

Original Article**KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTIONS REPORTING AMONG HEALTH CARE WORKERS AT DEVDAHA MEDICAL COLLEGE AND RESEARCH INSTITUTE, BHALUHI, RUPANDEHI*** Sanjeev Guragain¹, Namrata Upadhayay²¹Department of Pharmacology, ²Department of Physiology, Devdaha Medical College and Research InstituteSubmitted: 5th-February-2024 Revised: 11th-March-2024 Accepted: 21st-May-2024DOI: <https://doi.org/10.3126/mjen.v3i01.67441>**ABSTRACT****Background:**

Adverse drug reactions (ADRs) are unintended and noxious responses of a drug when used at normal doses in human beings. Increased incidence of ADRs is the challenge for the health care workers (HCWs) throughout the world. Therefore, we focused to assess the knowledge, attitude and practice of ADRs among HCWs at tertiary care hospital, Devdaha.

Methods:

This study is a cross-sectional questionnaire based descriptive study. The validated questionnaire consists of questions that contains scores to categorize knowledge and attitude among HCWs. It also documented practice adopted by the HCWs at the hospital. Out of 50 HCWs approached, 26 gave consent to participate in the study. The collected data were entered in excel and expressed in percentage or frequency.


Results:

All HCWs, 26 (100%), have heard about pharmacovigilance. However, only 11 (42.31%) participants have adequate knowledge regarding ADRs. In which, 22 (84.62%) expressed desire to report ADRs that they encounter during their medical practice. But, they have not reported any ADRs till date. Moreover, only 12 (46.15%) participants have positive attitude towards ADRs reporting. In case of practice, nine (34.62%) participants mentioned that the main factor that hinders them to practice reporting of ADRs is unavailability of the ADRs reporting form in the institute. Almost all (21) HCWs wanted training in pharmacovigilance.

Conclusion:

All HCWs are fully aware of ADRs but most of them show inadequate knowledge regarding ADRs. Over half of them lack positive attitude towards ADRs reporting and the practice of ADRs reporting is not satisfactory. Further, proper training of pharmacovigilance and form to report ADRs reporting should be provided in the hospital.

Keywords: Adverse drug reactions (ADRs), Health care workers, Pharmacovigilance

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INTRODUCTION

Adverse drug reactions (ADRs) are unintended and noxious response of a drug when it is used at normal doses in human beings¹. The ADRs might be of minor, serious and fatal forms. The minor ADRs are such as gastritis, nausea, vomiting, skin rashes^{2,3}. The serious ADRs are such as delirium, syncope, hyperkalemia and Steven Johnson Syndrome^{4,5}. The fatal ADRs are such as gastrointestinal haemorrhages, central nervous system haemorrhages, cardiovascular disorders, and renal dysfunction⁶. ADRs are one of the causes for the morbidity and mortality of the patients. According to one study, the mortality rate due to ADRs was 2.9% (56/1951)⁷. Spontaneous reporting of adverse drug reactions is the global trend carried out by HCWs⁸. However, there are data that show underreporting of ADRs which is a grave problem⁹. Adverse drug reactions can lead to many admissions in hospitals¹⁰. This will increase the burden in the hospital and needs more health workers to manage cases. Further, lack of knowledge on ADRs may lead to poor prognosis and eventually death of the patients.

Pharmacovigilance is the science that deals with the identification, assessment, and prevention of adverse drug reactions. The information collected from pharmacovigilance is helpful to educate doctors regarding adverse drug reactions of the particular drug¹¹. Post-marketing surveillance is the other tool to assess the adverse drug reactions¹². It is done in the market for those drugs that have passed the phase three drug trials. However, there is scanty information known about the safety profile of the drug even after the post-marketing surveillance¹¹. This might be due to less practice of doing post-marketing surveillance. Patients' reporting is also the other way of reporting ADRs. There is evidence of finding fatal adverse drug reactions in the patients even after the use of drugs for many years¹³. Therefore, reporting of ADRs is very crucial to minimize casualties of patients.

In a study, it was found that knowledge, attitude, and practice of health care professionals towards ADR reporting were low¹⁴. Similarly, it was found that there is underreporting of ADRs in some countries such as in India⁹, Nigeria¹⁵ and China¹⁶. However, there are reports that mention good pharmacovigilance and ADRs reporting in some

countries such as Jordan, Oman and Kuwait¹⁷. In one of the study done at Manipal Teaching Hospital, Nepal, health care professionals had poor knowledge, attitude and practice towards adverse drug reactions reporting¹⁸. Further, we did not encounter ADRs reporting form in our hospital. Therefore, we felt underreporting of ADRs in the hospital. Hence, we planned to explore the knowledge, attitude and practice of ADRs reporting among health care professionals in tertiary care hospital of Devdaha. Further, this study might solve the problems of underreporting of adverse drug reactions in the hospital.

METHODS

This study was a cross-sectional descriptive study carried out at Devdaha Medical College and Research Institute (DMCRI) from June 16, 2022 to April 11, 2023. Purposive convenient sampling technique was applied in the study. All the available health workers in the OPD were approached and those who gave consent to participate were included in the study. Estimated sample size was 50 as per the full time workers availability and turnover of the health care workers in the hospital. However, only 26 participants gave consent to participate in the study. Health care workers (mainly doctors, interns, nurses and HA) working in various departments such as Internal Medicine, Orthopedics, General Surgery, Pediatrics, Psychiatry, Obstetrics and Gynecology, Dermatology, Wards, Emergency, Intensive care unit were included in the study. Health care workers of the laboratory and non-medical staffs were excluded from the study.

Ethical clearance to conduct the research was taken from Institutional Research Committee (IRC) of Devdaha Medical College and Research Institute (DMCRI). Informed consent was taken from the health care workers prior to the research. The validated questionnaire¹⁹ was slightly modified and administered to the participants. The modification was done in those questions which were not aligned with the context of Nepal as in the reference questionnaire¹⁹. Further, before administration of the questions the content validity was checked by the expertise and ambiguous option or questions were removed.

In the slightly modified version, following

changes were done according to the context of Nepal and objective of the study:

1. On question number three of section B.1: What is your understanding about pharmacovigilance? In this question options were removed and made an open ended question; as: What is your understanding of pharmacovigilance? Write in brief.
2. Regulatory body in context of Nepal was updated in knowledge section B-3 reporting on ADRs.
3. Patients' questionnaire was to assess patients' knowledge, attitude and practice (KAP) about ADRs which was excluded in our study because our sample population was HCWs not patients.
4. In section D, addition of a new question as: Have you encountered demise of patients due to ADRs? List the drug/drugs that caused demise.
5. Another modified question is: Which of the following factors hinder adverse drug reaction (ADR) reporting in DMCRI? (Section D, question no. 12)

Scoring of Questions: Questionnaire was distributed to HCWs. They submitted to researchers after filling it out on the desk. The questions consist of both close ended and open ended types. The scores in the knowledge and attitude were converted into percentage. In the knowledge field, the HCWs with correct score >80% (viz: >10 out of 13 obtained score) are considered to having adequate knowledge of ADRs whereas score \leq 80% are considered to have inadequate knowledge. Similarly, in the field of attitude, HCWs with the score >80% (i.e. 36 out of 45 points) are considered to have positive attitude towards ADRs reporting while \leq 80% to have negative attitude. The cut off points in knowledge and attitude fields were taken from the similar research done in Nigeria¹⁹. Scoring was not adopted in the practice domain because it consists primarily of open ended questions.

The collected data were entered in excel and expressed in percentage. For open ended questions, data were categorized according to the type of responses and later expressed in percentage or frequency.

RESULTS

All the 26 HCWs responded to the questionnaire. The male participants were more 17 (65.38%) than the female participants 9 (34.62%). Among various professional cadres of HCWs, MD-consultants were more in our study, Table 1. We found almost equal proportion of high (46.15%) and low (53.85%) experienced personnel in the study. Health care workers with age group 31-45 years were more 16 (61.54%) as compared to 20-30 years age group. Most of the nurses denied to fill out because they were unaware of the term pharmacovigilance and did not provide consent to participate in the study.

Table 1: Demographic characteristics of healthcare workers, n=26

Variables	No. of participants
Male	17 (65.38%)
Female	9 (34.62%)
Age (20-30yrs)	10 (38.46%)
Age (31-4yrs)	16 (61.54%)
Intern Doctors	9 (34.62%)
MD-consultant	16 (61.54%)
Nurse	1 (3.85%)
Medical Officer	0 (None)
Married	18
Single	8
Low Experience (1-8yrs)	14 (53.85%)
High Experience (9-16yrs)	12 (46.15%)

In our study, 11 (42.31%) participants had adequate knowledge regarding adverse drug reactions because they had > 80% score (Table 2B). 26 (100%) health workers had heard about pharmacovigilance. Out of them, majority 9 (34.62%) came to know about pharmacovigilance through trainings and seminars. Out of 26 participants, 15 (57.69%) told that pharmacovigilance is the identification and prevention of ADRs. 24 (92.31%) participants have the knowledge that an adverse reaction can not only be experienced by a patient using orthodox medicines. They can also be experienced by herbal medicines as well.

According to table 2C, 19 (73.08%) participants thought that they should report any ADR of a drug to both health care workers and patients. 16 (61.54%) of the participants mentioned that they never came across the ADRs reporting form. Moreover, 23 (88.46%) of the participants told that there is no ADRs reporting form in DMCRI.

Only 2 (7.69%) participants mentioned that the correct regulatory body responsible for monitoring adverse drug reactions in Nepal, which is Regional Centre, that shows that most of them have low level of knowledge in reporting ADRs.

Table 2: Assessment of knowledge and awareness of pharmacovigilance and adverse drug reactions among health workers

A. Pharmacovigilance

Variables/Questions	Frequency	Percentage
1. I have heard about pharmacovigilance: (n=26)		
Yes	26	100
No	0	0
2. If YES, sources of knowledge of pharmacovigilance:		
a. Advertisement	1	3.85
b. From other professionals	7	26.92
c. Through trainings and seminars	9	34.62
d. Book	7	26.92
e. Self-study	1	3.85
f. Social media	1	3.85
3. My understanding of pharmacovigilance is :		
a. Identification and prevention of ADRs	15	57.69
b. Study of ADRs and their management	5	19.23
c. Monitoring of ADRs	4	15.38
d. Consequences of ADRs	2	
4. Serious adverse drug reaction is: (One or more than one options)		
a. A reaction that will lead to hospitalization	16	61.54
b. A reaction that resolves on its own	1	3.85
c. A reaction that is life-threatening	22	84.62
d. A reaction that requires another drug treatment	11	42.31

B. 13-item knowledge questions in adverse drug reactions (n = 26)

Variables/ Questions	Yes/Percentage	No/Percentage
1. An Adverse drug reaction is a side effect that is commonly experienced when patient is using a drug	16 (61.54)	10 (38.46) ^a
2. An adverse drug reaction is an unintended effect of the drug during its administration	24(92.31) ^a	2(7.69)
3. An adverse drug reaction is a predicted and expected reaction to a drug	8(30.77)	18 (69.23) ^a
4. An adverse drug reaction is the same as a side effect	3(11.54)	23(88.46) ^a
5. An adverse reaction can only be experienced by a patient using orthodox medicines	2(7.69)	24(92.31) ^a
6. An adverse reaction can be experienced by a patient using herbal/traditional medicines	19(73.08) ^a	7(26.92)

7. All adverse drug reactions are known before drug gets into market for use	9(34.62)	17(65.38) ^a
8. All adverse drug reactions experienced by a patient taking a drug should be reported and documented	24(92.31) ^a	2(7.69)
9. Only intolerable reactions to a drug should be reported	4(15.38)	22(84.62) ^a
10. Adverse drug reaction may not be documented if the patient was appropriately counseled against such reaction	8(30.77)	18(69.23) ^a
11. The best method of addressing adverse drug reaction is to use or recommend another drug to counter-act the drug effect	12(46.15)	14(53.85) ^a
12. There is no need to report an adverse drug reaction that is already documented in drug literature insert	3(11.54)	23(88.46) ^a
13. Reporting and documentation of adverse drug reactions is important	25(96.15) ^a	1(3.85)
Overall cut off for Knowledge Score >80	Frequency (%)	Remarks
	11 (42.31%)	Adequate Knowledge
Score ≤ 80	15 (57.69%)	Inadequate Knowledge

^aCorrect response to that variable correct answer could be Yes or No, depending on the statement variables.

Maximum obtainable score by one individual =13, Percentage knowledge score of an individual = individual score divided by 13 and multiplied by 100. For example: If one individual obtains score 13 in all 13 statements then the percentage knowledge score of that individual = (13/13) X 100 = 100%; having adequate knowledge with cut off > 80%. Similarly, if an individual obtains 5 correct responses in 13 statements then the percentage knowledge score of an individual = (5/13) X 100 = 38.46%, having inadequate knowledge with cut off < 80%. Therefore, 11 individuals had more than 80% individual score indicating adequate knowledge.

C. Reporting on ADRs

Variables/ Questions	Frequency	Percentage
1. I should report an adverse drug reaction to:		
a. Any health worker	7	26.92
b. Only senior health workers		
c. Patients		
d. a+ c (Any health worker + Patients)	19	73.08
2. I have come across the adverse drug reporting form:		
Yes	10	38.46
No	16	61.54
3. I have form in my facility:		
Yes	3	11.54
No	23	88.46

4. If No, what are the challenges in obtaining the form?		
a. No idea	11	42.31
b. Concerned authority not interested	6	23.08
c. Lack of awareness	3	11.54
d. Team members are not concerned or interested	2	7.69
e. Unknown about availability	4	15.38
5. The regulatory body responsible for monitoring adverse drug reactions in Nepal is/are:		
a. Department of Drug Administration (DDA) of Nepal	14	53.85
b. World Health Organization	2	7.69
c. Regional Centre	2	7.69
d. All of the above	8	30.77
6. If an adverse drug reaction were to occur in your health facility, would you be able to report it?		
Yes	18	69.23
No	8	30.77
7. If yes, how and where would you report such adverse drug reaction?		
a. DDA	8	30.77
b. Medicine Department	1	3.85
c. Hospital Pharmacy Department	6	23.08
d. Hospital Administration	3	11.54
8. If NO, Please state the challenges that prevent you from reporting and managing such drug reactions.		
a. Till now not faced such problems	2	7.69
b. Lack of reporting and analyzing system	3	11.54
c. Administrative challenges	2	7.69
d. No channel to reach DDA	1	3.85

Out of 26 participants, 22 (84.62%) express desire to report all the adverse drug reactions they encounter. 24 (92.31%) healthcare workers out of 26 mentioned that ADRs reporting is part of their responsibilities. 25(96.15%) of healthcare professionals mentioned that training of health care professionals can aid adverse drug reaction reporting. Majority of the healthcare professionals 25 (96.15%) reported that pharmacovigilance should be included in training for health workers. Majority of the participants 22

(84.62%) accepted that reporting adverse drug reactions is part of their professional obligation. 12 (46.15%) participants had positive attitude towards ADRs reporting as they obtained score >80% which is explained in table 3.

Table 3: Assessment of attitude of health workers to Adverse Drug Reactions reporting

Attitudinal statements (n=26)	Agree (%) (SA + A)	Undecided (U) (%)	Disagree (%) (D+SD)
1. I would report all adverse drug reactions I encounter	22(84.62)	1(3.85)	3(11.54)
2. ADR reporting is part of my responsibilities as a health care professional	24(92.31)	0	2(7.69)
3. Training of health care professionals can aid adverse drug reaction reporting	25(96.15)	1(3.85)	0
4. I would be more likely to identify and report important adverse reactions if I received some training on pharmacovigilance	25(96.15)	1(3.85)	0
5. Reporting adverse drug reactions is part of my professional obligation	22(84.62)	0	4(15.38)
6. Pharmacovigilance should be included in training for health workers	25(96.15)	1(3.85)	0
7. I would be likely to report only life-threatening/severe adverse drug reactions	13(50)	3(11.54)	10(38.46)
8. I would be likely to report only previously unknown adverse reactions	7(26.92)	4(15.38)	15(57.69)
9. I do not think that tolerable, mild adverse drug reactions should be reported	5(19.23)	7(26.92)	14(53.85)
Overall cut-off for attitude score (%)	Frequency(%)		
Score >80	12 (46.15)		
Score ≤80	14 (53.85)		

Statements 1 to 6 are positive statements with score as strongly agree (SA)=5, agree(A)=4, undecided (U)=3, disagree (D)=2, strongly disagree (SD)=1, whereas statements 7 to 9 are negative statements with reverse scoring which are as: SA=1, A=2, U=3, D=4, SD=5. Here, Agree= SA+A and Disagree= SD+D; Total obtainable score=45. Percentage score obtained= individual score divided by 45 and multiplied by 100.

Majority of HCWs; i.e. 25 (96.15%) had never been trained on pharmacovigilance. On a scale 1-10, many of the healthcare professionals 21 (80.77%) rated their interest (6-10) to undergo on pharmacovigilance training. 13 (50%) out of 26 participants mentioned that knowledge about reporting and managing ADRs were the possible advantages of obtaining pharmacovigilance training. 15 (57.69%) of participants occasionally encountered adverse drug reactions at DMCR. Whenever they encounter adverse drug reactions, 19 (59.38%) told that they treated the symptoms with another drug whereas 11 (34.38%) provided

counseling to the patients. 3 (11.54%) participants had encountered demise of the patients due to ADRs of (intravenous fluids / intravenous pantoprazole and lignocaine infiltration). 9(34.62%) participants told that unavailability of the ADRs form was the main factor hindering them to report ADRs in DMCRI.

Table 4: Assessment of adverse drug reaction practices among healthcare workers

Questions/ Variables (n=26)	Frequency	Percentage
1. I have ever been trained on Pharmacovigilance:		
Yes	1	3.85
No	25	96.15
2. If Yes, please indicate the year you received such training and the organizations involved	2018 AD	
3. On a scale of 1-10, please rate your interest to undergo training on pharmacovigilance. (1: minimum interest to 10: maximum interest)		
a. 1-5	5	19.23
b. 6-10	21	80.77
4. Possible advantages of obtaining pharmacovigilance training (List):		
a. Proper monitoring of ADRs	3	11.54
b. Save the lives of the patients	6	23.08
c. Knowledge about reporting and managing ADRs	13	50
d. Better clinical outcome	4	15.38
5. How frequently do you encounter adverse drug reactions in your practice at DMCRI?		
a. Occasionally	15	57.69
b. Very often	3	11.54
c. Not experienced till date	6	23.08
d. 50% of all patients	1	3.85
e. No reply	1	3.85
6. Measures I take in case if I encounter adverse drug reactions: (n=32) ^a		
a. Refer to a secondary health care facility	1	3.13
b. Treat symptoms with another drug	19	59.38
c. Nothing, reaction resolves on its own	1	3.13
d. Provide counseling to patients	11	34.38
7. I have encountered demise of patients due to ADRs: List the drug/ drugs that caused demise.		
Yes	3 (iv fluids / iv pantoprazole and lignocaine infiltration/ Etoricoxib)	11.54
No	23	88.46

8. Factors hindering ADRs reporting in DMCRI:		
a. Reporting of ADRs is complicated	1	3.85
b. Insufficient clinical knowledge	5	19.23
c. Fear of liability/ response	2	7.69
d. No time to report ADRs	3	11.54
e. ADRs I've seen are not life-threatening/ severe enough	4	15.38
f. Unavailability of form	9	34.62
g. Lack of experience in filling forms	2	7.69

^a Multiple Response

DISCUSSION

Unintended and harmful effects of a drug when it is used at standard doses in humans are termed as adverse drug reactions (ADRs)¹. The validated questionnaire consisting of open and closed ended questions were used to assess knowledge, attitude and practice of ADRs reporting among HCWs.

In our study, 42.31% HCWs have adequate knowledge of ADRs reporting which is in contradiction from a finding in Philippines where 77% had adequate knowledge of ADRs reporting²⁰. This shows that about 60% of HCWs lack adequate knowledge of ADRs reporting in DMCRI. About 81% rated high desire to go on training on pharmacovigilance. This indicates a need of proper training to HCWs on pharmacovigilance, to minimize the effect of ADRs in patients.

We found that, very few participants, 7.69%, correctly mentioned that the regulatory body responsible for monitoring adverse drug reactions in Nepal is Regional Centre which shows that almost all of them have very low level of knowledge in reporting ADRs. But in some other study done in Nepal, 46.1% participants mentioned the correct regulatory body for ADRs that shows higher percentage of knowledge in them as compared to ours¹⁸. It may be due to the small sample size in our study or they might have received training.

In our study, 61.54% of the participants mentioned that they never came across the ADRs reporting form which is similar to the study done in Nepal where it is mentioned that 89.8% of the participants were unaware of the ADRs reporting form²¹. Therefore, knowledge about the existence

of ADRs reporting form should be provided to HCWs.

In our study, majority of the participants 84.62% accepted that reporting ADRs is a part of their professional obligation which is similar to the finding where majorities 80.9% of them have opinion that ADRs reporting is the combined responsibility of doctors, nurses, pharmacists and medical interns¹⁸. This shows that attitude of HCWs in reporting ADRs in our study is positive. In this study, 46.15% participants had positive attitude towards ADRs reporting as they obtained score >80%, which is similar to the finding where more than half (53.7%) of the 190 healthcare professionals were found to have a positive attitude towards ADR reporting²².

In our study, 96.15% participants were never trained on pharmacovigilance which is similar to the finding from one study where 86.2 % of the participants had not been trained on pharmacovigilance¹⁹. In our study, 80.77% of the participants rated their interest (6-10) to undergo on pharmacovigilance training whereas in another study, 89% of the participants rated their interest (8-10) to undergo on pharmacovigilance training¹⁹. In this study, when the participants were asked about possible advantages of obtaining pharmacovigilance training, 50% of them answered that training will help them obtaining knowledge about reporting and management of ADRs. The other advantages mentioned were as proper monitoring of ADRs (11.54%), saving the patients' lives (23.08%) and to obtain better clinical outcomes (15.38%). This indicates that they need a proper pharmacovigilance training to enhance their knowledge and practice.

In this study, when participants were asked about 'What measures do you take in case if you encounter adverse drug reactions?' 59.38% mentioned that they would treat the symptoms with other drug whereas 34.38% mentioned that they would provide counseling to the patients. To treat the symptoms with other drug is a good practice than providing counseling to the patients. This implies inadequate knowledge of HCWs to manage ADRs. This seems a proper training has to be implemented for minimizing ADRs related demise of the patients.

In this study, 11.54% participants encountered demise of the patients due to ADRs by some drugs

such as intravenous fluids, intravenous pantoprazole and lignocaine infiltration. There are reports that show demise of hospitalized patients due to ADRs of antiretroviral drugs (for HIV/AIDS) and drugs for Tuberculosis, i.e. 2.9% (56/1951)⁷. This shows that hospitalized patients are at high risk of ADRs due to drugs. Therefore, such patients need careful monitoring to prevent the deaths due to ADRs of drugs.

In our study, 34.62% participants told that unavailability of the ADRs form was the main factor hindering them to report ADRs in DMCRI; similar finding was found in other study done in Nigeria¹⁹. Therefore, DDA must actively involve in providing ADRs forms to HCWs at DMCRI. The governing bodies, both DDA and hospital should increase the pharmacovigilance centers and provide continuous training to HCWs. This will help HCWs to report ADRs immediately when they encounter and can manage the patients accordingly. Moreover, this will also help the government to ban those drugs that have higher rate of ADRs mortality. This will also check and balance the pharmaceutical companies to produce and supply quality drugs in the market.

The limitation of our study is small sample size which is unavoidable, because most of them denied participating in the study. Small sample size might be due to poor knowledge and lack of practice among HCWs. This further raise a concern about the monitoring by the DDA in the hospital is not well maintained. Therefore, for the patients' safety it is very crucial to adopt the practice of pharmacovigilance and ADRs reporting attitude by healthcare workers at the hospital.

CONCLUSION

Lastly, it can be concluded that there is inadequate knowledge regarding pharmacovigilance and adverse drug reactions among majority of HCWs. About half of the participants have positive attitude towards ADRs reporting. Many of the participants failed to report the ADRs occurring at hospital due to the unavailability of ADRs reporting forms. This shows that proper training regarding pharmacovigilance and ADRs reporting system has to be conducted for the HCWs. Moreover, DDA must involve in providing ADRs forms and strictly regulate for

the use of them across the country to minimize ADRs mortality.

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