

## An exercise to sensitize undergraduate medical students about adverse drug reactions: An analysis

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### Abstract

**Introduction:** Reporting of adverse drug reaction (ADR) is vital activity for the success of pharmacovigilance and healthcare professionals. The doctors play a pivotal role in the success of such activity. The one of the reason for under-reporting of ADR has been lack of training in undergraduate medical curriculum. Therefore, we conducted an exercise to sensitize the undergraduate students (UMS), the future doctors, regarding ADR reporting and analysed their patterns of ADR reporting.

**Materials & Method:** The current study was observational study, conducted at department of Pharmacology, Shri B. M. Patil Medial College & Hospital, BLDE University, Vijayapura, Karnataka. At the beginning of the 5th term (3rd term of Phase-II of MBBS), UMS were given an ADR reporting form, which was designed by department of Pharmacology keeping in 2nd year UMS. This form is different from 'suspected adverse drug reaction reporting form, available from Central Drugs Standard Control Organization (CDSCO). The form was printed with role number for each student. Each form was duly signed by Head of the department. The students were issued only one form bearing their role number. Immediately after distributing the forms, students were briefed about identifying the ADRs and reporting. Opportunity was also utilized teach the students about pharmacovigilance programme in India and importance of ADR reporting.

The students were given a time of 7 days from the issue of ADR form to fill the form. Once student goes to the ward he she has been posted by clinical departments, he she will go through the drugs administered to patients in a ward. He she then go through the textbooks about the medication administered to the patient first, then they were advised to examine the patient for known ADRs from the textbooks. Once they appreciate ADRs in patient and assign it to possible drug, they fill the details in the form given to them. If they don't find ADR in particular patient, they move on to next patient.

Once student identifies an ADR s, he she will write it into the form. The same was cross-checked and signed by Assistant Professor, department of Pharmacology posted in the drug information centre, situated in Shri B. M. Patil Medial College & Hospital, BLDE University, Vijayapura, Karnataka and by Clinical Pharmacist. The form then submitted to the department and were then analysed. The data was analysed by the MS Excel and Graph Pad Prism (Demo) software.

After entire exercise was over, students were given feedback about entire activity in the class and an emphasis on ADR, Pharmacovigillance was reinforced.

**Results:** In a class of 116 students, all were issued one ADR forms each. Only 95 students out of 116 returned with duly filled forms and submitted them to the department. Out of 11 students who did not submit the ADR forms, 7 students did not bother to collect the ADR forms, 3 did not write ADR for reasons unknown and one student reported that he lost the ADR form.

Students reported a total of 256 ADRs from 95 ADR forms over one week time. Out of these 256 ADRs, there were 33 different types of ADRs were found. A total of 77 drugs reported from these ADR forms. On an average each ADR form had 2.72 ADRs reported per prescription. The average number of drugs per patient, which students have gone through were 2.69. Though there were more than one ADR is reported for each drug, so there were 3.32 ADRs reported per drug being prescribed. Headache (n=61) and Nausea (n=60) followed by and vomiting (n=21) were commonly reported ADRs.

**Conclusion:** The students were interested in the activity but needs prompt guidance from the teaching faculty to correct their mistakes.

### Introduction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.<sup>(1)</sup> This is the one of the important, yet under-recognized branch of medicine especially in our country. One of vital part of this activity is reporting of Adverse Drug Reaction (ADR) which is defined as "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."<sup>(1)</sup>

Apart from data on morbidity and mortality, data on economic burden of ADRs is well established in developed countries, where 4.9–7.7% of admissions are

related to adverse drug events<sup>(2,3)</sup> and direct medical costs of ADRs cost them (USA) whopping \$30-\$130 billion annually.<sup>(4,5)</sup> The data on burden of ADRs on health care cost is limited, few studies indicate that on an average, Rs. 65 per ADR was additional burden in small study on 267 patients from Karnataka, India.<sup>(6)</sup>

Reporting of adverse drug reaction (ADR) is vital activity for the success of pharmacovigilance. Healthcare professionals, especially doctors play a pivotal role in the success of such activity.<sup>(7)</sup> This reporting of ADRs is not appreciated enough by the important stake-holders like clinicians thus leading to poor number of ADRs being reported in our country leading to delay in achieving the goals of pharmacovigillance. One of the reason could be lack of

awareness regarding ADRs and its reporting in their curriculum. Therefore, we conducted an exercise to sensitize the undergraduate students (UMS), the future doctors, regarding ADR reporting and analysed their patterns of ADR reporting.

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Students reported a 33 different ADRs in different frequencies. Following table shows the frequency with which each ADR occurred from 77 drugs contained in 256 ADRs reported from 95 students.

**Table 1: Types and Frequency of ADRs**

S. No.	Type of ADR	Frequency
1	Nausea	62
2	Headache	60
3	Vomiting	24
4	Abdominal pain	14
5	Dizziness	12
6	Rash	9
7	Diarrhoea	7
8	Fever	
9	Constipation	6
10	Epigastric pain	5
11	Weakness	
12	Anorexia	4
13	Drowsiness	
14	Muscular weakness	
15	Pain at injection site	
16	Dry mouth	3

Nausea and headache has been reported by nearly 62.23% of students, followed by vomiting (9.37%), abdominal pain (5.47%), dizziness (4.69%) and diarrhoea (2.73%).

Blurring vision, fatigue, insomnia, itching sensation in eye, joint pain, pain abdomen, sedation occurred twice and back pain, chest pain, chills, cough, dyspepsia, loss of libido, palpitation, peripheral oedema, rigors were described at one instance.

Highest number of ADRs/prescription were reported from following drugs, Zidovudine+Lamivudine (15), Ciprofloxacin (9), Tinidazole (5) and tramadol (6).

### Discussion

Success of Pharmacovigilance programme depends on prompt reporting of ADRs. But under reporting has been well known problem in India and even in developed countries.<sup>(8,9)</sup> Common reasons for under reporting in clinicians is fear of litigation, ignorance, lethargy, fear of appearing ridiculous for reporting merely suspected ADRs,<sup>(10)</sup> insufficient training to identify ADRs, and little to nil awareness of Pharmacovigilance program and lack of sensitization to the undergraduate medical students regarding ADR reporting.<sup>(11)</sup> Additionally this

activity also makes them go through the ADRs from textbook, which helps them remember ADRs of the drugs they come across during the activity. Therefore this study was conducted to sensitize the UMS for ADR reporting and find out commonly occurring errors in their reporting.

The whole exercise was mainly intended to give a first-hand experience to the students regarding ADR reporting than actually finding out diagnosis of ADR, as it is difficult for III term students of II- MBBS students to diagnose an ADR, whenever they did, was promptly appreciated. This study was done to find pattern, behaviour and mistakes of ADR reporting by beginners.

Despite the activity is made compulsory for UMS, there were only 11 students who did not respond to ADR reporting. Students reported 33 different types of 256 ADRs from 77 number of drugs. Analysis of ADR forms reveals that almost 63% of the student reported ADRs are Nausea and Headache. Though we could not examine each patient as the ADRs came from different departments at different timings. So we could not examine and verify each and every ADR. But in whatever patients of nausea and headache, we examined there was either lack of proper history taking, examination or students were biased towards “filling” up of ADR form at the earliest, as they had textbooks with them. Also, some students revealed that nausea and headache were “convenient” for them to write. There were two students who even reported Nausea, vomiting for rabeprazole and even for ondansetron. Such students were asked to re-write ADR. This flawed reporting is due to inadequate training and a negative attitude towards reporting ADR<sup>(12)</sup> and problem of what to report in ADR was the common problem in our students and in developed country like Netherlands.<sup>(13)</sup>

Despite of the negative findings in reporting by students, we also came across with few students who did proper history taking, examination and with the help of consultant during their clinical posting. Those students came close to actually diagnosing an ADR and reporting the same properly, were well appreciated and encouraged.

As observed in many studies in India, many doctors, post-graduate students, pharmacy students lack knowledge, attitude towards ADR reporting.<sup>(14,15,16)</sup> Therefore it is important to Sensitize UMS early is very important. Also our current curriculum has little space for the one of the important aspect of pharmacotherapy, i.e. adverse drugs reactions, which in turn achieves the goals of pharmacovigilance programme. Therefore it is important to develop a habit of being vigilant on ADR and reporting the same among students, especially at early part of medical education. And we felt that the second year of MBBS is ideal phase where these habits can be inculcated effectively.

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