International Journal of Scientific Reports
Alam K et al. Int J Sci Rep. 2021 Aug;7(8):382-387
http://www.sci-rep.com
pISSN 2454-2156 | eISSN 2454-2164
DOI: https://dx.doi.org/10.18203/issn.2454-2156.IntJSciRep20212833

Original Research Article

Assessment of knowledge, attitude and practice of pharmacovigilance and adverse drug reactions reporting among the community pharmacies in Dharan

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Received: 03 May 2021
Accepted: 02 June 2021

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ABSTRACT

Background: Community pharmacist's (CPs) knowledge, attitude and practice (KAP) of pharmacovigilance and adverse drug reactions (ADR) play a vital role in preventing harmful effects of medicine. The objective was to assess the KAP of pharmacovigilance and ADR reporting among CP.
Methods: A cross-sectional study was carried out among 132 CP in Dharan between February-March 2019 by using a self-administered 25-item semi-structured questionnaire. The KAP score was categorized as good (score 13-25) and poor (score 0-12). The descriptive statistics were calculated using Microsoft excel 2010.
Results: Out of 132 pharmacies, only 77 responded giving a response rate of 58.3%. There were 45 (58.4%) male. Majority of the participants (45, 58.4%) had completed diploma in pharmacy course. Only 23 (29.9%) respondents gave the correct responses regarding the definition of pharmacovigilance and 23.4% were aware of the national pharmacovigilance centre. 50.9% agreed that reporting of ADRs is a part of pharmacist duty and it was important to report ADRs and was leading cause of hospitalization. Sixty three (81.8%) participants had never ever been trained on how to report ADR. Seventy (90.9%) participants were willing to report ADR, however, 51 (66.2%) had never seen the ADR reporting form. Only 3 (3.9%) participants had good KAP score (23.33±1.54).
Conclusions: Despite of relatively better attitude towards pharmacovigilance and ADR reporting, they had a limited knowledge and practice with regard to ADR reporting and pharmacovigilance. The study findings highlights the need to strengthen the community pharmacovigilance program for safer medication use at the community level.

Keywords: Adverse drug reaction, Attitude, Knowledge, Practice, Pharmacovigilance

INTRODUCTION

The WHO defines ADR as a response to a drug that is noxious and unintended and that occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiologic function.[1] ADRs are considered a major cause of patients' morbidity, mortality, hospital admissions as well as increasing length of hospitalization and cost of treatment.[2] It affects irrespective of the age group of patients worldwide with varying magnitude of causing morbidity and mortality.[3] ADRs are reported to be the 4-6th leading cause of death in the United States of America.[4] A study from South India revealed that 0.7% of hospital admissions were due to ADRs and a total of 3.7% hospitalized patients experienced ADRs of which death accounts for 1.3%.[5]

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.[6] It is essential for the safe, rational as well as cost-effective utilization of medicines worldwide and plays an important role in improving the clinical outcomes and also decreasing mortality and morbidity rate.[7] In Nepal, ADR reporting is not mandatory for healthcare professionals. Though the need of pharmacovigilance had been identified early, it was started several years after its establishment. The department of drug administration (DDA), Nepal took the initiatives to set up a pharmacovigilance program in 2002.[8] In the year 2004, pharmacovigilance activities were initiated and Nepal became a full member of the international pharmacovigilance programme in 2007. DDA is the national pharmacovigilance center and there are 12 regional pharmacovigilance centers in the country.[9] The hospitals report ADRs to the regional pharmacovigilance centers from where the reports are sent to the national pharmacovigilance center which ultimately reports to the uppsala monitoring centre (UMC), Sweden through Vigiflow.[10]

CPs are key personnel in the Nepalese healthcare delivery system in addition to physicians and paramedics. They are present throughout the country in rural, semi-urban and urban areas and handle prescriptions, dispense medicines, provide symptomatic care and act as a referral service for higher level patient care.[11] They are considered as one of the most accessible and affordable health care facility to patients. The role of CP has evolved substantially in recent time.[12] CPs have been trained to monitor and report ADRs in Nepal.[11] Along with their role in providing drug information they can also participate in detection and reporting of ADRs more than any other healthcare professionals. The success of pharmacovigilance activities heavily relies on the participation of the healthcare workers like CPs as they perform the daily duties of dispensing, counseling and administration of medication and monitoring of patients.[13] To date few studies have been carried out in CP to assess the practice of adverse drug reaction reporting in Nepal. The knowledge and attitude of pharmacists greatly affect the pharmacovigilance practice. Hence, assessing the KAP of pharmacovigilance among CPs would give the insight on the existing structure and system and the ways to improve it. The objective of the study was to assess the knowledge, attitude and practice of pharmacovigilance and adverse drug reactions reporting among community pharmacists in Dharan.

METHODS

A cross-sectional study was conducted over a period of one two month (February-March 2019) among dispenser in community pharmacy in Dharan. The dispensers who gave consent were enrolled in this study. The sample size of 66 was calculated using Raosoft calculator where sample population was 200, level of confidence 95% and 10% margin of error.[14] A semi-structured questionnaire was adopted from previous studies with minor modifications to suit the study population.[15-17] It consisted of sociodemographic characteristics of participants, questions on knowledge of pharmacovigilance (10 items having yes/no response), questions on attitude related to ADR reporting (9 items having yes/no response) and questions on practice of pharmacovigilance (6 items having yes/no response). Each correct answer and each positive response were given a score of 1 whereas the negative response or wrong or missed responses were given a score of 0. The maximum KAP score was 25. At first, questionnaire was prepared in English by research team. Translation in Nepali and back-translated into English was done by two independent translator. The validity and reliability of the questionnaire was measured by pretesting in seven CPs and those participants were not included in the data analysis. Ethical approval was obtained from Nepal health research council, a legitimate body to issue ethical approval in Nepal. Questionnaire was distributed to pharmacist and appropriate time was given to recheck their response. Later questionnaire was collected back by researcher. The data were entered into Microsoft excel 2010 and descriptive statistics like mean, frequency and percentage were calculated. The KAP score was categorized as good (KAP score 13-25) and poor (KAP score 0-12). The data were presented as tables and graphs. Statistical package for the social sciences (version 21) was used for the statistical analysis.

RESULTS

Out of 132 pharmacies, only 77 participants responded giving a response rate of 58.3%. Most of them 45 (58.4%) were male. Majority of the participants (45, 58.4%) had completed diploma in pharmacy course followed by orientations course (21, 27.2%). Most of them (33, 42.9%) were in the age group 21-30 years and 33 (42.9%) had experiences of 1-5 years (Table 1).

There were 10 questions to assess knowledge of the community pharmacists about ADR reporting and pharmacovigilance. Among the respondents, only 23 (29.9%) respondents gave the correct responses regarding the definition of pharmacovigilance while more than two-third of them were unaware of the national pharmacovigilance centre. Similarly, 38 (49.4%) respondents knew the definition of ADR (Table 2).

There were 9 questions to assess attitude of the community pharmacists about ADR reporting and pharmacovigilance. Table 3 shows the attitude of pharmacovigilance and ADR reporting among the respondents. More than 50% agreed that reporting of ADRs is a part of pharmacist duty and it is important to report ADRs leading to hospitalization (Table 3).

There were 6 questions to assess practice of the community pharmacists about ADR reporting and

pharmacovigilance. Table 4 shows practice of the participants toward pharmacovigilance and ADR reporting. Out of 77, 63 (81.8%) participants had never ever been trained on how to report ADR. Seventy (90.9%) participants were willing to report ADR, however, 51 (66.2%) had never seen the ADR reporting form (Table 4).

The mean KAP score was highest among participants with bachelor of pharmacy (23.3±1.54) followed by participants with diploma in pharmacy (9.4±3.28). Only 3 (3.9%) participants had good KAP score (Table 5).

Table 1: Sociodemographic characteristics of the study participants (n=77).

Variables	Category	Frequency (%)
Gender	Male	45 (58.4)
	Female	32 (41.6)
Age group (in years)	21-30	33 (42.9)
	31-40	16 (20.8)
	41-50	22 (28.6)
	>50	6 (7.8)
Professional qualification	Bachelor of pharmacy	3 (3.9)
	Diploma in pharmacy	45 (58.4)
	Orientation course	21 (27.3)
	Others	8 (10.4)
Years of experience	Up to 5	33 (42.9)
	6-10	17 (22.1)
	11-15	11 (14.3)
	16-20	4 (5.2)
	>20	12 (15.6)

Table 2: Knowledge of pharmacovigilance and ADR reporting (n=77).

S. no.	Questions	Responses	Frequency	Percentage
1.	Definition of pharmacovigilance: the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.	Yes	23	29.9
		No	54	70.1
2.	The most important purpose of pharmacovigilance is to identify safety of drugs, to calculate incidence of ADRs, to identify predisposing of ADRs and to identify unrecognized ADRs.	Yes	16	20.8
		No	61	79.2
3.	Adverse drug reactions is noxious and unintended response to drug and occurs at normal dose.	Yes	38	49.4
		No	39	50.6
4.	Are you aware of the existence of national pharmacovigilance centre in Nepal?	Yes	18	23.4
		No	59	76.6
5.	Type A adverse drug reaction is more common.	Yes	13	16.9
		No	64	83.1
6.	Serious adverse event is fatal in nature, life threatening, cause congenital abnormality and requires prolonged hospitalization.	Yes	34	44.2
		No	43	55.8
7.	Thalidomide tragedy makes many countries to established drug monitoring system in around 1960s.	Yes	15	19.5
		No	62	80.5
8.	Anaphylactic reaction is a life-threatening adverse drug reactions.	Yes	29	37.7
		No	48	62.3
9.	All healthcare professional including doctor, nurse, pharmacist are responsible for reporting adverse drug reaction.	Yes	46	59.7
		No	31	40.3
10.	All type of ADR is most important to report.	Yes	16	20.8
		No	61	79.2

Table 3: Attitude of pharmacovigilance and ADR reporting (n=77).

S. no.	Questions	Responses	Correct response	
			Frequency	Percentage
1.	What factor do you think is important in your decision to report an ADR?	Seriousness of the reaction	45	58.4
		Unusual reaction	21	27.3
		Reaction to a new product	23	29.9
		New reaction of existing product	14	18.2
		Confidence in the certainty of ADR	25	32.5
2	Reporting of ADRs is a part of pharmacist duty.	Yes	40	51.9
		No	37	48.1
3	Monitoring of drug safety is important.	Yes	51	66.2
		No	26	33.8
4.	It is important to report ADRs leading to hospitalization.	Yes	43	55.8
		No	34	44.2
5.	It is important to report ADRs leading to a life-threatening situation.	Yes	56	72.7
		No	21	27.3
6.	It is important to report ADRs leading to congenital abnormality.	Yes	56	72.7
		No	21	27.3
7.	It is important to report ADRs leading to persistence disability or incapacity.	Yes	33	42.9
		No	44	57.1
8.	It is important to report ADRs to answer the questions that may arise in my practice.	Yes	21	27.3
		No	56	72.7
9.	Reporting of ADRs is important to show patients that their concerns are taken seriously.	Yes	28	36.4
		No	49	63.6

Table 4: Practice of the participants toward pharmacovigilance and ADR reporting (n=77).

S. no.	Questions	Responses (%)	
		Yes	No
1.	Have you ever been trained on how to report ADR?	14 (18.2)	63 (81.8)
2.	Have you ever experienced adverse drug reactions in your patient during your professional practice?	36 (46.8)	41 (53.2)
3.	Have you ever reported ADR to the pharmacovigilance center?	13 (16.9)	64 (83.1)
4.	Have you ever seen the ADR reporting form?	26 (33.8)	51 (66.2)
5.	Do you keep record of ADR?	20 (26.0)	57 (74.0)
6.	Are you willing to report ADR?	70 (90.9)	7 (9.1)

Table 5: Mean KAP score of the participants (n=77).

Educational qualification	Means (±SD) score			
	Knowledge	Attitude	Practice	Total
Bachelor of pharmacy (n=3)	7.67±0.58	11.33±0.58	4.33±1.11	23.3±1.54
Diploma in pharmacy(n=45)	2.20±1.79	5.83±1.94	1.67±1.21	9.4±3.28
Orientation course (n=21)	2±1.58	4.6±3.21	2.29±1.30	8.4±3.21
Others (n=8)	2±1.41	6±0.81	2±0.82	10±1.83

DISCUSSION

Pharmacovigilance detects, assesses, understands and prevents adverse drug effects or any other drug related problems. Its ultimate aim was to ensure patient safety and rational use of medicines once a new medicine was released for general use in the patients.[6] The present study was a questionnaire-based study which included community pharmacists from Dharan, Nepal. This was one of the few studies in Nepal that evaluated the KAP of community pharmacists regarding pharmacovigilance and ADR reporting. In the present, the response rate was 58.3% and in contrast to this a higher response rate (82%) was seen in a study by Piparya et al.[18] A lower response rate (21.8%) was reported by Srikanth et al.[19] The participants might thought that their participation could place an additional burden on them and hence the response rate was lower in our study. They for some

reason might have believed that participation in the study and filling the proforma would create problems for their practice. Majority of the study participants (58.4%) were male in the study which was similar to the findings of Piparya et al and Madu et al.[18,20] Only 3.9% and 58.4% participants had completed bachelor of pharmacy and diploma in pharmacy in present study. In contrast to this, most of the participants (79.6%) had completed bachelor in pharmacy in an Indian study.[18] This finding highlighted those medicines were dispensed by persons who don't have any pharmacy degree in around 40% of the community pharmacies in our country which is an alarming situation. It was urgent for the government to implement the pharmacy practice guidelines strictly for patient safety. More than 90% of the participants were in the age group 21-50 years and similar findings had been reported in an Indian study.[18] However, only 80% patients were in the age group pf 21-50 years in another study.[20] Most of the participants had up to 5 year of professional experience and this finding was in accordance with the other study.[20] The mean KAP score was highest among participants with bachelor of pharmacy and only 3 (3.9%) participants had good KAP score. These findings emphasized the need of continued pharmacy education toward pharmacovigilance.

Among the respondents, one third knew the definition of pharmacovigilance and similar findings was also reported by Indian studies.[18,21] More than two-third of them were unaware of the national pharmacovigilance centre. In contrast to this, only 15.04% participants were aware of national pharmacovigilance centre in an Indian study.[18] Similarly, half of the participants (50.6%) did not know the definition of ADR. A lower percentage of participants (37.5%) in a study conducted in India were able to define ADR correctly.[19] Three fifth (60%) of the participants were aware of the fact that all healthcare professionals including doctor, nurse, pharmacist are responsible for reporting adverse drug reaction. Lack of knowledge leads to under reporting of ADR. Unless the CPs were well educated regarding the pharmacovigilance program and ADR reporting, the patient safety will be in doubt. The study findings advocated that the government should implement regular awareness program on pharmacovigilance to educate them.

Most of the participants had positive attitude toward pharmacovigilance. More than half of the participants (51.9%) agreed that reporting of ADRs was a part of pharmacist duty and it was important to report ADRs leading to hospitalization. Similar finding was also reported by other studies.[18,22,23] More than two third (72.7%) of the participants thought that it was important to report ADRs leading to a life-threatening situation and congenital abnormality. As more than 90% CP were willing to report ADR, they had already started to understand the importance of pharmacovigilance program. If CP are trained, there would be a positive drive towards increase in ADR reporting and thereby would help in maintaining the safety profiles of drugs.

The practice of pharmacovigilance among the participants was poor. Most of the participants (81.8%) had never ever been trained on how to report ADR. Only one fifth of participants had gotten training on pharmacovigilance in the present study and a higher percentage of the participants had got training of pharmacovigilance in an Australian study.[24] This might be due to well-functioning of their pharmacovigilance program. Despite half of the participants (46.8%) experienced adverse drug reactions in the patient during their professional practice, most of them (83.1%) had never reported ADR to the pharmacovigilance center. These findings indicated very low participation of the pharmacists in pharmacovigilance activities. Similar finding was also reported in various studies.[25,26] As most of the participants (90.9%) were willing to report ADR, the government should focus on proper education of pharmacovigilance activities. However, 51 (66.2%) had never seen the ADR reporting form.

Pharmacists are the first point of contact to patients in Nepal as they are considered cheaper, faster and people have also much easier access to them for medical consultation. Availability of ADR reporting form and effective ADR reporting system in community pharmacies are an essential element in pharmacovigilance program. Education and frequent training for them would be an ideal way to make them more aware of pharmacovigilance program and to establish a spontaneous ADR reporting system among community pharmacies in Nepal which will ultimately improve patient safety.

Limitations

The study had small sample size. It was restricted to Dharan sub-metropolitan, therefore, results may not be generalized to whole country or other regions of Nepal.

CONCLUSION

The present study concludes that CPs had poor knowledge and practice of pharmacovigilance and ADRs reporting. The finding suggests the urgent need of frequent educational programs or trainings or workshops to raise awareness toward ADRs. Pharmacovigilance authorities should take necessary steps to design interventional programs in order to increase the knowledge and awareness of pharmacists regarding the ADR reporting process. The findings of our study suggests that there is scope for improving the ongoing pharmacovigilance activities in Nepal through continuing educational programs and trainings.

ACKNOWLEDGEMENTS

The authors would like to thanks the study participants.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by Nepal Health Research Council

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Cite this article as: Alam K, Karki B, Gupta AK, Sarraf DP, Wagle S. Assessment of knowledge, attitude and practice of pharmacovigilance and adverse drug reactions reporting among the community pharmacies in Dharan. Int J Sci Rep 2021;7(8):382-7.