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## Online validity and accuracy of references within drug promotion materials in orthopaedic out-patient department

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### Abstract

Background - In the era of evidence based medicine, correct and relevant information should accompany any broadcast of pharmaceutical related knowledge. A substandard piece of information has potential for negative impact on care-giver and patient at large. The claims about any pharmaceutical agent with respect to its action, complications or superiority over other ones should be based on strong level of evidence for better knowledge that is aimed at positive impact on judicious decision making and good outcome of therapy. It is thus important that periodic assessment of claims made by promotional materials should be done to ensure their validity and not rely on marketing noise.

A detailed study of drug promotion materials collected in orthopaedic out-patient department within a period of four months (Oct 2015 to Jan 2016) was done with special attention to presence, quality and validity of information or claims made within it. 238 random materials were collected in a defined period, out of which 120 excluded in first and 72 in second evaluation. The remaining 46 materials with 65 references in total were part of study. The references were searched over world wide web for its validity, ease of availability and correctness.

Majority (26, 56.52%) of the materials were without proper references. Most of the references were about mechanism of action followed by superiority to other drugs. There was deficiency in the presented references including lack of author name, wrong volume of journal or problem with easy identification over net in most references (32, 49.23%). Pain medication were followed by antibiotics and calcium related agents in number of references present. The wrong referencing and difficult to trace the source were leading problems noted on online assessment. The quality of promotional material should quote well substantiated evidence about mechanism of action, superiority and rationale of its use. The evidence thus garnered should be of highest level or from standard reference text book. The preferable use of digital object identifier (doi) is advisable for better search of the articles to check on internet. For ease of quick navigation through referencing articles use of technology like quick response (QR) codes may be considered in the future.

**Keywords:** promotional literature, drug marketing, orthopaedics, education, evidence, references

### Introduction

Evidence based medicine has been a buzzword in recent times and becoming a significant issue in patient management by providing effective guidance and education to the care-giver. The doctors have traditionally been kept informed and updated about latest developments in pharmaceutical world with special regard to newer drugs and their role in various ailments by medical representatives. Direct to physician (DTP) marketing has been the traditional way of drug promotion across the globe. The print materials have been an important vehicle of correspondence in this regard. Changing times have witnessed adoption of recent technologies like web based platforms or social media as promotion strategy. Verbal broadcasting of information has long been a common practice and sometimes only means of knowledge about particular drug to a busy practitioner<sup>[1]</sup> Most of times it is combined with print materials as reminders or ready reckoner. The print materials not only describe about drugs including their salient features like mode of action and associated complications but also claim superiority of a particular product over other one in terms of pharmacological profile and safety.

Appropriate criteria have been established regarding definition and proper usage of the promotional strategy [2]. These materials often lack due substantiation in their claims or do it in an inaccurate manner [3]. Prior studies have also found various inadequacies and inaccuracies in the promotional facts [4, 5]. In this era of instant information the validity of the print advertisement should be assessed for accuracy to ensure better information to doctors that passes down to patient for optimal health management.

### Materials and Methods

The printed materials displaying pharmaceutical endorsement by their corresponding medical representatives were collected over a period from October 2015 to January 2016 from Orthopedics out-patient department in single unit (three OPD days a week). A total of 268 print materials of all kinds with drug information from the unit were sorted and evaluated. Out of these 16 were patient education materials and 24 were instruction materials for healthy exercise, plaster care and diet for better bone health and gout prevention. These along with any material with >4 printed pages were excluded from study. The remaining 238 materials were subjected to evaluation and further exclusion. Care was taken to avoid duplication of the material in the study. 74 of these were further excluded because of various reasons including being paper reprints, newsletters or having webinar information and duplicate content. 40 of these were product monographs, more than four print page materials or brochures about showing company achievements or newer method of drug formations. Four materials were along with small book and two with compact disc of surgical procedures and thus also excluded. These 120 materials in total were excluded from the study. Remaining pamphlets describing the pharmacological properties, efficacy, advantages and superiority over other drugs were then separated for final evaluation. The presence or absence of appropriate references for their claims and accuracy, adequacy was noted for each object. The 72 materials were without due referencing to drug related information so were not included in the study to result in a final number of 46 materials, with one or more references, for evaluation. The last reassessment of the level and accuracy was done by manual browsing of the given references as it is through Google search engine. The assessment of referencing was done as per Vancouver style of referencing. The type of source of references and its online presence and ease of retrieval of data were also noted for each. The various reference errors were given codes (Table- 1) and appropriate codes were then ascertained for each pharmaceutical agent (Table -2).

### Results

Majority (192 out of 238, 80.67%) of the materials neither had any references written nor indicated to be provided on request. None of these provided, along with the information material, copies or link to the relevant research article. Very few of them (two), however, had indicated further data to be provided on request. They were all excluded from the study. A total of 46 print promotional materials were evaluated for use of references within them, their online presence, validity and how easily a lay person can search the proper reference

material. Many consisted of multiple references thus making 65 references in total. Only two references were provided with complete abstract of the article they cited. The types of pharmaceutical agents were divided in to various groups like pain medications, antibiotics, calcium and vitamin D related drugs, osteoarthritis related agents and miscellaneous. Pain medication, antibiotics and calcium related products were leading in references they cited with 19(45.65%), 15(32.60%) and 12(26.08%) respectively. Mechanism of action (21, 45.65%) was leading area of referencing followed by superiority claims (13, 28.26%) and basic physiological or pharmaceutical information (11, 23.91%). Majority references were derived from journals followed by book/monograph and newspaper article in 39(84.78), 06(13.04%) and 01(0.21%) cases respectively. There was wrong referencing noted in 14(30.43%) and difficult localization in 05 cases (10.86%) respectively. Difficult localization was considered when more than 05 webpage changes while searching the reference.

### Discussion

Despite being a common advertising and knowledge providing medium, the drug promotion literatures enlist fewer references to the information they convey. As it is a printed document and may affect the prescribing behavior of clinician or the affect the knowledge of concerned patient, it is desirable that claims in the piece are substantiated by strong evidences. If proper references is not given, some form of indication toward the references should be made so that it can be cross checked for its accuracy by clinician and general public alike. There have been studies describing unethical behavior with respect to hiding negative information about the product in the past that has potential for irrational and harmful use [6]. The omission or willful neglect of proper referencing is another factor to contribute a bad policy in this regard [7]. The improper presentation has been reported from countries across the globe and not limited to one particular region [8, 9]. As per previous works, a sizeable number of promotional materials thus do not follow any code of conduct [10]. A majority of these materials do not even follow WHO guidelines.<sup>11</sup> It becomes worrisome when marketing tactics succeed in altering and modifying doctors' behavior in perception and prescription of medicines, as various studies reveal [12, 13]. Clinicians do believe that there is substantial lack of information regarding adverse reaction, interaction, pricing and contra-indications in promotion materials and advocate stringent regulatory guidelines [14]. In our study, majority of the materials were lacking the appropriate referencing including some with no referencing at all. The limitation of the study is small sample pool within shorter duration but these small samples suggest that larger data over the period might be worse. Internet has been instrumental part of our lives today and serves as ever present repository of relevant data on various discipline. It is often a key source of information and also to validate certain facts with the help of various search engines. It has been used constructively for education and treatment purposes in healthcare settings [15, 16]. The print materials of any kind should therefore convey data with references that could be checked online at any time for its validity and other relevant details.

**Table 1:** Codification of common errors in referencing noted after online scrutiny.

Serial No.	Type of references	Error/ Fallacy Code
1.	Inappropriate referencing	A
	Author name not mentioned or wrong	A1
	Journal name not mentioned or wrong	A2
	Page number not mentioned or wrong	A3
2.	Difficult online localization	B

**Table 2:** The presence of errors with each pharmaceutical agent.

Serial no.	The pharmaceutical agent (Group)	Errors and number
1.	Pain medication (NSAIDs)	A1 - 02, A 2 - 03, B - 01
2.	Pain medication (non-NSAIDs)	A2 - 01, B - 02
3.	Calcium preparations± Vit. D preparations	A 1- 04 A3 - 02 B - 01
4.	Antibiotic(oral) preparations	A2 - 01, A 3- 01 B - 01

### Conclusion

Pharmaceutical companies should, on their part, must ensure to cite best references with highest level of evidence in support of claims made in the promotion material or better still provide relevant copies of research articles with the concerned material. In cases where references are not provided for lack of space, appropriate digital object identifier (doi) number of the article or quick response codes corresponding to the article can be used. In addition to that a statement that additional information or full text article should be provided on request and a notification in this regard should be printed on promotional material. This shall be a basic tenet in any knowledge driven society.

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