Deolekar, et al.: Assessment of knowledge of medical students about promotional drug literature using the WHO criteria

Assessment of Knowledge of 2\textsuperscript{nd} Year Medical Students Regarding Promotional Drug Literature using the World Health Organization Criteria

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ABSTRACT

Objective: Education of medical students has a crucial role to play in preparing future practitioners to respond appropriately to drug promotion. Inappropriate prescribing practices without necessarily benefiting the patients contribute to increased health-care costs if prescriber is not aware of the World Health Organization (WHO) criteria for ethical medical drug promotion 1988. Hence, this study was conducted with objective to assess the knowledge of 2\textsuperscript{nd} year medical students about the WHO criteria for promotional drug literature.

Materials and Methods: This observational study was conducted in the Pharmacology department of tertiary care hospital. 200 2\textsuperscript{nd} year medical students were given a promotional drug literature and were asked to evaluate it according to the WHO criteria on prescribed pro forma.

Results: 41% medical students were aware of the WHO criteria. 11% students calculated the importance of reference of scientific literature. 35% evaluated the importance of name and address of manufacturer or distributor. 30% evaluated necessity of dosage form and regimen. 72% evaluated the importance of active ingredients. 45% students evaluated the importance of other ingredients or adjuvant known to cause problem. 85% students calculated the importance of major drug interactions. 74%, 78%, and 62% students calculated the importance of drug-related precautions, contraindications, and warnings. 100% students calculated the importance of brand and generic name and approved therapeutic uses by 98% students.

Conclusion: The study showed that medical students have less knowledge about the WHO criteria of promotional drug literature. They require constant education regarding the WHO guidelines as these literatures often influence prescribing behaviors of physicians.

KEY WORDS: 2\textsuperscript{nd} year MBBS students, promotional literature, World Health Organization criteria.

Introduction

The World Health Organization (WHO) defines medicinal drug promotion as “all informational and persuasive activities done by manufacturer and distributors so as to induce the prescription, supply, purchase, and use of drugs which are medicinal.”\textsuperscript{[1]}

Despite the importance of the pharmaceutical industry, a substantial amount of pharmaceutical companies’ expenditure is targeted at the promotion of pharmaceuticals to increase sales. This affects among others the quality, frequency, and costs of prescribing as well as the sustainability of health-care systems and may additionally result in patients receiving suboptimal care. It is therefore essential that health-care professionals understand these pharmaceutical promotion strategies and have the skills to respond appropriately. However, physicians and medical students alike underestimate the effects of promotion on their prescribing behavior and receive little to no training on how to critically assess these sophisticated pharmaceutical promotion activities.\textsuperscript{[2]}

Pharmaceutical companies are supposed to follow the ethical guidelines for drug promotional activities. At the international level, there are two main guidelines in existence. One is “Ethical criteria for medicinal drug promotion” recommended by WHO, 1988\textsuperscript{[3]} and the other one is the Code of Pharmaceutical Marketing Practices recommended

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Different modes of drug promotion include visual aids, leave behinds, leaflets, and audiovisuals. Medical practitioners, however, have no training on the proper way to utilize these promotional materials. Even in the presence of several guidelines to evaluate the quality of promotional materials, the practice of irrational prescribing is still rampant.

Like doctors, medical students are also exposed either during their medical course or during internship to drug promotion. Hence, if prescribers rely on the information from drug advertisements, it can result in irrational prescribing. Hence, to prevent irrational prescribing, there is a need to educate practitioners regarding critical analysis of drug advertisements. This can be achieved by imparting knowledge regarding drug advertisements during the MBBS course and more so during the 2nd year when they are taught pharmacology.

Materials and Methods
This observational questionnaire-based study was conducted in the various departments of tertiary care hospital. 200 2nd year medical students were given a promotional drug literature and were asked to calculate according to the WHO criteria on prescribed pro forma under following headings.

1. The names of the active ingredients using either international non-proprietary names or the approved generic name of the drug;
2. The brand name;
3. Content of active ingredient(s) per dosage form or regimen;
4. Name of other ingredients known to cause problems;
5. Approved therapeutic uses;
6. Dosage form or regimen;
7. Side-effects and major adverse drug reactions;
8. Precautions, contraindications, and warnings;
9. Major interactions;
10. Name and address of manufacturer or distributor;
11. Reference to scientific literature as appropriate.

Data were collected, and knowledge of every point of the WHO criteria was evaluated in percentage.

Results
200 2nd year medical students were assessed for knowledge of promotional drug literature using the WHO criteria, and following results as shown in Table 1 were obtained.

| WHO criteria                              | Evaluation by number of students (%) |
|------------------------------------------|-------------------------------------|
| Generic name                             | 200 (100)                           |
| Brand name                               | 200 (100)                           |
| Active drug                              | 144 (72)                            |
| Approved therapeutic uses                | 196 (98)                            |
| Other ingredients known to cause problems| 90 (45)                             |
| Dosage form                              | 60 (30)                             |
| Regimens                                 | 60 (30)                             |
| Side effects/adverse effects             | 170 (85)                            |
| Precautions                              | 74 (37)                             |
| Contraindications                        | 78 (39)                             |
| Warning                                  | 62 (31)                             |
| Major drug interactions                  | 170 (85)                            |
| Manufacturers/distributors name and address| 70 (35)                          |
| References                               | 22 (11)                             |

WHO: World Health Organization

41% medical students were aware of the WHO criteria. 11% students estimated the importance of reference of scientific literature. 35% assessed the importance of name and address of manufacturer or distributor. 30% evaluated necessity of dosage form and regimen. 72% calculated the importance of active ingredients. 45% students estimated the importance of other ingredients or adjuvant known to cause problem. 85% students evaluated the importance of other ingredients or adjuvant known to cause problem. 85% students evaluated the importance of major drug interactions. 74 (37%), 78(39%), and 62(31%) students calculated the importance of drug-related precautions, contraindications, and warnings. 100% students projected the importance of brand and generic name and approved therapeutic uses by 98% students. This study finding is similar with the study done by Jaiswal et al.

Discussion
This questionnaire-based 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.
Medical representatives also lack sufficient medical and technical knowledge to present information on pharmaceutical products correctly and in a responsible manner. There is a tendency for drug companies not to highlight or lay emphasis on contraindications and adverse effects. Such parameters need critical analysis. Pharmaceutical information such as presence of excipients, shelf life, and legal category is sometimes missed out in drug advertisements and keeps the doctors unaware of such important information. Most of the drug advertisements highlight efficacy claims without stressing on safety claims. Hence, medical practitioners should be cautious in judging the claims made by the company.

In our study, as per calculations from Table 1 only 35% were able to judge the safety and efficacy claims correctly. Similar results were obtained in a study conducted by Nagabushan and Shashikumar.

The WHO ethical criteria for medicinal drug promotion state that the word “safe” should only be used if properly qualified. According to the Code of Pharmaceutical Marketing Practices of the IFPMA 2012, words like “safe” and “no side effects” should generally be eluded. 55 students felt that the given promotional drug literature mentioned the drug as “safe” but does not seem as properly qualified.

References are an integral part of drug advertisements because most of the claims should be substantiated by the references. Most of the advertisements do not contain references for the claims made.

In our study, less number of students was able to identify the importance of references significantly while large number of students was able to identify and analyze 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.

In a study conducted by Sayyad et al., educational training was given due importance in undergraduate medical students. Information about medicines is necessary to help prescribers. 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.

The misuse of prescription drugs resulting from physician reliance on promotional materials can create medical problems that endanger patients. Ziegler et al. concluded in their study that physicians generally failed to recognize inaccurate statements in drug promotional materials. This was due to fact that medical practitioners have not been properly trained to evaluate promotional materials.

A step that could 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 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.

Indeed efforts of practitioners, pharmaceutical companies, and regulatory body are needed which are the only way to accomplish rational prescribing.

It is observed that there is a paucity of teaching programs or educational initiatives that are conducted to teach drug promotion to medical students. Hence, training medical students to evaluate and criticize promotional literatures appropriately make them more adept for future clinical practice.

Each and every country must improve their health system by getting right number of service providers with the right skills at the right place and this is also suggested by WHO.

**Conclusion**

Education of medical students regarding critical analysis of drug advertisements has an essential role to play in preparing future practitioners to respond to drug promotional activities ethically. Future prescribing practices henceforth will be improved if the necessary skills and critical attitudes for rational therapy are reinforced during the medical undergraduate years.

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