RESEARCH BRIEF

Assessment of a Pharmaceutical Advertisement Analysis Module in a Drug Literature Evaluation Course

Mohamed Ezzat Khamis Amin, PhD, Youssef Fattouh, PharmD

Faculty of Pharmacy, Beirut Arab University, Beirut, Lebanon

Submitted June 28, 2016; accepted September 10, 2016; published August 2017.

Objective. To evaluate the impact of an educational module on students' self-efficacy when analyzing the content of promotional drug brochures (PDBs) and to assess the students' value of PDBs' as an educational tool.

Methods. Third-year bachelor of pharmacy students participated in a one-hour lecture and a two-hour laboratory. Students completed a survey before and after participating in the module.

Results. The module elicited a statistically significant change in students' self-efficacy beliefs regarding evaluating promotional drug brochures, while the average perceived value of promotional drug brochures did not change significantly after the module.

Conclusion. A brief educational module can increase students' self-efficacy in evaluating the content of PDBs.

Keywords: Pharmaceutical promotion, pharmacy students, pharmaceutical advertisement, drug literature evaluation

INTRODUCTION

The implications of pharmaceutical promotional tools on the behavior of health professionals have been growing in recent years. Pharmaceutical advertisements have been criticized for manipulating or biasing the message resulting to inappropriate therapeutic choices, damaging public health, and escalating health care costs.^{1,2} While improved regulation and redesigned incentive systems are important strategies in tackling this issue, educational training for medical and pharmacy students is crucial to prepare future practitioners to respond appropriately to drug promotion.³⁻⁵ Pharmacy students need this kind of training. Pharmacists are often members of committees that decide on a formulary or protocol and may be subjected to promotional pressures by representatives.⁶ At times, pharmacists need to appraise promotional materials to be able to deal with prescribers who may have been influenced by these materials. Pharmacists who are educated on different aspects of pharmaceutical promotion are in a better position to put forward a rational argument for the appropriate use of medicines.⁷

The World Health Organization (WHO) issued a set of international standards comprising ethical criteria for

the promotion of medicinal drugs.⁸ Endorsed by the World Health Assembly in 1988, the criteria aimed to give stakeholders a useful framework for developing measures to ensure that promotional practices involving drugs follow acceptable ethical standards. The criteria provided a frame of reference for judging proper behavior in drug promotion, including an evaluation of the content of advertisements and package inserts. However, the criteria did not include measures for a more detailed analysis of texts, references, graphs, photographs, and other images in print pharmaceutical advertisements. More recently, Health Action International (HAI) and WHO published an educational manual that medicine, pharmacy, nursing, and other health discipline instructors can use to train students on how to recognize and respond to pharmaceutical promotion before they start prescribing and dispensing medicines.² The manual, *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide*, covers a number of topics, including common marketing techniques used by the pharmaceutical industry. Particularly relevant to this paper is a specific chapter in this manual that provides guidance for a detailed analysis of texts, references, graphs, photographs, and other images in print pharmaceutical advertisements.

An international survey of educational initiatives on pharmaceutical promotion found that while many medical and pharmacy educators recognize the need for education about drug promotion, the incorporation of this

Corresponding Author: Mohamed Ezzat Khamis Amin, Manchester University College of Pharmacy, 10627 Diebold Road, Fort Wayne, IN 46845. Tel: 260-470-2719. E-mail: mohamedezzatz21@gmail.com

topic in educational curricula is still limited.⁹ Many respondents cited inadequate time allocation as a barrier to successful inclusion of an educational program on drug promotion that meets educators' goals. An interesting finding was that the topic was often integrated into therapeutics, pharmacology, or professional ethics classes. The survey indicated that many educators aimed to include critical appraisal of drug promotion in future educational activities.

Biostatistics and drug literature evaluation courses are typically designed to provide a foundation of evidence-based medicine skills for pharmacy students. These courses teach students how to critically evaluate the medical literature and identify findings that have implications for pharmacy practice. Key objectives for these courses are to enable the students to demonstrate a fundamental knowledge of common statistical principles and tests useful in analyzing scientific data; identify appropriate statistical tests for different types of research data and study designs; critically evaluate professional, lay, and scientific literature in a logical, systematic fashion, and apply principles of evidence-based medicine to make informed health care decisions and recommendations. Accordingly, students would be well-equipped to take a module where they can critically assess various aspects of print pharmaceutical advertising including texts, references, graphs, photographs, and other images at the end of such a course. A module also would provide an opportunity where the significance of some of the studied topics, such as measuring the effect size of an intervention, is highlighted.

In Lebanon as in many other countries, pharmaceutical representatives frequently use promotional drug brochures (PDBs) to persuade clinicians to adopt their products. These PDBs often contain misleading data and selective quotations.¹⁰⁻¹³ The objective of this study was to evaluate the impact of an educational module on students' self-efficacy when analyzing the content of PDBs as examples of print pharmaceutical advertisements and on students' views of the value that PDBs have as educational tools. This research was based on the hypothesis that pharmacy students' self-efficacy would increase and the perceived value of print pharmaceutical advertising would decrease after participating in this educational activity.

METHODS

The study population consisted of 80 third-year bachelor of pharmacy (BPharm) students who were enrolled in the Spring 2016 biostatistics and drug literature evaluation class at the Beirut Arab University Faculty of Pharmacy. All students participated in the module. This

student cohort was not exposed to other topics addressing drug promotion in the curriculum prior to this experience. Exempt status approval was obtained from the Beirut Arab University Institutional Review Board.

Biostatistics and drug literature evaluation is a core class for third-year BPharm students at Beirut Arab University. The course is administered in weekly 1-hour lectures and 2-hour discussion sessions. Two faculty members taught the course in Spring 2016. The class is designed to provide students a foundation of evidence-based medicine skills. Its overall goal is for students to develop the ability to critically evaluate the pharmacy and medical literature to identify findings that have implications for pharmacy practice.

The module was implemented in the last two weeks of class. The first component was a 1-hour lecture on pharmaceutical promotion. The lecture covered these topics: WHO ethical criteria for medicinal drug promotion; a review of relative risk reduction, absolute risk reduction, and number needed to treat calculations; examples of misleading claims in different sections of pharmaceutical print advertising including text, graphs, photographs, or other images and references; and checklist items that can be used to evaluate these sections. Finally, an example of misleading claims that can be made on studies that utilize survival analysis was provided.

The second component of the module was a 2-hour exercise in which students were required to analyze two PDBs according to a set of criteria shown in Table 1. The criteria were adapted from a WHO/HAI publication that focused on analyzing pharmaceutical advertisements.² The session started with the instructors reviewing the checklist criteria with the students. Each student received a copy of the two PDBs to analyze along with a copy of the criteria in Table 1. One PDB was for a prescription medication, and the other was for an over-the-counter medication. Students were given 35 minutes to analyze the PDBs according to the set criteria. After submitting their form to the instructors, students then reanalyzed the same advertisements using the same criteria with their team of 4-5 classmates and reached a consensus. Each team had 25 minutes to finish the task. After each team analyzed and submitted their group form to the instructors, a member from each team presented the team's findings relevant to particular gaps they identified in one of the PDB sections. Instructors provided oral feedback on answers immediately after a student's presentation. Instructors encouraged the teams to appeal their incorrect answers to encourage students to review the material, evaluate their understanding of the criteria, and defend the choices they made. Instructors facilitated a classroom discussion between the teams to explore the perspectives of students'

Table 1. Print Pharmaceutical Advertisements Evaluation Checklist

Ethical Criteria for Medicinal Drug Promotion					
Criteria	OTC		Prescription		
	C	NC	C	NC	
Generic name was mentioned					
Brand name was mentioned					
Content of API(s) per dosage form					
Name of additive(s) was mentioned					
Approved therapeutic uses were mentioned					
Dosage form or regimen was stated					
Side effects and major ADR were mentioned					
Precaution, contraindication and warnings were mentioned					
Major interactions were stated					
Name and address of manufacturer and distributor were stated					
References to scientific literature were cited					
Data and Graphs					
Criteria	OTC		Prescription		
	N/A	C	NC	N/A	
All info presented as ARR or NNT					
Info. about blindness were mentioned					
Info. about randomization were mentioned					
CI and/or <i>p</i> value were provided upon claiming statistical significance					
All graph axes were clearly labeled					
All graphs were not obscured by visual materials					
All graph titles were clear (do they explicitly and completely say what the graph is about?)					
References					
All references were written using legible font size					
All references were complete and retrievable					
All references came from peer-reviewed journals					
Text					
Generic and brand names were mentioned in the same frequency and font size					
Emotive expressions were not used					
Claims about surrogate endpoints were linked to their meaningful clinical outcome					
Safety and effectiveness information are given same placement and prominence					
Economic claims gave actual prices of different alternatives and were not vague (eg, cost less)					
Pictures and Images					
Images do not construct mythical or misleading associations between diseases and product					
Depicted patients' characteristics match the target population					

Abbreviations: OTC=Over the Counter; C=Compliant; NC=Non-compliant; N/A=Not applicable; API= Active Pharmaceutical Ingredient; ADR=Adverse Drug Reaction; ARR=Absolute Risk Reduction; NNT=Number Needed to Treat; CI=Confidence Interval
If applicable, explain how the advertisement was "non-compliant"

from other teams. The exercise was repeated four times because students were split into four discussion teams for the entire semester.

The survey was developed specifically for this study and consisted of three sections. A panel of four faculty and

students reviewed the face validity of the survey questions. The first section addressed the key construct of interest, which was a student's self-efficacy when analyzing the content of a PDB. The format and design of this section, as well as response choices, were based on Bandura's guide

for constructing self-efficacy scales.¹⁴ Perceived self-efficacy is concerned with people's beliefs in their capabilities to produce given attainments.¹⁵ This section consisted of six items pertaining to students' self-efficacy beliefs regarding the evaluation of PDBs. Students were asked to rate their degree of confidence on a scale of 0 to 100 in which 0 equaled "cannot do at all" and 100 equaled "highly certain can do." Table 2 includes the six items and the results of the self-efficacy section of the survey. To construct an aggregate self-efficacy measure, the six numbers reported by students were averaged. This average generated an overall indicator of the students' self-efficacy.

The second section consisted of four items that focused on students' views of the value that PDBs have as an educational tool on effectiveness, safety, cost effectiveness, and information concerning a drug product in general. Responses for this section were rated on a 5-point scale, where 1=not at all useful; 2=slightly useful; 3=somewhat useful; 4=useful; and 5=extremely useful. The four numbers reported by the students were averaged to obtain an aggregate measure of perceived value of PDBs. This average generated an overall indicator of the value of PDBs as perceived by students. Table 3 includes the four items and the results of the perceived value of PDBs as educational tools.

The third section consisted of two items that covered perceived usefulness of the lecture and exercise addressing pharmaceutical promotion and evaluation of PDBs.

Students were informed that all responses would be kept confidential and anonymous. Students received information on the module format before the lecture and were given samples of PDBs to be analyzed in the second component of the module so that students who had not been exposed to PDBs before were acquainted with their main organizational structure. A pretest survey was administered to students before the lecture, while the

post-test survey was administered immediately after students finished the second component of the module.

Descriptive analyses generated frequencies, means, ranges and standard deviations as relevant. Cronbach's alpha was used to analyze internal consistency of the scale assessing self-efficacy beliefs regarding PDB evaluation as well as the scale assessing their perceived value. Pre- and post-survey data for perceived value of PDBs were analyzed for significance using paired sample *t*-tests. However, the data resulting from measuring self-efficacy pretest did not pass the Shapiro-Wilk test for normality. Thus, Wilcoxon signed rank tests were used to analyze the differences between pre- and post-test results for self-efficacy beliefs regarding PDB evaluation. Statistical significance was set a priori at $p < .05$. Data were analyzed using STATA Version 12 (StataCorp LP, College Station, TX).

RESULTS

Out of 80 students, four did not complete the pre-module survey forms. Hence, only 76 students who filled out both the pre- and post-module surveys were included in the analysis. Eighty-one percent ($n=62$) of students were female, and the average age was 22 years (range: 20-32). Cronbach alpha calculations indicated pre-module findings for each scale to have good internal consistency. The two scales, self-efficacy in evaluating PDBs and perceived value of PDBs were both internally consistent with Cronbach's alpha scores of .79 and .71, respectively. Student perceptions of the usefulness of the module components were mostly positive. No student reported finding the lecture or the exercise not at all useful. Nine percent of students found the lecture to be slightly or somewhat useful. Fifty-two percent found the lecture useful, and 29% found it to be extremely useful.

Table 2. Students' Self-efficacy Beliefs Regarding Evaluating Promotional Drug Brochures (PDBs) Before and After the Module (N=76)

Item	Pre-test Mean (SD)	95% CI	Post-test Mean (SD)	95% CI	<i>p</i> -value
Evaluate a PDB's adherence to the World Health Organization's ethical criteria	41 (26)	35-47	78 (16)	75-82	<.001
Evaluate text presented in a PDB	62 (20)	57-66	82 (11)	79-85	<.001
Evaluate graphs presented in a PDB	62 (20)	57-67	81 (11)	79-84	<.001
Evaluate pictures and images presented in a PDB	69 (22)	64-74	85 (13)	82-88	<.001
Evaluate references presented in a PDB	57 (25)	51-62	83 (12)	80-85	<.001
Evaluate a PDB in general	58 (18)	54-63	84 (11)	80-84	<.001
Overall Score	58 (15)	54-62	82 (9)	80-84	<.001

Students were asked to rate their degree of confidence by recording a number from 0 to 100, where 0=cannot do at all, 50=moderately can do, and 100=highly can do

Abbreviations: SD=Standard Deviation; PDB=Promotional Drug Brochure; CI=Confidence Interval
p-values from Wilcoxon signed rank tests

Table 3. Students' Perceived Value of Promotional Drug Brochures (PDBs) Scale Results Before and After the Module (N=76)

Item	Pre-test Mean (SD)	95% CI	Post-test Mean (SD)	95% CI	p-value
How valuable is a PDB as an educational tool on the effectiveness of a drug product?	2.3 (1.0)	2.1-2.5	2.6 (0.9)	2.4-2.8	.04
How valuable is a PDB as an educational tool on the safety of a drug product?	1.8 (1.2)	1.5-2.0	2.0 (1.2)	1.8-2.3	.12
How valuable is a PDB as an educational tool on the cost effectiveness of a drug product?	2.2 (1.1)	2.0-2.5	2.0 (1.2)	1.7-2.2	.17
How valuable is a PDB as an educational tool on all kinds of information concerning a drug product?	2.1 (1.0)	1.9-2.4	2.2 (1)	2.0-2.4	.67
Overall Score	2.1 (0.8)	1.9-2.3	2.2 (0.9)	2.0-2.4	.48

Scale Scores: 1=Not valuable at all, 2=Slightly valuable, 3=Somewhat valuable, 4=Valuable, 5=Extremely valuable

Abbreviations: SD=Standard Deviation; PDB=Promotional Drug Brochure; CI=Confidence Interval

p-values from paired sample *t*-tests

Ten percent of students found the exercise to be slightly or somewhat useful. Forty-six percent found the exercise useful, and 33% found it extremely useful.

Table 2 reports the pre- and post-module mean scores for each of the six items in the self-efficacy beliefs regarding evaluating PDBs. The module elicited a statistically significant change in students' self-efficacy beliefs regarding evaluating PDBs. ($p<.001$). The mean self-efficacy composite score rating increased from 58 (SD=15) before the module to 82 (SD=9) after the module. Table 3 reports the pre- and post-module mean scores for each of the four items in the perceived value of PDBs scale. The average perceived value of PDBs as educational tools did not change significantly before and after the module (2.1 vs 2.2, $p=.76$).

DISCUSSION

The main findings of this study support the hypothesis that an educational module consisting of a one-hour lecture and a two-hour laboratory session would significantly improve students' self-efficacy for analyzing the content of a PDB. Pharmacy students had intermediate levels of perceived value of PDBs and fairly high levels of self-efficacy beliefs regarding evaluating PDBs before the module. It is possible that offering the module toward the end of a drug literature evaluation course contributed to these ratings. It is encouraging that despite the fairly high levels of self-efficacy beliefs regarding evaluating PDBs before the module, a significant improvement in post-module self-efficacy scores was observed.

Students' perceptions of perceived value of PDBs did not change after taking the module. It is possible that students learned new information about the drugs in the PDBs they analyzed, which might have contributed to keeping the post-module scores from declining. Research indicates that most doctors think information from

pharmaceutical companies is biased, but many think it is useful.¹⁶ Naik and colleagues found that US pharmacy students had an overall negative attitude toward print advertisements using the professional labeling format, but an overall positive attitude toward the print advertisement using the patient labeling format.¹⁷ Students in our study evaluated print advertisements that were designed for health professionals. It is possible that, similar to the US study, students would have demonstrated a positive attitude toward patient labeling formats. However, Lebanon, like many other countries, follows a more paternalistic model of health care compared to the US. This difference could have negatively affected Lebanese students' attitudes toward print advertisements using the patient labeling format compared to their US peers. Qualitative research may be needed to identify how students come to form such attitudes on print advertising and other tools of pharmaceutical advertising.

Mintzes' seminal survey provided a snapshot of educational initiatives for pharmacy and medical students about drug promotion around the world.⁹ Her findings indicated that lectures and small group discussions in tutorials or workshops were the most frequently reported educational techniques, with 46% of responding pharmacy schools utilizing critical analysis of sample advertisements as an educational technique. Despite this finding, the number of published studies describing initiatives to educate pharmacy or medical students about critical appraisal of pharmaceutical advertisements remains remarkably low. This international survey indicates that only 9% of respondents reported carrying out some form of evaluation other than student course appraisals or counts of numbers of students attending courses.⁹ It would be useful for pharmacy educators to be more proactive in evaluating their educational interventions and sharing them with colleagues.

Suryawati and Santoso evaluated a module on critical evaluation of drug advertisements and found that participants were able to identify misleading/incorrect information in selected drug advertisements up to 12 months after the intervention.¹⁸ More recently, Shankar and colleagues implemented a novel nine-hour module held over a period of four months among Nepalese medical students that was based on the WHO/HAI manual on pharmaceutical promotion.¹⁹ Their intervention resulted in a change in respondents' attitudes and perceived skills related to analyzing drug information, analyzing pharmaceutical representative presentations, using statistics in critical appraisal, and educating consumers about promotion. While the module in Shankar and colleagues' study covered all topics relating to pharmaceutical promotion that were in the manual, our module focused on analyzing pharmaceutical advertisements. It is unclear from the Nepalese study whether group work included an activity like the one we describe in the second component of our module. Unlike, the above-mentioned school, pharmaceutical promotion as a topic at the faculty of pharmacy in Beirut Arab University is spread over several classes. The student cohort that was included in this study had not been exposed to other topics addressing pharmaceutical promotion in the curriculum prior to this experience. However, as part of a major curriculum revision, future cohorts will be exposed to coursework and activities addressing pharmaceutical promotion in drug literature evaluation, public health and ethics classes. The goal of incorporating the topic into different parts of the curriculum is to have an ongoing exposure for students regarding the pharmaceutical promotion throughout their training.

Activities similar to the module we described can be implemented with students or health professionals. It also may be useful to include as an educational component for preparing pharmaceutical representatives focusing on academic detailing. One of the goals of academic detailing traditionally has been to improve clinical practice through peer-to-peer educational outreach.^{20,21} Academic detailing aims to leverage the communication approach of pharmaceutical industry representatives. The capacity to analyze and comment on pharmaceutical advertisements would provide a useful tool when academic detailers encounter and provide advice to targeted clinicians.

This is the first study that provides a detailed training for pharmacy students on critical appraisal of PDBs. It is also the first study that reports placing such a module in a drug literature evaluation course. This study has limitations. Incorporation of this module has limited generalizability, as it was only incorporated and assessed at a single university with a single student cohort. These results

should be validated at other universities with multiple cohorts. It is also possible that the choice of PDBs to include in the exercise has influenced students' perceptions of the value of PDBs. Future studies should validate our results through implementation of a similar educational activity. It would be interesting to test interprofessional education as a pedagogical approach for preparing health professions students on handling pharmaceutical promotion and analyzing pharmaceutical advertisements.

CONCLUSION

A module designed to enable students to critically appraise print pharmaceutical advertisements increased students' self-efficacy in evaluating the content of print pharmaceutical advertisements.

REFERENCES

1. Mansfield PR. Banning all drug promotion is the best option pending major reforms. *J Bioeth Inq.* 2005;2(2):75-81.
2. Mintzes B, Mangin D, Hayes L. *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide.* Geneva, Switzerland: World Health Organization and Health Action International; 2011.
3. Austad KE, Avorn J, Kesselheim AS. Medical students' exposure to and attitudes about the pharmaceutical industry: a systematic review. *PLoS Med.* 2011;8(5):e1001037.
4. Mansfield PR, Lexchin J, Wen LS, et al. Educating health professionals about drug and device promotion: advocates' recommendations. *PLoS Med.* 2006;3(11):e451.
5. Kumar CJ, Deoker A, Kumar A, Kumar A, Hegde BM. Awareness and attitudes about disease mongering among medical and pharmaceutical students. *PLoS Med.* 2006;3(4):e213.
6. Ghaibi S, Ipema H, Gabay M. ASHP guidelines on the pharmacist's role in providing drug information. *Am J Health Syst Pharm.* 2015;72(7):573-577.
7. Wiedenmayer K, Summers RS, Mackie CA, Gous AG, Everard M, Tromp D. *Developing Pharmacy Practice: A Focus on Patient Care.* Geneva, Switzerland: World Health Organization and International Pharmaceutical Federation; 2006.
8. World Health Organization. *Ethical Criteria for Medicinal Drug Promotion.* Geneva, Switzerland: World Health Organization; 1988.
9. Mintzes B. *Educational Initiatives for Medical and Pharmacy Students About Drug Promotion. An International Cross-sectional Survey.* Geneva, Switzerland: World Health Organization; 2005. Document reference (WHO/PSM/PAR/2005.2).
10. Mikhael EM. Evaluating the reliability and accuracy of the promotional brochures for the generic pharmaceutical companies in Iraq using World Health Organization guidelines. *J Pharm Bioallied Sci.* 2015;7(1):65-68.
11. Cardarelli R, Licciardone JC, Taylor LG. A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: is what they tell us important and true? *BMC Fam Pract.* 2006;7:13.
12. Randhawa GK, Singh NR, Rai J, Kaur G, Kashyap R. A critical analysis of claims and their authenticity in Indian drug promotional advertisements. *Adv Med.* 2015;469147.
13. Rohra DK, Gilani AH, Memon IK, et al. Critical evaluation of the claims made by pharmaceutical companies in drug promotional material in Pakistan. *J Pharm Pharm Sci.* 2006;9(1):50-59.

14. Bandura A. Guide for constructing self-efficacy scales. In Pajares F, Urdan T, (Eds). *Self-efficacy Beliefs of Adolescents*. Greenwich, CT: Information Age Publishing; 2006:307–337.
15. Bandura A. *Self-efficacy: The Exercise of Control*. New York, NY: Freeman; 1997.
16. Norris P, Herxheimer A, Lexchin J, Mansfield P. *Drug Promotion: What We Know, What We Have Yet to Learn*. Geneva, Switzerland: World Health Organization and Health Action International; 2005.
17. Naik RK, Borrego ME, Gupchup GV, Dodd M, Sather MR. Pharmacy students' knowledge, attitudes, and evaluation of direct-to-consumer advertising. *Am J Pharm Educ*. 2007;71(5):Article 86.
18. Suryawati S, Santoso B. Drug advertisements: a critical lesson for Indonesian students. *Essent Drugs Monit*. 1997;23:23.
19. Shankar PR, Singh KK, Piryani RM. Knowledge, attitude and skills before and after a module on pharmaceutical promotion in a Nepalese medical school. *BMC Res Notes*. 2012;5:8.
20. Soumerai SB. Principles and uses of academic detailing to improve the management of psychiatric disorders. *Int J Psychiatry Med*. 1998;28(1):81-96.
21. Shankar PR, Jha N, Piryani RM, Bajracharya O, Shrestha R, Thapa HS. Academic detailing. *Kathmandu Univ Med J (KUMJ)*. 2010;8(29):126–134.