



Received on 10 September, 2015; received in revised form, 15 December, 2015; accepted, 19 February, 2016; published 01 March, 2016

ASSESSMENT OF THE DEGREE OF AWARENESS AMONG PHYSICIANS AND PATIENTS ABOUT DRUG PACKAGE INSERTS

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Key words:

Package Insert, Patient Leaflet Information, Drugs, Awareness

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ABSTRACT: The package inserts (PI) are a valuable source of information on drugs for physicians and patients. However, the degree of awareness of PI & their perceptions at both physician and patient front has not been studied in India in current times. The study was undertaken to assess the degree of awareness regarding information in drug package inserts at a tertiary care centre in western India. A questionnaire based survey was conducted among 100 physicians and 100 patients. The questionnaire mainly focused on the level of awareness, understanding and utility of information given in PI. The responses were collated and analyzed. The results showed that 20% of the physicians admitted that they rarely or never referred to PI. 30% did not consider the PI to be important in their clinical practice & 18% did not feel the need for PI to be always available. 64% opined that the language was too technical for comprehension by lay persons. Only 10% said that they always asked their patients to read the PI. Although 98% of patients knew what a PI was, 30% did not read it because of comprehension problem. Also 28% suggested that the language be made simpler and easily understandable. The study showed that despite providing detailed information, PI was not optimally used in most cases. Physicians did not feel the need to use them as sources of information whereas, in patients the technical language acted as a barrier to effective use.

INTRODUCTION: The Package Insert (PI) or patient leaflet information is the printed information that accompanies a drug product that aims to provide essential information for the safe and effective use of the drug to physicians and patients. These package inserts are an essential feature of drug packaging, which ideally are available for the prescription medicines and are considered as the primary source of information for health care professionals regarding the indications, contraindications, risks and adverse effects of drugs ^{1, 2, 3}.

The target group for these package inserts varies across various geographies. In the United States of America, the FDA approved 'package inserts' are meant for healthcare professionals ⁴ whereas it is aimed for patient education in the European Union ⁵. Although Indian regulations as per 'Section 6' of 'Schedule D (II)' of the Rules of the 'Drugs and Cosmetics Act (1940) and Rules (1945)', pertaining to labelling and packaging information of drugs, lists the headings according to which information should be provided in the package inserts, it does not specify information which would be valuable to the patients ⁶.

The objective of providing drug information is not to create a medical standard of care but is to inform physician or patient the benefits and risks associated with the medication ⁷. Most healthcare professionals rely on these package inserts to update their knowledge and provide drug related

QUICK RESPONSE CODE	DOI: 10.13040/IJPSR.0975-8232.7(3).1258-62
	Article can be accessed online on: www.ijpsr.com
DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.7(3).1258-62	

information to patients. This is particularly more important for new drugs when the text books or the literature may not have yet been updated to include the information pertaining to the drug, making PI as important source of information. Similarly literate patients to read these inserts in order to gain more details regarding the drugs that they are consuming, with special regard to the precautions and potential side effects of these medications. However, the information provided is often extremely technical and may be difficult for patients to comprehend. Also the level of the awareness among patients may vary from country to country since the level of education would be different. Against this background, the current study was planned with the objective of assessing

the degree of awareness among Indian physicians and patients from a tertiary care hospital regarding information given in the drug package inserts.

MATERIALS AND METHODS:

An anonymised questionnaire based survey was conducted among 100 physicians and 100 patients following approval from the Institutional Ethics Committee. All the subjects who agreed to complete the questionnaire and were willing to provide consent were included in the study. The survey was available in three languages (English/Hindi/Marathi). The participants were given the questionnaire in the language that he/she was comfortable with.

TABLE 1: THE QUESTIONS ASKED THROUGH QUESTIONNAIRE

Questions for Physicians	
1.	Percentages who read the package insert.
2.	Percentages who understand the relevance of a package insert.
3.	Percentages who have requested their patients to read the package inserts for drug details.
4.	Percentages who have explained the details of the package inserts to their patients.
5.	Percentages who have had patients asking them questions after reading the information given in the package insert.
6.	Percentages that have had patients complaining of adverse effects similar to that mentioned in the package insert.
7.	Percentages that have had queries in the package inserts and have informed the medical representatives regarding the same.
8.	Percentage who feel that package inserts are a necessary add-on to drug information.
Questions for Patients	
1.	Percentages who read the package insert.
2.	Percentages who understand the relevance of a package insert.
3.	Percentages who understand the details of a package insert.
4.	Percentages who have questioned their physicians on the information given in the package insert.
5.	Percentages who have understood the drug related adverse reactions
6.	Percentages who feel that package inserts are a necessary add-on to drug information.

RESULTS AND DISCUSSION:

Results with physicians as sample study:

Out of a total of 100 physicians to whom the questionnaires were distributed, 86 returned the completed questionnaires and hence were considered to be a part of the study.

When asked about the frequency of their reading the package insert (PI), 14% of responses suggested very often, 34% mentioned often, 32% occasionally, 12% rarely & 8% participants accepted that they never read it. Amongst the participants, 30% mentioned that PI is insignificant/not important in their practice and another group of 30% thinks it is good to know new things. 23% think it is an important guideline in their practice and only 17% think it is a must read document (Fig.1).

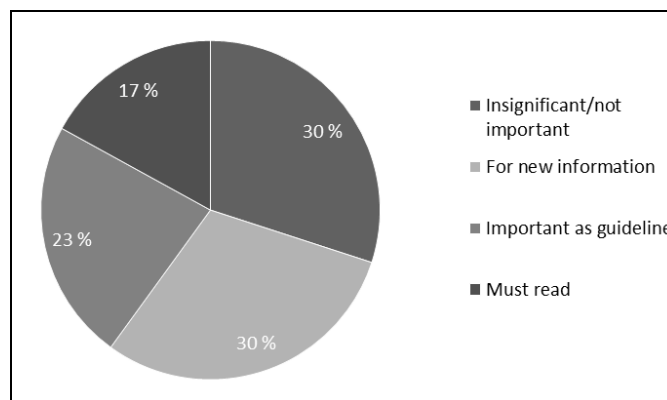


FIG. 1: PERCEPTIONS OF PHYSICIANS ON THE USE OF PI

A good number of physicians, 75% think that PI should be made compulsory with the drug packing for all the drugs whereas around 7% were uncertain and 18% felt there is no need for it to be compulsory. A good 93% physicians feel that PI is

helpful in their practice whereas 7% didn't find it useful to them.

Regarding the language, a majority of about 64% physicians have felt that the language written in the PI is quite technical and not understood by the layman. Whereas 36% felt that even layman could get the information in the PI. The suggestion of PI to be limited and precise was agreed by 32% of the participants whereas 26% felt that language should be easy and understandable by everyone. Another group of 26% felt that it should always be in the local language. Few participants (5%) also suggested to have more information in PI. Interestingly, 11% physicians were in favour of other changes like magnification of the font size, use of pictorial representations, etc.

We also analysed if the physicians direct patients to read the PI and 62% of the participants mentioned that they direct the patients to read the PI only if they feel it is essential, 28% don't feel the need to do so & only 10% of the physicians always direct their patient to read the PI. 59% of the physicians feel that PI helps the patient, 17% feel it is not useful for the patient whereas 24% were uncertain. When asked if all the adverse events are mentioned in PI, 58% of the physicians feel that all the adverse events are mentioned, 38% feel that not all adverse events are mentioned whereas 4% physicians were uncertain about the details of adverse events in PI.

Other sources of drug information that physicians refer to are books (36%), internet (20%), drug index (16%), journal (10%), medical representative (6%) & colleagues (1%).

Results with patients as sample study:

A high percentage of 98% of the patient knew what a PI is with only 2% patients being unaware about it. 29% of the patients claimed themselves to be going through PI occasionally & 27% accepted that it is only a rare practice. 24% patients mentioned that they never read it, 11% mentioned it was often read and 9% reported to read it very often.

The reason why patients can not read it was because of the language comprehension problem in 30% of patients. Some patients (26%) mention that

since the physician has prescribed the drug, they didn't find it necessary to read the PI by themselves. The reading was reported to be time consuming by 22% of patients while 14% patients mentioned that they didn't read it purely due to their ignorance about PI.

In case patients were not able to read PI only 44% very oftenly consulted physician. According to 64% of patients, PI was occasionally missing in their drug packing. 70% of the patients perceived PI as an appendage to their prescription by the physician, 14% regarded as an important source of drug knowledge & 16% regarded it as useless.

The study also evaluated recommendations on changes needed in PI to make it more useful. 28% patients feel that the language needs to be easy and understandable, 24% feel that it doesn't need any change, 12% would prefer it in local lang, another 12% wish to have more details about the drug and 10% want PI to be provided with shortened and precise information (Fig. 2).

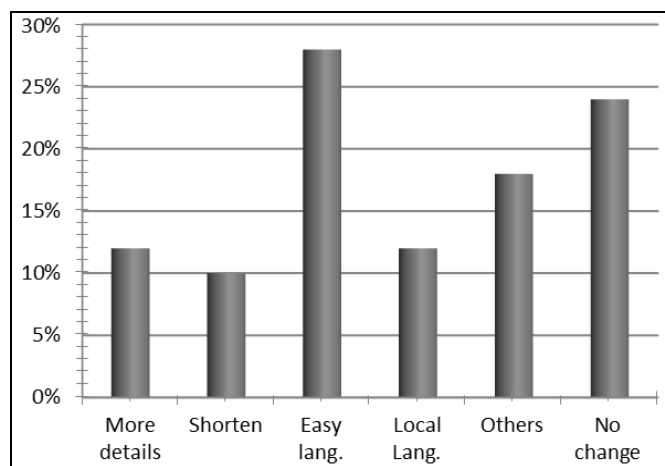


FIG. 2: CHANGES RECOMMENDED IN PRESCRIBING INFORMATION BY PATIENTS

DISCUSSION: Physicians feel that even though PI is always present and is handy source of information, but still, many physicians do not feel any need to read it or are short of time. Though the package inserts are being distributed along with the prescription drug according to the guidelines but the advantage of distributing it is not being achieved. It should be available for the patients to provide essential drug information like dose, side effects and any other additional information which would be useful to them. Since the language used

is technical and challenging for the patients to comprehend, it leads to 51% of patients never or rarely referring to it.

Regarding the adverse events, the PI mentions minor side events such as headache and nausea and also includes serious but rare events such as teratogenicity and carcinogenicity often reported from animal studies. It may be difficult for physicians and patients to understand the common adverse events from the long list of adverse events and hence the frequency of adverse events if mentioned would be useful. However, if the PI is meant for patients then the rare but serious adverse events should not concern the patients and physicians may need to counsel the patients and spend more time in making in creating awareness⁵. Right now the PIs are of benefit only to the literate population. A vast majority of patients in India are illiterate and hence the objective of informing the patient can be achieved by adding graphic representations and figures showing methods of drug administration.

As reported earlier, 98% of the patients knew what a PI is but only 49% of them read it which could possibly imply that it's not that there is lack of awareness but still very fewer efforts are made with only 10% of the physicians always directing them to read it. Even though only 48% of the physicians refer to the PI quite often, 75% of them feel that PI be made compulsory.

Another important issue with the package inserts is the technical language. A study conducted in the USA showed that limited understanding of the English language can result in poor comprehension of the written instructions and hence compliance on the part of the patient⁸. Patient misunderstanding of instructions on prescription drug labels is common and a likely cause of medication error and less effective treatment. A study conducted by Davis *et al* showed that the use of precise wording on prescription drug label instructions can improve patient comprehension⁹. However; patients with limited literacy were more likely to misinterpret instructions despite use of more explicit language and hence need to be separately addressed in country like India.

Similarly, another study showed that patients with low literacy had difficulty understanding prescription medication warning labels. Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple-step instructions¹⁰. Many of the studies carried out till date has looked at the presentation and completeness of clinically important information provided in the package inserts^{11, 12}.

The results of these studies have shown although the package inserts appear to have improved over the past decade there is still a definite need to further refine the clinical information contained^{10, 23-16}, to minimize the risks to patients. Both the regulatory authorities and drug manufacturers should implement appropriate measures to regulate the quality and quantity of information in the patient package inserts which will better direct health practices to the benefit of the patients.

CONCLUSION: Although the awareness about package inserts was found among physicians as well as patients, it was not being optimally used. There are changes recommended for optimum utilization of the package insert by physicians and patients alike. To achieve its goals, the drug's package insert should be clear and comprehensible to convey the intended use of the product, provide an adequate direction for use, warn against potential harmful effects and provide instructions for appropriate length of treatment and when to seek medical advice. The language needs to be simplified when it is meant for patients and use of alternate methods such as pictorial representations when possible could be explored for illiterate patients.

ACKNOWLEDGEMENT: The study was funded by the Indian Council of Medical Research

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How to cite this article:

Singh KR, Munshi R and Arora D: Assessment of the Degree of Awareness among Physicians and Patients about Drug Package Inserts. *Int J Pharm Sci Res* 2016; 7(3): 1258-62. doi: 10.13040/IJPSR.0975-8232.7(3).1258-62

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