

Awareness of Adverse Drug Reactions and its Reporting among Third-year Undergraduate Medical Students

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ABSTRACT

Background: Drug is a double-edged sword. Though important, Adverse Drug Reactions under-reporting is real and is mainly due to lack of awareness. No published research has ever evaluated the perspective of third year medical students towards Adverse Drug Reactions reporting. The objective of the study was to evaluate awareness of Adverse Drug Reactions and its reporting among Third-year Medical Students of BP Koirala Institute of Health Science.

Methods: It was a descriptive cross-sectional questionnaire-based survey using google form conducted between 09/01/2020 to 09/28/2020. Any consenting third-year medical student of BP Koirala Institute of Health Science was eligible. Descriptive analysis of the data was performed using Microsoft Excel. Ethical clearance was obtained from Departmental-Research-Unit which is under IRC.

Results: Out of 80 eligible students, 79(98.75%) participated in the survey. 31.6(25%) had reported Adverse Drug Reactions. 36.7(29%) were aware of National Adverse Drug Reactions monitoring service. 12.7(10%) were aware of BPKIHS ADR monitoring. Again, 35(49.30%) were familiar with Adverse Drug Reactions to a particular drug whereas 29(40.85%) and 28(39.44%) were even familiar with Adverse Drug Reactions to a new product and Adverse Drug Reactions of serious (life or organ threatening) nature respectively. Regarding barriers to Adverse Drug Reactions reporting, 64(83.12%) were uncertain how to report; 39(50.65%) were unaware of existing National ADR system and 33(42.86) could not decide if it was an Adverse Drug Reactions. Regarding recommendations to improve Adverse Drug Reactions reporting, 73(94.81%) recommended education and training, 57(74.03%) stressed on collaboration among health professionals; 52(67.53%) said Adverse Drug Reactions reporting should be professional obligation whereas 51(66.23%) highlighted feedback from Monitoring Centers.

Conclusions: We evaluated the awareness of Adverse Drug Reactions and its reporting among third-year medical Students of the institute which was relatively poor compared to other study population like doctors and pharmacists.

Keywords: ADR; BPKIHS; MBBS; students.

INTRODUCTION

Adverse Drug Reaction (ADR) is any unintended drug consequence.¹ Drug is a double-edged sword.² It increases care expenditure and death.^{3,4} Scenario is more common among extreme of ages.^{5,6} Pharmacovigilance aims at getting the best outcome from treatment with medicine.⁷

ADR stands among top five leading causes of death in the United States.⁸⁻¹⁰ There may be high incidence of ADR in Nepal but there is no proper reporting system.¹¹⁻¹³ Causes for under-reporting include fear of litigation,

guilt, ambition, ignorance, lethargy, lack of awareness, motivation, training and most importantly, time among health-care providers.¹⁴

So, we undertook this study so that future healthcare manpower of our institute get familiarized with ADR reporting system, report it when appropriate and also minimize preventable ADR.

The objective of the study was to evaluate the awareness of ADR and its reporting among Third-year medical Students of BPKIHS via online tool during lockdown period.

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METHODS

It was a descriptive cross-sectional questionnaire-based census survey carried out between 09/01/2020 to 09/28/2020 during Research Project of concerned medical students. Study-tool was self-validated questionnaire prepared in free google-form with link distributed via web-based platforms mainly personal e-mails. Any consenting BPKIHS student in third year MBBS was eligible. Students involved directly in conduction of the study were excluded from the study. Study population was 94 third year medical students (2020) of the institute. Since six students aided smooth conduction of the study, our study population was 88 third year medical students of the institute. Questionnaire consisted of two multiple choice questions (MCQ) on personal details of the respondents, five MCQs on Knowledge and practical experience of the respondent on general ADR, one MCQ with seven different responses on Knowledge or practical experience about uncommon ADR, one MCQ with 13 different responses on possible barriers faced on ADR reporting and one MCQ with 7 different responses on recommendations to improve ADR reporting. Descriptive analysis of the data was done using microsoft excel and latest available Statistical Package For Social Sciences (SPSS) software. Ethical clearance was taken from Departmental Research Unit (DRU) under Institutional Review Committee (IRC).

RESULTS

Total eligible students were 88. Eight students participated in the pilot-study. Cronbach alpha, a measure of scale reliability was calculated to be 0.792, which assured acceptable internal consistency. Based on that, we assumed reliability of the study was adequate. Again based on suggestions made by subject and linguistic experts, few modifications were brought in the questionnaires and applied on the rest of the group which were 80 in number. Out of which, only 79 students filled the onlineGoogle-form at least partially. Thus, our response rate became 98.75%.

66.66% (52) respondents were male .One participant did not reveal one's gender status.Age range of 79 participating students were between 20-25. 30.38%(24) students were of 22 years of age in their current third year MBBS.

Table 1. Knowledge on ADR reporting among students (Respondents, N=79).

Knowledge on ADR reporting	Percentage(N=79)
ADR reporting frequency.	31.60 (25)
Being aware of national ADR monitoring service	36.70 (29)
Being aware of ADR monitoring at our centre.	12.70 (10)
Knowing how to get ADR forms to report.	1.30 (1)
Knowing where to submit ADR forms after filling ADR	1.30 (1)

In multi-response question, "Do you have knowledge of or have you ever seen following ADR being reported?", 71 students participated with at least one response. Altogether there were 157 responses (Table 1)

*: students have never seen or studied before

** : Serious nature: Organ or life threatening

***: Considered "unusual" by their teacher, mentor or senior

Table 2. Knowledge or practical experience on different ADR.

Do you have knowledge of or have you ever seen following ADR being reported?	Total responses (N=157)	Responders' percentage (N=71)
ADR well recognized to for a particular drug	35	49.30
ADR to a new product*	29	40.85
ADR of Serious Nature**	28	39.44
ADR to traditional medicine	22	30.99
Any ADR to an old product	16	22.54
ADR never reported before	15	21.13
Unusual ADR**	12	16.90

On being asked with multi-response question, "What are the Barriers on ADR reporting?", only 77 students participated with at least one answer. There were total 335 responses.

Table 3. Barriers on ADR reporting.

What are the Barriers on ADR reporting?	Total responses (N=335)	Responders' percentage (N=77)
Uncertainty on how to report.	64	83.12
Unaware of existing national ADR system.	39	50.65
Could not decide if it's an ADR.	33	42.86
Insufficient information about the patient.	29	37.66
Lack of professional environment to discuss about ADR.	25	32.47
Reporting form not available when needed.	22	28.57
No feedback provided to reporters.	21	27.27
No motivation to report.	21	27.27
Fear of legal liability after reporting.	20	25.97
Lack of time to actively look for ADR.	17	22.08
The reaction is already known to this medicine.	15	19.48
Difficult to admit harm to patient.	13	16.88
Lack of time to fill the form.	9	11.69
Forget to report.	7	9.09

Seventy-seven students via 343 responses reported how to improve ADR reporting.

Table 4. Recommendations to improve ADR reporting.

What are your recommendations to improve reporting?	Total responses (N=343)	Responders' percentage (N=77)
Education and training on detection and reporting of ADR.	73	94.81
Collaboration among health professionals.	57	74.03

Making ADR reporting professional obligation.	52	67.53
Feedback from national/ Regional ADR monitoring system.	51	66.23
Development of ADR reporting team within hospital.	46	59.74
Simplifying ADR form.	40	51.95
Remuneration on reporting.	24	31.17

DISCUSSION

It was an online validated questionnaire-based survey done on views and experiences of third year undergraduate medical students of a well-recognized medical Institute of Nepal on awareness of ADR and its reporting during lockdown period. This study was important because studies have shown that knowledge and inclination towards ADR reporting and taking preventable ADR into consideration do not only prevent morbidity but also mortality.^{1,8} With this background, the uniqueness of the study was in being the first of its kind among Nepalese undergraduate medical students, who have potential direct involvement with the pharmacological intervention in patient management in the very near future. Besides, they are not only the future work pillar of drug treatment but also spokespersons of the pharmacovigilance to their relatively naïve senior and junior fellow colleagues whom they have to work hand in hand with.

Knowledge on ADR reporting was poor (Table 1). Though one third participants told that they had reported ADR, almost no student (less than one percent) knew how to get ADR form and where to submit it. It means, by reporting they did not mean written reporting to the ADR reporting centre. Most of them were even also unaware of national (63.3%) and local (87.3%) monitoring centre services. Considering the same state of affairs even among the post hippocrate-oath physician in Malaysia it might not be considered that pathetic as in a survey conducted by Aziz et al among hospital doctors, 81.4% physicians suspected an ADR but did not report it and about 40% were not even aware of the national reporting system in Malaysia.¹⁵ The picture was also neither encouraging among pharmacist as Elkalmi et al. found that although community pharmacists considered ADR reporting to be their professional duty, they had little knowledge of the national reporting system and limited access to the ADR reporting forms.¹⁶

Most students already knew or had seen ADR well recognized to for a particular drugs, ADR to a new product or ADR of Serious Nature. For the nature of the reactions and the alarm they cause, these reactions are naturally more commonly reported and remembered. It was found in line with studies conducted among hospital pharmacists in the HongKong¹⁷ and UK.¹⁸

Most students (83.12%) in our study, opined that the main barrier on ADR reporting is “uncertainty on how to report”. However, in a Malaysian study conducted by Muhammad Abdul Hadia et. al among registered hospital pharmacists from 10 randomly chosen public hospitals, the main obstacle (54.60%) in ADR reporting was “Insufficient information from patient”. In the same study, “uncertainty on how to report” constituted only 12.90% cause of Barrier.¹⁹ In another study done in Northern China “insufficient clinical knowledge” accounted for 68.60% barrier for ADR reporting. “Lack of confidence in associating and recognizing ADR” was the major cause of underreporting in studies performed among physicians and hospital pharmacists respectively in the UK (88%)²⁰ and China (81.9%).²¹

Most respondents in our study suggested that further “Education and training on detection and reporting of ADR” would improve reporting rates. Same was the conclusion of a Malaysian study.¹⁹ Over and above, the effectiveness of educational interventions to improve ADR reporting has already been documented in a randomized controlled trial.²²

Importance of ADR monitoring and reporting cannot be underestimated in the scenario of underdeveloped country like Nepal.²³ Strength of our study was it was first of its kind from Nepal. Besides, it was validated, online survey with high response rate so external validity to identical population if published early will be high. Our main limitation could be it was a conclusion from a small homogenous undergraduate medical student of a single medical institute mostly consisting of Nepalese and Indian students. It may make external validity questionable to other groups. Furthermore, Respondents’ bias cannot be denied.

CONCLUSIONS

We evaluated the awareness of ADR and its reporting among third-year medical Students of the institute which was relatively poor compared to other study population like doctors and pharmacists. Awareness of ADR and its reporting can be improved further by education and training.

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Competing interests: None

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