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Original Research Article

Pharmacovigilance: Knowledge, Attitude and Practice among Medical Professionals at a Tertiary Care Hospital in Nepal

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ABSTRACT:

Introduction: Awareness regarding pharmacovigilance and adverse drug reaction reporting by the medical professionals significantly contribute to the safer use of medicine. Therefore, the objective of this study was to assess the knowledge, attitude and practices regarding pharmacovigilance among the medical professionals at a tertiary care hospital in Nepal.**Methods:** This study was a descriptive cross-sectional study conducted at Lumbini Medical College and Teaching Hospital. Printed questionnaires were distributed to all the medical professionals and collected data were analyzed to find the knowledge, attitude and practices of the medical professionals regarding pharmacovigilance.**Results**: A total of 107 medical professionals, 77 (71.96%) males and 30 (28.04%) females, participated in the study. The overall response rate was 98.16%. In this study,70.1% of medical professionals knew the definition of pharmacovigilance, and more than half of the participants(63.6%) did not know the existence of the national pharmacovigilance centre. Regarding attitude, 52.3% of the medical professionals strongly agreed that adverse drug reaction reporting and monitoring system were beneficial to patients or improved patient care. Half of the medical professionals would sometimes counsel the patients about adverse drug reactions.Almost half of the medical professionals mentioned that the major factor behind underreporting was insufficient knowledge of where to report adverse drug reactions. Training on pharmacovigilance was the main recommendation from the participants (52.3%) to improve the pharmacovigilance program. **Conclusion:**There is room for improvement in the knowledge, attitude and practice of the participants.Most medical professionals suggested training or continuing medical education as a way to improve pharmacovigilance programs.

Keywords: Adverse drug reactions, Attitude, Knowledge, Medical professionals, Pharmacovigilance, Practice

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INTRODUCTION:

World Health Organization(WHO) defined pharmacovigilance as the science for detecting, assessment, understanding and prevention of adverse effects or any other drug related problems.[1] Pharmacovigilance

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program helps prescribers know about the adverse effects of the drug.[2]

Once a drug is marketed for community use, it is necessary to observe the effects produced by the drug, whether it is an adverse reaction or a beneficial effect, in order to prevent the occurrence of disasters like thalidomide disaster.[3] Majority of adverse effects of drugs or drug interactions with foods or other toxicities are known after the drug is released, but the rare adverse effects can be observed after using the drugs on a large population.[4] A pharmacovigilance program can help to detect such rare adverse effects of the drug. Therefore, pharmacovigilance centers are formed in WHO member countries, which regulate the safety of the drugs.

Nepal government in 2004 appointed the Department of Drug Administration (DDA) as the focal point for regulating the adverse effects of drugs, which relay the information to the international drug monitoring center (Uppsala Monitoring Center, Sweden).[5] There are thirteen regional pharmacovigilance centers recognized by DDA in Nepal.[6] Manipal Teaching Hospital and Tribhuwan University Teaching Hospital are the first and the second regional pharmacovigilance centers in Nepal.[7]

Although the National Pharmacovigilance Centre requests hospitals to report adverse drug reactions (ADRs), Nepal does not have strict rules for reporting ADRs and it operates voluntarily. Considering the participation of several countries in the WHO drug monitoring program for several years,compared with the reporting rate, the total number of cases reported by the regional pharmacovigilance centers is as low as only 547 ADR cases.[6] The present reporting trend of Nepal depicts substantial underreporting, as it is advisable to have reporting rate of 200 or more per million population per year.[5] Lengthy reporting time, lack of time and insufficient knowledge about the reporting mechanisms are the main factors behind ADR underreporting.[8]

As the pharmacovigilance program is immature in Nepal, it is necessary to enhance the program among medical professionals (MPs). Knowledge, attitude and practice (KAP) of MPs regarding pharmacovigilance are related to ADRs reporting.[9] Therefore, to improve the pharmacovigilance program, MPs should improve their KAP. So, the objective of this study was to assess the knowledge, attitude and practice regarding pharmacovigilance among MPs at a tertiary care hospital.

METHODS:

This was a cross-sectional descriptive study conducted over a period of one month (10 June, 2020 to 10 July 2020) at Lumbini Medical College and Teaching Hospital (LMCTH).

The study targeted all the medical professionals (Consultants, Residents and Medical Interns) working at LMCTH and the total number of medical professionals working at the study site was 109. The study was conducted after obtaining ethical clearance from the Institutional Review Committee (IRC-LMC 05-D/020). As the size of the target population was small (109 participants), we attempted to include all MPs working at LMCTH.Those participants who incompletely filled the questionnaire and did not want to take part in the study were excluded from the study. A self-administered questionnaire was prepared by the authors after reviewing the published literature, and the face validity was obtained from two subject experts before initiating the study.

The questionnaire was divided into four parts. The first part included the demographic profile of the participants. The second part consisted of knowledge-based questions about

pharmacovigilance (multiple choice questions with single response) including definition and objective, the existence of the National Pharmacovigilance Center and the International Center for causality assessment of adverse drug effects. The third part consisted of questions related to the attitude toward pharmacovigilance measured in the Likert scale, which ranged from 'strongly agree' to 'strongly disagree'. The fourth part included pharmacovigilance practices and the major factor discouraging ADR reporting along with the major recommendation for improving the pharmacovigilance program through single-answer multiple-choice questions.

The self-administered questionnaires in the printed form were distributed to the consultants, residents and medical interns in their respective departments, and the objective of the study was explained to them, and informed consent was obtained. If they were not able to fill the questionnaire instantaneously, they were asked to fill up the questionnaire in their free time and submit it to the respective departmental front desk. The complete filled up questionnaires were collected on the same day or the next day.

After completion of data collection, data were entered in Microsoft Excel and analyzed with Statistical Package for Social Sciences (SPPS) software version 21. Statistical tools like mean, frequency, standard deviation were used to describe the socio-demographic profile of the participants along with the level of knowledge, attitude and practices regarding pharmacovigilance.

RESULTS:

Socio-demographic profile: Of the total 109 medical professionals, 107 participants (39 consultants, 25 residents and 43 medical interns) responded with a response rate of 98.16%. There were more male participants (77, 71.96%) than females(30, 28.04%). The mean age of participants was 30.64± 8.28 years, with a minimum age of 23 years and maximum age of 72 years.

Knowledge regarding Pharmacovigilance (PV): Of the total participants, 70.1% of MPs knew the definition of pharmacovigilance in accordance with WHO and 55.1% of the participants knew the objective of pharmacovigilance.Almost four fifth (82.24%)of MPs knew the regulatory body responsible for monitoring ADRs in Nepal, whereas only 16.8% of MPswere aware of the responsible organization for International Drug Monitoring (Uppsala Monitoring Centre) (Table 1).

Attitudes regarding Pharmacovigilance: Of the total participants, 55.1% agreed and 28.0%strongly agreed that pharmacovigilance topics be covered in detail in the undergraduate syllabus.About four-fifth of the participants (79.4%) strongly agreed that MPs should know the ADRs due to particular drugs and about half of the participants (49.5%) strongly agreed that training should be arranged for medical professionals in order to improve the pharmacovigilance program.Half of the MPs (50.5%)strongly disagreed that the reporting of ADRs in hospitals is not required. A large number of MPs (42.1%)neither agree nor disagree about the need for financial rewards for reporting ADRs (Table 2).

Practice regarding Pharmacovigilance: Thirty-one (29%) MPs mentioned that they had observed ADRs in patients during their practice. Most of the MPs (81.3%) had never seen the adverse reaction reporting form. Nearly half (49.5%)of the MPs would sometimes counsel the patients about ADRs, while 45.8% of all MPs always counseled the patients (Table 3).

Table 1: Knowledge regarding pharmacovigilance (N=107)

Particulars	Frequency (%)
Pharmacovigilance is	
a. The process of improving the safety of drugs.	11 (10.3)
b. Science of monitoring adverse drug reaction (ADR) occurring in a hospital.	12 (11.2)
c. Detection, assessment, understanding and prevention of adverse effects.	75 (70.1)
d. Science detecting the type and incidence of ADR after a drug is marketed.	9 (8.4)
The objective of Pharmacovigilance is	
a. To identify safety of the drug.	59 (55.1)
b. To calculate incidence of ADRs.	11 (10.3)
c. To identify predisposing factors to ADR.	19 (17.8)
d. To identify previously unrecognized ADRs.	18 (16.8)
The organization responsible for international drug monitoring is	
a. International Network for the rational use of drugs.	40 (37.4)
b. European Medicines Agency.	2 (1.9)
c. Uppsala Monitoring Centre.	18 (16.8)
d. United states food and drug administration.	47 (43.9)
Do you know the existance of the National Pharmacovigilance Program in Nepal?	
a. Yes	39 (36.4)
b. No	39 (36.4)
The regulatory body responsible for monitoring ADRs in Nepal is	
a. NMC (Nepal Medical Council).	9 (8.4)
b. NMA (Nepal Medical Association).	10 (9.3)
c. DDA (Department of Drug Administration).	88 (82.3)
A scale used to establish the causality assessment of an adverse drug reaction is	
a. Modified Harbwig scale.	39 (36.4)
b. Naranjo Algorithm.	53 (49.5)
c. Child Pugh score.	5 (4.7)
d. Schumock and Thornton Scale.	10 (9.3)

Table 2: Attitudes regarding Pharmacovigilance (N=107)

Particulars	Strongly disagree: n (%)	Disagree: n (%)	Neither agree nor disagree: n (%)	Agree: n (%)	Strongly agree: n (%)
Medical Professionals should know the adverse drug reactions (ADR) due to particular drugs	-	1 (0.9)	-	21 (19.6)	85 (79.4)
ADR reporting and monitoring system benefit patient or improve the patient care.	1 (0.9)	-	2 (1.9)	48 (44.9)	56 (52.3)
Training should be arranged for medical professionals in order to improve the pharmacovigilance program.	-	-	7 (6.5)	47 (43.9)	53 (49.5)
Pharmacovigilance topics should be covered in detail in undergraduate syllabus.	-	-	16 (14.9)	59 (55.1)	30 (28.0)
Reporting ADR should be financially rewarded.	5 (4.7)	20 (18.7)	45 (42.1)	29 (27.1)	8 (7.5)
Reporting ADR in the hospital isn't required.	54 (50.5)	39 (36.4)	3 (2.8)	7 (6.5)	4 (3.7)

Table 3: Practices regarding pharmacovigilance (N=107)

Particulars	Frequency (%)
Have you reported any adverse drug reactions (ADRs) that you have observed in a patient during your practice?	
a. Yes	31 (29.0)
b. No	76 (71.0)
Do you counsel patients regarding possible ADRs?	
a. Sometimes	53 (49.5)
b. Always	49 (45.8)
c. Never	5 (4.6)
Have you ever seen the adverse drug reaction reporting form?	
a. Yes	20 (18.7)
b. No	87 (81.3)
Have you ever received a patient with an adverse event related to drugs or other health products?	
a. Yes	83 (77.6)
b. No	24 (23.4)

Factors discouraging ADR reporting and suggestions for improvement: Almost half of the MPs mentioned that the major factor behind underreporting was insufficient knowledge of where to report ADRs. Similarly,15.9% of the MPs mentioned that they were not aware of the need to report ADRs, and 17.8% did not know how to report ADRs. The major suggestions from the participants regarding improvement of the pharmacovigilance program were regular conduction of training (52.3%) and continuing medical education (CME) (19.6%)as shown in Table 4.

DISCUSSION:

This study was conducted at LMCTH to assess the KAP regarding pharmacovigilance among the medical professionals. In this study, the number of male participants (n=77) was higher than that of females (n=30).

Table 4: Major factors discouraging adverse drug reaction (ADR) reporting and major suggestions to improve pharmacovigilance program (N=107)

Particulars	Frequency (%)
Major factor behind underreporting:	
a. Not aware that ADRs need to be reported.	17 (15.9)
b. Do not know where to report.	54 (50.5)
c. Do not know how to report.	19 (17.8)
d. Diagnosing ADR is difficult for me.	2 (1.9)
e. Patient management was more important than reporting.	15 (14.0)
Major suggestion:	
a. Training regarding pharmacovigilance should be provided to the medical professionals	56 (52.3)
b. CME (continuing medical education) should be conducted regularly.	21 (19.6)
c. Reporting ADRs should be compulsory.	9 (8.4)
d. The centre should be established inside the hospital premises.	21 (19.6)

A study conducted by Kunnoor NS et al. and Shroukh WA et al. found male participants were higher than female participants, which was the same as our result.[10,11]However, KC S et al. and Thamir M et al. found that female participants were higher than male participants because they had included the nurses in their study population where mainly the female population were studying nursing in Nepal.[5,12] The overall response rate in our study was 98.16%, which was higher than the studies conducted by Palaian S et al. (70.8%), Fatemah MA et al. (82.6%) and Gupta P et al. (77.2%).[9,13,14] This might be because we repeatedly followed up the MPs, and our sample size was small.

The correct definition and objectives of the PV program were known by 70.1% and 55.1% MPsrespectively, in our study. The same line of results was also reported by Fatemah MAet al. and Gupta SK et al.They found that 61.5% and 62.4% of participants of these respective studies knew the correct definition of PV,while 74.8% and 66.3% knew the purpose of PV.[13,15] Surprisingly, only 16.8% of MPs knew the organization responsible for the International Drug Monitoring Center, and 36.4% knew the existence of the National PV center in Nepal.

However, Gupta P et al.study found 43% of the participants knew the existence of the National PV center.[14] Similarly, Oshikoya KA et al. showed 51.5% of participants were aware of the existence of the national PV center.[16] Naranjos scale is a widely used scale for causality assessment for ADR evaluation.[17] Only half of the participants(49.5%) knew the specific scale for causality assessment in our study. This might be because the content of the pharmacovigilance program was not adequately included in the undergraduate syllabus of Bachelor of Medicine and Bachelor of Surgery (MBBS).

Our result showed most of the MPs strongly agreed that they should know the ADRs of a particular drug (79.4%), andhalf (52.33%) of all MPs strongly agreed that ADR reporting and monitoring system were beneficial to improve patient care.However, a higher percentage (97.0%) of participants reported that the reporting of ADR is necessary in a study conducted by Gupta SK et al. in India.[15] This might be because the regulatory bodies regularly review India's pharmacovigilance program, while Nepal's pharmacovigilance program is in the amateur stage.

The study conducted by Katekhaye VM et al. found 54% of participants wanted financial reward in order to improve the pharmacovigilance program,whereas our study showed that only a few (7.5%) medical professionals strongly agreed about the need for financial reward.[4] Furthermore, Gupta SK et al. and Das L et al. found 92.1% and 96.67% of participants agreed that the medical professionals must be taught in detail to improve the safety of drugs.[15,18] Our study found that 83.1% of the medical professionals agreed (55.1% agreed and 28% strongly agreed) that pharmacovigilance topics should be covered in detail in the undergraduate syllabus.This difference might be because of giving less emphasis on the syllabus by our participants.

Twenty-nine percentage of MPsreported that they had observed ADRs during their practices. This result is very low compared to the study conducted by Srinivasan V etal. and Kunnoor NS et al.[2,10] The study conducted by Srinivasan V et al. found that 75.2% of participants had seen ADR form.[2] Our study found only 15.9% of the participants had seen ADR form. Palaian S et al. found that 70.08% of participants received patients with ADR, whereas our result showed that 77.6% of participants received patients with ADR during their practices that were almost similar .[9]

Regarding the major factors responsible for underreporting the adverse drug reactions, our study found that 50.5% of participants did not know where to report. Compared to studies conducted by Fatemah MA et al. and Mishra PS et al., their result showed that 68.9% and 60% of participants said that they had poor knowledge of how to report the ADRs.[13,19] However, Fatemah et al. allowed multiple responses to their question. For improving the pharmacovigilance program, majority of the participants(52.3%) suggested that training regarding PV be provided to medical professionals.

A limitation of this study was that it was a single center research and did not include pharmacists and nurses as the study population.

CONCLUSION:

Two-thirds of the medical professionals working at the study site gave the correct definition of pharmacovigilance according to WHO, and more than half of the participants did not know the existence of the National Pharmacovigilance Program in Nepal. The major reason for underreporting among the medical professionals was that they did not

know where to report ADRs, and more than half of the participants suggested that training be provided to medical professionals to improve the pharmacovigilance program.

Conflict of Interest: The authors declare that no competing interests exist.

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