Effect of webinar based teaching module on adverse drug reactions reporting by the medical undergraduates: An Quincy experiment

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Abstract— *The main hurdle to spontaneous reporting is underreporting of adverse drug reactions. If the medical students are sensitized in their early training period about the adverse drug reaction reporting, this problem could be solved completely. This present study was conducted to find out the effectively of training the medical students about filling the adverse drug reactions reporting through e-modules. This study was done on second year medical undergraduates. These students were trained to fill the adverse drug reaction form by e-modules and they were then given one month duration to collect the adverse drug reactions in patients receiving DOTS therapy at their institution. They were ask to fill and submit the adverse drug reactions reports from their respective colleges. All the collected forms by the students were then mailed to adverse drug reaction monitoring center at SMS Medical College to assess the quality. A total of 50 students from different government medical colleges of Rajasthan volunteered to participate in this study. In duration of one month 130 adverse drug forms were collected. Out of which 116 adverse effects (89.23%) were reported accurately. So it can be concluded that considerably valuable and clinically relevant adverse drug reactions were reported by the students. If medical undergraduates' are exposed to adverse drug reactions reporting early in their training then pharmacovigilance program can achieved milestones.*

Keywords: Adverse Drug Reaction (ADR) Reporting, E-Modules, Medical Undergraduates, Pharmacovigilance Program of Government of India (PvPI).

I. INTRODUCTION

The Pharmacovigilance Program of India (PvPI) was initiated by the Central Drugs Standard Control Organization, New Delhi, under the aegis of the Ministry of Health and Family Welfare, Government of India in July 2010 to ensure spontaneous reporting of the adverse drug reactions by the health care professionals.[1] Although this program is running smoothly in our country still the problem of underreporting continues to prevail. The reporting quality is also not up to mark.[2,3] In the light of above scenario it is crucial to train our undergraduates in reporting of adverse drug reactions as they will be future prescribers.

The medical undergraduates are being taught extensively about adverse drug reactions in their pharmacology curriculum through lectures, practical's, and tutorials. However this type of training deprives them from the real skills for detection of ADRs, critical evaluation of the cause, and monitoring. By training the medical undergraduates with the current pharmacovigilance program we

could shape them into effective health-care professional.[4] Hence, this study was planned to implement ADR reporting skill in MBBS students through webinars and find out the effect of these e-module webinars.

II. METHODOLOGY

This Quincy experimental study was conducted on 50 medical students of various medical colleges under department of Pharmacology, SMS Jaipur, Rajasthan.

The study was done after obtaining the approval from Institutional Ethical Committee. The study design was a prospective. The second professional MBBS students of all the government medical institutes who gave written consent were enrolled for participation in the study.

2.1 Development of Webinar based Adverse Drug Reaction Reporting Training

All the volunteered students were taught through webinars to fill the Suspected Adverse Drug Reaction Reporting Form" of the Pharmacovigilance Program of Government of India (PvPI). These webinars were prepared by trained faculty of the Pharmacology department of SMS Medical College. The adverse effect (AE) case narrative for 5-7 different adverse drug reactions (ADRs) were used in these webinars to train the students to fill the ADR reporting form. The AE narrative included the patient details, description of the symptoms of ADR, investigations done, specific and concomitant treatment given to the patient. Based on these narratives first the students were trained how to fill the form.

2.2 Reporting of Adverse drug reactions by the trainees

All the trained medical students were then asked to collect adverse drug reactions in patients receiving DOTS therapy at their parent institution in one month and report it to adverse drug reactions monitoring center at SMS Medical College by e-mail. Students were asked to exclude the patients receiving treatment regimens other than DOTS and also human immunodeficiency virus (HIV)-positive cases.

2.3 Assessment

All the collected forms were assessed for its accuracy by officers at adverse drug reaction monitoring center at SMS Medical College. And results were noted.

2.4 Statistical Analysis: Analysis

All the collected data were entered in MS Excel worksheet 2010. Qualitative data were expressed in percentage and proportions. Accuracy of forms was expressed in percentage.

III. RESULTS

Finally in this study, a total of 50 students from different government medical colleges of Rajasthan volunteered to participate in this study.

In duration of one month 130 filled suspected adverse drug forms were collected. Out of these 130, 116 adverse effects (89.23%) were reported accurately as shown in Figure 1.

Out of these 116 correct adverse reactions, 90 (77.59%) were from first line drugs of DOT and rest (26 i.e. 22.41%) were from second line. When gender wise distribution of the patients who had adverse drug reactions to DOTS therapy was analysed it was observed that in first line of drug M:F ratio was 1.9 and in second line of drugs it was 0.63. (Figure 2)

Figure 1
Quality of the collected adverse drug reactions

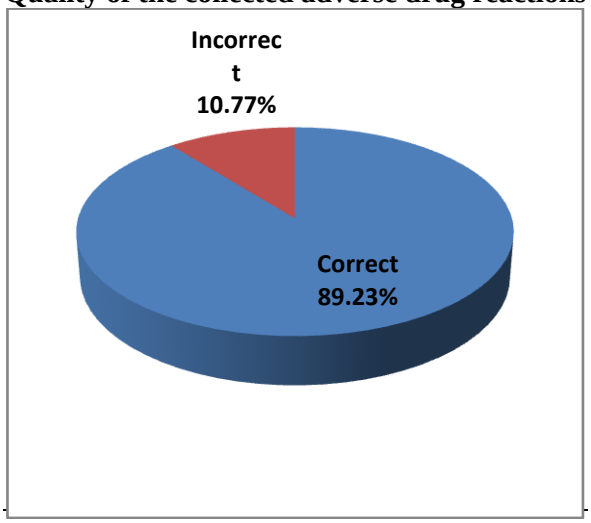
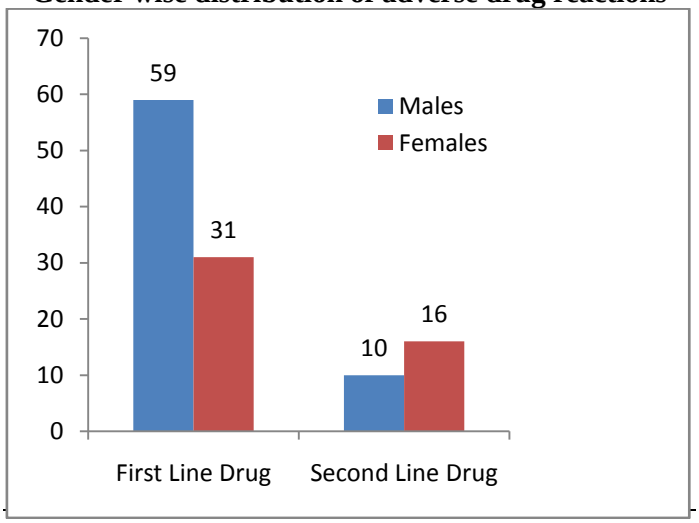


Figure 2
Gender wise distribution of adverse drug reactions



When pattern of adverse drug reactions with antitubercular drugs used in DOTs were analysed it was found that vomiting was the most common adverse drug reaction with every antitubercular drug except in Kenamycine where hearing loss was most common ADR. Other ADRs were with various antitubercular drugs used in DOTs were depicted in Table 1.

Table 1
Distribution of various adverse drug reactions of antitubercular drugs used in DOTs

Drugs (Number of ADR reported)	Type of adverse drug reactions reported	Frequency	Percentage
Isoniazid (22)	**Vomiting**	12	54.5
	Loss of appetite	1	4.5
	Psychosis	1	4.5
	Abdominal pain	6	27.3
	Migraine	1	4.5
	Anaemia	1	4.5
Rifampicin (29)	**Vomiting**	19	65.5
	Loss of appetite	1	3.4
	Dizziness	3	10.3
	Skin allergy	3	10.3
	Anaemia	3	10.3
Pyrazinamide (19)	**Vomiting**	8	52.1
	Diarrhoea	1	5.3
	Migraine	1	5.3
	Anaemia	1	5.3
	Skin Allergy	3	15.8
	Dizziness	3	15.8
	Pedal edema	2	10.5
Ethambutol (20)	**Vomiting**	12	60
	Optic neurtitis	1	5
	Constipation	2	10
	Anaemia	1	5
	Skin allergy	2	10
	Weezing	1	5
	Hyperbilirubinemia	1	5

Ethionamide (13)	**Vomiting**	9	69.2
	Abdomen pain	1	7.7
	Swelling	1	7.7
	Hearing loss	1	7.7
	Diarrhoea	1	7.7
Cycloserine (7)	**Vomiting**	2	28.6
	Itching	1	14.3
	Abdomen pain	1	14.3
	Swelling	1	14.3
	Hearing loss	2	28.6
Kanamycin (6)	**Hearing loss**	4	66.7
	Optic neuritis	1	16.7
	Vomiting	1	16.7

IV. DISCUSSION

In this study, training of ADR reporting skill was implemented in medical undergraduates through e-modules. This innovative module not only sensitized the medical undergraduates about PvPI but also inculcated the ADR reporting habit in them for future. In a previous Malaysian study 67% final year nursing students opined that the ADR monitoring program of their country is essential and it is their duty to report ADR.5 As regards performing causality analysis of an ADR, it is a skill in itself and requires different training than mere ADR reporting and filling the form accurately. After an extensive literature search, we did not come across studies evaluating an educational strategy on ADR reporting in medical undergraduate students; hence, the comparison of ADR reporting performance with other studies could not be done.

The most common (66.37%) ADRs reported were involving gastrointestinal system. These results were similar to another Indian study in patients receiving DOTS therapy in which 53.52% of the adverse drug reactions were involving gastrointestinal system.6 Our country has to depend on adverse drug reaction data of western countries for taking regulatory decisions related to patient safety. This is because of poor participation of health-care professionals in the ADR reporting.7

By participating in this study and collecting the adverse drug reactions themselves the students moved from novice stage to advanced beginner milestone in ADR reporting skill. This can be reflected from the adverse drug reaction data they collected from their respective colleges. If this skill is translated to proficiency stage in future and voluntary self-reporting ADR by them at a later stage is improved then it will be the real success of this training module.

Underreporting of adverse drug reactions which is the main problem in India8 can be improved by this strategy. Limitation of our study include that the webinar training program to introduce the culture of self reporting was undertaken for only at the second professional MBBS students. Also to achieve competency in clinical practice, it is essential that the skill be reinforced at appropriate time intervals to all the medical undergraduates and difficulty level also must be changed.

Thus, if all medical colleges in India train their students in the ADR reporting skill then only the future health-care professionals will be competent and confident in reporting the ADR.

V. CONCLUSION

This present study concluded that training the medical students on ADR reporting skills was effective using the e-module as the performance of students in reporting adverse effects was appreciable. Educating MBBS students will produce health-care professionals competent in pharmacovigilance.

CONFLICT OF INTEREST

None declared till now.

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