

An Interprofessional Module To Improve Adverse Drug Reporting Skills In Medical And Dental Undergraduates: A Collaborative Approach

Dr. Kudaravalli Jyothsna*, Mr. Anand Kukkamalla**, Dr. Saju Binu Cherian***

*Bhaskar Medical College, Hyderabad, Telangana, India -500075

**Melaka Manipal Medical College, Manipal, Karnataka, India

***Apollo Institute of Medical Sciences and Research, Hyderabad, Telangana, India.

Abstract:

Introduction:

One of the most important objectives of quality assurance is the reduction of the incidence of ‘adverse events’ associated with the process of care. The most fraudulent undesirable iatrogenic events seemed to be linked to medical drug therapies¹⁻⁷. Registered healthcare professionals must ensure that their knowledge and skills are up to date and are based on current evidence, to reduce the risk of complications occurring with the use of these devices. Health care professionals identify and report any suspected ADR to their national pharmacovigilance center. Registered healthcare professionals must ensure that their knowledge and skills are up to date and are based on current evidence, to reduce the risk of complications occurring with the use of these devices. 2nd year MBBS and Dental students lack or have inadequate clinical skills that leads to leads improper mastery and thereby leading to poor health outcome of patients. There is an alarming increase in the subject load for 2nd-year students focussing more lot of (theoretical) knowledge aspects, improper facilities for learning skills, Increased workload, lack of motivation as perceived by the faculty and students, and the method of conducting classes leading to dropouts for classes. As a result, students are not concentrating on clinical skills and more concentrating on theory exams. With the plan of introducing the CBME curriculum to focus on skill training, this area must be addressed as well to augment the training²³.

Methods:

The project was a prospective cohort study conducted in Bhaskar Medical College. The period of Study was September 2020 to September 2021. My project includes Module: ADR reporting. The study Population was 2nd year MBBS students, and 2nd year BDS students. The sample size is 130 members -2nd-year MBBS students and 80 members – 2nd year BDS students. Informed consent was taken. Ethical committee approval was taken.

Results:

Results were evaluated by paired t.test for Pre-test and Post-test. An intervention checklist was evaluated by absolute values and percentages. Feedback(self-assessment) had been taken from students. There was an improvement too. Three sessions of interventions in 3 conditions were conducted and a checklist of items was evaluated.

Discussion:

There was an improvement from 1st session to 3rd session as in identifying serious adverse events reported correctly (53.2%-81.9%) in MBBS and (63.4%-81.7%). Feedback had been taken qualitatively and quantitatively from students for three procedures. Interprofessional reflective tool was taken from stakeholders.

Conclusion:

On the whole improvement in cognitive skill (knowledge part) by ADR reporting to improve clinical skills of participants.

Key Words: Adverse effects, Medical errors, Medical students, ADR reporting

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I. INTRODUCTION:

One of the most important objectives of quality assurance is the reduction of the incidence of “adverse events” associated with the process of care¹⁻³.

Health care professionals identify and report any suspected ADR to their national pharmacovigilance center or to the manufacturer spontaneously. ADR reports play a major role in identification of adverse signals which are not detected in earlier clinical trial or other pre-marketing studies. Serious adverse events are less than 5-10% of events actually reported²⁸.

2nd-year MBBS and Dental students lack or have inadequate clinical skills that lead to leads improper mastery and thereby leading to poor health outcomes of patients. There is an alarming increase in the subject load for 2nd-year students focussing more lot of (theoretical) knowledge aspects, improper facilities for learning skills, Increased workload, lack of motivation as perceived by the faculty and students, and the method of conducting classes leading to dropouts for classes. As a result, students are not concentrating on clinical skills and more concentrating on theory exams. With the plan of introducing the CBME curriculum to focus on skill training, this area must be addressed as well to augment the training²³.

Skills being an important component of the competency of medical and dental students, Students who are poorly trained or lack appropriate skill training will not effectively perform their duty, fail inpatient care, improper prescription, no proper treatment and management leading to improper health outcomes for the patients²⁴. This leads to a drastic fall in the patients reporting for treatment. An IP approach on imparting skill training will indeed benefit the students and make them field-ready. This would indeed improve the health outcomes of patients²⁵.

Aim and Objective:

The present study aimed to improve the competency of medical and dental undergraduates in reporting ADRs

Objective:

By the end of this module, 2nd year MBBS and BDS students should know and demonstrate the skill of reporting ADRs.

II. METHODOLOGY:

Place of Study: Bhaskar Medical College, Sri Balaji Dental College, Hyderabad, Telangaana

Period of Study: September 2020 to September 2021

Study Design: Prospective Cohort Study. Project includes the module.

Assessing ADR reporting

Study Population: 2nd year MBBS students, and 2nd year BDS students

Sample Size: The sample size is 130 members -2nd-year MBBS students and 80 members – 2nd year BDS students.

Intervention:

1. Preparation of an IP module focusing on skill training
2. IP module focusing on training ADR reporting. It's a prospective cohort study.
3. IPE team includes include one physician, one dentist, two pharmacologists, one pharmacy faculty, one nurse, and one social worker.
4. Module : for evaluation of ADR reporting 1st session along with 2nd and 3rd sessions were conducted online. Intervention part included taking classes and they were conducted among 2nd year MBBS (94 students) and 2nd year dental students (82 students) in 3 sessions in power point presentation. Each session after presentation asked them to fill the ADR reporting form. Informed consent was taken from students before the procedure starts. The module included Pre-test, Intervention1, Post-test 1, Intervention 2, and 3 followed by Post-test2. Questionnaires were given for pre-test and post test . They were assessed by the Likert scale. . The intervention was assessed based on the OSCE checklist form. The checklist was validated by internal and external validators.

Data Collection Methods:

Pre-test and Post-test questionnaire for module 1, 2 and 3 were collected on online session through google forms. Intervention performed by taking power point class on ADR reporting and were evaluated by checklist.

Data Analysis:

Quantitative data (Pre-test – Post-test) was analyzed by students t-test for the data between sessions and also by Median and interquartile range. P-value <0.05 is significant. Global score and legibility score were conducted in between MBBS and BDS students on ADR reporting. They evaluated by T.test. Intervention data was collected in the form checklist (Yes-1, No-0). The intervention was evaluated as absolute values and percentages.

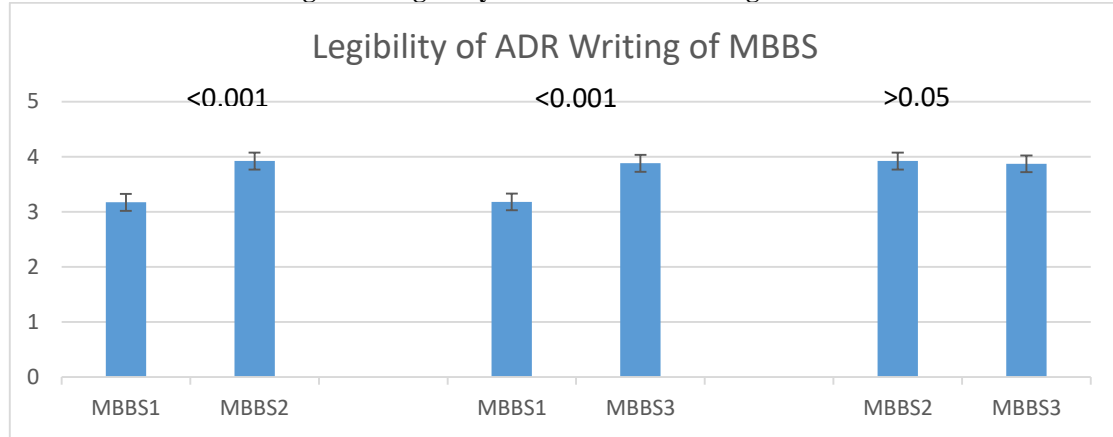
Qualitative data analysis was done for feedback in the form of challenges and reflections for ADR reporting. They were collected in google forms.

Ethics Approval:

Institutional Ethical committee approval was taken. (IEC/FACULTY/5/09-2020). Informed consent was taken from participants after explaining the procedure.

III. Results

Figure 1: Legibility scores of ADR Writing- MBBS

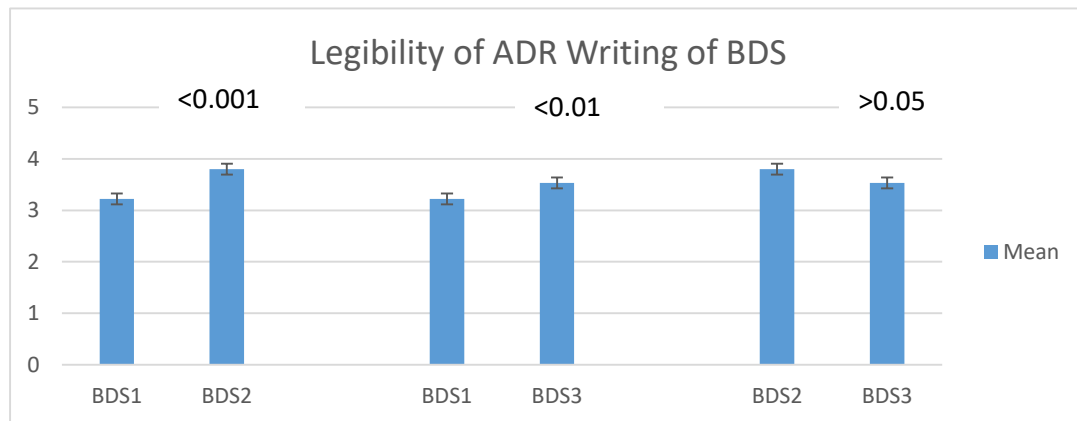


Legibility of ADR writing in MBBS students.

MBBS1= MBBS students 1st session:
MBBS2= MBBS students 2nd session:
MBBS3= MBBS students 3rd session.

Graph depicts comparison of mean legibility score of ADR writing in MBBS students. Legibility was better among different sessions of MBBS.

Figure 2: Legibility scores of ADR Writing – BDS



Legibility of ADR writing in BDS students.

BDS1= BDS students 1st session:
BDS2= BDS students 2nd session:
BDS3= BDS students 3rd session:

Graph depicts comparison of mean legibility score of ADR writing in BDS students. Legibility is better among sessions of BDS.

Table 7: Comparison of pre test-post test scores of MBBS and BDS students on ADR Reporting module

Parameters	MBBS Students n=94			BDS Students n=82		
	Mean ±SD	Media n (IQR)	p-value	Mean ±SD	Median (IQR)	p-value
1. ADR (Adverse drug reaction) is defined as any noxious, unwanted effect of drug doses used in humans for prophylaxis, diagnosis and therapy						
Pre Test	4.30±1.0	5(4,5)		4.45±0.7	5(4,5)	
Post Test 1	4.50±0.6	5(4,5)	0.02	4.62±0.5	5(4,5)	<0.05
Post Test 2	4.60±0.9	4(4,5)	<0.05	4.49±0.8	5(4,5)	>0.05
2 Augmented effects of drug is characteristic of Type A ADRs						
Pre Test	4.46±0.8	5(4,5)		4.30±0.9	5(4,5)	
Post Test 1	4.51±0.6	5(4,5)	>0.05	4.5±0.5	5(4,5)	<0.05
Post Test 2	4.44±0.9	5(4,5)	>0.05	4.47±0.7	5(4,5)	<0.05
3.Bizarre effects of drug are characteristics of Type B ADR						
Pre Test	4.39±0.9	5(4,5)		4.29±1.0	5(4,5)	
Post Test 1	4.52±0.6	5(4,5)	>0.05	4.54±0.6	5(4,5)	<0.05
Post Test 2	4.45±0.9	5(4,5)	>0.05	4.53±0.7	5(4,5)	<0.05
4. According to Rawlins-Thompson classification type-D ADR includes delayed adverse reactions						
Pre Test	3.84±1.1	4(3,5)		3.9±0.9	4(3,5)	
Post Test 1	4.39±0.6	4(4,5)	<0.001	4.3±0.7	4(4,5)	<0.001
Post Test 2	4.41±0.9	5(4,5)	<0.001	4.4±0.8	5(4,5)	<0.001
5. Pharmacovigilance program is for monitoring, assessment, detection and prevention of Adverse drug reactions						
Pre Test	4.40±0.9	5(4,5)		4.52±0.8	5(4,5)	
Post Test 1	4.60±0.6	5(4,5)	0.02	4.58±0.5	5(4,5)	>0.05
Post Test 2	4.64±0.4	5(4,5)	>0.05	4.45±0.8	5(4,5)	>0.05
6. All ADRs are reported to CDSCO(Central Drug Standard Control Organization)						
Pre Test	4.14±1.1	4(4,5)		3.27±1.4	4(2,4)	
Post Test 1	4.52±0.6	5(4,5)	<0.001	3.94±1.1	4(3,5)	<0.001
Post Test 2	4.47±0.9	5(4,5)	0.01	4.40±0.9	5(4,5)	<0.001
7. When drug metabolism is temporarily changed can alter the occurrence of a drug – ADR						
Pre Test	3.77±0.9	4(3,4)		3.68±0.9	4(3,4)	
Post Test 1	4.48±0.6	5(4,5)	<0.001	4.18±0.7	4(4,5)	<0.001
Post Test 2	4.35±0.9	5(4,5)	<0.001	4.34±0.8	5(4,5)	<0.001
8.Uppsala monitoring center is located at Uppsala						
Pre Test	4.12±1.3	5(4,5)		4.38±1.1	5(4,5)	
Post Test 1	4.46±0.6	5(4,5)	<0.001	4.55±0.6	5(4,5)	0.05
Post Test 2	4.33±1.2	5(4,5)	>0.05	4.47±0.7	5(4,5)	>0.05
9. VigiBase is the WHO global database of individual case safety reports (ICSRs)						
Pre Test	4.23±0.9	5(4,5)		4.40±0.9	5(4,5)	
Post Test 1	4.52±0.5	5(4,5)	<0.001	4.48±0.6	5(4,5)	>0.05
Post Test 2	4.36±0.9	5(4,5)	>0.05	4.54±0.7	5(4,5)	>0.05
10. ADR monitoring is helpful in providing updated drug safety information to health care professionals						
Pre Test	4.36±0.8	5(4,5)		4.17±0.9	4(4,5)	
Post Test 1	4.62±0.6	5(4,5)	<0.001	4.42±0.6	4(4,5)	<0.01
Post Test 2	4.47±0.9	5(4,5)	>0.05	4.41±0.9	5(4,5)	0.05
11. ADR monitoring caters information about quality and safety of pharmaceutical products						
Pre Test	4.22±0.8	4(4,5)		4.15±0.6	4(4,5)	
Post Test 1	4.54±0.6	5(4,5)	<0.001	4.3±0.7	4(4,5)	>0.05
Post Test 2	4.48±0.9	5(4,5)	<0.01	4.62±0.6	5(4,5)	<0.001
12. National coordinating center (NCC) is located at Ghaziabad.						
Pre Test	4.14±1.2	5(3,5)		4.33±1.1	5(4,5))	
Post Test 1	4.54±0.6	5(4,5)	<0.001	4.5±0.7	5(4,5)	>0.05
Post Test 2	4.47±0.9	5(4,5)	<0.01	4.47±0.9	5(4,5)	>0.05
13. CDSCO (Central Drug Standard Control Organization) is located in New Delhi						
Pre Test	4.11±1.17	5(4,5)		4.37±1.1	5(4,5)	

Post Test 1	4.57±0.6	5(4,5)	<0.001	4.65±0.5	5(4,5)	<0.001
Post Test 2	4.51±0.9	5(4,5)	<0.01	4.45±0.9	5(4,5)	>0.05
14. Pharmacovigilance is also known as post marketing surveillance						
Pre Test	3.79±1.1	4(3,5)		3.45±1.2	4(2,4)	
Post Test 1	4.40±0.7	5(4,5)	<0.001	4.11±0.9	4(4,5)	<0.001
Post Test 2	4.31±1.1	5(4,5)	<0.001	4.34±0.9	5(4,5)	<0.001
15. Pharmacovigilance programme of India (PvPI) was approved by the ministry of health and family welfare						
Pre Test	4.04±1.0	4(4,5)		3.87±1.1	4(3,5)	
Post Test 1	4.48±0.7	5(4,5)	<0.001	4.48±0.7	5(4,5)	<0.001
Post Test 2	4.43±1.0	5(4,5)	<0.01	4.49±0.8	5(4,5)	<0.001
16. Drugs which are absolutely contraindicated in pregnancy fall under category X						
Pre Test	4.14±1.1	5(3,5)		4.18±0.9	4(4,5)	
Post Test 1	4.58±0.5	5(4,5)	<0.001	4.45±0.7	5(4,5)	<0.01
Post Test 2	4.4±0.9	5(4,5)	<0.05	4.43±0.8	5(4,5)	<0.05
17. The incidence of ADR is highest in elderly than younger population						
Pre Test	4.13±1.0	4(4,5)		4.04±1.1	4(4,5)	
Post Test 1	4.5±0.7	5(4,5)	<0.001	4.39±0.7	4(4,5)	<0.001
Post Test 2	4.3±1.1	5(4,5)	>0.05	4.45±0.8	5(4,5)	<0.01
18. Idiosyncrasy is a genetically determined adverse drug reaction						
Pre Test	4.07±1.2	4(3,5)		3.78±1.1	4(3,5)	
Post Test 1	4.51±0.9	5(4,5)	<0.001	4.22±0.9	4(4,5)	<0.01
Post Test 2	4.41±0.9	5(4,5)	<0.01	4.34±0.9	5(4,5)	<0.001
19. TDM (Therapeutic drug monitoring) is done for drugs with low therapeutic index(TI)						
Pre Test	3.98±1.1	4(3,5)		3.94±1.1	4(4,5)	
Post Test 1	4.23±1.1	5(4,5)	<0.05	4.30±0.5	4(4,5)	<0.01
Post Test 2	4.44±0.9	5(4,5)	<0.001	4.48±0.7	5(4,5)	<0.001

The table represents the comparison of the pretest and posttest scores of the questionnaire pertaining to ADR reporting.

Table 7 This table shows mean with standard deviation, median and interquartile range of ADR reporting. The pre-test was done before the intervention. Post-test 1 was done after 1st intervention. Post-test 2 was done after 3rd intervention. Pharmacovigilance was also known as post marketing surveillance to be taken agreed in the post-test 2 than pre-test (<0.001) by both groups (MBBS and BDS students). Interquartile range (IQR) same, indicate same distribution. While the incidence of ADR was highest in elderly than younger population that shown with significant improvement in post-test (<0.001) compared to pretest in both groups. IQR was the same. On the whole distribution of post-test 1 was the same as post-test 2.

Table 8: Checklist of ADR Reporting for MBBS and BDS students
 The table represents the comparison of the checklist of the intervention pertaining to ADR reporting.

Parameters	Number and Percentages of respondents											
	MBBS 1 st session		MBBS 2 nd session		MBBS 3 rd Session		BDS 1 st session		BDS 2 nd Session		BDS 3 rd session	
	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
A. Patient Information:												
1.Student has mentioned the patient's initials	71 (75.5)	23 (24.5)	81 (86.2)	13 (13.8)	88 (93.6)	6 (6.4)	74 (90.2)	8 (9.8)	76 (92.7)	6 (7.3)	73 (77.7)	9 (22.3)
2.Student has written the age at time of event or Date of birth	91 (96.8)	3 (3.2)	90 (95.7)	4 (4.3)	93 (98.9)	1 (1.1)	82 (100)	0 (0)	82 (100)	0 (0)	82 (100)	0 (0)
3. Student has included the gender of patient	94 (100)	0 (0)	93 (98.9)	1 (1.1)	94 (100)	0 (0)	81 (98.8)	1 (1.2)	81 (98.8)	1 (1.2)	82 (100)	0 (0)
4.Student has included the weight in kgs	93 (98.9)	1 (1.1)	93 (99)	1 (1.1)	94 (100)	0 (0)	80 (97.6)	2 (4)	78 (95.1)	4 (4.9)	81 (98.8)	1 (1.2)
B. Suspected Adverse Reaction:												
5. Student has written the date when the reaction started (dd/mm/yyyy)	71 (75.5)	23 (24.5)	81 (86.2)	13 (13.8)	87 (92.5)	7 (7.5)	31 (37.8)	51 (62.2)	48 (58.5)	34 (41.5)	65 (79.3)	17 (20.7)
6.Student mentioned the date of recovery from ADR	63 (67.1)	31 (32.9)	68 (72.4)	26 (27.6)	72 (76.6)	22 (23.4)	31 (37.8)	51 (62.2)	37 (45.1)	45 (54.9)	44 (53.7)	38 (46.3)
7.Student has correctly written the description of reaction or problem	64 (68.1)	30 (31.9)	71 (75.5)	23 (24.5)	80 (85.1)	14 (14.9)	53 (64.6)	29 (35.4)	62 (75.6)	20 (24.4)	58 (70.7)	24 (29.3)
C. Suspected Medication (s):												
8.Student has correctly written the name of the medicine – (Brand name, Manufacturer, Batch.No., Expiry date, Dose and Route, Therapy dates, Indication and Causality assessment)	72 (76.6)	22 (23.4)	83 (88.2)	11 (11.8)	85 (90.4)	9 (9.6)	35 (42.7)	47 (57.3)	53 (64.6)	29 (35.4)	72 (87.8)	10 (12.2)
9.Student has included the action taken	88 (93.6)	6 (6.4)	84 (89.4)	10 (10.6)	72 (76.6)	22 (23.4)	80 (97.6)	2 (4)	78 (95.1)	4 (4.9)	65 (79.3)	17 (20.7)
10.Student has mentioned if any reaction reappeared after reintroduction	88 (93.6)	6 (6.4)	83 (88.3)	11 (11.7)	90 (95.7)	4 (4.3)	60 (73.2)	22 (26.8)	62 (75.6)	20 (24.4)	71 (86.6)	11 (13.4)
11. Student has written the concomitant use of any medicine (Name, dose, route, frequency therapy dates (onset date, stopped date), indication)	80 (85.1)	14 (14.9)	62 (65.9)	32 (34.1)	65 (69.2)	29 (30.8)	64 (78.1)	18 (21.9)	62 (75.6)	20 (24.4)	42 (51.2)	40 (48.8)
12.Student has mentioned the relevant tests/ laboratory data with dates	68 (72.3)	26 (27.7)	75 (79.8)	19 (20.2)	74 (78.7)	20 (21.3)	63 (76.8)	19 (23.2)	58 (70.7)	24 (29.3)	58 (70.7)	24 (29.3)
13.Student has filled all the relevant medical/medication history	88 (93.6)	6 (6.4)	78 (82.9)	16 (17.1)	74 (78.7)	20 (21.3)	75 (91.5)	7 (8.5)	77 (93.9)	5 (6.1)	76 (92.7)	6 (7.3)
14.Student has mentioned the seriousness of reaction	50 (53.2)	44 (46.8)	73 (77.7)	21 (22.3)	77 (81.9)	17 (18.1)	52 (63.4)	30 (36.6)	57 (69.5)	25 (30.5)	67 (81.7)	15 (18.3)
15.Student has mentioned the outcomes (What is the meaning of this statement?)	45 (47.9)	49 (52.1)	83 (88.3)	11 (11.7)	66 (70.2)	28 (29.8)	36 (43.9)	46 (56.1)	53 (64.6)	29 (35.4)	50 (60.9)	32 (39.1)
D.Reporter Details:												
16.Student has mentioned the name and professional address	74 (78.7)	20 (21.3)	72 (76.6)	22 (23.4)	63 (67.0)	31 (33.0)	39 (47.6)	43 (52.4)	43 (52.4)	39 (47.6)	53 (64.6)	29 (35.4)
17.Student has mentioned the date of reporting ADR (dd/mm/yyyy) format	59 (62.8)	35 (37.2)	66 (70.2)	28 (29.8)	45 (47.9)	49 (52.1)	25 (30.5)	57 (69.5)	21 (25.6)	61 (74.4)	69 (84.2)	13 (15.8)

Checklist of intervention on ADR reporting was noted. It was coded 1(Yes)/0(No). Total number of Yes/No were counted and percentages were measured in 1st,2nd,and 3rd sessions with in MBBS and BDS students. Intervention was conducted, in three sessions among MBBS and BDS students. Student mentioned the seriousness of reaction improved from session 1(53.2%) to session 3(81.9%) in MBBS students and 63.4% to 81.7% in BDS students. Most of them showed improvement from the 1st session to the 2nd and 3rd session.

Table 9. Comparison of Global score of checklist on ADR Reporting

Parameters		Mean ±SD	t-test (P=value)
Between MBBS 1st session and MBBS 2nd session	MBBS 1st Session	5.78±1.7	<0.001***
	MBBS 2nd Session	6.91±1.7	
Between MBBS 1st session and MBBS 3rd session	MBBS 1st Session	5.78±1.7	<0.001***
	MBBS 3rd Session	6.72±1.5	
Between MBBS 2nd session and MBBS 3rd session	MBBS 2nd Session	6.91±1.7	0.18
	MBBS 3rd Session	6.72±1.5	
Between BDS 1st session and BDS 2nd session	BDS 1st Session	4.07±1.5	<0.001***
	BDS 2nd Session	5.18±2.1	
Between BDS 1st session and BDS 3rd session	BDS 1st Session	4.07±1.5	<0.001***
	BDS 3rd Session	6.39±1.6	
Between BDS 2nd session and BDS 3rd session	BDS 2nd Session	5.18±2.1	<0.001***
	BDS 3rd Session	6.39±1.6	

The table represents the comparison of the global score of the checklist of intervention pertaining to ADR reporting.

Table 9 shows mean with standard deviation, and p-value (t.test) of global score were measured between 1st,2ndand 3rd sessions with in MBBS and BDS students. Global score with ADR reporting was significantly improved from MBBS 1st session to MBBS 3rd session (0.001). There was improvement between BDS 3rd session and BDS 1st session (<0.001) and BDS 3rd session.

Self- evaluation analysis:

Self-evaluation of learning process after administration of the module of ADR reporting was analyzed from students by administering a peer validated questionnaire have 9/7 items(Likert scale) and 2 questions to document their challenges/limitations and shared their reflections on prescription writing, ADR reporting and IV cannulation respectively for MBBS and BDS students. Most of them were positive reflections.

IV. Discussion

Spontaneous reports play a major role in identification of adverse signals which were not detected in earlier clinical trails²⁸.

The overall incidence of serious ADRs was 6.7% and of fatal ADRs is 0.32% in hospitalized patients, making these reactions between the fourth and sixth leading cause of death, respectively.(Lazorou J et. al.). Present study it was 74% and 77% MBBS students, 76% and 67% BDS students mentioned correctly ADR and its seriousness.

The presence of only 13 common data elements depicts a significant variability in the content of the various reporting forms of different countries namely Medwatch, Yellow Card, CDSCO, etc. Patient's demographic variable which includes patient's age, sex, body weight, height, body mass index (BMI), and body surface area (BSA) is an important parameter for evaluating an ADR. Although the age was mentioned in all ADR forms, other details were not reported. BMI and BSA determine the correct dosage for a particular individual, especially for drugs with low therapeutic index. Patient's weight and height determine BMI and BSA which makes their mention important. Another parameter of special consideration is ethnicity, which emphasizes the diversity of different ethnic groups to associated risk factors⁷.

Similarly sex, patient's medical history, allergic status, relevant laboratory data, pregnancy status, and habits of patients are important contributing parameters assessing causality. Suspected and concomitant drug details are essential for assessment of reported ADR. Suspected drug name, its dose, route of administration, frequency, start date, stop date, and its indication correlates reported ADR and suspected drug. Similarly concomitant drug details (such as name of drug, route, dose, frequency, start, stop date, and indication) determine whether ADR is due to suspected drug or due to drug–drug interaction, which stands as a common cause in the present poly-pharmacy practice. These data elements relate whether the ADR is solely due to pharmacological property of the suspected drug or due to incorrect dose or frequency of suspected or concomitant drug. In that case, the information classifies the reported ADR as medication error, which is not an ADR, but is another type of drug related problem.

Dechallenge and rechallenge are essential information which assess causality. On analyzing the forms, dechallenge information is reported only in USA, Canada, India, Malaysia, and Sweden while rechallenge information is reported in Argentina, New Zealand, USA, UK, Canada, India, Malaysia, Singapore, Sweden, and South Africa. ADR details such as severity and seriousness distinguish ADR-related intensity and outcome.¹⁹

Product manufacturer's name, batch number, registration number of the manufacturer help to trace the problem if associated with a particular batch of the drug. The last section of an ADR form should have reporter and institution details, which authenticates the report. There was improvement from session 1 to session 3, because of practice

Outcomes:

Seriousness of reactions were correctly reported and improved from 53.2% to 81.9% in MBBS students and 63.4% to 81.7% in BDS students. Whereas it was 95% accurate in study by Papiya Bigoniya et.al., Pharmacist and paramedical staff could play an important role in ADR reporting, because they were responsible for drug administration and recording side effects²⁸.

Improved motivation among 2nd year MBBS and dental students and orientation towards clinical skills training. Increased satisfaction among students. Increased knowledge of skills among students¹⁸. Improved clinical skills development among students¹⁹. Improved knowledge and training skills amongst the IP team members. Patient's health outcomes were improved; they were discharged healthy. IP module to be institutionalized.

Limitations

Medication errors are common in general practice and hospitals. Errors in the act of writing ADR reporting in medical decisions can result in harm to patients.

V. Conclusion

It was shown that ADR reporting should be intensively taught during undergraduate study and this should be reinforced at the start of internship as well as periodically thereafter through continual education programs.

On the whole improvement in cognitive skill (knowledge part) by ADR reporting and improve clinical skills of the student. The students learned the skills that were taught as an interprofessional approach which was very useful. Interprofessional reflective tool has taken from stakeholders.S

VI. Implications

Prescription writing has to be properly addressed about its correctness and appropriateness. Any errors in the procedure have to be eliminated. The rational use of medicines should be practiced which begins with defining the therapeutic objective, choosing the right medicine which is specific to the patient's needs, followed by monitoring of response to therapy. ADR reporting can alert the responsible physician about possible ADR, without time gap.

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