Submitted: 15/03/2024 Accepted: 14/06/2024 Published: 30/06//2024

Assessment of Knowledge, Attitude and Practice of Community Pharmacists towards Adverse Drug Reactions Reporting in Pokhara

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ABSTRACT

Introduction: The pharmacovigilance activities were initiated since 2004 AD which promote Adverse Drug Reactions (ADRs) reporting in hospital-based set-up in Nepal. But the system lacks—robust activities related to ADRs and its reporting on community-based pharmacy. The role of pharmacist is very essential in preventing harmful effects of medicine.

Objective: The main objective of the research is to assess the knowledge, attitude and practice of community pharmacists towards ADR reporting and to correlates the KAP scores with the demographic distribution of the respondents.

Methods: A cross-sectional study was carried out by using a self-administered structured questionnaire. During the study period 132 pharmacists working at community pharmacies in Pokhara were selected and they were interviewed.

Results: Out of 132 pharmacies visited, with an overall response rate of 65.33%, only 87 pharmacists agreed to response. There were 56 males and 31 females. The pharmacists with post-graduation degree had a high KAP score (21.00) followed by PharmD (19.5), graduate pharmacists (19.35), and then assistant pharmacists (13.8).

Conclusion: Majority of the pharmacist had relatively better attitude but good knowledge towards ADRs and pharmacovigilance. In spite of that the knowledge and attitude could not reflected on the practice of ADR reporting. The majority of respondents emphasize the reporting of ADR from ground level is essential, so that the outcome-based treatment can enhance the patient's safety.

Keywords: Adverse Drug Reaction; pharmacovigilance; pharmacist.

INTRODUCTION

The Thalidomide disaster, a monumental tragedy

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Citation

Chaudhary A, Pariyar S, Dahal B, Thapa S. Assessment of Knowledge, Attitude and Practice of Community Pharmacists towards Adverse Drug Reactions Reporting in Pokhara. Nepal J Health Sci. 2024 Jan-Jun;4(1): 39-49.

in healthcare history, resulted in a significant loss of life. However, it also spurred the

establishment of health safety regulatory bodies. Responding to this, the World Health Organization (WHO) created the Programs for International Drug Monitoring (PIDM), collaborating with the Centre for International Drug Monitoring (CIDM) in Uppsala.^{1,2} WHO's focus on drug safety and promotion of Pharmacovigilance (PV) at the country level involves the detection, assessment,

understanding, and prevention of adverse effects or other potential drug-related problems. ^{3,4}

The Pharmacovigilance (PV) program provides drug-related information and patient safety education to enhance public health quality, enabling the effective assessment of drugs' riskbenefit profiles.⁵ The Department of Drug Administration (DDA) and the national pharmacovigilance center are actively working on ADR monitoring, established in 1979 under the Drug Act of 1978. While the importance of PV in global community pharmacy dates back to the 1960s, Nepal adopted it in 2004. The National Pharmacovigilance Centre of Nepal (NPCN) became a full member of the International Pharmacovigilance Program in 2007.6,7

In Nepal, ground-level hospitals report ADRs to regional pharmacovigilance centers, then to the national center, and finally to the Uppsala Monitoring Centre in Sweden. Community pharmacists play a vital role in this process due to their close connection with patients.^{8,9} The study aims to assess the knowledge, attitude, and practice (KAP) of community pharmacists toward ADR reporting. The research emphasizes the need for a community-based ADR reporting and monitoring system to improve healthcare outcomes.

METHODS

A cross-sectional study was conducted among community pharmacists in Pokhara, Kaski,

Nepal. The first pharmacovigilance center of Nepal is Manipal Teaching Hospital, which is located in Pokhara. Therefore, Pokhara was chosen as study site. A structured questionnaire was designed to assess the knowledge, attitude and practice of pharmacists in community pharmacies regarding ADR and its reporting. The research is approved by the Internal Research Committee (IRC), Sunsari Technical College, Dharan. IRC No: ST15RE113. The study was carried out for a period of 1 months, starting from May 2022 – Jun 2022.

Total Sample size was 132 where sample population (N) = 200; level of confidence = 95%; margin of error = 5%; Sample size for finite (N=200) population. The sample size was calculated by calculator.net (https://www.calculator.net/sample-size-

calculator.html), an online web server. Population size was taken on the basis of information obtained from the department of drug administration (DDA) regarding the registered pharmacy at Pokhara (about 200 retail pharmacy) (https://www.dda.gov.np/). The collected data were analyzed using Statistical Package for Social Sciences (SPSS version 26.0).

Special categories of registered pharmacist which include, diploma, graduate, post graduate and PharmD pharmacists after obtaining written informed consent were included in the study. Pharmacists who did not consent to interview and orientation trainee and other than pharmacy

health care professionals were excluded from the study.

The questionnaire was structured from previous published data 10-13 with minor modifications which was pretested and validated. The modified questions were approved by the expert from the related field. The reliability or content validation of the questionnaire was performed questionnaire 15 by pretesting the Community Pharmacists (CPs) in Pokhara, Western Nepal. The calculated Cronbach alpha value for pilot study was 0.70 and the pilot result did not include in final analysis. Moreover, the results obtained from 15 pharmacies were not included in this study. A score of '1' was given to each positive response whereas the score of '0'was given to each negative response. The maximum possible score was '27'. There were 10 questions regarding knowledge (maximum possible score is '10'), 9 question regarding attitude (maximum possible score is '9') and 8 questions regarding practice (maximum possible score is '8'). The KAP score can be classified as; low (0%-49%), intermediate (50%-74%) or high (75%–100%). ¹⁴ The questionnaire consists of four parts: demographic characteristics of participants, their knowledge, attitude and practice of **ADR** reporting and pharmacovigilance. The transcript for study was written in English but translation had been done in Nepali language (in case of necessary) without changing the meaning.

Face to Face interviewing technique was applied for obtaining responses from community pharmacies. Same process was applied to collect the responses for all community pharmacies. Every pharmacy was visited and the response of pharmacists regarding the research topic was collected. After filling up the questionnaire additional time was given to recheck their response.

RESULTS

Demographic analysis

Out of 132 pharmacies visited, with an overall response rate of 65.90%, only 87 pharmacists agreed to response. There were 56 males and 31 females. There were 23 graduates, 61 diploma, 1 post graduate and 2 PharmD pharmacist. Among the responders 36 were in the age group 18–27 years and 49.4% of them had experiences of 1–5 years followed by 33.33% who had experiences of 6–10 years. The characteristic features of the respondents are shown in Table 1.

Table 1: Demographic details of pharmacists

Parameters	Frequency
Gender	
Male	56 (64.36%)
Female	31 (35.63%)
Age (Years)	
18-27	36 (41.37%)
28-37	35 (40.22%)
38-47	14 (16.09%)
48 above	2(2.29%)
Qualification	

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61 (70.10%)
23 (26.43%)
1 (1.14%)
2 (2.29%)
43 (49.42%)
29 (33.33%)
9 (10.34%)
4 (4.59%)

20-above	2 (2.29%)		
Knowledge, attitude and p	ractice scores of the		
respondents			

The pharmacists with post graduate had a high score followed by PharmD and graduate than diploma (Figure 1). The detail about mean KAP scores of the respondents are presented in Table 2.

Table 2: Mean KAP scores of the respondents.

Professional qualification	Mean (±SD) score						
Trotessional quantication	Knowledge Attitude Practice Total score						
Diploma	6.22 (1.86)	5.74 (1.72)	1.84(1.58)	13.8 (2.40)			
Graduation	8.09 (1.53)	6.17 (1.34)	5.09 (1.81)	19.35 (1.52)			
Postgraduation	10 (0.00)	6.00 (0.00)	5.00(0.00)	21 (2.65)			
PharmD	8.00 (1.41)	6 (0.00)	5.5 (0.71)	19.5 (1.32)			

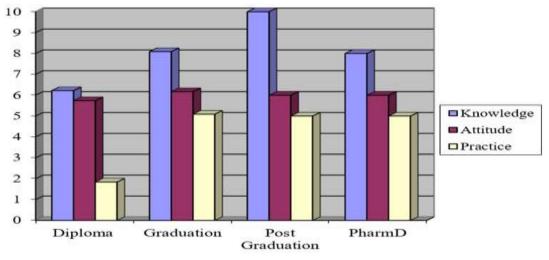


Figure 1: Mean KAP score of respondents vs. Professional qualification.

Male had a high score than female while age group of 18-27 had sore of 16.54 (4.10). The pharmacy graduate (B.Pharm) and PharmD graduate have score of 19.34 (3.19) and 19.50 (0.71) respectively (Figure 2). Other details are given in Table 3.

Table 3: Association of the mean KAP scores with respondents' demography

Parameters	Score s(±SD)
Gender	
Male	16.02 ± 4.37
Female	14.45 ±4.13
Age (Years)	

18-27	15.25 ±3.83
28-37	16.54 ±4.10
38-47	13.79 ±5.83
48 above	13.50 ±0.70
Qualification	
Diploma	13.81 ±3.69
Graduation	19.34 ±3.19
Post-Graduation	21 ±0.00
PharmD	19.50 ±0.71
Years of Experience	
5 years or less	16.07 (3.90)
6-10	15.41 (5.06)
11-15	14.40 (4.25)
16-20	13.25 (2.06)
20 above	16.50 (3.53)
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Figure 2: Educational qualifications of respondent vs mean KAP score.

Responses of the pharmacists to the knowledge related questions

About 10 knowledge related questions were distributed among the respondents. It was obtained that; all of the respondents were able to define the adverse drug reaction (100%) and differentiate adverse drug reaction from side effect. About 53(60.9%) respondents gave the correct answer regarding the definition of pharmacovigilance and 14(16.09%) respondents were aware of the Regional Pharmacovigilance Centre. Similarly, more than half (n=51; 58.6%) of the respondents were aware about the nearest pharmacovigilance center. Other responses are given in the Table 4.

Table 4. Responses of the pharmacists to the knowledge related questions

SN	Knowledge-related questions	Responses in number (%)				
1.	Do you know what adverse	Yes	No	-	-	
	reaction is?	87(100%)	-			
2.	Do you know the difference	Yes	No	-	-	
	between adverse effect and side	87(100%)	-			
	effect?					
3.	Factor which might increase the	Extreme ages	Genetic	Drug's	All	
	possibility occurrence of ADRs?	10 (11.49%)	factors	interaction	53 (60.91%)	
			10 (11.49%)	14 (16.09%)		
4.	What do you mean by	An error in	An error in	An error in	All	
	medication error?	dispensing	dosing	administration	73(83.90%)	
		5 (5.74%)	5 (5.74%)	4 (4.59%)		
5.	What factors should be taken	Full history	Nature of	Drug interaction	All	
	into account?	of patient	reaction		74(85.05%)	

6.	Which health care professionals	Doctor	Pharmacist	Nurse	All
	is responsible for reporting				46(52.87%)
	ADRs?				
7.	Are you aware that existence of	Yes	No	-	-
	ADRs reporting and monitoring	57(65.51%)	30 (34.49%)		
	system?				
8.	Define the term	The science	The science	Detection,	Don't know
	pharmacovigilance?	of detecting	of monitoring	assessment,	3 (3.44%)
		the type of	ADRs	understanding	
		ADR	16 (18.39%)	and prevention	
		15 (17.24%)		of ADRs	
				53(60.91%)	
9.	How many regional	5 centers	8 centers	10 centers	15 centers
	pharmacovigilance centers?	13 (14.94%)	20 (22.98%)	40 (45.97%)	14(16.09%)
10.	Which is nearest	MTH	WRH	Metrocity	Don't know
	pharmacovigilance center?	51(58.62%)	20 (22.98%)	hospital	13 (14.94%)
				3 (3.44%)	

Note: MTH = Manipal Teaching Hospital; WRH = Western Regional Hospital.

Overall, 8 statement and 1 question (n=9) regarding 'attitude' were distributed to the respondents. The respondents had a good attitude towards ADRs and its reporting. Around 85.50% participate showed positive attitude towards the question no 9. Very few pharmacy

professionals (36.78%) agree with consulting the physician is important before ADR reporting. Most of the respondents agreed on the mentioned statements associated with ADR reporting with correct response as mentioned in Table 5.

Table 5: Responses of the Pharmacists to the attitude related questions

		Responses in number (%)				
SN	Attitude-related questions	Strongly	Moderately	Neutral	Moderately	Strongly
		Agree	Agree		Disagree	Disagree
1.	Reporting ADRs is the part of	71	16	-	-	-
	professional obligation.	(81.60%)	(18.4%)			
2.	Consulting with physician is	32	30	25	-	-
	important before reporting an	(36.78%)	(34.48%)	(28.73%)		
	ADRs.					
3.	ADR reporting system would	76	11	-	-	
	benefit the patient.	(87.35%)	(12.65%)			

4.	Assistant pharmacist in	41	15	7 (8.04%)	20	4 (4.59%)
	detection and management of	(47.13%)	(17.24%)		(22.98%)	
	ADRs is useful.					
5.	I will report ADR if reporting	58	20	5 (5.74%)	4	-
	form distributed into	(66.66%)	(22.98%)		(4.59%)	
	pharmacy.					
6.	It is necessary to report	35	4	5 (5.74%)	11	32
	ADRs of OTC.	(40.22%)	(4.59%)		(12.64%)	(36.78%)
7.	Reporting should be	61	20	6 (6.89%)	-	-
	mandatory for practicing	(70.11%)	(22.98%)			
	pharmacist.					
8.	CPs discourage to report	(Don't	(Reporting	(ADRs	(Fear of the	(All)
	ADRs, reason behind it.	know)	may generate	detection	negative	58
		2 (2.29%)	extra work)	may go	impact	(66.66%)
			17 (19.54%)	wrong)	5 (5.74%)	
				5 (5.74%)		
9.	Why ADRs reporting should	(Don't	(To improve	(To	(To measure	All 77
	be done?	know)	patient safety)	identify	the incidence	(88.50%)
		-	5 (5.74%)	and detect	of ADRs)	
				new	1 (1.14%)	
				ADRs)		
				4 (4.59%)		

Eight questions related to practice of ADRs and its reporting were provided to the respondents. The data showed that, more than 82.76% of respondents had never ever been trained on how to report ADR. This illustrates the poor practice

of ADRs reporting activities at Pokhara. Many of the respondents (n=52, 59.71%) had never seen the ADR reporting form but 41.37% (n=36) were aware about how to report ADRs Table 6.

Table 6: Responses of the pharmacists to the practice related questions

SN	Practice-related questions	Yes	No
		Number (%)	Number (%)
1.	Have you observed a suspected adverse drug reaction?	70 (80.45)	17 (19.55)
2.	Your level of clinical knowledge makes it difficult to decide whether or not an ADRs has occurred.	49 (56.32%)	38 (43.68%)
3.	Do you keep record of ADRs?	13 (14.94%)	74 (85.06%)
4.	Have you ever seen the ADR reporting form?	35 (40.22%)	52 (59.71%)
5.	Do you know how to report ADRs?	33 (37.93%)	54 (62.07%)

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6.	Do you know from where to obtained ADR reporting	36 (41.37%)	51 (58.63%)
	form?		
7.	Have you ever trained on how to report ADRs?	15 (17.24%)	72 (82.76%)
8.	Have you ever reported ADRS to any reporting and monitoring centers?	4 (4.90%)	83 (95.40%)

DISCUSSION

This study was one of the few studies conducted in community pharmacies regarding KAP of ADRs and its reporting. The study displayed that the most of the community pharmacists had good to average score in KAP. Among them, pharmacist with post graduate degree have better score whereas, graduate pharmacist (B. Pharm /PharmD) have good score than assistant pharmacist (D. Pharm). All the pharmacists had positive attitude towards ADRs and its reporting. But there was lack of practices on ADRs reporting. Thus, this study revealed that, the community pharmacists were aware of ADR reporting and their mind set towards ADR reporting was also positive but it was not reflected on their daily life practices.

More than half of the respondents (n=61; 70.10%) were assistant pharmacists (D. Pharm), followed by graduate pharmacist (n=23; 26.43%), post graduate pharmacist (n=1; 1.19%) and PharmD (n=2; 2.29%). On associating demographic details of respondents, the study showed that, the mean KAP score of males (16.02) participants was quite more than the females (14.45). The result contrast to the research conducted Alam et. al. at Dharan,

which had response rate of 58.3%. Majority of participants (58.4%) had completed diploma in pharmacy as like in our research. Only 29.9% respondents gave correct definition pharmacovigilance, where as in our research 60.91 % respond correctly. Alam et al claimed that 23.4% respondents were aware of national pharmacovigilance center but our study showed completely opposite data of 65.51% response.¹⁵ Similarly, 50.9% agreed that reporting of ADRs is part of professional obligation whereas 81.60% respondent agreed in our research. However, 66.2% had never seen ADR reporting form.

Our study also suggests that the respondents under age group of (28-37) and having professional experience less than 5 years and above 20 years have comparatively better KAP regarding PV and ADRs reporting activities. It is disappointing that other age groups have slightly lower KAP. This score was very low among assistant pharmacist, which may be due to the almost negligible awareness programs regarding the PV and lack of sound strategies. Despite of having enthusiasm to report ADR, most of the respondents said that they have

never reported ADR. "The major reasons for under reporting of ADRs are lack of knowledge about the reporting procedure, unavailability of the reporting center mailing address, unavailability of the ADR report form, lack of knowledge of the existence of a national ADR reporting system". ¹⁶

Almost all healthcare professional agreed that the reporting of ADR is essential. In this study 132 community pharmacies were offered to participate but only 87 pharmacists agreed to participate. The response rate was 65.90% which was similar to a study done in CPs of UAE (response rate = 74.3%). From the study, they reported that 67% participants had a positive attitude towards making ADRs reporting mandatory for practicing pharmacist which is slightly more than our research (70.11%). ¹⁷

In South India, about 63.4% of the respondents were not aware of the existence of the national reporting system but in Pokhara only 34.49% respondents were not aware of the existence national reporting and monitoring system. In our study all the respondents (100%) correctly defined ADR which was similar to a study conducted by Noohu Abdulla Khan et al. (91.40%) (18) however, the result was far contrary with the result obtained by a study carried out in Delhi by Sah RK et. al (only 17%). ¹⁹ KC Santosh et al. conducted a study at four Regional Pharmacovigilance Center of Nepal and suggested the important factor on decision

making to report the ADR. Most of the factors like the nature of reaction, type of reaction, reaction to new and existing products, reported in our study were similar to the study carried out by KC Santosh et al. among healthcare professionals.²⁰

A past study showed that healthcare professionals suspected many ADR cases in their professional life and even if they know that reporting them will benefit the patients' health, but unfortunately there are situations that are not reported. The worst reality was that, majority of them do not consider necessary to find out ADRs (96%). A majority of respondents did not report ADRs (90%) even though, majority of them felt ADR reporting is important.²¹ The participants in our study also showed the same behaviour regarding ADR identification and ADR reporting. Though, a study conducted in UAE showed that 80.45% of pharmacist working at CPs had seen (suspected) patient experiencing an ADR, unfortunately 97.86% had not reported to the pharmacovigilance center, and only 3.6% of pharmacists reported ADRs to the pharmacovigilance center. ²²

Another study showed that 18.5% of respondents report to the government ADR center and only 5% kept record of ADRs.²³ Our finding indicated that, about 15% of respondents reported ADRs to the governing body, and 49.2% had lack of information about obtaining the ADR reporting form. A questionnaire-based study on the PV were conducted by Thapa S. at

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Dharan and reported that the pharmacy student and community pharmacist had broad knowledge and positive attitude towards the ADR monitoring and reporting to concern authority. ²⁴ The finding of this study coincides the result obtained from our study.

CONCLUSIONS

The present study concludes that community pharmacists had better knowledge and attitude but poor practices of ADRs reporting. The finding suggests the urgent need of frequent educational programs or trainings or workshop to raise awareness towards ADRs and its

reporting. From this study, it is concluded that almost all the pharmacists were in the opinion that the ADR reporting should be practice in community pharmacy. This indicates that the attitude towards PV is very good among pharmacist. The study also shows that the assistant pharmacists (Diploma in Pharmacy) are least aware about ADR identification and reporting but they have more exposure with patients in community pharmacy. Therefore, proper educational program and training session should be conducted periodically.

Conflict of Interest: None

NJHS

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