



Analysis of patient's knowledge of the prescribed drug and awareness of general population regarding package insert: A cross sectional survey

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ABSTRACT

There can be various ways of communicating the important aspects of medication to the patients, one of which is package insert. Is this transcript really serving the purpose in Indian population. Our survey evaluates patient's knowledge of the prescribed drug regimen and scores for the same and also highlights different issues of Package Inserts (PI) from the patient's perspective.

This was a cross sectional, open label, time bound study. Majority (68%) of patients were occasional readers (read it sometimes) of PI with only 12% of total who read the given information completely. Chronic disease sufferers had a greater knowledge (79.8%) as compared to those coming for the treatment of minor ailments (44%). It can be a potential source of information provided its amended keeping in point the need of the society.

INTRODUCTION

Package insert which is often found with the medicines is a potential source of information and it is also legally bound and regulated by the legislative health authorities. In India the concept of package insert is governed by the 'Drugs and Cosmetic Act (1940) and Rules (1945)' [3]. Section D (II) of the Rules lists the headings according to which information should be provided in the package inserts. [1]

Studies have shown that the Package Insert (PI) helps bridge the information gap between health care providers and patients and enhances patient's knowledge about medications [2,3]. But the current estimated doctor population ratio in India is 1:1700 as compared to a world average of 1.5: 1000. The Medical Council of India Board of Governors after detailed inputs from various working groups came to a consensus that the targeted doctor population ratio would be 1: 1000 and achievable by the year 2031. [4] Due to such a scenario, health professionals have limited time to convey comprehensive information and there is a definite gap (both communicative as well as informative) between physicians and patients. And to the contrary, in this modern era, educated patients surge for more and more information about the medicines administered to them. A pilot study done by George et al, in which Patients who received a leaflet, were more likely to be

completely satisfied with their treatment and with the information they had been given. They were also more likely to know the name of their medicine and much more aware of potential unwanted effects as compared to those who did not receive a leaflet. [5] On the same background, this survey evaluates Patient's knowledge of the prescribed drug regimen and scores for the same.

'Section 6.2' mandates that the package insert must be in 'English and must include information on therapeutic indications, posology and method of administration, contraindications, special warnings and precautions, drug interactions, contraindications in pregnancy and lactation, effects on ability to drive and use machines, undesirable effects, and antidote for overdosing. 'Section 6.3' mandates pharmaceutical information on list of excipients, incompatibilities, shelf life as packaged, after dilution or reconstitution, or after first opening the container, special precautions for storage, nature and specification of container, and instruction for use/ handling. It is not mentioned clearly, whether the package inserts are directed only at the physicians or at the patients as well. [1]

So far, assessments of the package inserts of drugs by patients as well as physicians in India are rare. So along with the appraisal of Patient's knowledge of the prescribed drug regimen, our survey also attempts to assess the importance of different issues of Package Inserts (PI) from the patient's perspective.

MATERIAL AND METHODS

Study design

Focusing on expectations and preferences of patients regarding package inserts, a set of questions was prepared for patients or their attendants. Along with the Performa, the patients were given a set of Checklist to assess their information about the prescribed medication, with an aim of highlighting the patient's knowledge about the same. The checklist and scoring was done according to Young et al.[6]

Patients who were prescribed medications coming to the pharmacy, in the vicinity of tertiary health care centre Faridkot, were approached on every odd day of the week for 4 months, and were requested to fill up these after explaining them the nature of study. Those who were not able to fill up these performas individually were helped by their attendants for the same. Out of total of 1300 performas distributed, a total of 1237 completely filled performas were analysed in our open label, time bound study.

INCLUSION AND EXCLUSION CRITERIA

Those prescribed a medication by registered medical practitioner, patients with normal vision or minor refractive errors and those willing to give their inputs were included in the survey.

All the patients with vision problems, those coming for self medication and not willing to give their inputs were excluded from the study.

RESULTS

The study completion rate was 95.15%. As evident from the analysis, majority (68%) of patients were occasional readers (read

Table 1. Socio-demographic data :

Gender	M	765	61.8%
	F	472	38.15%
Education	Uneducated	331	26.7%
	Graduate	637	51.5%
	Post graduates	269	21.74%
Chronic disease sufferers	Total	606	
	Read package insert	484	79.8%
Others (minor/acute ailments suffers)	Total	631	
	Read package insert	278	44.05%
Columns of PI most read	Diagrams	1020	82.45%
	Illustrations of usage.		
	Dosage	655	52.95%
	Uses	402	32.5%
	Contraindication	83	6.7%
	Pregnancy and lactation warning	80	6.5%
	Overdose	35	2.82%

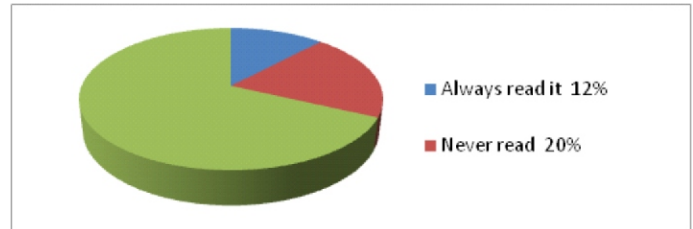


Fig. 1. Percentage of population reading package insert.

it sometimes) of PI with only 12% of total who read the given information completely. (Figure 1) The column most sought by majority (82.45%) was the diagrams and the illustrations shown on the package insert informing how to use the medication, proper placement of devices if any followed by dosage to be taken (52.95%), uses of the drug (32.95%), contraindication (6.7%), use in pregnancy and lactation warnings if any (6.5%), and overdose (2.8%). (Table 1)

Chronic disease sufferers had a greater knowledge (79.8%) as compared to those coming for the treatment of minor ailments (44%). Font size in the range of 9 to 14 was not a problem and majority (76%), did not recommend any change in the font size.

The checklist (pertaining to patient education about drug regimens) filled up by patient indicated the information of the patient regarding the formulation, device, ointment, pills etc. what so ever was prescribed to the patient. Again the completed 1237 checklists were analyzed. Maximum number of patients (585) scored in the range of 9-11, which indicates yet for 9-7 items of the checklist the patient was ignorant and needs to be told by the health personal, followed by a score of 6-8 (347), 12-14 (247), 3-5 (42), 15-17 (26). None of the patients had a complete 100% information about the medication as the person with score 0 was nil in number. Similarly none of the patients was totally unaware of what he was taking and the reason for the same indicated as neither of the surveyed patients scored 18. (Figure 2)

DISCUSSION

The prescribing guidance by the current concept of Package insert being followed in India, is inadequate in serving its purpose to the patients. In developing countries like India, plenty needs to be done for improvement of PI.

As evident from the results, only 12% of our patients were the readers who gained the knowledge from package insert. This diverts from the literature of the developed nations where 79.6% of volunteers said that they "always" read the package inserts of newly prescribed drugs.[7] Previous results also support our findings that in rural India it was observed that significantly large number of people (40%) do not even read package inserts.[8]

So a considerable difference can be noted in the patient's attitude and awareness in developing nations as compared to developed whenever they are prescribed with a new medication. Education plays a significant role for the same. As in our results, a considerable number of participants were uneducated (26.7%) which might be the cause that 20% of the total never ever read the information leaflet. For a country like India, where literacy levels are low and various systems of medicines are in place, the language issue becomes all the more important. Information must be disseminated in clear and understandable terms for the users, in the official languages, which the respective users are expected to understand the best.[9] This practice is also under implementation by the multi linguistic European Union, where the 'Patient

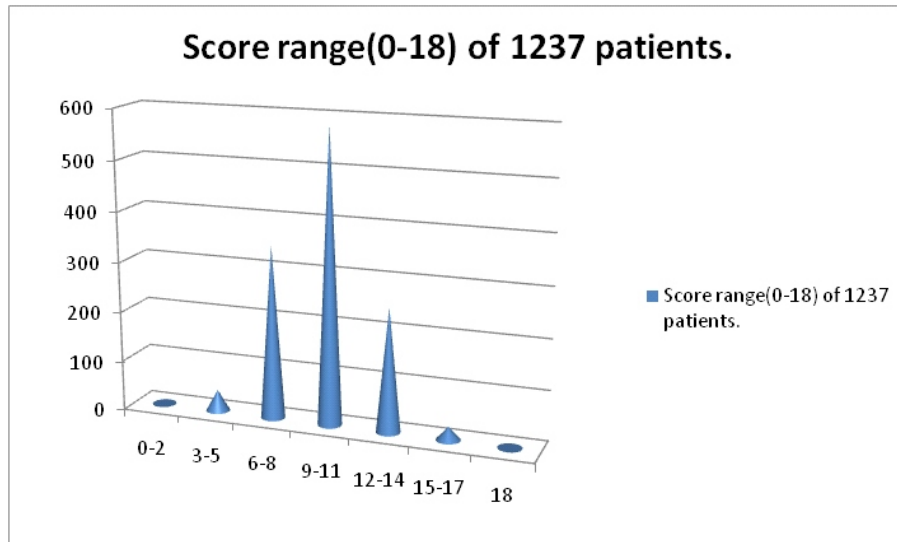


Fig. 2. Scoring of the patient education about drug regimens according to checklist of Young et al. Score 0 = None of the items needs to be explained to the patient (best information to the patient). Score 18 = Maximum number of items which still need to be explained (poor information to the patient).

information leaflets' are disseminated in the respective national languages.[10]

A significant difference was noted in the chronic disease sufferers knowledge as compared to the one being prescribed occasionally (44%), the reason being repeated visits to the physicians, repeated prescriptions to them, more frequently buying medications and hence reading the package insert. However in a study to determine that do women read the oral contraceptive (OC) patient package insert, 89% stated that they had read the patient package insert which was included with their 1st pill pack, but only 31% said they read it each time they received a new pack. [11]

Scoring of the patients pertaining to patient education about drug regimens prescribed, maximum score was between 9-11. The majority of the respondents were unaware of the following information:

- The brand and generic names.
- When to take the medication relative to meals, sleep, and activities.
- What to do in case a dose is missed.
- What to do if a serious complication occurs.
- Possible drug interactions with other prescription drugs.
- Possible drug interactions with over-the counter medications.
- Effects of foods on the medication and any need for changes in diet.
- The methods and importance of monitoring.
- The need to tell other health care providers about drug therapy.

The above data highlights the incomplete flow of information from physician to patient, which can further lead to :

- ❖ Increased number of Adverse drug reaction.

- ❖ Sub therapeutic efficacy of the prescribed medication.
- ❖ Non compliance.

But health personal can raise the question that in doctor population ratio of 1:1700,) is it possible to cover up all the aspects to each and every patient? The answer would be surely no and that's where PI plays the imperative role of filling the gap between the two. It can be a potential source of information provided its amended keeping in point the need of the society. The various suggestion which we received for improving it were that it should be written in both English as well as in local language , should be available with each and every medication, important and relevant information should be highlighted and categorized as 'Must read' segment for the patients, and physicians must themselves encourage the patients to read the same.

Font size in the range of 9 to 14 was not a problem with those having no visual problems , but needs to be analyzed in those visually impaired . In accordance with the literature, larger font size can lead to handling difficulties [12], and also was not desirable by our participants.

Contrary to the previous data available of developing countries like India, our study covers a large number of participants , belonging to different category of ailments and represents both educated as well as uneducated strata of population. To our best knowledge, the current study is unique in sense that it evaluates the patient education about the prescribed drug regimens. Weakness also prevails in our data as it's a cross sectional study, it could have improved by some post intervention analysis (patient education etc.).

Patients of both sexes, all age groups and social classes are reported to found to benefit from the leaflets and almost everyone (97%) thought they were a good idea.[13] This indicates PI is momentous in every aspect. So for the proper functioning of the health care system a well informed patient may establish a two way channel with the help of PI to extract the maximum useful information regarding disease process and therapy and also reinforce the patients memory by this written transcript.

REFERENCES

- 1 Ministry of Health and Family Welfare, Government of India. The Drugs and Cosmetics Act and Rules. 2003. p. 312. Available from: <http://cdsco.nic.in/html/copy%20of%201.%20d&cact121.pdf>/accessed April 2012.
- 2 Regner MJ, Hermann F, Ried LD. Effectiveness of a printed leaflet for enabling patients to use digoxin side-effect information. *Drug Intell Clin Pharm.* 1987; 21(2):2004.
- 3 Mottram DR, Reed C. Comparative evaluation of patient information leaflets by pharmacists, doctors and the general public. *J Clin Pharm Ther.* 1997; 22(2):12734.
- 4 Vision 2015 .Medical Council of India March 2011; 10. http://www.mciindia.org/tools/announcement/MCI_booklet.pdf/accessed April 2012.
- 5 George CF, Waters WE, Nicholas JA. Prescription information leaflets: a pilot study in general practice. *Br Med J (Clin Res Ed).* 1983 Oct 22; 287(6400):1193-6.
- 6 Young LY, Koda-Kimble MA, et al. Handbook of Applied Therapeutics, Sixth Edition. Applied Therapeutics, Inc. 1996. Table 10.9, page 10.12.
- 7 Fuchs J, Hippus M , Schaefer M. A survey of package inserts use by patients. *Hospital Pharmacy Europe* . 2005;4:2931.
- 8 Kaikade SB , Jha RK . Assessment of Awareness and Attitude Towards Package Inserts Amongst Rural Population. *RJPBCS.* 2011; 2(4): 982.
- 9 Dr. Jignesh K. Ved . Package Inserts in India: Need for a Revision. *International Journal of Pharma Sciences and Research (IJPSR).* 2010; Vol.1(11),454-456.
- 10 Anonymous. Electronic Medicines Compendium. EMEA. 2010. Available from: <http://www.medicines.org.uk/emc/>
- 11 Casey FG, Fluitt DM, Wiatt AL. The patient's understanding of the oral contraceptive patient package insert. *Mil Med.* 1983 ;148(3):276-8
- 12 Fuchs J, Heyer T, Langenhan D, Hippus M. Influence of Font Sizes on the readability and Comprehensibility of Package Inserts *Pharm. Ind.* 2008; 70(5), 584592.
- 13 Gibbs S, Waters WE, George CF. Prescription information leaflets: a national survey. *JR Soc Med.* 1990; 83 (5): 292-7