Attitude of Doctors and Nurses towards Adverse Drug Reaction Reporting at a University Teaching Hospital

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ABSTRACT

Introduction: Spontaneous reporting of adverse drug reaction (ADR) is the main stay of pharmacovigilance. However the major limitation of this method is underreporting as it depends entirely on the participation of the health care professional. This study aimed to identify factors that discourage ADR reporting and possible ways to improve ADR reporting.

Methods: This is a questionnaire based cross-sectional descriptive study employed at a tertiary level teaching hospital from December 2020 to March 2021 after approval from institutional review committee. All the doctors and nurses were included in the study and the data were collected using structured questionnaire.

Results: Total numbers of participants were 283. Among them, 260(91.9 %) had encountered a patient/s with ADR and 119(45.6%) had documented ADR. However, there was no reporting to the pharmacovigilance centre/ unit of the hospital.Out of 283 participants, 123 (43.5%) agreed that the major discouraging factor to report ADR was unavailability of reporting form. Similarly decision to report ADR depended on new reaction to an existing product 217(76.7%) followed by seriousness of the reaction 213 (75.2%). The 245(86.7%) participants have recommended to conduct awareness among healthcare professional and 208(73.3%) to train healthcare professional to improve ADR reporting.

Conclusion: Even though the large numbers of participants have encountered patient/s with ADR but documentation of ADR is less. Further, none have reported due to limited knowledge regarding"what, how and where to report ADR"? In addition to these, unavailability of ADR reporting form was the major discouraging factor to report ADR.

Key word: Adverse drug reaction reporting; Attitude; Pharmacovigilance.

INTRODUCTION

Adverse drug reaction (ADR) is one of the major public health problems. ADRs are not only responsible for nonadherence to drug but also increases the risk of hospitalization as well as results in mortality.[1-4] Moreover, ADR creates heavy economic burden on individuals and health care system.[5,6] However, more than half of the ADRs are preventable.[7] The safety evaluation of drug is done in a controlled setting before authorization for use. After approval, when drug is used in large population most of the ADR are revealed.[8,9] Therefore, to ensure the safe use of drug, it is necessary to detect and report the ADR during post marketing surveillance. Despite this, most of the ADR remains undocumented.[10,11]

Among the various methods, spontaneous reporting is mainstay of ADR reporting during post marketing surveillance. The major drawback of this method is under reporting as it requires active participation from the reporters such as doctors, nurses and pharmacist.[10,11] The reporting rate of ADR is 5%-10%. Studies shows that

inadequate knowledge, lack of attitude and practice towards ADR reporting are among the main reason associated with underreporting.[12-16] This study was conducted to find out the attitudes of doctors and nurses towards adverse drug reaction reporting and factors which influences ADR reporting; and to find out possible ways to improve ADR reporting.

METHODS

This is a questionnaire based cross-sectional descriptive study conducted from December 2020 to March 2021 after approval from institutional review committee (Ref: drs1807081180). A pre-designed questionnaire was adopted from previous study and was used after minor modifications. The questionnaire used for study was divided into six sections. The first section collected demographics details of participants. The second section gathered information on whether participants have experienced and reported ADR. The third and fourth part contained five level likert scale (1 = strongly disagree and 5 = strongly agree) questions designed to obtain factors that discourage ADR reporting and factors that affect the decision to report ADR. The last two Sections consisted of single question each regarding ways to improve the ADR reporting and feedback they would like from Nepal Pharmacovigilance Programme. In these sections multiple selections were available.All the doctors and nurses working at Patan Academy of Health Sciences (PAHS), Patan hospital were included in the study. Google form of questionnaire was created to collect data from doctors. Institutional email addresses of doctors were obtained from information technology section, PAHS. Then the link to the google form was sent through email to individual doctors by principal investigator and seven days were given to fill out the form. After seven days, two reminder emails were sent one week apart and those not responding were excluded from the study. For nurses, questionnaires were distributed face to face in their respective department by investigators. Seven days were given to fill out the form. After seven days, they were reminded two times personally by same investigators one week apart and those not responding were excluded from the study. The participation was voluntary and filling out the form was considered as consent given. The collected data were then entered into Statistical Package for Social Sciences (SPSS) version 17 for windows. Categorical variables as well as likert scale were presented as number with percentage.

RESULTS

Out of total 283 participants in the study, 62 were doctors and 221 were nurses. Among the respondent, 260 (91.9 %) had observed a patient with an ADR, however, only 119(45.6%) had reported. Of 119 participants who have reported ADR, none of them have reported to the pharmacovigilance centre/ unit of the hospital. Out of 283 respondents, 123(43.5%) agreed and 108(38.2%) disagreed that the major discouraging factor to report ADR was unavailability of reporting form. In contrast, 155(54.8%) disagreed and 81(28.6%) agreed on belief that only safe drug is marketed as a major discouraging factor.(Table 1)

Table 1: Factor discouraging to report of ADR

Factors	Strongly disagree n (%)	Moderately disagree n (%)	Neutral n (%)	Moderately agree n (%)	Strongly agree n (%)
Concern that the report may be wrong	48(17)	75(26.5)	75(26.5)	80(28.3)	5(1.8)
Lack of time to fill in a report and a single unreported case may not affect ADR database	71(25.1)	57(20.1)	47(16.6)	61(21.6)	47(16.6)
Not confident to decide whether or not an ADR has occurred	38(13.4)	71(25.1)	89(31.4)	66(23.3)	19(6.7)
Lack of time to actively look for an ADR while at work	75(26.5)	67(23.7)	61(21.6)	52(18.4)	28(9.9)
Fear of legal liability by reporting adverse reaction	57(20.1)	52(18.4)	80(28.3)	61(21.6)	33(11.7)
Concern that a report will generate an extra work	52(18.4)	61(21.6)	85(30)	66(23.3)	19(6.7)
Belief that only safe drugs are marketed	80(28.3)	75(26.5)	47(16.6)	34(12)	47(16.6)
Think that you may have caused a patient harm	66(23.3)	76(26.9)	47(16.6)	66(23.3)	28(9.9)
Ambition to publish case report personally	71(25.1)	42(14.8)	108(38.2)	38(13.4)	24(8.5)
Reporting forms are not available when needed	47(16.6)	61(21.6)	52(18.4)	61(21.6)	62(21.9)
Other colleagues are not reporting	44(15.5)	71(25.1)	83(29.3)	42(15.2)	42(14.8)

Regarding the decision to report ADR 217(76.7%) respondent agreed that new reaction to an existing product, 213(75.2%) agreed on seriousness of the reaction, 202(71.3%) unusual reaction, 188(66.7%)reaction to a new product to be most influential factor. (Table 2)

Table 2: Factors influencing decision to report ADR

Factors	Strongly disagree n (%)	Moderately disagree n (%)	Neutral n (%)	Moderately agree n (%)	Strongly agree n (%)
Seriousness of the reaction	14(4.9)	42(14.8)	14(4.9)	94(33.2)	119(42)
Unusual reaction	5(1.8)	5(1.8)	71(25.1)	127(44.9)	75(26.4)
Reaction to a new product	9(3.2)	14(4.9)	71(25.1)	108(38.1)	80(28.6)
New reaction to a existing product	5(1.8)	14(4.9)	47(16.6)	104(36.7)	113(40)
Confidence in the diagnosis of ADR	52(18.4)	52(18.4)	61(21.6)	61(21.6)	57(20)

The possible ways to improve ADR reporting suggested by 245(86.7%) was awareness among healthcare professional, by 208(73.3%) was training to the healthcare professional, by 189(66.7%) was make reporting a professional obligation by 170(60%) was involve pharmacist for ADRs reporting and by 160(56.7%) was collaboration among other healthcare professional.
Participants who would like to receive feedback in the form of international drug safety information were 236 (83.3%), regular newsletter on current awareness in drug safety were 203(71.1%), information on new drug adverse reactions by newsletter were 184(65%), annual national statistics were 151(53.3%) and individual response to report were 151(53%).

DISCUSSION

This study found that 260 (91.9%) participants had experienced a patient with an ADR but none of them have reported to pharmacovigilance (PV) center. Finding of current study was in accordance to various studies conducted in Nepal,[16-18] India[19-21] and Pakistan.[22-24] but differed from the studies conducted in developed countries like France, Netherland, Sweden and UK where ADR reporting rate was as high as 70%.[22] The high reporting rate may be because these countries have well established PV programme whereas in developing countries including Nepal it is in early stage.

Doctors who have documented ADR have either shared it during the meeting, recorded in department register or reported to pharmacy. Similarly, nurses have reported to doctor or shared with their fellow nurses. Hussain et al.[23] found that ADR were reported verbally in the meeting, to the hospital pharmacy or to the hospital management. Studies have also shown that the nurses mainly report to the doctors or to their head or to pharmacist.[25, 26] The possible reason for not reporting to PV unit in our study may be lack of knowledge of existence of PV centre/unit and reporting process. The study conducted by Gidey K et al.[27] had found that the lack of knowledge is a key factor for underreporting.

Major discouraging factor for reporting ADR was unavailability of reporting form. Unavailability of reporting form has been identified as an important factor that negatively affect ADR reporting in various studies.[15, 18, 28] We found that the time constraint was not a major issue while reporting ADR which was similar to Adisa[28] but inconsistent to Rashmi et al.[16] Singh et al.[17] ,Gupta et al.[29] and Shah et al.[30] The participants of our study has been reporting verbally in meeting, to the colleagues or to the pharmacy therefore time may not have been a prominent obstacle for them. However, if they knew the process of reporting .i.e. filling the form and reporting to the concerned department, there is a chance of different opinion. New reaction to an existing product followed by seriousness of reaction was the most influential factor. These finding suggest that participants have limited knowledge on type of ADRs to report because all ADR should be reported including less severe or already known. Various studies have also identified that healthcare professional's decision to report ADR dependent on type and seriousness of reaction.[18,22,23,28] Respondent suggested that awareness and training of healthcare professional would lead to increase in reporting rate

Awareness among healthcare professional, training to the healthcare professional and making reporting personal obligation were recommended by studies as a different ways that could encourage ADR reporting as well.[12,23,31] Other studies have recommended reminding the HCP, providing points in continuous professional development and financial incentives.[32] Doctors and nurses would like to receive feedback in the form of International drug safety information, regular newsletter on current awareness in drug safety and new drug adverse reactions, individual response to report and annual national statistics.

CONCLUSION

Participants have observed patient/s with ADR but documentation of ADR is less. Further, none have reported ADR to pharmacovigilance center. Major discouraging factor to report ADR was unavailability of ADR reporting form. It is suggested to conduct awareness programme as well as making ADR reporting form

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