

Original Research Article

Evaluation of user's perspective on readability and understanding of medicine package inserts

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ABSTRACT

Background: Aim of this study was to evaluate the user's perspective on readability and understanding of Medicine package inserts (MPIs).

Methods: A cross-sectional study was conducted in the community pharmacy settings, encompassing participants from urban and rural areas of Pune, Mumbai, and Thane districts. The user's ability to read and understand was assessed using a 3-point Likert scale and was correlated to their socio-demographic characteristics using Pearson's coefficient. Also, the difference in the means between the groups was analysed using the student's test. A p-value ≤ 0.05 was considered statistically significant.

Results: Out of 502 respondents, most of the participants had the habit of reading MPI (51.3%). Although, on correlating the level of difficulty to the participant's socio-demographic characteristics, a little difficulty in reading (57.8%) and understanding (60%) of instructions respectively were reported in participants of the age group: 38-57 years (57%; 60%), who were graduate (70.2%; 69.8%), and was significantly associated to their area of residence ($p < 0.5$). Addressing the language barrier and providing MPI in their native language increased participants' readability by a whopping 57%, who earlier stated 'difficulty to read (70.49%)' as the major factor to not refer MPIs.

Conclusions: More than half the respondents (51.4%) usually read the MPI. Nonetheless, people stated that they faced difficulty in reading and understanding it. Diversifying this data by age and level of education can help policymakers ensure a user-directed upgrade of the package inserts and implement patient education in the users' native language by healthcare providers such as pharmacists.

Keywords: Barriers, Misinterpretation, MPI, Readability, User centred approach

INTRODUCTION

Package inserts are usually the first printed source of information for the user. European Medical Agency, National Agency for Food and Drugs (NAFDAC) and the United States Food and Drug Administration have published detailed rules and guidelines, stating the requirements and format of labelling for human prescription and biological products.¹⁻³

A medication package inserts (MPI) primary goal is to encourage proper medication usage and prevent medication errors. Also, it should be free from any misleading or diverting promotions, and be in a form that the patient will understand to prevent adverse drug reactions or irrational use of drugs. Many of the studies indicated that more than half of the patients (63%) misunderstand one or more drug-related instructions which leads to hospitalisation (12%).⁴ Thus, medicine package inserts can prove to be an essential tool in

preventing such health hazards by providing crucial drug-related information.

In India, the structure of PIs is regulated by the Drugs and Cosmetics Act (1940) and Rules (1945), Schedule D (II) sections 6.2 and 6.3, mandating the package inserts to be printed in 'English'.⁴ However, due to illiteracy, most of the patients do not refer them and subsequent studies have shown that even physicians do not discuss some aspects of drug therapy with their patients. About 25-30% don't receive counselling from pharmacists, while 47% do not receive any verbal or pictorial information about the drug or its use.^{2,5} There exists a paucity of studies from Eastern countries that focus on patient centred approach, rather than merely evaluating the quality of package inserts. Through our study, we aim to not only identify the challenges faced by users but also conduct interventions to discover the crux of the problem causing it. We aspire to publish our findings in an international community-based journal, to draw attention to problems faced by medication users from developing countries.

METHODS

The cross-sectional study included participants from Pune, Mumbai and Thane districts. The study was carried out for a duration of 6 months; from October 2020 to March 2021. The participants who were included in our study were of 18 years of age or older, provided their consent and used medicines dispensed with secondary packaging.

A pilot study involving 50 participants was conducted to generate feedback on problems to be addressed using the questionnaire. Electronic informed consent was obtained for each participant once they were informed about the study's purpose, process, and benefits. The use of MPI was evaluated using a bipartite questionnaire, where the participants were asked if they used MPI; and, if not, what the reasons were for the same. Participants who

replied affirmatively on MPI usage were then asked whether they found the package inserts necessary, and if yes, then to state the reasons for it. The respondents were then evaluated regarding their difficulties in reading and understanding the MPI using a 3-point Likert scale (very difficult, little difficult, not difficult). A few participants who found the language barrier to be a major cause were provided with instructions translated to their native language, printed in the same font size as the original (to avoid bias), and were asked if it reduced their level of difficulty in interpreting the instructions or not.

The data were then tabulated, indicating the frequency of each type of response, and presented in tables and charts. Pearson's χ^2 test was used to compare proportions between participants' socio-demographic characteristics such as age, gender, level of education, area of residence, etc, and the level of difficulty in reading and understanding instruction printed on MPIs. The continuous variables were presented as mean \pm SD (standard deviation), and the difference in the means between the groups was analyzed using the student's "t" test. The qualitative variables were presented as numbers and percentages. The statistical analysis was done using SPSS statistical software version 20. The p value of <0.05 was considered significant.

RESULTS

Total 514 responses were collected, of which 502 met the inclusion criteria. Among the 502 participants, more than half of the respondents were females 269 (53.59%), and were significantly higher ($p < 0.001$) in the age group of 38-57 years of age (57.97%). 25.29% of respondents had primary education or lower, proving to be a statistically significant parameter in participants' readability and understanding of printed instructions. The majority of users were employed (42.03%) and residing in the urban area (57%). An outline of socio-demographic data has been presented in Table 1.

Table 1: Socio-demographic details of the respondents.

Parameters	No. of participants (n=502)	Percentage of participants	P value
Age group (years)	18-37	158	31.47
	38-57	291	57.97
	58-77	49	9.76
	Above 77	4	0.8
Gender	Male	233	46.41
	Female	269	53.59
Level of education	Uneducated	19	3.78
	Primary education	108	21.51
	Secondary education	75	14.94
	Undergraduate	182	36.25
	Postgraduate	118	23.52
Place of residence	Rural	216	43
	Urban	286	57
Employment status	Student	45	8.96
	Employed	211	42.03

Continued.

Parameters	No. of participants (n=502)	Percentage of participants	P value
Self-employed	130	26.00	
Unemployed	116	23.01	

The majority of the participants suffered from diseases like diabetes (27.5%), hypertension (23%), and respiratory disorders/diseases (10.5%) along with other diseases as depicted in Figure 1. Figure 2 illustrates the use of medicine package inserts, which was highly observed for tablets (25.7%), aerosol (20%) and droplet preparations (9.5%).

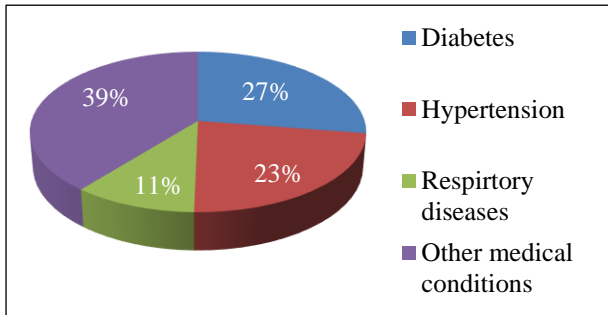


Figure 1: Participant's medical condition.

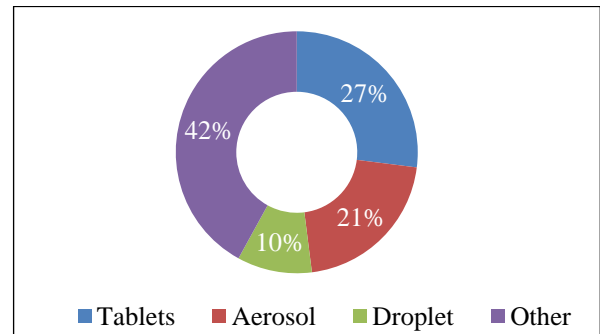


Figure 2: Use of medicine package inserts.

Out of 502 participants, 258 (51.4%) stated that they had the habit of reading medicine package inserts dispensed with their medication and found them necessary (Figure 3). Of the 244 (48.6 %) who did not refer to package inserts, most of them found it difficult to read (70.5%), among other reasons listed below under Figure 4.

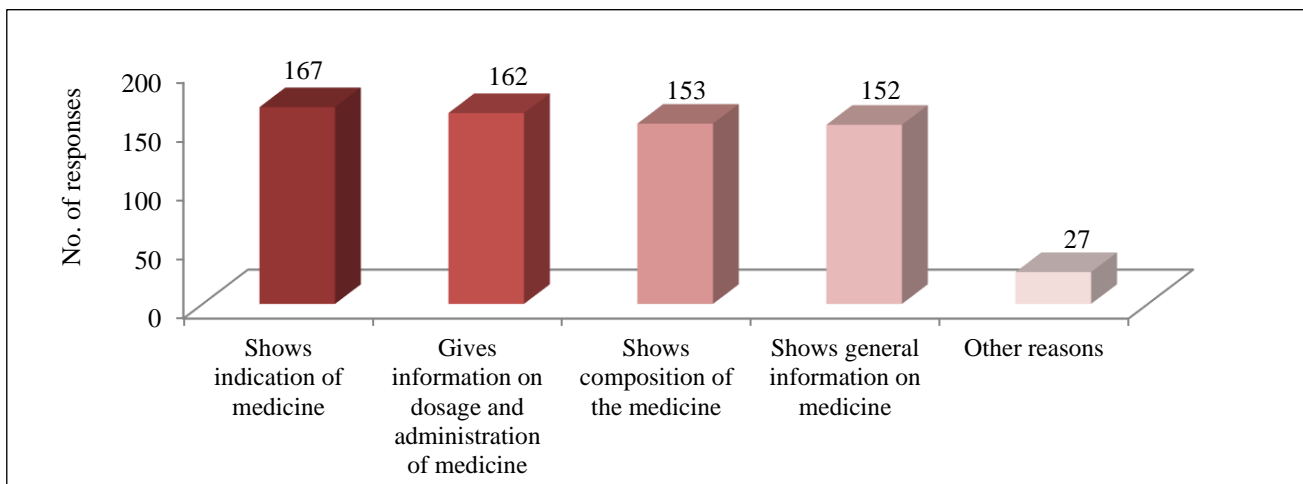


Figure 3: Reasons for considering medicine package inserts necessary (n=258).

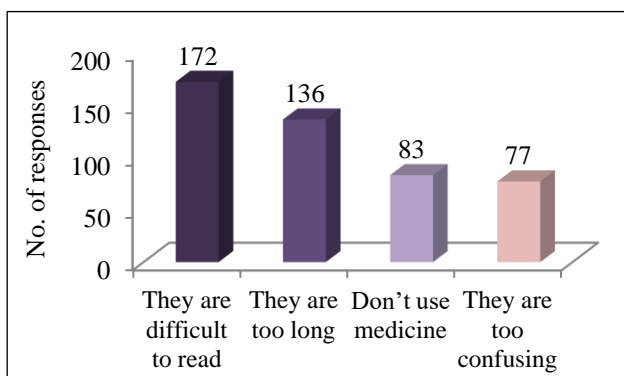


Figure 4: Reasons for not reading MPI.

The extent of readability and understanding of the user was assessed using a three-pointer scale which evaluated the level of difficulty faced by them. While evaluating the readability of package inserts by the participants, it was found that almost half of them found it a little difficult (48.21%), which was highly observed in participants within the age group 38-57 years, males, who were graduate, employed and residing in the urban area. A similar observation was seen in understanding medicine package inserts (40.84%), where participants could not understand medication package inserts. The participants found that readability and understanding were found to be significantly little difficult, than high or no difficulty ($p < 0.001$) (Figure 5 and Figure 6 respectively).

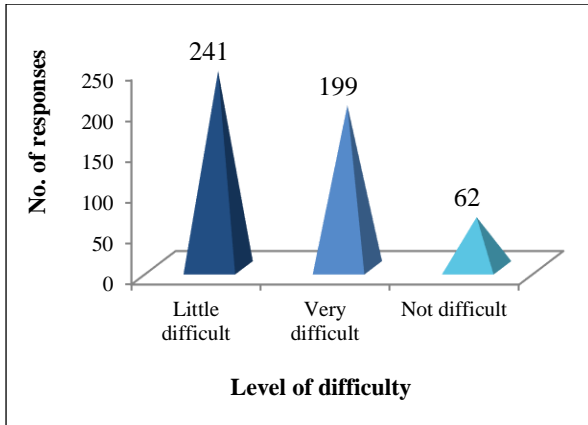


Figure 5: Difficulty in readability of MPI.

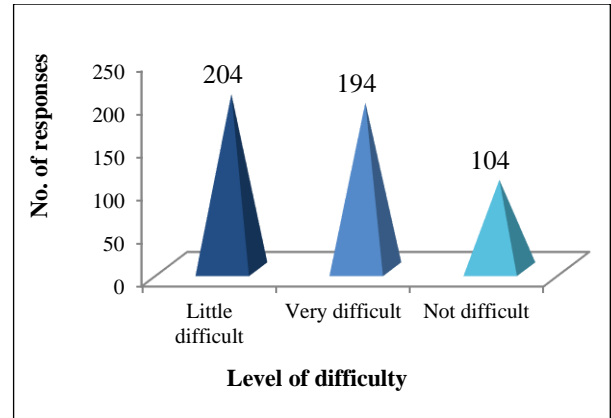


Figure 6: Difficulty in understanding of MPI.

Table 2: Difficulty in readability characterised by socio-demographic details of participants.

Parameters		Difficulty in readability (n=502)		
		A little difficult	Not difficult	Very difficult
Age group (years)	18-37	90	40	28
	38-57	140	21	130
	58-77	12	1	36
	above 77	0	0	4
Gender	Female	102	31	100
	Male	140	31	98
Employment status	Employed	130	35	46
	Self-employed	56	8	66
	Student	29	14	2
	Un-employed	27	5	84
Place of residence	Rural	79	38	99
	Urban	163	24	99
Educational status	Post graduate	68	17	33
	Primary education	29	0	79
	Secondary education	42	12	21
	Under graduate	102	33	47
	Uneducated	1	0	18

Table 3: Difficulty in understanding characterised by socio-demographic details of participants.

Parameters		Difficulty in understanding (n=502)		
		A little difficult	Not difficult	Very difficult
Age group (years)	18-37	67	60	31
	38-57	123	41	127
	58-77	15	3	31
	above 77	0	0	4
Gender	Female	83	52	98
	Male	122	52	95
Employment status	Employed	112	58	41
	Self-employed	49	14	67
	Student	19	23	3
	Un-employed	25	9	82
Place of residence	Rural	79	45	92
	Urban	126	59	101
Educational status	Post graduate	56	35	27
	Primary education	23	2	83

Continued.

Parameters	Difficulty in understanding (n=502)		
	A little difficult	Not difficult	Very difficult
Secondary education	38	18	19
Under graduate	87	49	46
Uneducated	1	0	18

Upon co-relating socio-demographic characteristics of participants with readability (Table 2) and understanding (Table 3), it was observed that people with lower educational levels and residing in rural areas had more difficulty in reading and understanding medication package inserts.

DISCUSSION

To avoid serious adverse events due to misinterpretation and to aid the correct interpretation of MPis, developed countries have reduced their complexity by the inclusion of pictograms, complemented with verbal instructions.^{6,7} In developed countries, medicine package inserts are majorly referred to and understood by the well-literate population. However, in developing countries like India, we did not see much awareness about medication package inserts and their use. Most studies in India have shown that about 6.3% of medicine package inserts show information about adverse drug reactions.⁸ The patient-to-doctor ratio in India is 1:1700 which is lesser than the recommended fraction of 1:1000, and thus instances occur where doctors are unable to provide complete information about the therapy. Also, studies carried out in India only focus on the completeness or quality of information provided, by use of the Flesch reading ease (FRE) score and internationally accepted Baker Able leaflet design (BALD) criterion.⁹ It is equally important to apply the user-centred approach to bridge the gap leading to incompliance.

Our study aimed at the people in urban and rural areas, concerning their socio-demographic characteristics being a barrier faced while referring to the medicine package inserts. Educational background plays an important role in understanding information, and therefore our prime objective was to identify all the barriers and difficulties faced by users. The majority of respondents in our study were under the age group of 38-57 years of age (58%), with 36% undergraduate and 42% employed. The age group of 38-57 show a significant difference between the rest of the groups in reading and understanding medication package inserts. The age group mostly consisted of educated, employed and participants from urban areas. Even though coming from an educational background, the participants could not understand the medicine package inserts completely. This is mainly due to the complex nature of medicine package inserts, with small font size, and too confusing. Thus, the respective regulatory bodies can consider the factors mentioned above to make package inserts more readable and thus be understood by every age group to improve patient compliance.

The study conducted in developing countries shows a lack of awareness of medication package inserts and their understanding of patients was not satisfactory. Our study assessed that a total of 167 respondents considered medication packages insert necessary as they can show indication for the prescribed drug. On the other, 172 participants stated that the medication package inserts are difficult to read and understand. This shows that the general population taken in our study rely on medication labels but faced some complications in understanding them. European Commission has proposed guidelines on the readability of medicine package inserts and considered factors like the type of font and font size to improve the patients' readability.¹⁰ For instance, a study conducted in Iran shows that 70% of the medicine package inserts are difficult to read.¹¹

The study contains a total of 21% of the participants who only had primary education, whereas 48.21% of participants found medication package inserts a little difficult to understand. Although, Fuchs et al in their study, state that educational level wasn't associated with participant's degree of understanding.¹² In developing countries, users tend to understand better with pictograms, verbal communications and one-to-one interaction, where there is a scarcity of independent sources of medical information. The study conducted in Sudan shows that package inserts from developed countries tend to contain more information when compared to package inserts from developing countries.¹³ A study from Brazil by Pizzo et al observed that 60% of participants read the medicine package inserts which is similar to our finding states as 51.4% and nearby to the study conducted in Portugal by A. cavaco which was 53%.^{6,14} This indicates that developing countries have a lower rate of readability and comprehensibility towards medication labels.

Our study also found that a total of 258 participants (51.4%) refer to medication package inserts, out of which 167 say they prefer it for indication and 162 refer it for understanding dosage and administration of the medicine. This is significantly lower compared to a study from Belgium where 71% read it for all medications, supporting the hypothesis indicating restricted use of PIs in developing countries.¹⁵

The findings from "Analysis of package inserts orally administered in Indian Market" concluded that 95% of medicine package insert contains contraindication and side effects, which contradicts the patient perspective as they state that only 59% show general medicine information.¹⁶ This difference and gap in opinion can be

ascribed to a lack of understanding of medicine package inserts which can be improved in the future. The factors associated with lack of understanding were mainly stated as, too long to read by 136 participants and difficult to read by many 172 participants.

Most of the users are in the criteria of not reading the medication package inserts because they found the MPI difficult to read (70%); The study from Brazil, observed that 57% found it difficult to read and 54% found it difficult to understand under another study from Brazil.¹⁴ A similar finding was observed when the doctor's perspective was taken on their patient's level of comprehensibility where they claimed that about 61.5% did not understand the instructions.¹³ In comparison to our study, the finding claimed a much higher level of difficulty in readability (88%) and understanding (79%). Again, this can be linked to the socio-demographic factors of education and employment status or the lack of literacy, awareness, and complexity of the medicine package inserts.

A study by Gibbs et al, concluded that verbal advice complemented with package inserts leaflet greatly enhanced the knowledge level of the patient up to 67% for understanding its uses and side effects of the medication, compared to 40% of patients at entry-level.¹⁷ But in India, verbal advice is preferred when compared to medication package inserts. This results in imparting half the information and can result in medication errors. Thus, implementing a proper strategy can change this scenario where the patient will get up-to-date information along with understanding the given instructions.

During our study, we also addressed the language barriers as a probable cause for users being unable to read and understand information. Our hypothesis was confirmed when 68% of participants stated that with the provision of package inserts in regional language, their ease to interpret somewhat increased. Although there no measures or steps are taken for medicine package inserts in India concerning a pharmacovigilant approach to assist in readability and improve leaflets, decreasing the incorrect use of medication.¹⁸ Implementing such a system will improve the quality of information of medicine package inserts, and change the complex nature of medicine package insert into a simple format that will be easy to read and understand by the general population.

CONCLUSION

The study concluded that medicine package inserts were mostly used by participants who were literate and employed. A larger portion of the users from Pune, Mumbai and Thane usually read the medicine package inserts. Nonetheless, people stated that they have difficulty reading and understanding it, especially those of a lower educational level and residing in rural areas. The majority of the problems encountered were the font

size, length of package inserts and complexity of reading the labels and medicine package inserts.

It is important to address the above factors and also the difficulties arising due to the language barrier.

Hence there is a need for change in designing the medication package inserts and medication labels by the respective bodies where users' perspectives should be considered according to their needs. By focusing on the patient's perspective and not just the qualitative analysis, problems such as patient compliance could be addressed and adverse events or medication errors could be avoided. Our findings can be useful for manufacturers and drug regulatory agencies to produce more readable and understandable medicine package inserts.

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Ethical approval: The study was approved by the Institutional Ethics Committee of Bharati Hospital and Research Centre, Pune (REF: BVDUMC/IEC/98)

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