

Evaluation of impact of educational modules in improving the adverse drug reaction reporting from MBBS students

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Abstract: *Objective:* To evaluate the impact of various educational modules implemented for second year MBBS students in their participation and reporting of ADRs to ADR Monitoring Centre (AMC). *Background:* To create awareness in students about importance of ADRs and their recognition as they are associated with high degree of morbidity and mortality. Medical council of India has made it mandatory that each medical college in India should have functioning pharmacovigilance program so that voluntary reporting of adverse drug reactions (ADRs) can be enhanced. *Method:* We have implemented clinical vignettes on ADR exercises in the practical curriculum. ADR crossword and ADR Photognosis competitions being the two optional modules conducted at the end of each four system to 2nd MBBS pharmacology students (120 students of 2012-13 batch MBBS students). Impacts of implementation of these modules were evaluated by objective and subjective yardsticks. *Results:* There has been extremely significant ($p < 0.005$) increase in reporting of ADRs from attached teaching hospital where these students are posted for clinical training when compared to those students who were not exposed (Student's t-test). It has also been found that there was statistically significant increase in student participation as well as percentage of correct responses to ACEM and APCM exercises (Student's t-test). *Conclusions:* We conclude that by introducing educational programs in their curriculum, we can enhance their knowledge on ADR monitoring and reporting from teaching hospitals.

Keywords: ADRs, Educational modules, MBBS Students, Pharmacovigilance.

Introduction

Adverse drug reaction (ADR) is defined by World Health Organization (WHO) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function” [1]. ADRs are one of the major health care problems occurring throughout the world. They affect the people with varying magnitudes, causing both morbidity and mortality [2-3]. Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [4]. Under-reporting of adverse drug reaction is common problem worldwide. In one of the study conducted, it has been found that four types of obstacles are mainly responsible for spontaneous reporting of ADRs. These were problems with the ADRs diagnosis; problems with the usual workload and lack of time; problems related to

the organization and activities of the Pharmacovigilance system; and problems related to potential conflicts [5]. The problem of under-reporting with respect to nursing staff and problems in reporting ADRs are well documented in the study conducted in one of the study conducted in Ajman teaching hospital [6].

Several studies conducted in India has come out with slightly different reasons for under reporting. The major factors found to be responsible for underreporting of ADR include inadequate risk perception about newly marketed drugs, fear factor, diffidence, lack of clarity of information on ADR form about reporting, lethargy, insufficient training to identify ADRs, lack of awareness about existence of Pharmacovigilance program and reporting and inadequate risk perception of over-the-counter (OTC) product [7]. With view of enhancing the reporting adverse drug reactions in India, the ministry of health and

Family Welfare has begun National Pharmacovigilance Program of India PvPI in the year 2009-2010. Currently Central Drug Standards Control Organization (CDSCO) is coordinating the Pharmacovigilance activity in India. The problem of reporting in different place are different because of paucity of resources, skilled manpower, knowledge, attitude and practice of healthcare workers. Hence it is high time that we need to concentrate on newer methods that can enhance the reporting of adverse drug reactions. There are several ways and forums to address these issues as for as doctors and other healthcare professional are concerned. Many studies have shown that by conducting awareness programs through seminars, CMEs and workshops about how, what, where to report ADRs to all healthcare providers can improve the reporting of adverse drug reactions from various health care levels [8].

Educational activities for physicians, such as feedback sessions, can be integrated into the pharmacovigilance activities. Doctors who attended these educational activities are interested in reporting the ADRs and consider the sessions to be useful. Additional studies on the development and effectiveness of educational activities in pharmacovigilance are need of the hour [9]. However there are few studies conducted on second year MBBS students (who undergo training with pharmacology and therapeutics along with pathology, microbiology and Forensic Medicine) who are the future healthcare providers to the community [10-11].

If we educate and create awareness among the medical graduates in these early days of pharmacology learning and make them practically oriented to understand and report the ADRs, it will be productive when they become healthcare providers in future. Hence this study was conducted to evaluate the impact of formal and nonformal means of educational exercises on ADRs on ADR reporting from 2nd year MBBS students.

Material and Methods

The study was conducted in Indira Gandhi Medical College and Research Institute, Puducherry. We have implemented the course module in the 2nd year MBBS curriculum to a batch of 116 students (2012-13). The batch of

2011-2012 (120), were not exposed to these educational modules acted as comparator group. Three educational modules were related to ADRs and reporting implemented to enhance the understanding the basic concepts of ADR, reporting method of ADR to 2nd MBBS students.

Clinical Vignettes on ADRs Module (CVAM): This module consisted of two separate sessions. One on the theoretical aspects of ADR and Pharmacovigilance component (definition, organization and functioning) was taught as didactic lectures of 60 minutes. Second session on how, where and what to report were taught with the help of clinical vignettes in the practical teaching hours (120 minutes).

Students were made to solve these real clinical scenarios of ADRs and report these ADRs in the standard format of reporting designed by CDSCO (Suspected Adverse Drug Reaction Report Form). A sample of CVAM has been given (Box 1). Similar exercises were kept in one of OSPE station. The feedback of CVAM was collected through closed ended and open ended questions. However the students were asked to monitor and report the ADRs seen in their clinical postings. The percentages of these ADRs reported by students in two years (2011-12 and 2012-13 batch students) were calculated and analyzed.

Box 1: A 58-year-old hypertensive lady was on hydrochlorothiazide 12.5 mg + Amiloride 2.5 mg od since 3 weeks. She developed urinary tract infection for which tab Cotrimoxazole 160/800mg [Hindustan Antibiotics, Batch No. 7834/B, Exp. Date: June, 2015] bid for 5 days, was prescribed (on 21-03-2012). Patient noticed three, itchy, greyish black coin like lesions on the chest and back on 23-03-2012. The dermatologist advised her to stop both the drugs and sent her to medicine OPD suggesting change of antihypertensive medication. On follow-up visit, (14-04-2012) the lesions were less intense in color with no itching. Fill out the ADR form and do the causality assessment.

ADR Crossword Exercise Module (ACEM): This type of optional competitive exercise which was initiated to create interest amongst student with respect to ADR. This exercise is like any other crossword puzzle, the difference being, it is entirely related to drug and ADRs pertaining to one particular system of pharmacology. At the end of each system (Gen Pharmacology, ANS Pharmacology, CNS Pharmacology and CVS

Pharmacology) a crossword exercise was displayed in the department notice board. Students were instructed to give complete the exercise at the earliest. (24 hours). Number of completed responses, total number of participants within this period was taken into account. ADR Crossword exercise done is given in Fig 1.

Fig-1: Showing ACEM (ADR Crossword Exercise Module-1) on ANS Pharmacology

A ¹	T	R ²	O	P	I	N	E	T ³	M	A	P ⁴	E ⁵
		I		C ¹⁶			T ⁶				H	P
		M		L		V ⁷	A	M ⁸		C ⁹	E	I
S ¹⁰	C	O	P	O	L	A	M	I	N	E	N	N
B ¹¹		N		N		R	S	D	E	V	T	E
E		A		I		E	U	O	S	I	O	P
C		B		D		N	L	D	M	M	L	H
L		A		I		I	O	R	O	E	A	R
O		N		N		C	S	I	L	L	M	I
F		T		E		L	I	N	O	I	I	N
E	N ¹²	I	C	O	T	I	N	E	L	N	N	E
N			R ¹³	A	Y	N	A	U	D	E	E	
Q ¹⁴	U	I	N	I	N	E	A ¹⁵	P	N	O	E	A

Across (Left to right)	Above Downwards
1. Contraindicated in elderly male patient (8) 3. Synthetic ganglion stimulant (3) 10. Drug causing twilight sleep (11) 12. Natural ganglion stimulant (8) 13. Non selective beta blocker that are contraindicated in this disease (8) 14. An alkaloid that can be used as a muscle relaxant (7) 15. Depolarizing blocker that can cause this adverse effect (6)	2. Cannabinoids receptor-1 antagonist being tried as antismoking (10) 4. Used to treat dermal necrosis in accidental extravasations of NE (12) 5. Shows biphasic response (11) 6. Floppy iris syndrome is its adverse effect (10) 7. Antismoking drug having suicidal tendency (11) 8. Drug which causes hypertension in supine posture (9) 9. Used in Xerostomia (10) 11. Used to relieve painful spasticity (8) 16. Dry mouth, Nasal Stuffiness and impotence are my adverse effects – who am I ? (9)

ADR Photognosis Competition Module (APCM): This was another novel type of exercise in which students were given the opportunity to identify rare ADRs through photos displayed. A colour photo of a particular ADR was displayed in the

notice board and certain clue is given below the exercise. After the end of stipulated time (24 hrs), number of correct responses, numbers of participants were noted. An example of APCM has been given in Fig 2.

A questionnaire containing ten closed ended and three open ended questions were introduced to know the response of these exercises by students. The assessment of closed ended questionnaire was based on five point LIKERT scale. (Fully agree, partly agree, don't know, partly disagree and fully disagree). The three open ended questions were on CVAM, ACEM & APCM.

Fig-2: Showing ADR Photognosis Competition Module



Statistical Analysis: The impacts of these modules were evaluated using subjective and objective means. Descriptive statistics is used to analyze the response to these questionnaires. Percentages were calculated for analyzing the ADR report, student participation, correct responses. Student t- test was used to analyze the result of number of ADR reported by two batch

of students as well as ACEM & APCM. P value less than 0.05 is considered statistically significant.

Results

It has been observed from our study that 61.8% (fully and partly) students benefitted in understanding the risks of ADRs against the rest. 56.4 % (fully and partly) of students opined that they fully understood the process of ADR reporting, whereas 32.6 % students totally disagreed with this type of ADR exercise teaching. Around 75 % of students agreed that ADR exercise should be part of pharmacology curriculum. It was also observed that more than 60% of students were in position to report ADR on their own if they happened to come across ADR.

Majority of students (83%) students were not in a position to do the causality analysis in spite of explaining in details whereas only 17% students were confident enough of doing the causality analysis on their own for a given ADR. Nearly 77% of students felt language is not a barrier in understanding and answering the ADR crossword competition whereas around 9 % students felt they find it difficult in understanding the questions. Most of the students opined that these exercises should be conducted more frequently (69%).The feedback of students are shown in Table 1.

Questions	Agree (%)	Partly Agree (%)	No Comments	Partly Disagree (%)	Disagree (%)
1. The ADR exercise taught me the risks with the use of drugs	43.6	18.2	14.4	10.8	13
2. The ADR exercise teaching helped me to understand the reporting system of ADRs in India.	40	16.4	10.9	12.6	20
3. I think the ADR exercise should be part of pharmacology curriculum on a regular basis	59.2	15.8	5.5	11	8.5
4. I am in a position to report the ADR to the concerned if I happened to come across an ADR	47	15.7	13.7	8.9.	14.7
5. I am in a position of doing causality assessment on my own for the reported ADR	10.5	6.3	56.8	14.7	11.7

Questions	Agree (%)	Partly Agree (%)	No Comments	Partly Disagree (%)	Disagree (%)
6. I am enjoying the ADR crossword exercises displayed in department	45.6	20	25.4	5.4	3.6
7. I think language is a barrier in understanding and participating in crossword competition	6.6	2.7	76.9	6.9	6.9
8. I really think CROSSWORD has enhanced my knowledge regarding ADR	37.3	13.7	17.6	17.6	13.8
9. I think ADR Photognosis competition has enhanced my knowledge regarding ADR	30.6	12.3	34.6	12.3	10.2
10. I think these two exercises have to be conducted on more frequent basis	54.7	14.7	18.9	5.3	6.4

Table-2: Showing the response of students to open ended questionnaire regarding CVAM, ACEM and APCM exercises.

Open ended Question	Responses
1. What is your opinion regarding ADR Crossword Exercise Module (ACEM)? (other than the above)	a. Very challenging (4) b. Made me to think (2) c. Witty (1) d. Waiting to see when is the next crossword coming up (4) e. Thought provoking (1) f. Made me to search other speciality books too (2) g. Should reward all who have completed exercise (7) h. Should be conducted in practical class under supervision and reward those who have completed (3) i. Why don't other depts. do this type of activity? (5)
2. What is your opinion regarding ADR Photognosis Exercise Competition (APEM)? (other than the above)	a. Please display picture of good clarity (11) b. tired of searching books (3) c. Incentive to all those who gave correct answer (6) d. Some students are cheating by taking clinical staffs help (5) e. Should be displayed fortnightly (3) f. Unique way of exercise. Enquired with my friends studying in other colleges g. Novel type (1)
3. Mention one reason that made you to report ADR to ADR Monitoring centre?	a. Internal exercise marks (26) b. Wanted to implement what I have understood (4) c. My duty to report (2) d. To know what I have understood is correct or not (3) e. Really interested in this field of Pharmacology (1)

Numbers in bracket showing the number of response given by students.

Responses to open ended questions strengthened the students' opinion that they not only liked the exercises but also eagerly awaiting for such non formal exercises as mentioned in Table 2.

Objective Assessment: There has been extremely significant ($p < 0.0005$) increase from 31% to 78% in the reporting of ADRs by 2nd MBBS students

who have been exposed to these educational modules when compared to those students who were not exposed (Table 3).

Table-3: Depicting the percentage of ADRs (out of total ADRs) reported by two batches of students.

Month	Percentage of ADRs reported by 2011-12 Batch students (120)	Percentage of ADRs reported by 2012-13 Batch students (116)
October	Nil	Nil
November	Nil	66
December	Nil	63
January	33	80
February	45	66
March	33	78
April	66	90
May	33	78
June	37.5	80
July	28	55
August	Nil	72
September	33	70
Total	31	78*

* $P < 0.005 (=0.002)$, Extremely significant (Two tailed P value) Student 't' test $t = 8.3983$, $df = 3$, Mean \pm SEM = 30.85 ± 3.676

It has been found that student participation in ACEM increased significantly (21% to 38%) ($P < 0.01$) indicating increased awareness, greater knowledge and confidence in the subject among the students (Table 4 & 5). We could also appreciate a marginal increase in percentage of

correct responses in both the exercises over the sessions i.e 5.5% to 25.5% in ACEM ($P < 0.05$) and 9.5% to 25% ($P < 0.05$) in ADR Photognosis competitions as depicted in Table 4 & 5.

Table-4: Showing percentage of student participation and correct responses in ACEM

SI No	ACEM				
	Total No. of Students	Student Participated	Percentage (%) of participation*	No. of Completed response	Percentage of correct answer (%) **
Gen Pharm.	116	24	21	02	9.5
ANS	116	35	30	05	17
CVS	116	40	34.5	07	17.5
CNS	116	44	38	11	25

* $P < 0.005 (=0.0035)$ extremely significant, $t = 8.3983$, $df = 3$, Mean \pm SEM = 30.875 ± 3.676
 ** $P < 0.05 (=0.0121)$, Significant $t = 5.4493$, Mean \pm SEM = 17.250 ± 3.166 , $df = 3$.

Table -5: Showing percentage of student participation and correct responses in APCM

SI No	APCM				
	Total No. of Students	No. of Student Participated	Percentage of participation*	No. of Correct response	Percentage of correct response**
Gen Pharma	116	18	15.5	01	5.5
ANS	116	32	27.6	04	12.5
CVS	116	36	31	07	19.4
CNS	116	42	36.2	12	28.5

* $P < 0.01 (=0.0082)$, Highly significant, $t = 6.2757$, $df = 3$, Mean \pm SEM = 32.00 ± 5.10
 ** $P < 0.05 (=0.0439)$, Significant $t = 3.3548$, Mean \pm SEM = 16.475 ± 4.911 , $df = 3$.

Discussion

Voluntary reporting of adverse drug reactions from the clinicians, nurses are part of pharmacovigilance all over the world. However it has not paid much dividend in reporting adverse drug reactions as it was evident from several studies [5-8].

Hence there is a need to overcome the above limitation. Even though there are several studies conducted involving undergraduates, they are mainly based on analyzing the knowledge, attitude and practice of undergraduates towards pharmacovigilance and not concentrated on how the changes made in training undergraduates yielded the results [10-11]. There are also reports in the literature suggesting interventions to be made in the medical curriculum that all and health related schools should be restructured with respect to pharmacovigilance without any delay and hesitation [8].

Clinical Vignette on ADR Module (CVAM): There are several published studies which had revealed that problem based learning in the form of clinical vignettes has helped the students to fare better academically and to understand and apply the facts practically [12]. Application of clinical vignettes in teaching medical student is proven and time tested method [13].

In our study more than 50% students fully agreed with this type of exercises with another 25% partly agreed so. Hence implementing this type of module in ADR teaching is not only effective but also well accepted by our students. Apart from this, the exercise was well perceived by students in terms of understanding of adverse effects of drugs, understanding of reporting system, method of reporting ADR. Probably because of the complexity in understanding causality assessment, only few could analyze the causality of ADR without assistance (16.8%).

Open ended questions always give an opportunity to express about their feeling about the given subject. In our study, students gave lot of positive aspects of these exercises which once again proved their opinion regarding these type of exercises. There was a statistically significant increase in percentage of reporting of ADRs from 31% to 78% ($p < 0.005$) by the MBBS students

who have been exposed to these types of exercises as given Table 3. It has been found that the steady increase was seen during the period from Jan- April period. This could be due to acquaintance with the subject, better knowledge gained by this period (covered six months of learning pharmacology) relatively free from exam mode and could be due to the combined effect of all three modules of exercises.

ADR Crossword Exercise Module (ACEM): Crossword as an active method of learning has been tried by many medical educationists [14-17]. If implemented carefully it can be a very good teaching-learning method even though it requires great care, considerable time, and different kind of approach as well as dedication by teacher. Our student enjoyed this ACEM (65.6%) and their knowledge enhanced while solving these crossword puzzle (51%). As we have to meticulously frame the clues; a great degree of caution must be exercised while doing it. Our students never felt language is the barrier in non participation (76.9%) as depicted in) Table 1.

ADR Photognosis Competition Module (APCM): Our students also felt and appreciated that APCM as we can make out from the results (Table 1). They also felt these two modules, (ACEM & APCM) should be conducted more frequently (69%) (Table 1). They also gave valuable, critical feedbacks to the open ended questionnaire which will help us refine out teaching module in future (Table 2).

Conclusions

We conclude from this study that by conducting such novel educational programs in curriculum we have seen an improvement in student awareness on ADR monitoring and ADR reporting from teaching hospital.

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