADRs if it was compulsory to report, were encouraged by the administration, were provided a simplified method, regular guidelines, training and feedback from relevant authorities. These findings are aligned with similar findings from different studies where health care professionals cited similar motivations to report ADRs along with emphasizing the importance of regular training and a simple reporting system provided by the drug regulatory authority and hospital administration[12,25,29,38,39]. Hence future efforts must be done based on the above suggestions to improve overall reporting practices.

4.1. Limitations

Most respondents were young as they willingly and enthusiastically participated as compared to more experienced health care professionals including consultants, hence may have some impact on total knowledge score, yet the findings are on a large scale and are valuable input for further studies.

4.2. Recommendations

Our study findings strongly advocate the active collaboration of all stakeholders, i.e. drug regulatory authority, hospital administration, academia, and all health care professionals for the implementation of an active pharmacovigilance system to enhance ADR reporting. Practical solutions in the current situation might include workshops and training that should be held by national and provincial pharmacovigilance centers, the constitution of Pharmacovigilance units at the hospital level, and Interventional studies that should be carried out by the academia to establish the best possible ways to enhance the overall knowledge of health care professionals and hence improve practice.

5. Conclusion

The current study has highlighted and identified a major issue in Pakistan that is the lack of knowledge and poor reporting practices of health care professionals on ADR reporting and monitoring. However, among the healthcare professionals pharmacists had a better understanding of overall pharmacovigilance-related activities. Hence strategies should be devised by the stakeholders to properly train the healthcare professionals in this area to enhance overall patient safety and safe use of medicines.

Transparency

Declaration of funding

This paper was not funded.

Declaration of financial/other relationships

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Author contributions

MJHS and SAK: conceptualized the study. RK and MJHS: questionnaire development. MJHS, SMAA, TA, and MA: data collection. FUK, MJHS, JF, and QK: did the analysis. MJHS: drafted the preliminary manuscript. SS and SAK: revised and approved the manuscript.

Acknowledgements

The authors wish to thank all the doctors, nurses, and pharmacists who cooperated and participated in the current study and recorded their responses. We would also like to thank Mr. Sagar Singh who has worked hard on this project during the data collection process.

Data availability statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethical approval

The current study received approval from the research and ethics committee at the department of pharmacy, Comsats University Islamabad-Abbottabad Campus, Pakistan with reference no. PHM.E.th/CF-M10/17-0043.

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