

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG PEOPLE WORKING IN COMMUNITY PHARMACY: A CROSS-SECTIONAL STUDY AT BANKE DISTRICT IN NEPAL

Aswani Chaudhary,¹ Arvind Kumar Gupta,¹ Balaram KC,² Niraj Prasad Sah,² Deependra Prasad Sarraf³

¹Department of Pharmacology, Nepalgunj Medical College and Teaching Hospital, ²MBBS Student, Nepalgunj Medical College and Teaching Hospital, Banke, ³Department of Clinical Pharmacology and Therapeutics, B.P. Koirala Institute of Health Sciences, Dharan, Nepal

ABSTRACT

The burden of ADRs is high globally and it accounts for considerable morbidity, mortality, and extra cost to the patients. Pharmacovigilance plays a significant role in the detection, assessment, understanding and reporting of ADRs. Objective of the study was to assess the knowledge, attitude and practice of pharmacovigilance among people working in community pharmacies in the Banke District. A prospective cross-sectional descriptive study was conducted among people working in community pharmacies in Banke district from February to March 2022 using a 20 item semi-structured questionnaire. Ethical approval was obtained from the institutional ethical review committee (501/078-079). Data were entered in Microsoft Office Excel 2010 and descriptive statistics like mean, frequency, percentage and standard deviation were calculated. Data were analyzed using SPSS-22 and data were presented as tables. Only 46 (22.89%) respondents knew the definition of pharmacovigilance. Mean knowledge score of the respondents was 2.87 ± 2.05 out of the maximum possible score of 10. Only 40 (19.9%) respondents had knowledge score $\geq 50\%$. Out of 201, 180 (89.55%) respondents thought that reporting of adverse drug reaction will be beneficial in the future. A total of 136 (67.66%) respondents had positive attitude towards pharmacovigilance. One hundred and seventy seven (88.06%) had not seen ADR reporting form. A total of 166 (82.59%) respondents had poor practice towards pharmacovigilance. Majority of the respondents had poor knowledge, positive attitude and poor practice of pharmacovigilance. There is urgent need of educational programs on pharmacovigilance to raise awareness.

KEYWORDS

Attitude, knowledge, pharmacovigilance, pharmacist

Received on: April 10, 2022

Accepted for publication: May 26, 2022

CORRESPONDING AUTHOR

Dr. Aswani Chaudhary
Lecturer,
Department of Pharmacology,
Nepalgunj Medical College and Teaching Hospital,
Banke, Nepal
Email: chaudharyaswani@gmail.com
Orcid No: <https://orcid.org/0000-0002-9484-5527>
DOI: <https://doi.org/10.3126/nmcj.v24i2.46042>

INTRODUCTION

Adverse drug reactions (ADRs) are harmful or unpleasant reactions resulting from an intervention related to the use of a medicinal product. It usually predicts hazards from future administration and warrants prevention, specific treatment, alteration of the dosage regimen or withdrawal of the medicinal product.¹ Patients usually suffers from ADRs during hospital stay and after discharge which affects adherence to the therapy and also the prescriber-patient relationship.^{2,3} Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other drug-related problem.⁴ It plays a significant role in the detection, understanding and reporting of ADRs. All healthcare professionals including doctors, nurses and pharmacists should report ADRs to the pharmacovigilance center. There is lack of culture of ADR reporting amongst healthcare professionals.^{2,5} The reasons responsible for this might include lack of knowledge of pharmacovigilance program, increased workload, lack of training, feeling of guilt, fear of litigation and ignorance.^{6,7}

People working in a pharmacy are one of the easily accessible healthcare professionals in the community and therefore, they can have a huge impact on pharmacovigilance program. Knowledge, attitude and practice (KAP) of people working in a pharmacy must be assessed frequently to know the gap in the system and reinforce the behavior. Sensitization of healthcare professionals is the progressive concern of the pharmacovigilance program and is the need of the hour. Most of the studies that had assessed KAP of pharmacovigilance had been conducted in doctors.⁸⁻¹⁰ The data is scarce on KAP of pharmacovigilance among people working in a pharmacy in our context.⁶ The present study was conducted to assess the knowledge, attitude and practice of pharmacovigilance among people working in a pharmacies in the Banke district.

MATERIALS AND METHODS

A prospective cross-sectional descriptive study was conducted among people working in a pharmacy in Banke district from February to March, 2022. The sample size was calculated using a single population proportion formula ($n = Z^2 * P * Q / L^2$) at a confidence interval of 95%, power of the study 80%, a margin of error of 10% and a proportion of event occurrence of 67.96% in a similar study.⁹ Based on the above assumption and after adding a 10% non-response rate, the minimum sample size required for the study

was 201. Purposive sampling method was used to select the study participants. The participants who did not give the consent to participate in the study were excluded.

A semi-structured questionnaire was prepared based on relevant literature for assessing KAP of pharmacovigilance.^{9,11,12} It comprised of 20 questions assessing the knowledge (10 items), attitude (5 items) and practice (5 items). All questions were close-ended and had been designed as multiple choices. Pretesting of the questionnaire was done on 10% of the randomly selected respondents. The questionnaire was modified based on the result of the pretest. It had been also reviewed by the research team and three subject experts. Ethical approval was obtained from the institutional ethical review committee (501/078-079). The questionnaires were distributed to the participants and were asked to fill it. It was collected after 24 hours. No incentive was given to the participants. Personal identifying information were not be collected to maintain the confidentiality of the participants.

Data were entered in Microsoft Office Excel 2010 and descriptive statistics like mean, frequency, percentage and standard deviation were calculated using SPSS-22. KAP score was calculated. One mark was given for each correct answer and zero for incorrect or unfilled questions. The knowledge were categorized as good (score 5-10) and poor (score 0-4). Attitude was categorized as positive (score 3-5) and negative (score 0-2). Similarly, practice was categorized as good (score 3-5) and poor (score 0-2). The findings were presented as tables.

RESULTS

Out of 240, a total of 201 people working in pharmacy participated in the study giving a response rate of 83.75%. One hundred and twenty seven (63.18%) were males and 54 (26.87%) had completed diploma in pharmacy course (Table 1).

Only 46 (22.89%) respondents knew the definition of pharmacovigilance. Thirty seven (18.41%) respondents were aware of the purpose of pharmacovigilance which is to identify the safety of drugs. Twenty eight (13.13%) respondents knew that VigiFlow is the "WHO online databases" for reporting adverse drug reactions (Table 2). Mean knowledge score of the respondents was 2.87 ± 2.05 out of the maximum possible score of 10 (Table 3). Only 40 (19.9%) respondents had a knowledge score of $\geq 50\%$ (Table 4).

Out of 201, 180 (89.55%) respondents thought that reporting of adverse drug reaction will be

Table 1: Socio-demographic variables of the respondents (n=201)

| S.N. | Variables | n | % | |
|------|---------------------------|--------------------------------|-----|-------|
| 1 | Gender | Male | 127 | 63.18 |
| | | Female | 74 | 36.82 |
| 2 | Age group (years) | 17 – 30 | 143 | 71.14 |
| | | 31 – 45 | 45 | 22.39 |
| | | 46 – 60 | 11 | 5.47 |
| | | More than 60 | 2 | 1.00 |
| | | Diploma in pharmacy | 54 | 26.87 |
| 3 | Educational qualification | Community medical assistant | 38 | 18.91 |
| | | Bachelor of pharmacy | 29 | 14.43 |
| | | Health assistant | 22 | 10.95 |
| | | Laboratory technician | 16 | 7.96 |
| | | Masters in pharmacy | 10 | 4.98 |
| | | Intermediate of science | 8 | 3.98 |
| | | Bachelor of science | 8 | 3.98 |
| | | Orientation course in pharmacy | 6 | 2.99 |
| | | Bachelor of commerce | 4 | 1.99 |
| | | SLC | 3 | 1.49 |
| | | Staff nurse | 3 | 1.49 |
| 4. | Professional experience | Less than 5 years | 125 | 62.19 |
| | | 5 years or more | 76 | 37.81 |

Table 2: Knowledge of pharmacovigilance among respondents (n=201)

| S.N. | Variables | n | % | |
|------|--|----------------------------------|-----|-------|
| 1. | Do you know adverse drug reaction reporting program in Nepal? | Yes | 111 | 55.22 |
| | | No | 90 | 44.78 |
| 2 | Do you know any nearby adverse drug reaction reporting centre? | Yes | 67 | 33.33 |
| | | No | 134 | 66.67 |
| 3 | National Centre of pharmacovigilance program in Nepal is situated at | Nepalgunj | 10 | 4.98 |
| | | Pokhara | 17 | 8.46 |
| | | Kathmandu | 98 | 48.76 |
| | | I do not know | 76 | 37.81 |
| 4 | Which one of the following is the “WHO online databases” for reporting adverse drug reactions? | Med watch | 5 | 2.49 |
| | | VigiFlow | 28 | 13.93 |
| | | VigiBase | 18 | 8.96 |
| | | MedRA | 10 | 4.98 |
| | | I do not know | 140 | 69.65 |
| 5 | Which adverse drug reaction should be reported? | Only serious or life threatening | 50 | 24.88 |
| | | Only severe and new | 33 | 16.42 |
| | | Mild to severe | 5 | 2.49 |
| | | All type of ADRs | 72 | 35.82 |
| 6 | A serious adverse drug reaction in Nepal should be reported to the regulatory body within: | I do not know | 41 | 20.40 |
| | | One day | 67 | 33.33 |
| | | Seven calendar days | 31 | 15.42 |
| | | Fifteen calendar days | 24 | 11.94 |
| | | Fourteen calendar days | 14 | 6.97 |
| 7 | The international center for adverse drug reaction monitoring and pharmacovigilance program is located in: | I do not know | 65 | 32.34 |
| | | The United States of America | 24 | 11.94 |
| | | Australia | 10 | 4.98 |
| | | France | 4 | 1.99 |
| | | Sweden | 38 | 18.91 |
| 8 | Herbal drugs have no side effects and are safe to use. | I do not know | 125 | 62.19 |
| | | Yes | 67 | 33.33 |
| | | No | 84 | 41.79 |
| | | I do not know | 50 | 24.88 |

Table 3: Mean knowledge, attitude and practice score of the respondents (n=201)

| Variables | Mean score | Standard Deviation | 90% CI |
|-----------|------------|--------------------|-------------|
| Knowledge | 2.87 | 2.05 | 2.59 - 3.16 |
| Attitude | 3.06 | 1.21 | 2.89 - 3.23 |
| Practice | 1.07 | 1.17 | 0.91 - 1.24 |

Table 4: KAP score category of the respondents (n=201)

| | n (%) | n (%) |
|-----------|--------------------------------|--------------------------------|
| Knowledge | Poor (score 0-4) | Good (score 5-10) |
| | 161 (80.10) | 40 (19.90) |
| Attitude | Positive (score 3-5) | Negative (score 0-2) |
| | 136 (67.66) | 65 (32.34) |
| Practice | Poor (score 0-2) | Good (score 3-5) |
| | 166 (82.59) | 35 (17.41) |

DISCUSSION

Pharmacovigilance, being an integral and essential part of patient care, has perceived several advancements globally over the past few decades. It plays a vital role in patient safety and should be the moral responsibility of every healthcare professionals to report ADRs which ultimately strengthens a pharmacovigilance program. Sensitization of healthcare professionals including people working in community pharmacy is the progressive concern of a pharmacovigilance program.¹³ They can play a great role in ADR reporting both in

Table 5: Attitude of pharmacovigilance among respondents (n=201)

| S.N. | Variables | n | % |
|------|--|---------------------------------|-----------|
| 1. | Does reporting of adverse drug reaction will be beneficial in the future? | Yes | 180 89.55 |
| | | No | 12 5.97 |
| | | Not sure | 9 4.48 |
| 2. | Should reporting of adverse drug reactions be mandatory for pharmacists? | Yes | 124 61.69 |
| | | No | 38 18.91 |
| | | Not sure | 39 19.40 |
| 3. | Which methods should be preferred by you for reporting adverse drug reactions? | Online | 91 45.27 |
| | | Telephone | 37 18.41 |
| | | Email | 46 22.89 |
| | | Post | 27 13.43 |
| 4. | As per your opinion, who should report the adverse drug reactions? | Medical and Paramedical persons | 36 17.91 |
| | | Patients/Consumers | 24 11.94 |
| | | Pharmacists | 58 28.86 |
| | | Anybody | 83 41.29 |
| 5. | The reporting of adverse drug reaction is necessary. | Yes | 160 79.60 |
| | | No | 30 14.93 |
| | | Not sure | 11 5.47 |

beneficial in the future. Ninety one (45.27%) respondents agreed that online should be preferred for reporting adverse drug reactions (Table 5). A total of 136 (67.66%) respondents had a positive attitude towards pharmacovigilance (Table 4).

One hundred and four (51.74%) respondents had experienced ADR due to any drugs during their professional practice and 177 (88.06%) had not seen ADR reporting form (Table 6). A total of 166 (82.59%) respondents had poor practice towards pharmacovigilance (Table 4).

community and hospital. The present study had assessed the KAP of pharmacovigilance among people working in community pharmacies. Almost half of the respondents did not have the recommended qualifications as per Drugs Act 1978 and its regulations according to which pharmacists, assistant pharmacists and pharmacy professionals are eligible to work in a pharmacy after registering with Department of Drug Administration.¹⁴ The number of qualified pharmacists is inadequate in our country which might compromise the delivery of quality pharmaceutical services and it also might have a huge impact on pharmacovigilance program.

Table 6: Practice of pharmacovigilance among respondents (n=201)

| S.N. | Variables | | n | % |
|------|---|-----|-----|-------|
| 1 | Do you have any experience of adverse drug reaction due to any drugs during your professional practice? | Yes | 104 | 51.74 |
| | | No | 97 | 48.26 |
| 2 | Have you ever been attend educational session about Pharmacovigilance? | Yes | 29 | 14.43 |
| | | No | 172 | 85.57 |
| 3 | Have you ever been trained on how to report adverse drug reactions? | Yes | 37 | 18.41 |
| | | No | 164 | 81.59 |
| 4 | Have you ever reported any adverse drug reaction to pharmacovigilance center? | Yes | 22 | 10.95 |
| | | No | 179 | 89.05 |
| 5 | Have you ever seen adverse drug reaction reporting form of Nepal? | Yes | 24 | 11.94 |
| | | No | 177 | 88.06 |

More than four-fifth (80.10%) of the respondents had poor knowledge of pharmacovigilance. More than half of the respondents (55.22%) knew the adverse drug reaction reporting program; however, only one-third (33.33%) of them knew the nearby ADRs reporting center. This was similar to other studies.^{9,15} About two-thirds (69.65%) of the respondents did not know that VigiFlow is used for reporting adverse drug reactions. VigiFlow provides secure, controlled and easy sharing of adverse event reports and used by more than 90 countries worldwide.¹⁶ Only 24 (11.94%) respondents knew that a serious adverse event should be reported to the regulatory body within fifteen calendar days which is recommended by the US Food and Drug Administration.¹⁷ Nearly two-thirds (62.19%) of the respondents did not know that the international center for adverse drug reaction monitoring and pharmacovigilance program is located in Sweden. This center, called as Uppsala Monitoring Center, is an independent center for drug safety and scientific research work. It collects and processes ADR reports to detect early signals of potential drug hazards.¹⁸ More than one-third (41.79%) of the respondents opined that herbal drugs have no side effects and are safe to use. Proper awareness program must be targeted at the people working in community pharmacy on safety of herbal medicines as they may produce negative effects ranging from mild to severe.^{19,20} Lack of knowledge of pharmacovigilance profoundly affects the pharmacovigilance system.²¹ There is need of the hour to educate the people working in community pharmacy on pharmacovigilance program through various workshops or seminars.

More than half of respondents (61.69%) agreed that ADR reporting should be mandatory and ADR reporting will be beneficial for future. These findings were in line with other study.⁹ Majority (41.29%) of them also opined that anybody can report ADR. All healthcare professionals (clinicians, dentists, pharmacists, nurses) and even patients and consumers can report ADRs

to pharmacovigilance center and this should be disseminated to all people working in community pharmacy through proper channel.²² The present study revealed that more than two-thirds (67.66%) of the respondents have positive attitude toward pharmacovigilance and similar finding was also reported in other studies.^{9,23} A positive attitude will help to strengthen the pharmacovigilance program if the people working in community pharmacy are trained on the topic through proper education, policy and guidelines.

The present study shows that majority (82.59%) of the respondents had poor practice towards pharmacovigilance and this was similar to other study.²³ Most of them (88.06%) had not yet seen ADR reporting form. They had low participation in ADR reporting as 89.05% respondents had not yet reported a single ADR to pharmacovigilance center. Similar findings were also reported by Poparva *et al.*⁹ Most of the respondents (81.59%) had not received training on the process of ADR reporting. These findings were in line with other reports.^{8,24} Training has a positive impact toward pharmacovigilance activities among health workers.^{11,25} Therefore, the policymaker and stakeholders should first pay the attention towards proper training of people working in community pharmacy on pharmacovigilance process. The findings of the present study provide a basis to develop and implement strategies to improve ADR reporting and to strengthen pharmacovigilance program.

The present study had some limitations. It had a small number of participants. As it was conducted in a single district, the findings may not be generalized to whole country. However, the scenario in other districts of the country might be similar. Being a self-reporting study, the findings might have been influenced by response bias and accuracy of recall by participants.

Although majority of the respondents had positive attitude toward pharmacovigilance, most of them had poor knowledge and poor

practice of pharmacovigilance. The study findings suggests urgent need for educational programs or workshops to raise awareness toward pharmacovigilance practice and ADR reporting process. It is necessary to offer hands-on training for spontaneous reporting of ADR.

ACKNOWLEDGEMENTS

We would like to thank all the participants.

Conflict of interest: None

Source of Research fund: None

REFERENCES

- Aronson JK, Ferner RE. Clarification of terminology in drug safety. *Drug Saf* 2005; 28: 851-70.
- Coleman JJ, Pontefract SK. Adverse drug reactions. *Clin Med (Lond)* 2016; 16: 481-5.
- Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance programme of India: recent developments and future perspectives. *Indian J Pharmacol* 2016; 48: 624-8.
- The importance of pharmacovigilance. World Health Organization, Geneva, 2002. Available at: <https://www.who.int/publications/i/item/10665-42493> (Accessed on 8th January, 2022)
- Ahmad A, Patel I, Balkrishna R, Mohanta GP, Manna PK. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: a pilot study. *Perspect Clin Res* 2013; 4: 204-10.
- Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharm Pract (Granada)* 2011; 9: 228-35.
- Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India. *Indian J Pharmacol* 2015; 47: 65-71.
- Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitude and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: an observational study. *J Nat Sci Biol Med* 2013; 4:191-6.
- Piparva KG, Singh AP. A cross-sectional pilot study of knowledge, attitude and practice of pharmacovigilance among pharmacists at Rajkot district. *J Basic Clin Pharmacol* 2017; 8: S20-S23.
- Ali MD, Hassan YA, Ahmad A, Alaqel O, Al-Harbi H, Al-Suhaimi NM. Knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process among health care providers in Dammam, Saudi Arabia. *Curr Drug Saf* 2018; 13: 21-5.
- Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK. A questionnaire study on the knowledge, attitude and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India. *Perspect Clin Res* 2015; 6: 45-52.
- Alshammari TM, Alamri KK, Ghawa YA, Alohal NF, Abualkol SA, Aljadhey HS. Knowledge and attitude of health-care professionals in hospitals towards pharmacovigilance in Saudi Arabia. *Int'l J Clin Pharm* 2015; 37: 1104-10.
- van Hunsel F, Härmark L, Pal S, Olsson S, van Grootheest K. Experiences with adverse drug reaction reporting by patients: an 11-country survey. *Drug Saf* 2012; 35: 45-60.
- Drug Act 1978. Department of Drug Administration, Kathmandu, Nepal, 2022. Available at: <http://www.dda.gov.np/content/drug-bulletin-of-nepal/> (Accessed on 21st March, 2022)
- KC Santosh, P Tragulpiankit, IR Edwards, S Gorsanan. Knowledge about adverse drug reactions reporting among healthcare professionals in Nepal. *Int'l J Risk Saf Med* 2013; 25: 1-16.
- Vogler M, Conesa HR, Ferriera KA et al. Electronic reporting systems in pharmacovigilance: the implementation of VigiFlow in Brazil. *Pharmaceut Med* 2020; 34: 327-34.
- Code of Federal Regulations Title 21. United States Food and Drug Administration, 2022. Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=312.32> (Accessed on 21st March, 2022)
- Hugman B. From the Uppsala monitoring centre: a review of viewpoint part 1 and part 2. *Drug Saf* 2005; 28: 645-6.
- Ardalan MR, Rafeian-Kopaei M. Is the safety of herbal medicines for kidneys under question? *J Nephroarmacol* 2013; 2: 11-2.
- Zhang J, Onakpoya IJ, Posadzki P, Eddouks M. The safety of herbal medicine: from prejudice to evidence. *Evid Based Complement Alternat Med* 2015; 2015: 316706.
- Pérez García M, Figueras A. The lack of knowledge about the voluntary reporting system of adverse drug reactions as a major cause of underreporting: direct survey among health professionals. *Pharmacoepidemiol Drug Saf* 2011; 20: 1295-302.
- Kalaiselvan V, Kumar P, Mishra P, Singh GN. System of adverse drug reactions reporting: what, where, how, and whom to report? *Indian J Crit Care Med* 2015; 19: 564-66.
- Alsaleh FM, Alzaid SW, Abahussain EA, Bayoud T, Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharm J* 2017; 25: 830-37.
- Remesh A. Identifying the reasons for under reporting of ADR: a cross sectional survey. *Res J Pharm Biol Chem Sci* 2012; 3: 1379-86.
- Jha N, Rathore DS, Shankar PR et al. Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal. *BMC Res Notes* 2017; 10: 4.