Research Article

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A study on patients behavior towards product information leaflets at basaveshwar teaching and general hospital

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Abstract

Background: Product information leaflets are available for most prescription medicines and many non-prescription medicines. Materials and Method: Aprospective and observational study was conducted at Basaveshwara teaching and general hospital with an aim to determine how many patients see, read and retain the PIL. **Results:** A total of About 216 patients visiting the out-patient departments were enrolled in the study. The study results showed that among 216 patients, 195(90.28%) patients completed the study. More number of patients 79(40.15%) belonged to old age, followed by Public servant& housewife 46(23.58%) followed by agricultre 12(6.15%) followed by student, business& others 4(2.05%). 142(72.82%) of patients were counseled in Kannada, 35(17.94%) patients in Hindi & 18(9.23%) patients in English. As Kalburgi is a multilingual city majority of the people speak Kannada and Hindi. The 195 patients were dispensed a total of 341 Medicines. For 26 items (7.63 per cent), there was no manufacturer's leaflet available for the pharmacist to supply with the medicine. 195 patients received at least one medicine with a leaflet. The leaflet was said to have been just noticed by 134 patients (68%). About 42 patients (21%) said they had read some part of the leaflet and 19 (9%) patients reported that they had read the leaflet completely. Conclusion: This study concluded that there is a need to improve the format, content and language of the package inserts in India. Pharmacist intervention is needed to improve patients reading habits for pils.Tighter monitoring of the inserts by regulatory bodies can help to enforce ideal labeling practices.

***Keywords*:** Medication adherence;Patientsbehavior, Information Leaflets.

Introduction

Product information leaflet is a document approved by the administrative licensing authority which is provided with the package of a drug. A package insert primarily directed at the prescribers is intended to provide information for the safe and effective use of the respective drug. It is also known as prescription drug label, prescribing information package inserts etc. [1]. Product information leaflet provide patients with

information about a specific medicine. These inserts are developed and produced by pharmaceutical industry and are included in the medicine package.

Need for product information leaflet

Despite the widespread use of prescription and OTC medications, patients' knowledge about their prescription medications is often inadequate. Previous studies Have shown that most patients do not take their medications precisely as prescribed. Cessation of drug therapy when patients apparently feel better, but before completing the full course, is a common finding.Such inappropriate use of medication may have resulted from a genuine lack of understanding and/or information about their disease state and its treatment regimen or simply Due to sheer complacency on the part of the patients. Most healthcare professionals agree that patients need unbiased, accurate information about the drugs they are taking. Over the past decade, public health policy has been evolving, with increased options available to consumers to obtain information on their prescribed medications. Despite the fact that physicians and pharmacists are the Preferred sources of information, Healthcare professionals do not always ensure optimal knowledge transfer [2].

Communication between doctors and patients is often inadequate.Information is better retained if given in writing and recently information leaflets have become popular.They satisfy and please patients and influence behavior although inadequacies are common.Written information as package inserts to accompany prescribed medicines have received particular attention as there is clear evidence that patients are poorly informed by traditional methods [3].

In recent years, public has become increasingly conscious about their health and wish to know more about the medicines they receive from the pharmacists. Due to heavy patient load, often doctors give limited information to the patients regarding their disease and medication usage. Majority patients may not be able retain the verbal information given by the doctors for long time. Print materials may act as valuable tools in these situations to retain the medication usage related information. Print materials can convey the basic information related to disease or medication and enabling the health care professional to concentrate on the diagnosis and treatment process. Information regarding the disease and medications is important in patients diagnosed with chronic and complex diseases such as diabetes, hypertension, asthma, angina and peptic ulcer. Long term management of these diseases involves the self-care by the patient. Several studies have shown that patients were not able to manage their diseases, because they do not receive the information necessary to manage the disease. Studies have shown that the qualities required for preparing a product information leaflet (PIL) are, information should be authentic and unbiassed, information given in the leaflet text should be optimum as per patients requirement, and the language used should be so simple and easy to understand the content of the information and the sentences should not be too long, emphasis should be made on avoiding self medication, sharing of medicines, and the reader should be motivated to use medicines only with medical advise. Good readability, layout and design are the important factors in developing the information leaflets [4].

There are two main reasons for supplying inserts to the patients.

- The first is to increase the effective use of medicine. The supply of printed information could increase the patients knowledge about their medicine(about the treatment, the instructions and the side effects), and it could change the attitude of patients(improve satisfaction with a medicine and influence risk-benefit assessment). The provision of information could also increase appropriate medicine taking behavior(compliance) and increase the number of reactions from patients(reporting any adverse drug reactions encountered and questions asked).
- The second reason for supplying inserts is that the patient has right to be informed.

Patients have three main purposes for reading inserts. In the first place, patients seem tobe interested in the information about safety related matters such as side-effects and risks involved. Patients need these information to make decision on whether to use a medicine or not. Secondly patientsneeds consult an interest to find out how to administer a medicine and thirdly patients read inserts to find out about the indications of a medicine. This last information can reassure patients by confirming that the appropriate medicine has been prescribed. It also tells patient which effects should be anticipated and whether these effects are positive should be cause for concern. In addition,

information given verbally is likely to be either misunderstood or forgotten. Therefore, it is now widely acknowledged that patients do require a certain amount Of information in order to use their drugs optimally [5].

Regulatory requirements for Product information leaflets

Regulatory requirements for drug package inserts or leaflets vary across nations. United States -Food and Drug Administration (US-FDA) and European Medicines Agency (EMA) amend their regulations governing the content and format of labelling for drug products from time to time. US-FDA has published a revised guideline in the Federal Register of January 2006, which is being followed by pharmaceutical industry of the country. It is important to note that while proposing these guidelines the agency has considered that it promotes correctproductuse decisions, decreased reading time, and increased the individuals' confidence in their ability to use that information. As per Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, medicinal products must be accompanied by package leaflet. It also emphasises that the package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately. Also, the directive states that package leaflet must be clearly legible in the official language or languages of the Member State(s) in which the medicinal product is placed on the market. Subsequently, EMA published several additional compilations relating to style matters and the use of terms in package inserts.Several Asian countries have also developed specific drug labelling requirements. The information appears to be directed specifically towards patients, as noted by the fact that pharmaceutical information is not required to be included in most cases. Japan, the most advanced country in terms of drug regulations in Asia, has a structure of package inserts which is similar to that utilised in the USA [6].

Materials and Method

Materials

Source of data

- In patients cards ,prescription ,PIL

Materials

- Specially designed questionnaires
- Case collection form
- Cases collected from MICU, ICCU, AMC, MMFW, FMFW, General Medicine Wards.

Method of collection of data

Study Site

Basaveshwara hospital pharmacy

Study duration

Study will be carried out for a period of 6 months.

Study design

A prospective and observational study

Study criteria

The study will be carried out by considering following criteria.

Inclusion criteria

1. Patients above the age of 18 yrs
2. Patients collecting their own medicine
3. Patients having sufficient knowledge of English and local language for interview
4. Patients available at hospitals ,pharmacy, medical shops and house visits the following weeks
5. Patients willing to participate.

Exclusion criteria

1. Patients below the age of 18 yrs.
2. Patients who are not collecting their own medicines.
3. Patients not having sufficient knowledge of English and local language for interview.
4. Patients not willing to participate.

Study Procedure

The study will be carried out at Basaveshwar hospital pharmacy of BTG Hospital, Gulbarga, after submitting protocol for ethical clearance from institutional ethics committee and with the prior permission. The patients will be enrolled into the study by considering the study criteria after taking their written consent to participate into the study. The questionnaires will be administered further the prescribed items in respect of whether a leaflet was supplied or not in pharmaceutical products and patients will be interviewed by homevisits 4-7 days after receiving the prescription ,A Suitable statistical method will be used for the data assessment.

Result and Discussion

Table-1: Details of Patient Enrolled into Study

Group	Total Number Of patient	Number of Drop outs	No. of patients Completing the Study
Male	122	15(6.94%)	111(51.39%)
Female	94	6(2.78%)	84(38.89%)
Total	**216**	**21(9.72%)**	**195(90.28%)**

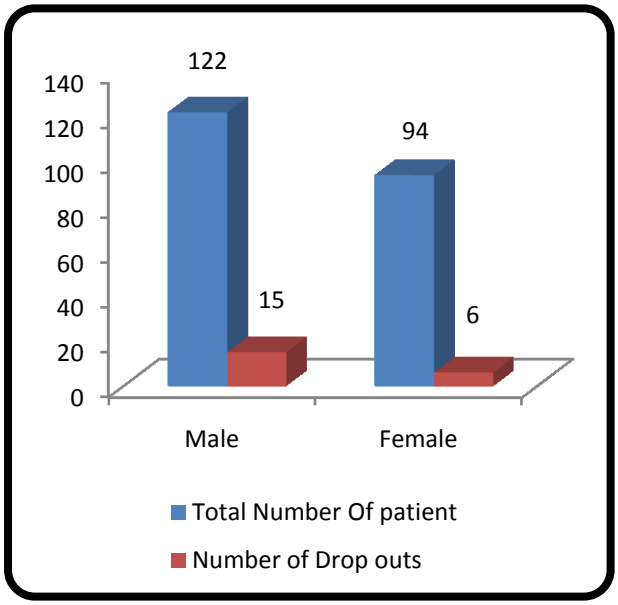

Figure-1: Graph showing details of patients Enrolled Into the Study

The result showed that out of 216 patients, 21(9.72%) patients were drop-outs and 195(90.28%) completed the study.

Table-2: Details of Gender Distribution of patients

Gender Distribution	Number of patients	% of Patients
Male	111	56.93
Female	84	43.07
Total	**195**	**100.0%**

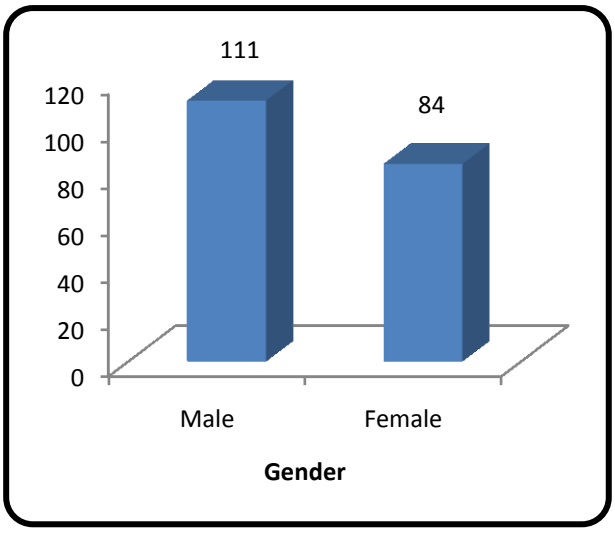

Figure-2: Graph showing gender distribution of the patients

Gender distribution of patients

The results showed that out of 195 of total patients, 111(56.92%) were males and 84(43.07%) patients were females. In our study, male patients were more in number as compared to female patients.

Table-3: Details of Age Distribution of the Patients

Age in Years	Number Of patients	% Of patients
16-30	6	3.07
31-45	30	15.38
46-60	76	38.97
61-80	83	42.56
Total	**195**	**100.0**

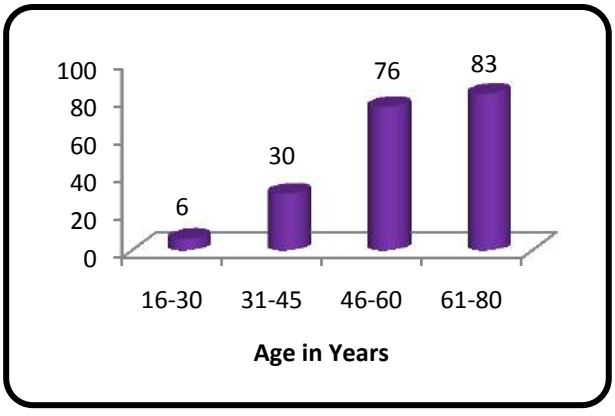

Fig. 3: Graph showing age distribution of patients

Age distribution of patients

The results revealed that most number of patients were in the age group of 61-80years i.e. 83(42.56%) followed by the patients in the age group of 46-60 years 76(38.97%) followed by the patients in the age groups of 31-45years 30(15.38%)followed by the patients in the age group of 16-30 years 6(3.07%).

Table-4: Details of Occupational Status of the patient

Occupation	No Patients	% of Patients
STUDENT	4	2.05
H/W	46	23.58
BUSSINESS	4	2.05
P/S	46	23.58
AGRI	12	6.15
O/A	79	40.51
OTHERS	4	2.05
Total	**195**	**100.00**

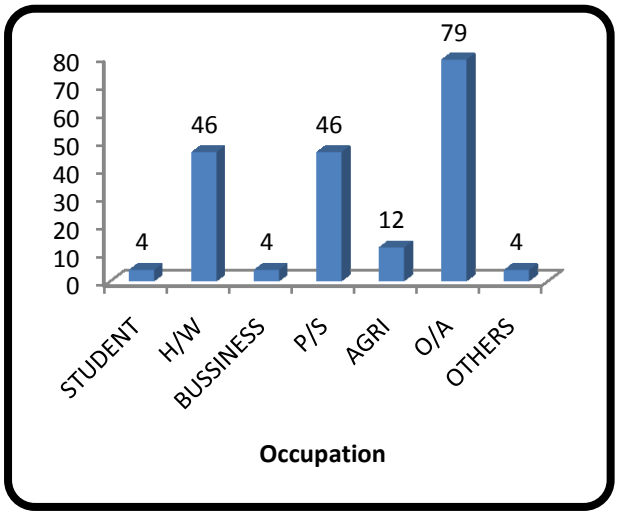

Fig. 4: Graph showing occupational status of the patients

Occupational status of the patients:

The results revealed that more number of patients 79(40.15%) belonged to O/A, followed by P/S and H/W 46(23.58%) followed by agriculture 12(6.15%) followed by student, business and others 4(2.05%).

Table -5 Details of Disease Condition of the patients

Disease	No Patients	% of Patients
HTN	68	39.08
DM	17	8.71
HTN&DM	18	11.79
ASTHMA	7	3.58
COPD	48	24.61
COPD&DM	4	2.05
COPD&HTN	5	2.56
HTN&ASTHMA	1	0.51
ALD&HTN	5	2.56
ALD	2	1.02
HTN&DM&COPD	5	2.56
TOTAL	**174**	**100.00%**

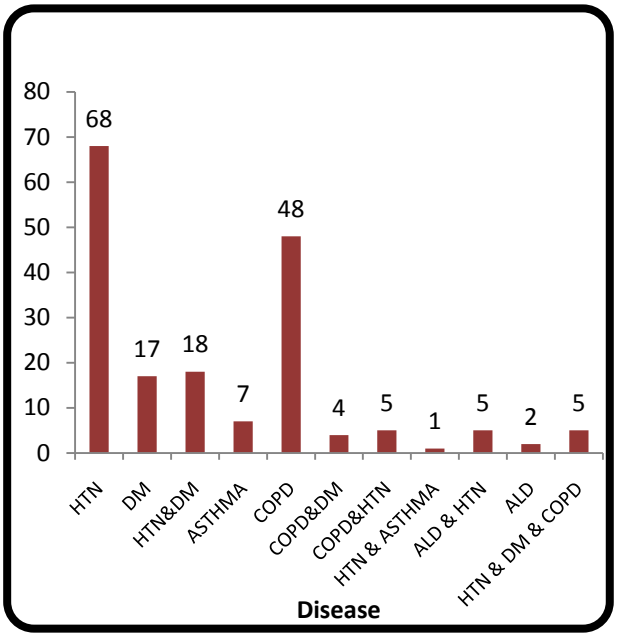

Figure -5 Graph showing details of Disease Specific Condition

Disease specific condition

The result shows that patients having HTN 78(40.00%) are more followed by COPD, 48(24.61%) followed by HTN&DM, 23(11.79%) followed by DM, 17(8.71%) followed by ASTHMA, 7(3.58%) followed by HTN&DM&COPD, ALD&HTN,& COPD & HTN 5(2.56%) followed by COPD&DM 4(2.05%) followed by ALD 2(1.02%) followed by 1(0.51%).

Table-6 Details of counseling languages for patients enrolled

Language	No patients	% of patients
Hindi	35	17.94
Kannada	142	72.82
English	18	9.23
TOTAL	**195**	**100.00**

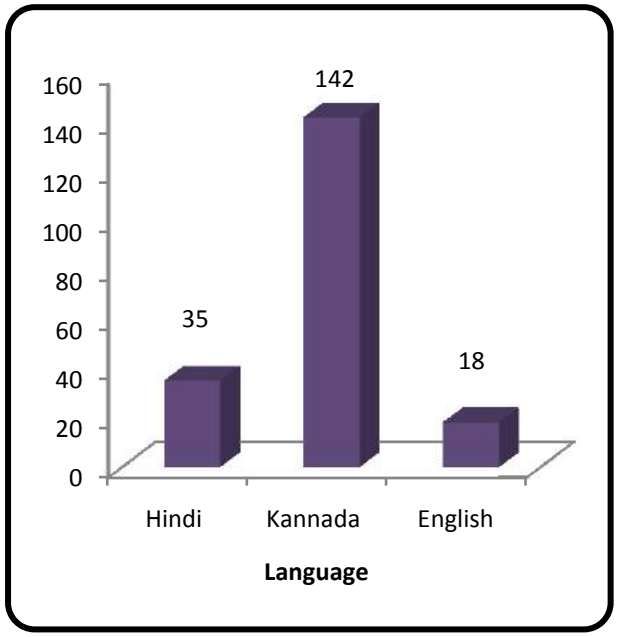

Figure-6 Graph showing details of counseling languages for patients enrolled

Language distribution

The results showed that 142(72.82%) of patients were counseled in Kannada, 35(17.94%) patients in Hindi & 18(9.23%) patients in English. As Kalaburagi is a multilingual city majority of the people speak Kannada, Hindi and other languages.

Table – 7: Details of Class of Drugs Prescribed to Patients

Class of Drugs	No of Drugs	% of Drugs
Antihypertensives	53	15.54
Antihistamines	14	4.10
Antidiabetics	13	3.81
Anbiotics	37	10.85
Vitamins	36	10.55
Antacids	25	7.33
Dyslipidemic	17	4.98
Diuretics	18	5.27
Antiasthmatic	33	9.67
NSAIDs	10	2.93
Antidiarrheols	24	7.03
Anxiolytics	15	4.39
Analgesics	23	6.74
Antipyratics	23	6.74
Total	**341**	**100.00**

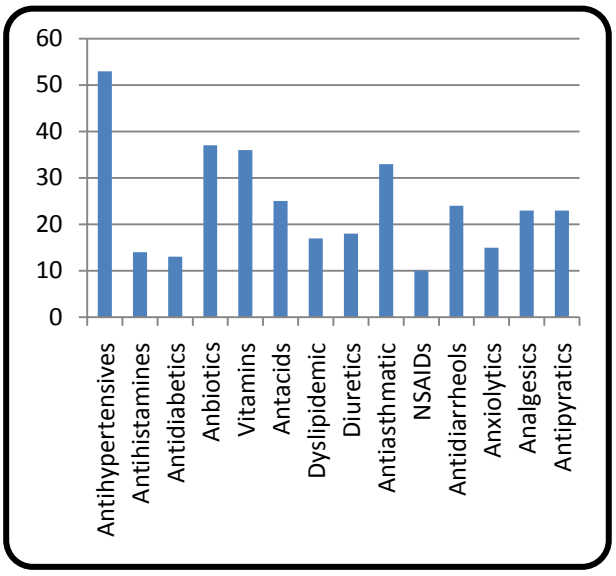

Figure – 7: Graph Showing Details of Classes of Drugs Prescribed to Patients

The result shows that Antihypertensives 53(15.54%) drugs were prescribed more followed by Antibiotics 37(10.85%), followed by Vitamins 36(10.55%), and followed by Antiasthmatic 33(9.67%).

Table – 8 Details of Prescribed Drugs to the patients

No of Prescribed Drugs	No of Drugs containing PIL	No of Drugs not containing PIL
341 (100.0%)	315 (92.37%)	26 (7.63%)

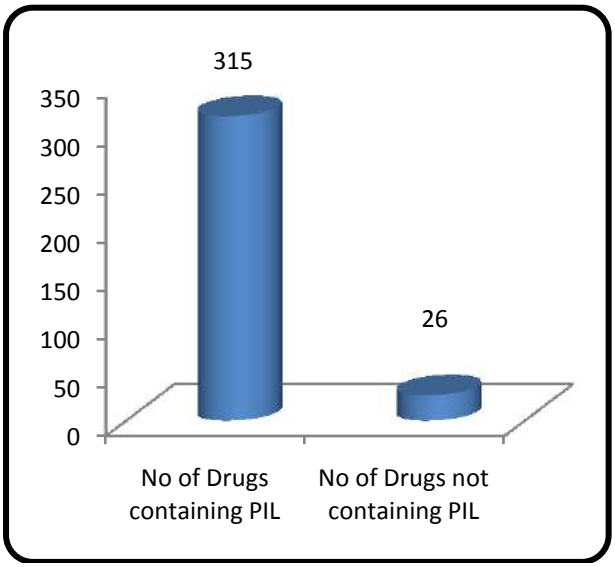

Fig. 8: Graph showing details of prescribed drugs with and without PIL

The result shows that out of total 341 Drugs prescribed to the patients, 315(92.37%) Drugs containing PILs and 26(7.63%) Drugs Not containing PILs.

PIL containing drugs prescribed to the patients:

A total of 195 patients were dispensed a total of 341 Medicines. For 26 items (7.63 %), there was no manufacturer's leaflet available for the pharmacist to supply with the medicine. 195 patients received at least one medicine with a leaflet. The leaflet was said to have been just noticed by 134 patients (68%). About 42 patients (21%) said they had read some part of the leaflet and 19 (9 %) patients reported that they had read the leaflet completely. Reasons given for not reading the leaflets at all is shown in the table No.9.

Table – 9: Reasons given for not reading the PIL (N=134)

Reason	No. of Patients	Percentage (%)
Leaflets read in the past	2	1.5
Never read leaflets	52	38.8
Too hard to understand	66	49.2
Too busy	14	10.5

Table – 10: Actions taken by patients as a result of reading the leaflet (N=61)

Action taken	Reasons	No. of patients
Returned to see general practitioner	Had skin reaction mentioned in leaflet	09
Returned to see pharmacist	Could not understand some part of the leaflet	07
Changed medicine-taking behavior	Information on inhaler technique Information on dose taking time	04 28
Stopped taking unnecessary medicines	Due to potential side effects	10
Took special precaution by breast feeding women	Due to precautions and contraindications in breast feeding women mentioned in the leaflet (3)	03

Summary

A prospective and observational study was carried out for 9 months in 152 type-2 diabetes mellitus in-patients (of either sex) admitted in general medicine wards with minimum of one year history of diabetes mellitus with or without comorbidity condition. The present study there was a significant impact of clinical pharmacist

provided patient counseling and patient education for improved medication behavior among type-2 DM patients.

Conclusion

This study examined the habits of patients regarding the reading of drug information leaflets, and the effect of reading the leaflet on medicine taking behavior and adherence to treatment. Out of 216 patients enrolled for the study, 195(90.28%) completed the study and the remaining did not turn for follow up. Among the 195 patients involved in the study, only 61(31.28%) were found to be interested and took actions as a result of reading the product information leaflet and the remaining 134(68.71%) did not show any interest in reading the product information leaflet. The numbers of patients who took specific action as a result of reading the leaflet, although small, represents a significant impact on the health service if the results are general is able. In particular, the 61 patients who said they had returned to see their GP represent just over 31% (out of the 195 who received a leaflet), and this figure, applied generally, would mean a significant increase in GP workload. 28 patients (45%) said they had changed their behaviour as a result of reading the leaflet, which shows that such leaflets have the potential to influence behaviour. These analyses are based on small numbers of patients and should be treated with caution. However, it suggests that, although only a minority of patients read some of the leaflet (and a smaller minority read it all), some patients make important changes to their medicine-taking behaviour, and others make contact with a health professional, as a result. This merits further investigation. Out of the 134 patients not shown any interest in reading the PIL, 66(49.25%) patients gave reason that it is hard to understand the leaflet, 54(40.29%) told that they never read the leaflet before and remaining 14(10%) gave reason that they were busy for not reading the PIL. So the pharmacist can play important role for improving the patients reading habits of pils ,since the present study is a pilot study and involving survey work. further work is needed on large scale and large population with pharmacist mediated counseling for patients to delivery necessary information and handling of pils. This study concluded that there is a need to improve the format, content and language of the package inserts in India. Pharmacist intervention is needed to improve patients reading habits for PIL. The main advantage of reading PILs is to increase the patients knowledge about their medicine (about the treatment & side effects) & finally to increase the effective use of medicine. Tighter monitoring of the inserts by regulatory bodies can help to enforce ideal labelling practices. Furthermore, the industry needs to revise its labelling methods. While there is a need to deliver necessary information accurately to the patient, it is also important from a logistical perspective to balance information against over-sized leaflets that are clumsy to handle and daunting to the patient. The text complexity and language is the main factor for not reading the prescription by the patients. It is important to realise that, apart from prescriber and pharmacist, patients are also end users of package insert. Currently in India, the structure and content of the information on the inserts is geared towards prescribers only. . Given the fact that unauthorized over-the-counter drug dispensing is a prevalent practice in India, and that patient education is in infant stages , there is a need for package inserts to be more patient-friendly and specifically designed to avoid medication errors. This can be achieved by conducting regular surveys to model the package inserts for the population. The similar work is done by D.K.RaynorPh.d and P Knapp Ph.d in “Do patients see ,read and retain the new mandatory medicine information leaflets.

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Conflict of Interests

The authors declare no conflict of interests regarding the publication of this article.

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