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ANALYSIS OF ADEQUACY OF INFORMATION PROVIDED ON VARIOUS DRUG INFORMATION SOURCES: AN OBSERVATIONAL, CROSS-SECTIONAL STUDY

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ABSTRACT

Prescribing medicine to patients does not complete the task but the medicine is to be taken rationally at proper time, proper dose, proper interval and the treatment is to be taken for the proper duration of time. For this many drug information sources are provided along with the medicines in the form of pamphlets, package inserts, leaflets etc. These sources prove to be beneficial both for the patient and the doctor. **Aim and Objective:** To assess the adequacy of information on drug information source. **Material and Methods:** Various drug information sources were collected and were assessed for adequacy. **Results:** A total of 150 drug information sources were assessed, out of which maximum were were package inserts. only 80.6% were legible, 46% were having pharmacokinetic information, 66.6% hadgeneric name of the drug, 80% had dose and dosage form displayed along with method of administration, side effects were shown by 65.3%, contraindications were shown by 33.3%, precautions were shown by 30.6%, price of the drug was given in 24.6%. Antidote in case of poisoning was given in only 13.3%, special situations like pregnancy and lactation was given in only 23.3%, name and address of the manufacturer was given in 31.3%. Reference of the information provided was given in only 50 drug information sources. **Conclusion:** All the drug information sources were incomplete in one or the other aspect and none was complete in itself. Laws should be made by Drug regulatory authorities to provide complete information for benefit of patient.

KEYWORDS: Package Inserts; Drug Information, Patient Information Leaflets; Patient Information Pamphlets; Drug regulatory authorities; Adequacy of information.

INTRODUCTION

Prescribing drugs to the patient is definitely a tough task when it comes to rational prescribing.[1,2] Rationality has been a major talk in present times. Medical science has been flooded with various types of drugs, but the patients suffer a lot when there is irrational prescribing of drugs along with a substandard compounding. Prescribing the drug rationally does not suffice. Providing right information to the patient regarding its use is of utmost importance. It is not possible for the doctor to write each and every information about the drug on the prescription neither is possible to talk about each prescribed drug in detail because of different pressures and patient burden. Therefore many drug information sources are provided in the form of pamphlets, package inserts, leaflets, medicinal covers. But the validity of the information provided on these sources should be mandatory so that the one reading such information sources may be rightly informed about everything. There are certain standards set up as per Drug and Cosmetic Act to provide package inserts having information related to the drug by the manufacturing companies.[3] Package inserts, leaflets, pamphlets serve as an important source of information regarding the drug for the patient, doctor and pharmacist.[4] It may contain information like efficacy, safety, tolerability, and price of drug. Besides efficacy and safety, price of not only the drug but whole treatment matters a lot because in developing countries like India, non affordability of the drug may lead to failure of treatment. A package leaflet is a leaflet containing the information for the end user accompanying the medicinal product.[5,6] The present study was done to assess the adequacy of the information provided in various sources.

MATERIALS AND METHODS

A cross sectional observational study was carried out in a tertiary care hospital of Jammu, GMC, Jammu after seeking permission of Institutional Ethics Committee, GMC Jammu.

A total of 150 drug information source leaflets were collected from the patients and OPD and were assessed for the adequacy. The data was tabulated and was expressed in percentage.

RESULTS

Table 1: showing type of drug information source.

Type of drug information source	Number (n)	Percentage (%)
Package inserts	100	66.6
leaflets	30	20
Pamphlets	14	9.3
Booklets	6	4

Table 2: Showing various parameters assessed from the drug information sources.

Parameter	Present n(%)	Absent n (%)
Legibility	121(80.6)	29(19.3)
Pharmacokinetic information	69(46)	81(54)
Generic name of drug	100(66.6)	50(33.3)
Dose and dosage form	120(80)	30(20)
Method of administration	125(83.3)	25(16.6)
Side effects	98(65.3)	52(34.6)
Contraindication	50(33.3)	100(66.6)
Drug or antidote to be taken in case of poisoning	20(13.3)	130(86.6)
precautions	46(30.6)	104(69.3)
Price of the drug	37(24.6)	113(75.3)
Special situation like pregnancy or lactation	35(23.3)	115(76.6)
Storage information	15(10)	135(90)
Instructions for use and handling	17(11.3)	132(88)
Shelf life	15 (10)	135(90)
Date on which information last updated	5(3.3)	145(96)
Name and address of manufacturer	47(31.3)	103(68.6)
Reference	50(33.3)	100(66.6)

Table 3: Showing the validation of reference used in the drug information sources.

Type of reference	N (%)
Meta analysis	4 (8)
Original article	10 (20)
Case series	1 (2)
Case reports	2 (4)
Book	4 (8)
Reference source not found	29 (58)

RESULTS

A total of 150 drug information sources were assessed, out of which 100 (66.6%) were package inserts, 30(20%) were leaflets, 14 (9.3%) were pamphlets and 6(4%) were in booklet form **(Table 1)**

Out of 150 drug information sources, only 80.6% were legible, 46% were having pharmacokinetic information, 66.6% were showing generic name of the drug, 80% had dose and dosage form displayed along with method of administration, side effects were shown by 65.3%, contraindications were shown by 33.3%, precautions were shown by 30.6%, price of the drug was given in 24.6%, storage information about the drug and shelf life was given in only 10% of drug information sources. Antidote in case of poisoning was given in only 13.3%, special situations like pregnancy and lactation was given in only 23.3%, name and address of the manufacturer was given in 31.3% where as alone name of the manufacturer was given in 66.6%, date on which information provided was updated was provided in only 3.3% of the drug information sources. **(Table 2)**

Reference of the information provided was given in only 50 drug information sources out of which 4 (8%) were metaanalysis, 10 (20%) were original articles, 1 (2%) were case series, 2 (4%) were case reports, 4 (8%) had reference from a standard book. 29 (58%) references given in the drug information source could not be found anywhere. **(Table 3).**

DISCUSSION

A total of 150 drug information sources were assessed, out of which 100 (66.6%) were package inserts, 30(20%) were leaflets, 14 (9.3%) were pamphlets and 6(4%) were in booklet form. Out of 150 drug information sources, only 80.6% were legible where as in the study of Prasad NS, 90% were legible.[7] 46% were having

pharmacokinetic information, 66.6% were showing generic name of the drug, 80% had dose and dosage form displayed along with method of administration, but other studies mentioned around 90% of the drug information sources had such parameters.[7,8] Side effects were shown by 65.3%, contraindications were shown by 33.3%, precautions were shown by 30.6%. Price of the drug was given in 24.6% in our study but in the study done by Prasad NS price was mentioned in 50% of the sources. (7) Storage information about the drug and shelf life was given in only 10% of drug information sources. Antidote in case of poisoning was given in only 13.3% of the drug information sources in our study but in the study done by Kalam et al. only 4% mentioned about antidotes.[9] Special situations like pregnancy and lactation was given in only 23.3%, name and address of the manufacturer was given in 31.3% where as alone name of the manufacturer was given in 66.6%. Address was not mentioned by maximum of the sources so that they may not be contacted easily. Date on which information provided was updated was provided in only 3.3% of the drug information sources. This may be due to the reason that older information is carried out and it is not updated regularly.

Reference of the information provided was given in only 50 drug information sources in contrary to other studies where it was mentioned in very less number of sources.[10] 4 (8%) were metaanalysis, 10 (20%) were original articles, 1 (2%) were case series, 2 (4%) were case reports, 4 (8%) had reference from a standard book. 29 (58%) references given in the drug information source could not be found anywhere. This may be because of false claims they make for more sale of drugs.

As mentioned by Shivkar, pharmaceutical companies and drug regulatory authorities both have equal obligation to ensure that the PIs contain all the information required by medical practitioners and patients and that this information should be periodically updated from time to time.[11] Self-regulation by pharmaceutical authorities can be of some help but the drug regulatory authorities should ensure that the guidelines for PIs are up to date and that these guidelines are strictly enforced in the preparation of PIs.

CONCLUSION

overall the drug information sources taken for evaluation were not complete in all aspects and the information was not validated as references with high level of evidence was mentioned in very few sources. Laws should be made by drug regulatory authorities to ensure proper and complete information may be provided by the manufacturers.

REFERENCES

1. Poudel A1, Palaian S, Shankar PR, Jayasekera J, Izham MI.Irrational fixed dose combinations in Nepal: need forintervention. Kathmandu Univ Med J (KUMJ), 2008; 6(23): 399-405.f drugs
2. Roshi, Tandon VR, Gupta BM, Gupta S. Prescription pattern of medicines in a tertiary care hospital: a cross-sectional study. Int J Basic Clin Pharmacol, 2019; 8: 1437-40.
3. Ministry of Health and Family Welfare. The Drugs and Cosmetics Rules, Drugs and Cosmetic Act 1945. Ministry of Health and Family Welfare, Government of India, 2003; 312.
4. Prasad NS, Revankar SP, Vedavathi H, Manjunath H, Hegde S. Analysis of completeness of drug package inserts available in India.Natl J Physiol Pharm Pharmacol, 2017; 7(11): 1139-1143.
5. 5.European Medicines Agency. Guidelines on the Packaging Information of Medicinal Products for Human use Authorized by the Community; 2008. Available from: <http://www.ec.europa. eu/health/documents/eudralex/vol-2_en>. [Last Accessed on 2017 Mar 23].
6. European Medicines Agency. Guidelines on the Readability of the Labeling and Package Leaflet of Medicinal Products for Human use Revision, 2009.
7. Prasad NS, Revankar SP, Vedavathi H, Manjunath H, Hegde S. Analysis of completeness of drug package inserts available in India.Natl J Physiol Pharm Pharmacol, 2017; 7(11): 1139-1143.
8. Deep N, Jose R, Chakraborty A. Medication package inserts: How far do they adhere to the guidelines? Int J Basic Clin Pharmacol, 2016; 6(1): 133-6.
9. Kalam A, Anwar S, Fatima A. Drug package inserts in India: Current scenario. World J Pharm Pharm Sci, 2014; 3(4): 385-92.
10. Winterstein AG, Linden S, Lee AE, Fernandez EM, Kimberlin CL. Evaluation of consumer medication information dispensed in retail pharmacies. Arch Intern Med, 2010; 170(150): 1317-24.
11. Joubert PH, Skene D. Attitudes of private medical practitioners towards package inserts and other drug information sources. S Afr Med J, 1984; 66(8): 306-7.