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ORIGINAL ARTICLE

DEVELOPMENT OF ADVERSE DRUG REACTION REPORTING CULTURE IN SECOND PROFESSIONAL MEDICAL UNDERGRADUATES AT TERTIARY CARE TEACHING HOSPITAL: A HEALTH IMPERATIVE

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ABSTRACT: BACKGROUND: Due to under reporting of ADRs by clinicians, second professional medical under graduates were sensitized about ADR reporting. **METHODS:** 'Sensitization of Medical Under graduates for ADR Reporting' (SMUAR Model) was introduced for promoting ADR notification by clinicians. One year prospective study was carried out in a tertiary care hospital with the help of 2nd Prof MBBS students. The students were asked to collect ADRs from clinical departments. Group of eight students were assigned to visit clinical departments (OPD/IPD) every consecutive month for a year. Naranjo's Scale was calculated for the reported ADRs. **RESULTS:** 72 ADRs were reported by batch 2010 of our tertiary care teaching hospital from Medicine, Dermatology, Surgery, etc. Maximum numbers of ADRs were reported by Medicine Department. Maximum ADRs (27) were reported in the age group of 21-40 years. The majority of the ADRs were reported with antimicrobials followed by analgesics, anti inflammatory and anti- pyretics. Most of the reported ADRs were skin related (52%) followed by gastrointestinal system (GIT) (16%) and central nervous system (CNS) (16%). Causality assessment by Naranjo's scale revealed that most of the ADRs belonged to "possible" 40(55.56%) category. Most of the ADRs (61.11%) were of Type A (Augmented / predictable). **CONCLUSION:** Due to the involvement of medical undergraduates ADR reporting increased in our institute. The 'SMUAR Model' used by second professional MBBS medical undergraduates, assisted clinicians to report ADRs more effectively. The use of this model may strengthen the Pharmacovigilance Program in India by increasing the spontaneous reporting by clinicians and hence promote safe use of drug in patients.
KEYWORDS: ADR, Pharmacovigilance, Reporting Practice, SMUAR.

INTRODUCTION: Spontaneous reporting of ADRs is important in the detection of unsuspected, serious and unusual ADRs that go undetected during the clinical trial phases. This has led to the withdrawal of many drugs in the recent past, e.g., rofecoxib, cisapride, terfenadine. Late or non reporting of ADRs only delays detection of serious ADRs and consequently has a major negative impact on the public health.[1] Pharmacovigilance Programme in India was initiated in the year 2001. Nearly a decade has elapsed but it is still in the stage of infancy.[2] Many factors are associated with ADRs under reporting among health professionals. They are namely financial incentives, legal aspects, problems associated with ADR-related knowledge, attitudes and excuses made by professionals like lethargy: the procrastination and disinterestedness in reporting or lack of time to find a report and other excuses.[3]

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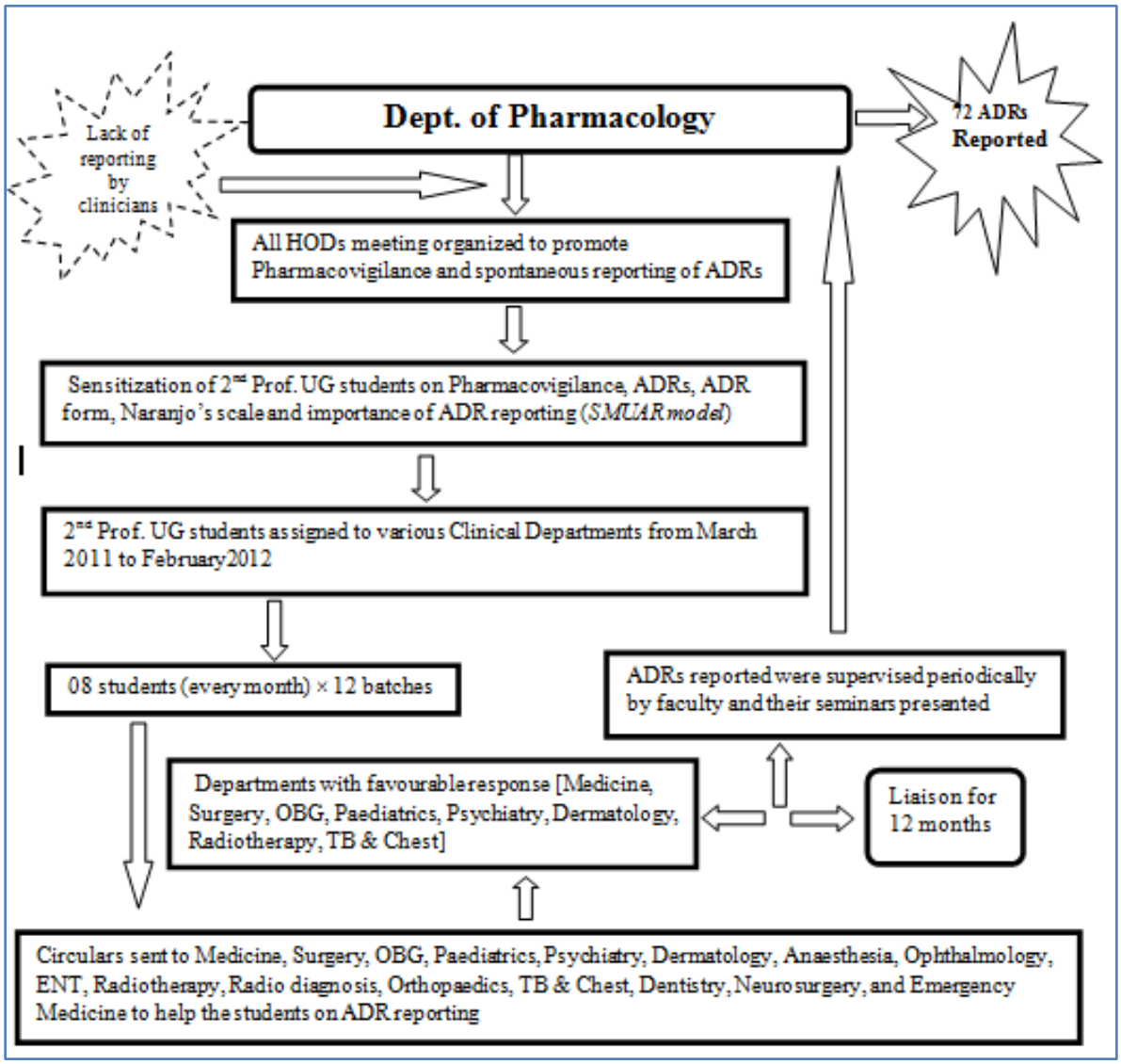
What This Study Adds: Our study was conducted with the aim to sensitize second professional MBBS students for spontaneous ADR reporting and consequentially promoting this practice amongst clinicians. By "A model for ADR reporting: Sensitization of Medical Undergraduates for ADR Reporting 'SMUAR Model'.

METHODS: This prospective study was carried out in our tertiary care teaching hospital, involving clinical departments from March 2011to February 2012 with the help of 2nd Professional MBBS medical undergraduate (UG) students. The Department of Pharmacology mobilized the students (Batch 2010) of this tertiary care teaching hospital about ADRs, ADR reporting form provided by Central Drug Standard Control Organization (CDSCO), India, Naranjo's scale and importance of ADR reporting.[4, 5]



2.1 A model for ADR reporting: Sensitization of Medical Undergraduates for ADR Reporting 'SMUAR Model'

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Every month roll number wise eight students were given the task to visit daily the allotted clinical department (OPD/IPD). Each month a faculty from the Department of Pharmacology was assigned the duty to cross check the ADRs reported by the students. To avoid false reporting we were constantly in touch with the respective clinicians. Data regarding age, gender, start of reaction, date of recovery, problem, suspected medication, dose and route of medicine administration, seriousness of reaction, concomitant medication and outcomes were collected. Once reported, ADRs were discussed in the Department of Pharmacology and students were promoted to calculate the Naranjo's Scale. Confidentiality of information was maintained throughout the study. The annual ADR report 2012 was finally emailed to National Pharmacovigilance Coordinating Centre; Indian Pharmacopeia Commission (IPC), Ghaziabad India.

RESULTS: On the basis of ADR reporting by batch 2010 students of our tertiary care teaching hospital we found that ADRs were reported by Medicine, Dermatology, Surgery, Obstetrics and Gynecology, Tuberculosis and Chest, Psychiatry, Pediatrics and Radiology Department. Maximum numbers of ADRs were reported by Medicine Department. Maximum ADRs (27) were reported in the age group of 21-40 years, followed by 21 ADRs in 41-60 years and 18 in < 20 years whereas only 6 ADRs were reported in the age group of >61 years.

No significant variation was seen in incidence of ADRs with gender, (men 53%, and women 47%). The majority of the ADRs were reported with antimicrobials followed by non-steroidal anti inflammatory medicine (Figure 1). Of all the antimicrobials, betalactams were responsible for maximum ADRs (Table 1). Oral route was the most common route in which maximum ADRs (52.7%) were reported followed by intravenous route (29.1%) and intramuscular route (5.5%). In 12.5% of the reported ADRs, route was not mentioned. Forty two patients were reported from the OPD and 30 patients were reported from the IPD. Most of the reported ADRs were skin related (52%) followed by gastrointestinal system (GIT) (16%) and central nervous system (CNS) (16%) (Figure 2), Causality assessment by Naranjo's scale revealed that most of the ADRs belonged to "possible" 40(55.56%) followed by "probable" 32(44.44%) relationship. Most of the ADRs 44 cases (61.11%) were of Type A (Augmented /Predictable) whereas 23 cases (31.95%) were type B (Bizarre/Idiosyncratic) with only five cases (6.94%) of type C (Chronic). The ADRs reported by various clinical departments followed the order of Medicine > Dermatology > Surgery > OBG > TB & Chest = Psychiatry > Radiotherapy = Pediatrics (Figure 3, Figure 1)

Group of antimicrobials (n=42)	Number (n=42)	Percentage (%)
Beta Lactums	19	45.2
Floroquinolones	5	11.9
Tetracyclines	4	9.5
Anti-tubercular Medicines	3	7.1
Sulphonamides and trimethoprim	3	7.1
MDT for leprosy	3	7.1
Antifungal	1	2.4

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Chloroquine	1	2.4
Amikacin	1	2.4
5FU and cyclophosphamide	1	2.4
Metronidazole	1	2.4

Table 1: Frequency of ADRs occurrence with various groups of antimicrobials

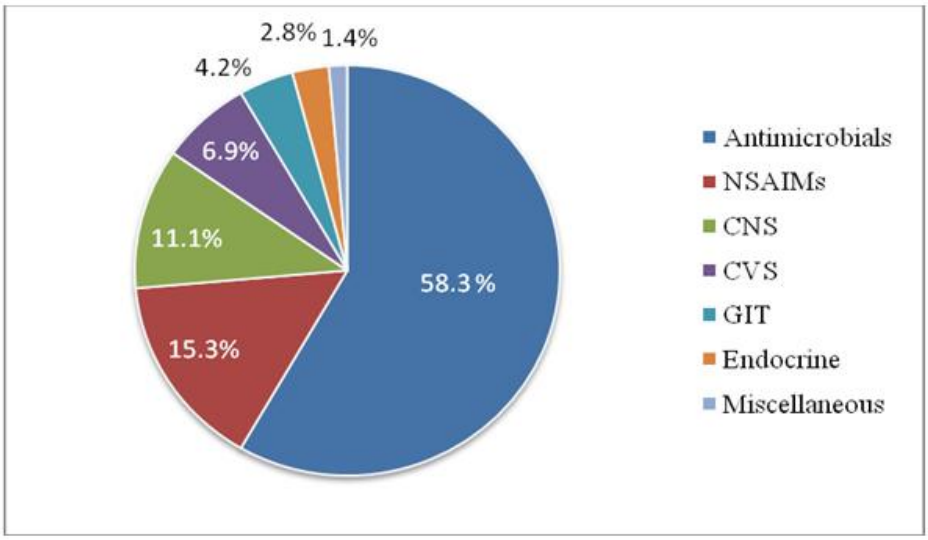

Fig. 1: Percentage of ADRs reported with the different pharmacological group

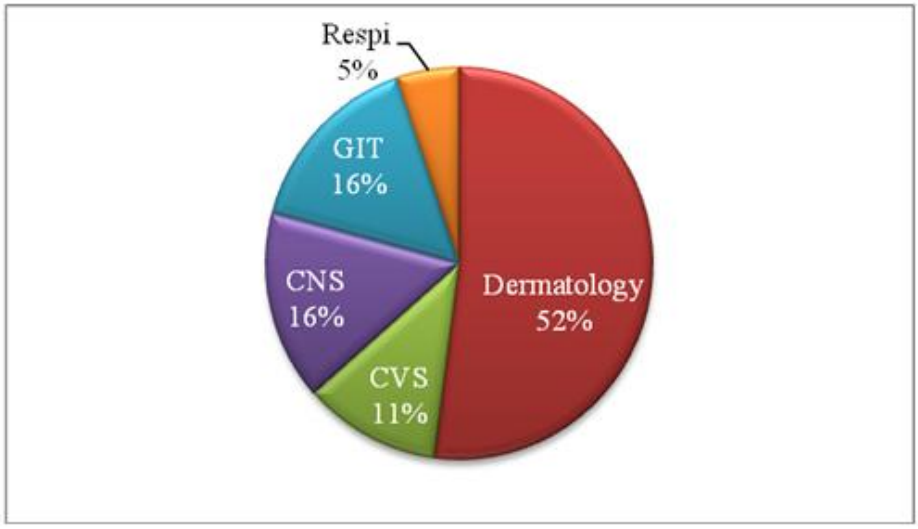

Fig. 2: Percentage of ADRs in relation to systemic involvement

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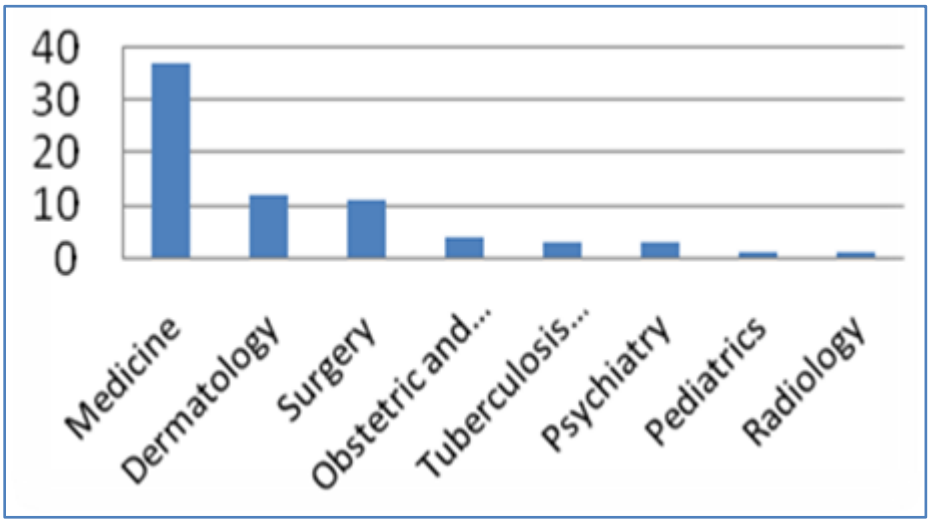

Fig. 3: Involvement of various Clinical Departments in ADR Reporting

DISCUSSION: Due to lack of interest shown by the clinicians in reporting ADRs (only two ADRs were reported in the year 2010-11), the Department of Pharmacology took an initiative and sensitized the second professional medical UG students to assist and help the clinicians for reporting ADRs. A significant shift in the number from two ADRs to 72 ADRs was observed in the year 2011-12 using 'SMUAR model'.

In our study, there was no influence of gender on the occurrence rate of ADR (Men: Women, 53: 47). Similar findings were observed in a study of 100 patients where 50 were men and 50 were women with an average age of 42.95 years.[6] We found that maximum ADRs were reported in the age group of 21-40 years (37.5%). Our findings differ with other studies where it was found that the incidence of ADR in relation to age was statistically significant in patients more than 60 years.[7]

Another study showed that significantly older patients were admitted with ADRs (median age 76 years, interquartile range 65-83).[8] As per the Medical records department (MRD), we found that in our hospital setup, geriatric group of patient reporting in outpatient/inpatient (OPD/IPD) is comparatively less than the other age group of patients. Reason for this might be correlated to surrounding demographic condition around the hospital, where it may not be easy for elderly patients to visit our tertiary centre from far-flung rural hilly areas. It has been observed in the study that out of 72 ADRs reported, Medicine Department has reported the maximum number of ADRs (51.4%) followed by Dermatology (17%) and Surgery (15%).

According to the Medical Records Department; the total numbers of patients reporting from March 2011 to February 2012 were 2,18,202. The total number of patients reporting to medicine department (39, 071 patients, 17.9%) was comparatively more than the surgery department (18, 149 patients, 8.3%) and also than other clinical departments. Therefore this could have led to more ADR reporting from Medicine Department.

In our study maximum ADRs were reported with antimicrobials (58.3%) followed by non steroidal anti-inflammatory medicine (15.3%) and CNS drugs (11%). Among the antimicrobials beta-lactams was maximally associated with ADRs (45%) whereas in five cases (11.9%) fluroquinolones

were responsible. This is consistent with results of previous studies where highest incidence of ADRs was induced by antimicrobials.[7, 9] We need to be more cautious on the use of antimicrobials and should encourage the rational prescription of antimicrobials especially the beta lactum groups.

Maximum number of ADRs was reported with oral route of administration of medicines in our study (52.7%). This could be due to more number of OPD patients reported by the students as 42 patients were from the OPD whereas 30 patients were from the IPD. This could also be due to the oral route being the most common route of medicine administration. 12.5% students had not mentioned the route of drug administration.

Maximum Causality assessment of the ADRs reported came in the possible or probable category of Naranjo's scale and 55.56% of ADRs had a possible relationship with Naranjo's scale. As rechallenge was not ethically permissible it was never tried with the suspected drugs. Blood level of the suspected medicine was not done due to lack of facilities in the institute. Also in all the cases the suspected medicines were stopped and dose was never increased or decreased for the suspected medicine. Neither the adverse drug reactions were confirmed by any objective evidence therefore it was difficult to get a definite relationship with the suspected ADRs. Many studies have reported that most of the ADRs accounted for the possible/probable category.[7, 9, and 10]

61.11% of ADRs were type A (augmented) reactions indicating that these reactions could have been prevented by rational use of medicines and 31.95% of the reactions were type B (bizarre) reactions which could not be predicted and prevented. In this study maximum ADRs were affecting the skin 52% whereas central nervous system and gastrointestinal system were affected by 16% only. This was in concordance with a study reported by Jose et. al that the most commonly affected organ system was Dermatological system (23.5%) with skin rash (10.5%) as the most frequent reaction. Another study has reported that the greatest number of ADRs were from the gastrointestinal system, 47.4% in retrospective study and 57.6% in prospective study.[7]

This 'SMUAR model' can be a breakthrough for reporting ADRs from the clinicians and also make the budding clinicians aware about the vigilant approach required for ADR reporting; thereby promoting safety of the mankind. A drastic improvement was seen in the annual ADR reports after the involvement of second professional medical UG students. Only two ADRs were reported in the year 2010-11 as compared to 72 ADRs in 2011-12.

There is a need for sensitizing the clinicians and medical undergraduates on importance of ADR reporting for safe use of medicines.[1] Students visiting clinicians everyday to ask whether there was any ADR in OPD/IPD not only reminded the clinicians on the importance of ADR reporting but also reduced the burden on the clinicians to fill the ADR forms. Students were also taught to calculate the Naranjo's scale and it was cross checked by the concerned faculty of Department of Pharmacology who had been allotted to monitor ADR reporting for that month.

Some of the students tried to copy the ADR reports of other students which were deleted from the study therefore a complete record of ADRs reported had to be maintained and cross checked by the faculty of Pharmacology Department and needed confirmation by the treating physician. We also felt that there was a need to encourage students to get photographs and mobile numbers after taking informed consent from the patients so as to minimize these errors.

Though OPD/IPD numbers were recorded in the ADR reporting form, a more vigilant approach to get a photocopy of the OPD/IPD card of the patient for future referral was also necessary after prior permission from the Institutional Head. Also once the patients report ADRs, free medical

services for the treatment of the ADRs and follow up of the patients reporting ADRs needs consideration by the institute. On the other hand, such a step may also de-motivate institutes to report ADRs. Some Departments never reported ADRs and a need was felt to organize workshops on Pharmacovigilance to sensitize clinicians on reporting ADRs. Clinicians fear reporting ADRs and wish to hide the identity of the prescriber and reporter of the ADR. Therefore, it becomes mandatory for pharmacologists to spread awareness and clear the misconceptions of clinicians on ADR reporting.[1] Please Note: This attempt by our Department of reporting 72 ADRs (Annual report 2011-12 published by Department of Pharmacology) with the help of second professional medical UG students does not mean that this is the in toto list of ADRs reported by the institute. Clinician might have published individual case reports on ADRs which is not in the knowledge of our department.

CONCLUSION: Due to the involvement of medical undergraduates ADR reporting has substantially increased (2 to 72) in our institute. The 'SMUAR Model' has not only helped clinicians to report ADRs eventually but has also inculcated an ADR reporting habit in budding clinicians. We expect that in the near future this approach will also motivate the clinicians for spontaneous reporting and thus enable to strengthen the Pharmacovigilance Programme of India.

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