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ORIGINAL ARTICLE

FACTORS AFFECTING ADVERSE DRUG REACTION REPORTING AMONG MEDICAL DOCTORS AT TERTIARY HEALTH CENTER, BIRGUNJ, NEPAL

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ABSTRACT

Introduction: *Adverse drug reactions and its underreporting exists globally so this study was conducted to know the factors which affected medical doctors from reporting at National Medical College and Teaching Hospital (NMCTH), Birgunj, Nepal.*

Materials and methods: *A descriptive cross-sectional study was conducted among clinical doctors. Self-administered questionnaire tool was used for the collection of data. The questionnaire consisted of demographic status, factors encouraging ADR reporting and factors discouraging ADR reporting. The distributive statistics like frequency and percentage were used.*

Results: *High response rate 88.51% with majority male participation (61.24%) were observed. Serious reactions encouraged about 96.06% of medical doctors whereas unusual reactions encouraged 94.94% of medical doctors. New products encouraged about 98.31% of medical doctors. The percentage of doctors not knowing how to fill and report adverse drug reaction was 76%. Constrainment of time to fill the form percentage was 64%. The percentage of medical doctors who agreed that reports lead to extra burden was 69%. Not reporting because no incentives percentage was 64%. Belief that only safe drugs are marketed 58%.*

Conclusion: *The study revealed that adverse drug reporting system is still in preliminary stages so timely training, seminars, inclusion in undergraduates about its importance should be done so create a positive attitude towards adverse drug reporting.*

Keywords: *Adverse Drug Reactions, , ADR Reporting, ADR Trainings, Medical Doctors*

INTRODUCTION

Adverse drug reactions (ADRs) affects globally both children and adults with 3.5-10% of hospital admission and are fifth leading cause of death in hospitalized patients. [1] It is defined by WHO as the "response to a drug which is noxious and unintended, and which occurs at doses normally used in man. for the diagnosis, prophylaxis and treatment of disease.[2] Post marketing surveillance has a pivotal role in assessing the safety and efficacy of drug after its launch in the market as during premarketing there is inadequate information about safety, drug interactions, effect of the drug after chronic use and its effect on children, pregnant lady, elderly.[3]

ADR reporting has significant role in reducing the suffering and for safety of thousands of patients lives so health care professionals should show keen interest in reporting as a part of their professional duty.[4] Many drugs have been withdrawn from the market after ADR reporting for instances Troglitazone (liver toxicity), Felbamate (aplastic anemia), Cerivastatin (Fatal rhabdomyolysis), and Thalidomide (Phocomelia).[5] However major drawback of this system is Under-reporting which has been seen throughout the world.

Department of Drug Administration (DDA) of Nepal has established a National pharmacovigilance center (NPC) for monitoring pharmacovigilance activities and currently there are 17 regional pharmacovigilance centers (RPC). Though there is encouragement of RPC to monitor adverse drug reactions but till now only 1204 ADR reports have been reported.[6] So ADRs reporting is still in preliminary stages in Nepal.

Different studies conducted in different parts of the world have shown various factors for underreporting among healthcare providers such as fear of litigation, ignorance, unavailability of form, unable to recognize ADRs, lack of awareness, motivation, training, time and etc.[7] So, this study was conducted to identify the factors which affect medical doctors for underreporting of ADRs as this type of study has not been conducted here and the findings of other studies might not be applicable here. This study information might help policy makers to design new strategies and interventions for the encouragement of ADRs reporting.

MATERIALS AND METHODS

A Descriptive cross-sectional study was conducted at National Medical College and Teaching Hospital (NMCTH) Birgunj, Nepal from June to July 2024 among all clinical doctors ready to give consent. Those doctors unwilling to give consent were excluded. Non probability convenience sampling method was applied.

Sample size calculation,

$n=N/1+Ne^2$

where, N= total population of clinical doctors (209)

e=allowable error (5%)

$n= 209/1+209(0.05)^2$

= 138

The calculated sample size was 138. A semi structured questionnaire was constructed after reviewing previously published articles and consent was taken from the contributed authors in this field.[8,9] The questionnaire consisted of demographic profile of the clinicians, factors encouraging ADR reporting and factors discouraging ADR reporting. Ethical clearance was obtained from Institutional Ethics Committee, NMCTH (F-NMC/703/080-081). The consent was undertaken from the participants. The questionnaires were distributed to the clinical doctors in their respective departments and collected after 30 minutes. Anonymity of the participants was maintained. The proforma was collected and checked for their completeness; missing/unfilled data were discarded.

Statistical analysis: The data was entered in Microsoft Excel 2007 and distributive statistics like frequency and percentage were used.

RESULTS

Among 209, only 185 clinicians participated, seven unfilled proforma were discarded giving a response rate of 88.51%. Most of the clinicians were male (61.24%), assistant professor (34.27%) and 57.3% of the participants were in the age group of 31 to 40 years.(Table 1)

Table 1: Demographic characteristics of the participants (n=178)

Variables		Frequency	Percentage
Gender	Male	109	61.24
	Female	69	38.76
Age in years	21 – 30	41	23.03
	31 – 40	102	57.30
	More than 40	35	19.66
Designation	Medical officer	33	18.54
	Postgraduate student	49	27.53
	Assistant professor	61	34.27
	Associate professor	11	6.18
	Professor	24	13.48

Table 2 shows the factors encouraging ADR Reporting. Serious reactions encouraged about 96.06% of medical doctors whereas unusual reactions encouraged 94.94% of medical doctors. Out of 178 medical doctors only 114 were encouraged to report ADR. New products encouraged about 98.31% of medical doctors.

Table 2: Factors encouraging ADR Reporting

Factors encouraging ADR Reporting	Agree n (%)	Disagree n(%)
1. Severe reaction	171(96.06)	7(3.93)
2. Unusual reactions	169 (94.94)	9(5.05)
3. New product	175(98.31)	3(1.68)
4. Definite about reaction	114(64.04)	64(35.95)

Table 3 shows the factors discouraging ADR reporting. Out of 178 medical doctors, 97 disagreed that the cause of discouragement of ADR reporting was that the report may be wrong; the percentage of doctors not knowing how to fill and report adverse drug reaction was 76%. Constrainment of time to fill the form percentage was 64%. The percentage of medical doctors who agreed that a report will generate an extra work was 69%. Not reporting because no incentives percentage was 64%. Belief that only safe drugs are marketed 58%.

Table 3: Factors discouraging ADR reporting

Factors discouraging ADR reporting	Agree n(%)	Disagree n(%)
1. Consider that thereport may be incorrect	81 (45.5)	97 (54.49)
2. Not Knowing how to fill and report Adverse drug reaction	136(76.40)	42(23.59)
3. Indecisive if adverse drug reaction has occurred	64(35.95)	114(64.04)
4. Constrainment of time to fill the form	115(64.60)	63(35.39)
5. Fear of legal issues by reporting	108(60.67)	70(39.32)
6. Burden of additional workload	124(69.66)	54(30.33)
7. Conviction that only approved and safe drugs are marketed	105(58.98)	73(41.01)
8. Thought thatsingle report doesn't make much difference	111(62.33)	67(37.64)
9. Ambition to publish case report personally	104(58.42)	74(41.57)
10. Unavailability of reporting forms when needed	127(71.34)	51(28.65)
11. Other colleagues aren't documenting ADR cases	93(52.24)	85(47.77)
12. Don't report ADR that are already known	112(62.92)	66(37.07)
13. Report only serious ADR	101(56.74)	77(43.25)
14. Lack of incentives	114(64.04)	64(35.95)

DISCUSSION

ADR reporting ensures that safe and effective drugs are marketed after its launch so that if undesirable effects of drugs occur it can be withdrawn timely from the market but underreporting has weakened this process.[10] In systematic review of 37 studies, over 12 countries done by Hazell and Shakir the median under reporting rate was 94% (inter quartile range 82-98%). This study also delineated that there was under- reporting of even serious adverse drug reactions.[11] So this study was conducted to determine factors affecting ADR reporting among medical doctors working at a tertiary health care center, Birgunj as they play a pivotal role in supporting the pharmacovigilance program.

Here, severe reactions inspired about 96.06% of medical doctors, unusual reactions 94.94% and new products 98% of medical doctors for reporting. This is in accordance with the study done by Prashar et .al among private healthcare professionals in Lusaka where 98% of them were encouraged to report if serious reactions occurred, 77% agreed to report for unusual reactions and 83% for new product.[12] The reason behind motivation of the medical doctors to report ADR might be their professional obligation.

However, there are some discouraging factors for reporting as in our study 45% didn't report considering that the report might be wrong. KC et. al study done in Nepal among healthcare professionals about reporting of adverse drug reactions 34% didn't report because of thought that the report might be wrong.[13] In a systematic review done by Abeijon et. al 56 articles showed lack of knowledge in recognizing ADR and its importance and also lack of training in where to report, when to report , describing the notification and how the information was further used; belief that only serious or unexpected ADRs should be reported.[14]In a study done by Kiran LJ et al more than 80% did not know where and how to report and lack of accessibility to ADR reporting forms. [15] In our study as well more than 70% didn't know where and how to report and lack of reporting forms when needed. The reason behind this might be unawareness about pharmacovigilance program, lack of feedback system after reporting so awareness programs should be conducted regarding the importance of ADR reporting system.

This study suggested that more than 60% had fear of legitimate issues, belief that only safe drugs are available in the market, thought that single report wouldn't significantly have an impact and also didn't report for already recognized ADR for that drug. These findings are discordant with the study done by Prashar et .al where the percentage was less than 20.[12] The reason behind this disparity might be variability in law system, misconception that only safe drugs are marketed. In our study more than 60% believed lack of incentives also a major cause of underreporting which was similar to study done by Gupta et al at SouthIndia.[16]

This study delineated the factors affecting ADR reporting in Nepal even in developed countries under reporting exists but in High income countries like US, UK, France, Germany, Canada And Australia reporting rates are high approximately 85%. Reporting system from Upper middle income and lower middle-income countries constitutes 7% and 8% respectively and less than 1% of reports are from low income countries.[17] To strengthen ADR reporting awareness programs, seminars, inclusion of importance of ADR reporting in curriculum of undergraduates should be done.

CONCLUSIONS

This study concludes that there are many factors for demotivation among medical doctors from reporting though it's their professional obligation. So, there should be awareness programs, trainings, seminars regarding the importance of adverse drug reporting. Such types of programs will help them in building positive attitude towards reporting system.

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