

## Teaching critical appraisal of drug promotional brochures on ability of medical students to identify violations of existing WHO Guidelines

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### ABSTRACT

**OBJECTIVES:** To determine the effect of training of appraisal of drug advertisement in medical students.

**MATERIALS & METHODS:-**A pre knowledge testing of the Interns and 2<sup>nd</sup> year MBBS students on ability to identify violations of existing guidelines was assessed using 5 promotional literatures. Training session was conducted on critical appraisal of medicinal drug promotion viz mention of Brand & Generic names, Dosage form, Ingredients causing problems, Precautions, Adverse drug reactions, Drug interactions, Address, and References. In the first session, lectures on critical appraisal methodology and the existing guidelines on medicinal drug promotion were given followed by small group discussions. This was followed by post training testing. The 2<sup>nd</sup> year students were followed up next year (3<sup>rd</sup> year) with pre-testing and post-testing after similar training.

**RESULTS:** The pre-test knowledge of Interns was found to be significantly lower ( $p < 0.05$ ) than 2<sup>nd</sup> year students in 8 out of 10 headings (except Brand name and therapeutic use). The post-test scores showed a statistically significant ( $p < 0.05$ ) improvement over the pre-test scores in both the groups. There was a statistically significant improvement in both the groups after training in criticizing promotional brochures according to WHO criteria. On follow-up, the 3<sup>rd</sup> year students showed significantly higher ( $p < 0.05$ ) awareness in pre-test scores in only 5 (generic name, dosage, precaution, ADR, DI) out of 10 headings. However, in post-training these students showed significant increase in 8 headings.

**CONCLUSION:** Current study shows that ability of medical students and interns to critically appraise the promotional literature is not up to the mark. However the teaching and training sessions lead to significant improvement in their ability to assess the promotional literature. Such training programs should be an integral part of syllabus in all years of undergraduate medical education including their internship year. There is a need to train undergraduate medical students on critical appraisal of drug advertisement that would be useful for future rational drug use in clinical practice.

**KEYWORDS:** Drug Promotional Brochures, promotional literatures, medicine promotion, World Health Organization criteria, Critical appraisal in undergraduate students.

### I. INTRODUCTION

Medicinal promotion is an important element of pharmaceutical innovation which is meant to transform research concepts into practical therapeutic tools. It also and links the effective therapy to health care system. It plays a crucial role in keeping the physicians updated about various aspects of pharmaceutical products and the newer therapeutic modalities, helping them provide the most appropriate solution for treating the patients<sup>(1)</sup>.

As per World Health Organization (WHO), definition drug promotion is 'all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drug'<sup>(2)</sup>. WHO has published ethical criteria for medicinal drug promotion in the year 1988 to evaluate the appropriateness of promotional drug literatures<sup>(3)</sup>.

Promotional materials may focus only the positive points and hide the negative aspects of a drug. Thus, the information contained in promotional materials may or may not be as accurate as it appears. Therefore it is necessary to obtain an in-depth understanding of the promotional advertisements before prescribing. For this, WHO has given the ethical criteria under which promotional advertisement should be criticized. Criticism on promotional literature should include the name of the active ingredient, brand name, content of active ingredient, other ingredients known to cause problems, approved therapeutic uses, dosage form or regimen, side effects, contraindications, major interactions, management in case of overdose or toxicity, storage conditions, pharmacokinetic profile, use in pregnancy and lactation, name and address of manufacturers or distributor, and reference to scientific literature. World Health Organization (WHO) also suggests that each country must ensure

that their health system get the right number of service providers with right skills at the right place. Indian health policy primarily focuses on improving the quality of medical education and updating curriculum in medical colleges<sup>(3)</sup>.

Training is teaching, or developing skills and knowledge that relate to specific useful competencies. It has specific goals of improving capability, capacity, productivity and performance and it directly contributes to the development of human resources in health sector. It is assumed that repeated training will improve effectiveness of services provided by healthcare professionals. Skills on critical appraisal of drug promotional literature can provide valuable information to medical trainees to practice evidence based medicine in future<sup>(4)</sup>.

The evidence suggests that drug promotions in exaggerated and certain facts are masked in a way that it affects rational prescribing practices. Marketing of new drugs by benefit driven drug companies may lead to their prescription without adequate knowledge of safety, therapeutic benefits or cost-effectiveness in the community<sup>(5)</sup>.

In the previous study conducted by same investigators and other<sup>(6,7,8,9)</sup>, it was found that pharmaceutical companies do not follow the WHO guidelines specially with regard to safety information like drug interactions, precautions, side effects which may mislead the prescribers. With this state of affairs the study was planned to determine the effect of training of critical appraisal of drug promotional literature on the ability of undergraduate medical students and interns, to identify violations of existing guidelines and to sensitize them regarding WHO criteria for medicinal drug promotion. This study also aimed to reveal the impact of repeated training in same population group.

## II. MATERIALS & METHODS

This study was conducted in BJ Government Medical College, Pune, India after getting approval from Institutional ethics committee. The study population included 2<sup>nd</sup> years MBBS students and Interns. Each student's written consent was taken before participation in the study. Only the students that were enrolled in the study in 2<sup>nd</sup> years (in 5<sup>th</sup> term) were re-sensitized when they reached in 3<sup>rd</sup> year (in 7<sup>th</sup> term) to find out how much they retain and reproduce the information. 50 promotional literatures were collected from drug companies from various clinical departments out of them five were selected and presented to medical students. This baseline assessment of student's knowledge and ability was performed to identify violations of existing WHO guidelines that included 11 important parameters in first session. Each student was asked to evaluate them in 1hr. This was followed by the second session where lectures on critical appraisal methodology (1hr) and the existing WHO guidelines on medicinal drug promotion were given followed by small group discussions for 30min. In the third session same brochures were given to all students again and conducted post session evaluation (1hr) which was conducted in similar way as pre-test. The scores obtained by the students in pre-test and post-test served as the pre and post-intervention measurements respectively. The criticism was evaluated using the checklist of WHO ethical criteria for medicinal drug promotion. For each correct parameter one mark for wrong parameter zero was given. Also a missed parameter was given zero. As each student had evaluated 5 promotional literatures on the 11 point WHO scale; hence an average response was calculated for each parameter for each student for the 11 point scale. Post-test average responses were compared to pre-test responses on the basis of standard promotional literature requirement parameters<sup>(3)</sup>.

The results were analysed using Student's paired t test using Graph pad prism-6 software.

## III. RESULTS

A total of 161 interns and 133 second year students were participated in this study. All second year students were followed up next year (3<sup>rd</sup> year). Table 1 and Figures I, II show the pre and post-test average scores in different groups as per WHO parameter. Results from post intervention assessment showed that there is higher score as compared to pre intervention score in all groups regarding most of the WHO criteria.

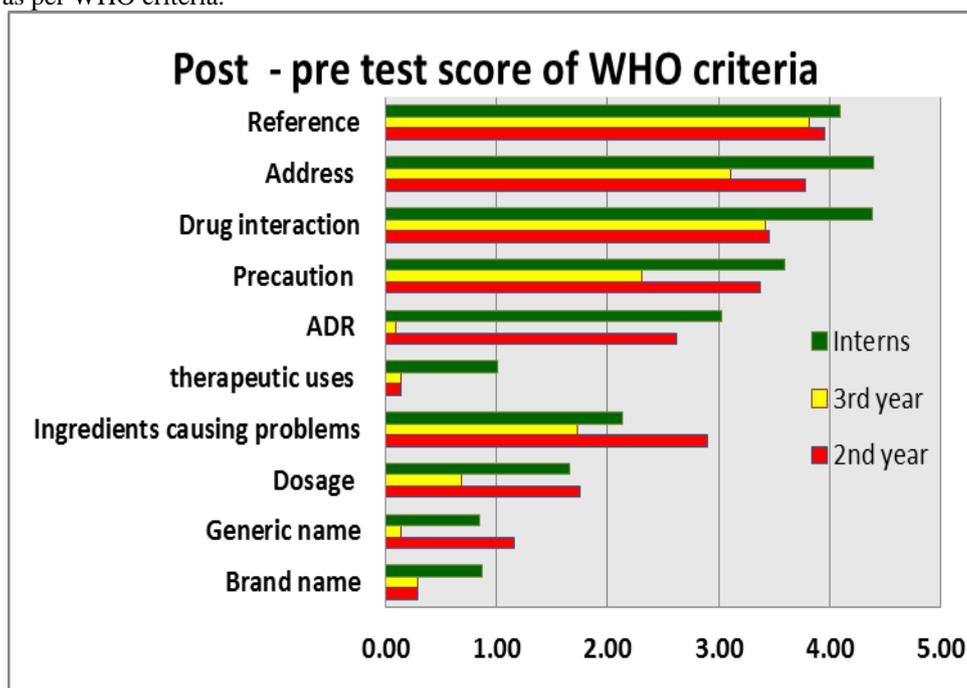
**Table.1** Difference between Student's evaluations of promotional brochures as per WHO criteria Post - Pre Test average score for each WHO parameter.

WHO Criteria	Average Score	Average Score	Average Score
Post score--Pre score	2 <sup>nd</sup> year	3 <sup>rd</sup> year	Interns
Brand name	0.29	0.07	0.87*
Generic name	1.17*	0.15	0.84*
Dosage	1.75*	0.69*	1.66*
Ingredients causing problems	2.90*	1.73*	2.13*
therapeutic uses	0.14	0.06	1.01*
ADR	2.62*	0.09	3.03*

Precaution	3.38*	2.31*	3.59*
Drug interaction	3.45*	3.42*	4.38*
Address	3.78*	3.11*	4.40*
Reference	3.95*	3.82*	4.09*

(\*statically significant value  $p < 0.0001$ ) Values are expressed as mean difference between Pre-test and Post- test for that parameter.

**Figure I-** Graphical presentation of (Table -1) Post - Pre Test data of Student's Evaluation of promotional brochures as per WHO criteria.



**Figure II-**Percentage of students answered correctly in pre and post-test as per WHO criteria

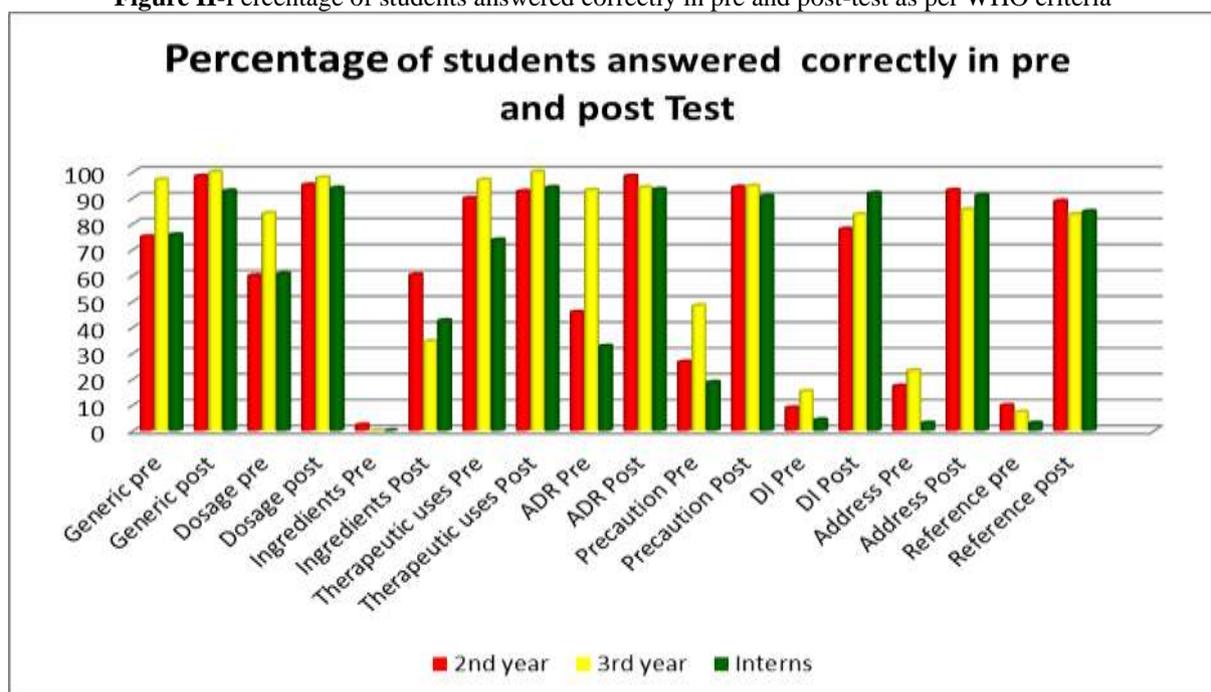


Figure III- Percentage improvement in knowledge of students after training

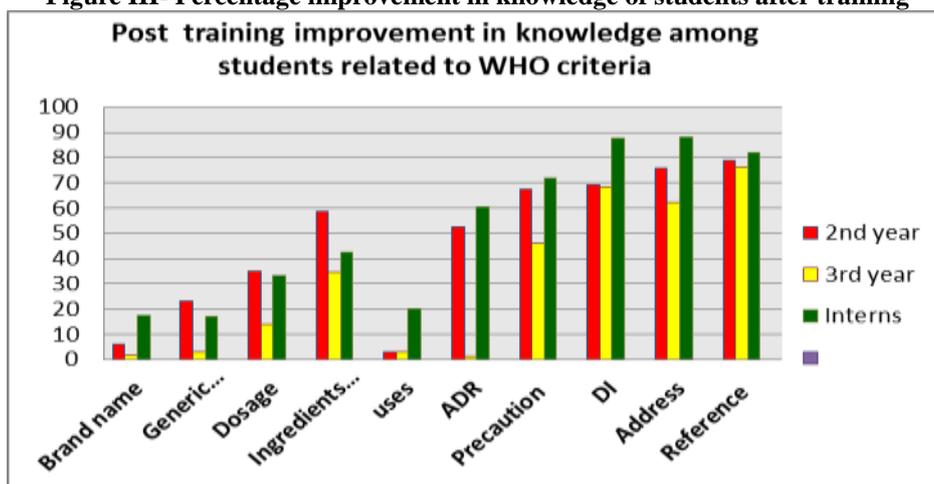
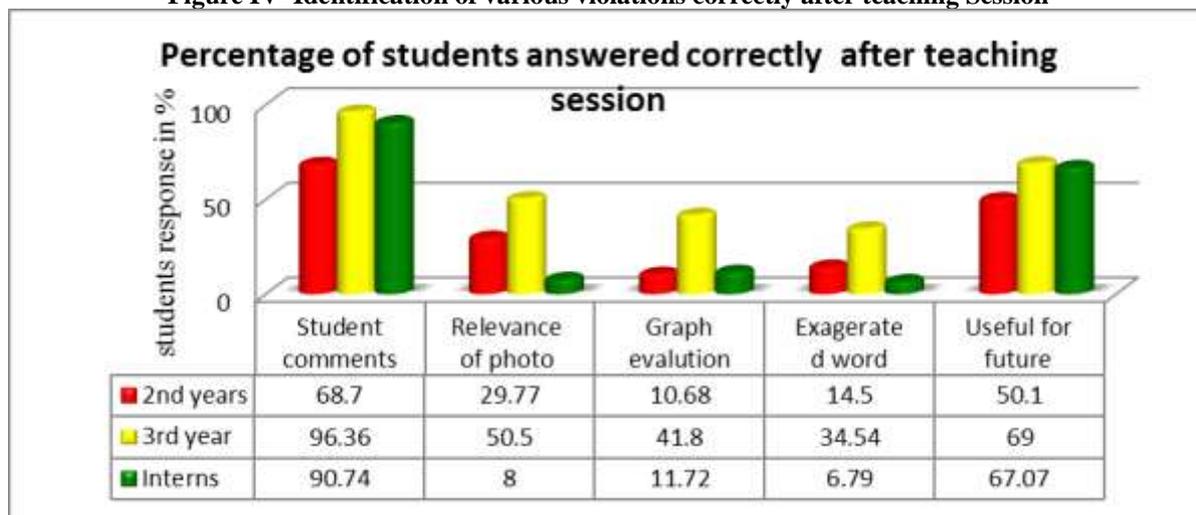


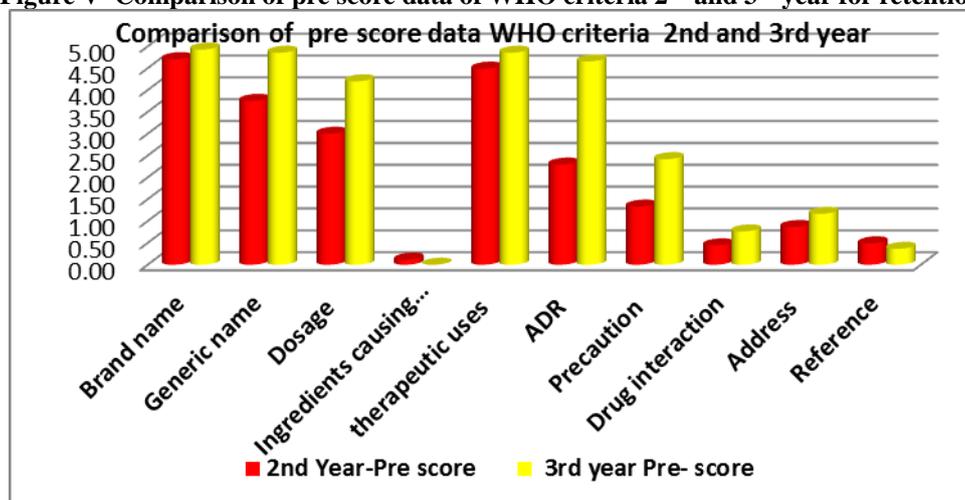
Figure III indicates that there was a significant improvement observed in student's performance. There was a distinct improvement seen related to Drug Interaction, manufacturer's address and References in all the groups.

Figure IV- Identification of various violations correctly after teaching Session



It is shown in Figure IV that 3<sup>rd</sup> year students were better in identifying violations correctly after the training session as compared to 2<sup>nd</sup> year students and interns.

Figure V- Comparison of pre score data of WHO criteria 2<sup>nd</sup> and 3<sup>rd</sup> year for retention.



Pre-test score of 3<sup>rd</sup> year student was compared with that of 2<sup>nd</sup> year students it was observed that pre-test score of 3<sup>rd</sup> year students was statically significant in five parameters (Generic name, Therapeutic use, Dosage, ADR, and Precaution). Also when the pre-test score of 3<sup>rd</sup> year student was compared with their respective post-test score it was observed that there was statically significant improvement in post test scores regarding Generic name , Therapeutic use, Dosage form, Adverse drug reaction and Precaution Therefore bringing forth the fact that the 3<sup>rd</sup> year student are well-learned on this topic due to a training session held in their 2<sup>nd</sup> year curriculum. This skill of criticism was reinforced by the repeated training session in 3<sup>rd</sup> year.

#### IV. DISCUSSION

This study unravels the fact that educational training in undergraduate medical students is an important aspect. Information about medicines is necessary to help prescribers to practice rational drug therapy. Pharmaceutical companies should provide reliable information in promotional literature which is essential for rational prescribing as recommended by WHO <sup>(3)</sup>.

This study was done in 161 interns and 133 second year students who were followed up to 3<sup>rd</sup> year. Considering the results for knowledge of Brand name there was significantly improvement in mean score of post-test (0.87) for interns whereas 2<sup>nd</sup> year students and following 3<sup>rd</sup> year there was no significant difference.

There was statistically significant improvement in knowledge about promotional brochures and commenting and criticizing abilities of undergraduate students after the training program. In a study conducted by Alvero RGY <sup>(10)</sup> on teaching critical appraisal of promotional brochures in a medical school in Philippines found that post intervention scores were significantly higher in those who underwent the teaching module on critical appraisal of medicinal drug promotion.

The present study focuses on the importance of training on critical appraisal of drug promotional literature to medical students to identify violations of WHO guidelines governing drug advertisement. Low pre-test score can be attributed to lack of specific training on evaluation .This is a consequence of lack of specific training on evaluation of drug promotional literature, in routine medical education curriculum . So training medical students to evaluate and criticise promotional literatures appropriately may make them more adept for future clinical practice <sup>(5)</sup>.

As regard Generic name observation in promotional literature there was significant improvement in the post –test score of 2<sup>nd</sup> year students which indicates that this activity needs to be included in 2<sup>nd</sup> year curriculum. These same students when followed up to 3<sup>rd</sup> year, were subjected to the pre and post-test , there was no significant difference in pre and post indicating that they retained the training effectively. This same exercise when done in fresh interns who had never received such training also showed a significant improvement in knowledge regarding Generic name observation. Knowledge regarding generic name is an integral part of good prescribing practice therefore above results emphasis the need of such training in under graduate curriculum. There was a significant improvement in score in post as regard to dosage form observation of on promotional literature in all the 3 groups. As dosage form is a minor information is written in different fonts on various promotional literature sources ; but as regards to therapeutic it is the main concern as right dose and right form make therapy effective <sup>(4)</sup>.

As regard to information about safety parameter like ADR, Precautions and drug interaction there was significant improvement in post test scores. As the participants of the all the 3 groups were unaware that one has to observe the said parameter in promotional literature. These parameters are an important part of training as promotional literature may be one of the important or seldom sole of information provider in a busy practitioner. This training will help the budding doctors to increase awareness about safe drug prescribing habit.

Address observation in promotional literature is a necessary part of the WHO criteria as it wants to strengthen the pharmaco-vigilance reporting from grass root level physician. As regard to such training there was a significant improvement in post test score in all the groups indicating the importance of such training (Table-1). References are an integral and important part of drug promotion yet many times they are missing , neglected or mentioned in very small font size which is not readable. References give the authenticity for claimed indications in the promotional literature. After training ,a statically significant improvement were observed in ability of students to comment appropriately about the references in the promotional literature. Similar results were also obtained on importance of knowing manufacturer’s address before and after training (Table -1).

Students were able to identify and analyse the relevance of images and catchy slogans given on the promotional drug literature used in this study. Images and slogans in brochures attract the attention of prescribers and patients as well. Students also reported their comments as this session was useful for future practice, they also able to identify that improper graphs axis, irrelevant photos and exaggerated word used in promotion literature. Third (3<sup>rd</sup> ) year students were better in identifying violations correctly after the training session as compared to second (2<sup>nd</sup> ) year students and interns(Figure IV). Therefore physicians and medical

professionals should be able to identify and analyse the correctness and authenticity of such statements that may make tall claims. Similar results were obtained in a study conducted by H. Nagabushan et al<sup>(4)</sup>.

It is observed that there is a paucity of teaching programs or educational initiatives that are conducted to teach drug promotion to medical students<sup>(5)</sup>. So more attention is required and sincere efforts must be taken by medical school or colleges to conduct more and more such programs so as increase awareness among medical students and emphasise it in the routine curriculum.

## V. CONCLUSION

Current study shows that ability of medical students and interns to critically appraise the promotional literature which may not be up to the mark. However the teaching and training sessions lead to significant improvement in their ability to assess the promotional literature.

Critical appraisal of drug promotional literature should be an integral part of syllabus in all years of undergraduate medical education as well as in internship year. A step that must be taken to address the problem is to develop programs that will teach future prescribers the necessary skills to critically appraise promotional materials. It is very important to lay down the foundation of rational drug use early even among medical students, before they are exposed to the constant barrage of promotional materials from the pharmaceutical industry. If prescribing doctors will be able to critically appraise the claims made in drug promotional materials, the problem of irrational drug use may be significantly reduced if not totally eliminated. Future prescribing practices henceforth will be improved if the necessary skills and critical attitudes for rational therapy are strengthened during the medical undergraduate years.

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