

Preparation, Validation and User-testing of Patient Information Leaflets on Diabetes and Hypertension

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Vooradi, *et al.*: Preparation, Validation, and User-testing of Patient Information Leaflets

A patient information leaflet is an educational material for educating patients regarding a disease, medications and lifestyle modifications for better care. The present study aimed at preparing, validating and user-testing of diabetes and hypertension information leaflets in different languages among patients. The patient information leaflets on diabetes and hypertension were prepared by referring to the primary, secondary and tertiary resources. The content of the leaflet was validated by an expert committee. The readability of leaflets has been assessed by Flesch Reading Ease and Flesch-Kincaid Grade Level scores using MS Office 2007. The patient information leaflets were translated into *Kannada* and *Malayalam* languages with the help of language experts. During the user-testing, baseline knowledge was assessed before providing the patient information leaflet followed by provision of leaflets to the patients. After allowing the patients to read the leaflet for a period of 20 min, patients have again been administered with a set of questions to assess their knowledge. The Flesch Reading Ease and Flesch-Kincaid Grade Level readability scores achieved for diabetes leaflets are 70.4 and Flesch-Kincaid Grade Level score achieved is 6.3 and for hypertension leaflets, the Flesch Reading Ease score is 68.3 and Flesch-Kincaid Grade Level score achieved is 6.9. User testing of the patient information leaflets on diabetes and hypertension in different languages have been carried out on 40 each diabetic and hypertensive patients using knowledge based questionnaire. Knowledge assessment after providing patient information leaflet, the mean scores have significantly risen from 44.80 to 87.99 and 63.19 to 90.13 with $p < 0.0001$, respectively in diabetes and hypertensive patients. It showed that patient education added with a well-designed patient information leaflet has a greater impact on knowledge of the patients towards their disease management, so that the medication adherence is improved.

Key words: Patient information leaflets, patient education, diabetes, hypertension, lifestyle modifications

Patient information leaflet (PIL) is an educational material for conveying patient education regarding disease, medications and lifestyle modifications for better patient outcomes. A PIL is a legal document included in every medicine package to present written information about the medication use. Patient education is one of the major management strategies for curing or preventing the progression of many chronic diseases. PILs are the best-utilized tools for the patients with chronic disorders such as diabetes, hypertension (HTN), asthma, chronic obstructive pulmonary disease, and rheumatoid arthritis. Lack of information has been identified as a major factor for the patients' improper medication. Hence patients must know their therapy properly to adhere to the medication. Providing patients with PILs was found to be effective in improving patients' knowledge, compliance and the awareness of their potential side effects^[1].

Written patient information is frequently used for the benefit of patients to complement communication with the doctors. It can also help reconcile the communication gap between the patient and the physicians and emphasize the warnings and instructions. Written information can draw the attention of the patients leading to medication adherence and change in their lifestyle. Manufacturers are providing PILs along with their products, which provides information on their medication regarding its administration, precautions and potential side effects^[2]. As per the Article 11 of Directive 2001/83/European Commission (EC), the

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content of PILs should be unbiased, evidence-based and presented in a clear, understandable and well readable way to suitable for laypersons^[3]. The EC issued a Guideline on the readability of the label and package leaflet of medicinal products for human use, which provided guidance on how to prepare well-readable and understandable package leaflets. As of November 2005, the EC guideline led to the introduction of readability user tests to demonstrate the readability and usefulness of the package leaflet to patients^[4].

Dowse *et al.* carried out the study to determine the influence of medicine labels incorporating pictograms on the understanding of instructions and on their adherence. The presence of pictograms was found to contribute positively both to the understanding of instructions and adherence^[5]. Diabetes is a life-long disease, difficult to treat, often leads to a variety of acute and chronic complications, seriously affecting the patient's quality of life^[6]. Kheir *et al.* evaluated the knowledge, attitude, practice (KAP) and psychological status of adult Qatari patients with type 2 diabetes mellitus to study the role of these factors in the ability of the patients to manage their diabetes and to achieve desirable health outcomes^[7]. According to Norris *et al.*, 50-80 % of diabetic patients have little knowledge about their disease and few skills to put to practice^[8]. McMurray *et al.* clearly showed that diabetes education and care management can significantly improve the patient outcomes, glycemic control and quality of life in diabetic patients^[9]. HTN is a serious and common condition, the prevalence of which is set to increase in the aging population, sedentary lifestyles and obesity^[10]. Studies have shown that dietary habit is an important lifestyle factor impacting on the risk of developing HTN^[10]. A study conducted by Arul *et al.* revealed the knowledge on HTN based on the questionnaire scores and the study confirmed that education with PIL significantly improved their knowledge regarding HTN. It may be concluded that the disease-specific knowledge through PILs is necessary to strengthen patients' self-confidence in the management of the disease and to improve self-management^[11]. The Dietary Approaches to Stop Hypertension (DASH) and the DASH-sodium trials are proved that dietary patterns are rich in vegetables, fruits, and low-fat dairy products and less in sodium, total fat, saturated fat, and dietary cholesterol lowers blood pressure effectively in prehypertensive and hypertensive adults^[12].

The glycemic control and blood pressure control is dependent on various factors such as the patient's

adherence to drugs, lifestyle changes and regular monitoring of blood glucose and blood pressure. This is highly influenced by effective patient education and counselling^[2]. Providing PILs containing all the information related to disease and its management along with lifestyle changes required by the patient will definitely help to maintain the blood glucose level and blood pressure, thereby preventing the complications by adhering to medication and with proper lifestyle modifications. So, the present study is aiming at preparing well designed PIL for diabetes and HTN. It can be further used by the clinical pharmacist during patient counseling either to inpatients or outpatients.

MATERIALS AND METHODS

The present study has been conducted for a period of eight months between August 2014 and March 2015 at a tertiary health care hospital in south Karnataka. Approval of the Institutional Ethics Committee (Ref. no. IEC 503/2014) has been obtained prior to the initiation of the study.

Preparation, validation, and translation of PILs on diabetes and HTN:

PILs were prepared for diabetes and HTN diseases and common drugs used for the treatment by referring primary, secondary and tertiary resources. Tertiary resources included Pharmacotherapy: A Pathophysiologic Approach^[13,14], Textbook of Therapeutics: Drug and Disease Management^[15,16], Harrison's Principles of Internal Medicine^[17,18]. The secondary resources were various databases such as Micromedex^[19], UpToDate^[20,21], Medscape^[22,23], Medline^[24,25] and WebMD^[26,27]. The primary resources included various articles related to patient education and information leaflets on diabetes^[28,29] and HTN^[30,31]. The content of the leaflet includes information on diabetes/HTN such as definition, risk factors, normal values of blood sugar level/blood pressure, complications, dietary requirements, exercise, lifestyle modifications and controlling blood sugar levels/blood pressure to overcome further complications and the information of commonly prescribed medications. The content of the PIL was validated by an expert committee consisting of a physician and four academic pharmacists. The changes were affected as per the directions of the expert committee and the leaflet has been prepared accordingly. Prepared PILs were assessed for Flesch Reading Ease (FRE) and Flesch-Kincaid Grade Level (FK-GL) scores by using MS Office 2007. Readability of the leaflets as per FRE and FK-GL depends on the

use of polysyllables, sentence length. Taking these issues into consideration, certain modifications were made in the leaflet in order to improve the scores of the leaflet. The score between 60 and 70 is largely considered acceptable. The following scale is used to assess the ease of readability in a document. Very easy (90-100), easy (80-89), fairly easy (70-79), standard (60-69), fairly difficult (50-59), difficult (30-49) and very confusing (0-29)^[32].

The prepared, validated and best scored English leaflets were assessed for the characteristics of layout and design of PIL by using Baker Able Leaflet Design (BALD)^[33]. Modifications like font, alignment, use of pictures and use of good quality paper have been carried out. After preparing the English leaflets with a good readability, layout, and design, PILs were then translated into *Kannada* and *Malayalam* with the help of experts who are familiar with the language and also medical terminology. Translated leaflets were then subjected to further validation tests. To check the consistency of translated materials, translated leaflet were back-translated into English from *Kannada* and *Malayalam* by language experts. The back-translated and original versions of leaflets were reviewed by a set of experts to find out the difference between the versions. After the validation, it was found that both the original and back-translated versions do not differ significantly. After the validation of translated leaflets, the leaflets were assessed for characteristics of layout and design by using BALD^[33].

Readability testing of PILs on the patients:

Readability testing of PILs on diabetes and HTN was performed on diabetic and hypertensive patients, who visited outpatient medical department of the hospital during the study period. Patients with minimum primary educational background have been selected from the three outpatient medicine units. The inclusion criterion was based on the patients who were diagnosed with diabetes and HTN more than 18 y of age with a written informed consent. The demographic details such as age, gender, and educational status, the length of disease, prescribed medications, and social habits of the all the included patients were documented in patient profile form.

Sample size:

The sample size was calculated on the basis of the change in patient's knowledge of user-testing scores from baseline (pre-intervention) to post-intervention scores by using the following formula mentioned in

the similar study conducted by Mateti *et al.* According to the equation, the minimum sample required for each disease in this study is 40^[34]. The patients were selected by convenience sampling. $n = (Z_{1-\alpha/2} + Z_{1-\beta})^2 \frac{\sigma^2}{d^2 + 2}$; $\sigma = 10$, $Z_{1-\alpha/2}$ is 1.96 (for $\alpha = 5\%$), where, $Z_{1-\beta}$ is 0.84 for 80% power; σ is the mean of the two standard deviations; d is the minimum significant difference in the two groups.

For the user-testing of PILs, 10 multiple choice questions were prepared based on the content of the leaflet on each disease. The questionnaire was validated by subject experts. A total of 15 patients participated in each of English and *Kannada* languages and 10 patients in the *Malayalam* language in each disease PIL. During the user-testing, baseline knowledge has been carried out before providing the PIL followed by provision of the leaflet to the patients. After allowing the patients to read the leaflet for a period of 20 min, patients have again administered with a set of questions to assess their knowledge. At the end of the user-testing, these scores were documented in a separate worksheet along with demography of the patient. After knowledge assessment, patients have then asked to document their opinion about the layout and design in a rating form. Patients have provided with designed leaflet for their assessment on leaflets. At the end of the study, the responses were evaluated using the following formula^[34], response evaluation = (total number of correct responses of patient / total number of actual responses) $\times 100$.

After assessing the knowledge about the information leaflets, the opinion of the patients was elicited about the content, layout, and design in a rating form containing 5 questions with a score range on a 4-1 scale. The maximum possible score for the user opinion is 20. The interpretation of the scores is as follows; if the score of legibility and content of the PILs is '20-14' considered as good, '14-9' considered as average, <9 considered as poor PIL^[34]. User-testing and user opinion testing questionnaire was validated before assessing the knowledge and user-opinion from the patients by an expert committee.

Statistical analysis:

Descriptive statistics was used to summarize the data and the user-testing data of baseline and after 20 min, scores were calculated by using paired student t-test with a p-value less than 0.05 considered as statistically significant. Data were analysed using SPSS version 15 software.

RESULTS AND DISCUSSION

PILs on diabetes, HTN and related medications were prepared in English version according to the guidelines. The prepared PILs were validated with the expert committee. After validation, the PILs were assessed for readability by FRE and FK-GL scores, and layout and design using BALD. The PILs were then translated into *Kannada* and *Malayalam* languages with the help of language experts. The translated PIL is validated with the experts and modifications have affected according to their suggestions. The final version of diabetes and HTN PILs in English, *Kannada* and *Malayalam* languages was assessed for user-testing in patients with diabetes and HTN.

After the preparation of English version of diabetes and HTN PIL, the PIL readability was assessed by using FRE and FK-GL scores. After the assessment of readability scores, to improve the scores, the leaflets were modified and readability scores were assessed, which have recorded improvement after each modification. The final FRE score achieved was 70.4 and FK-GL score achieved was 6.3 for diabetes PIL and both the scores, rates the diabetes leaflet as 'fairly easy'. The final FRE score achieved for HTN PIL was 68.3 and FK-GL score achieved was 6.9 and both the scores rate the HTN leaflet as 'standard'. The results in detail are presented in Table 1. The mean BALD assessment score for the english version of both diabetes and HTN leaflets was 30 and for *Kannada* and *Malayalam* version was 28 each. Evaluation of the BALD assessment scores for diabetes PIL is shown in Table 2. Similarly, we calculated a BALD score for all the version of diabetes and HTN PIL.

Off the 40 diabetic patients, most of the patients were men (61.9 %) and 50 % of the patients were educated

TABLE 1: READABILITY ASSESSMENT OF DIABETES AND HYPERTENSION PIL USING FRE AND FK-GL SCORES

Condition	Stage of preparation of leaflet	FRE score	FK-GL score
Diabetes	1	65.2	7.2
	2	66.7	7
	3	70.4	6.3
Hypertension	1	60.5	7.9
	2	65.2	7.2
	3	68.3	6.9

FRE=Flesch Reading Ease, FK-GL=Flesch Kincaid Grade Level

TABLE 2: BALD ASSESSMENT SCORE FOR DIABETES PIL IN ENGLISH LANGUAGE

Design characteristics	3 points	2 points	1 point	0 point
Lines 50-89 mm long			Yes	No
Separation between lines	>2.8 mm	2.2-2.8 mm		<2.2mm
Lines unjustified			Yes	No
Serif typeface		Yes		No
Type size	12 point	10-11 point	9 point	<9 point
The first line intended			Yes	No
Titles lower case			Yes	No
Italics		0 words	1-3 words	≥4 words
Positive advice		Positive		Negative
Headings standout		Yes		No
Numbers all Arabic			Yes	No
Boxed text			0-1 box	>1 box
Pictures	Words could not replace	In between	In between	None of superfluous
Number of colors	4	3	2	1
White space	>40 %	30-39 %	20-29 %	<20 %
Paper quality	>90 gsm	75-90 gsm		<75 gsm

Mm is millimeter and gsm is the paper thickness in grams per square meter

till high school. Out of 40 hypertensive patients most of the patients were men (59.5 %) and the majority of the patients are educated till high school (52.5 %). The other demographic details of the diabetic and hypertensive patients such as age, BMI, social habits such as smoking and taking alcohol were summarized in Table 3.

User-testing of PILs in different languages has been carried out in patients. As per the sample size, a total of 40 each of diabetes and hypertensive patients were included in the study. Among them, 15 patients each participated in English and *Kannada* version and 10 patients in *Malayalam* version in user-testing of PIL of each disease, respectively. User testing is done by administering validated knowledge based questionnaire on diabetes and HTN, before and after providing respective PILs to the patients. It was shown that the significant improvement in knowledge-based post-test scores when compared to pretest scores in diabetes

and hypertensive patients of all the three languages. Detailed results are represented in Table 4.

After assessing the knowledge, the overall user opinion of legibility and content of diabetes and HTN PILs has been evaluated using same patients. The majority of the patients have rated the diabetes leaflets as good (57.5 %) followed by average (40 %) and the HTN leaflets have been rated good (67.5 %) and followed by average (32.5 %). The detailed user-opinion scores of English, *Kannada* and *Malayalam* versions of diabetes and HTN PILs are summarized in Table 5.

TABLE 3: DEMOGRAPHIC DETAILS OF DIABETES AND HYPERTENSIVE PATIENTS

Demographic details	Diabetic patients, (n=40)	Hypertensive patients (n=40)
Age in years (mean±SD)	58.26±11	60±7.46
Gender		
Male	26 (61.9)	25 (59.5)
Female	14 (33.3)	15 (35.7)
Educational status		
Primary school	-	-
Middle school	1 (2.5)	3 (7.5)
High School	20 (50)	21 (52.5)
Intermediate	7 (17.5)	7 (17.5)
Graduate	12 (30)	9 (22.5)
BMI (kg/m²)		
Underweight (<18.50)	-	-
Normal range (18.50-24.99)	25 (62.5)	24 (60)
Overweight (25.00-29.99)	12 (30)	12 (30)
Obese (≥30.00)	2 (5)	4 (10)
Smoking		
Yes	4 (10)	3 (7.5)
No	36 (90)	37 (92.5)
Alcohol		
Yes	5 (12.5)	10 (25)
No	35 (87.5)	30 (75)

SD is standard deviation, BMI is body mass index. The data mentioned in the parentheses are number of patients (%)

TABLE 4: USER-TESTING OF DIABETES AND HYPERTENSION PILS IN THREE DIFFERENT LANGUAGE VERSIONS

Type of users/ languages (number of patients)	Pretest scores (mean±SD)	Post-test scores (mean±SD)	Mean difference (95 % CI)
DM/English (n=15)	43.26±17.91	92.14±9.73	48.87 (41.09, 56.65)*
HTN/English (n=15)	63.28±16.68	91.56±11.64	28.28 (19.19, 37.37)*
DM/ <i>Kannada</i> (n=15)	47.59±22.31	87.28±13.09	39.68 (28.47, 50.89)*
HTN/ <i>Kannada</i> (n=15)	64.30±19.49	90.70±11.28	26.40 (18.94, 33.86)*
DM/ <i>Malayalam</i> (n=10)	42.91±21.67	82.85±16.01	39.94 (31.49, 47.87)*
DM/ <i>Malayalam</i> (n=10)	61.39±6.90	87.13±10.55	25.74 (16.59, 34.89)*
Overall DM PIL users (n=40)	44.80±20.17	87.99±12.97	43.19 (37.65, 48.73)*
Overall HTN PIL users (n=40)	63.19±15.77	90.13±11.10	26.94 (22.08, 31.80)*

DM=diabetic patients, HTN=hypertensive patients, SD=standard deviation, CI=confidence interval. p≤0.0001 statistically significant compared to pre-test

PILs can act as educational material for providing patient education regarding disease, medications and lifestyle modifications for better patient outcomes. It is well established that patient education and patient involvement can lead to a better control over disease^[35]. A diabetic patient should have a working knowledge of diabetes such as symptoms, diabetic care and management for reducing the risk of hospitalization due to complications and for a better patient compliance^[36,37]. HTN is a common condition, the occurrence of which is set to increase in the aging population, sedentary lifestyle and obesity^[10]. Studies have shown that dietary habits are an important lifestyle factor impacting the risk of developing HTN^[10]. The present study was planned with an initiative to develop PILs on diabetes and HTN in south Indian languages like *Kannada* and *Malayalam* and to validate the leaflet for readability and user-testing. Among healthcare professionals, physicians and pharmacists play a significant role in the diagnosis of the disease and its management. Hence their opinion is of paramount importance. In the present study, the content of PILs has been validated by a physician and four academic pharmacists. Similarly, in studies conducted by Adepu and Swamy the content in the information leaflets has been validated by physicians and pharmacists^[38]. As per a study conducted by Mateti *et al.* the content validation has been done by three physicians and two academic pharmacists^[34]. In the study conducted by Roy *et al.* and the content validity has been done only by physicians^[39]. In the present study, user-testing was used to assess the readability of the leaflets. User-testing is the accurate method to assess the readability of the leaflets in any language.

The readability assessed by formulas FRE and FK-GL can only be applied to the English version leaflets and

TABLE 5: USER-OPINION SCORES OF DIABETES AND HYPERTENSION PILS OF THREE DIFFERENT LANGUAGES

Languages (no. of patients)	Interpretation of scores	No. of diabetic patients, (%)	No. of hypertensive patients, (%)
English (n=15)	Good	7 (17.5)	10 (25)
	Average	7 (17.5)	5 (12.5)
	Poor	1 (2.5)	–
Kannada (n=15)	Good	10 (25)	9 (22.5)
	Average	5 (12.5)	6 (15.0)
	Poor	–	–
Malayalam (n=10)	Good	6 (15.0)	8 (20.0)
	Average	4 (10.0)	2 (5.0)
	Poor	–	–
Overall diabetes PIL users (n=40)	Good	23 (57.5)	27 (67.5)
	Average	16 (40)	13 (32.5)
	Poor	1 (2.5)	–

readability of other language leaflets is not possible by this method. In the present study, the readability of English version of leaflets was assessed by FRE and FK-GL and English version of leaflets along with other languages (*Kannada* and *Malayalam*), readability was assessed by user-testing. The best readability scores achieved for the diabetes are FRE 70.4 and FK-GL 6.3, while for HTN PILs, FRE 68.3 and FK-GL 6.9. The similar study conducted by Adepu and Swamy^[38] has shown the best readability scores have been achieved for diabetes (FRE 84) and HTN (FRE 82) PILs. Whereas the study conducted by Roy *et al.* has shown the best FRE readability scores achieved for the diabetic foot ulcer PILs are 69.9^[38,39]. In the present study, these readability scores suggest that prepared diabetes and HTN PILs are 'fairly easy' and standard, respectively. Easiness in readability in PIL can be improved by using simple English words. It has been documented that a well-designed leaflet can contribute to responsible medicine-taking by patients and improves patients' ability to find and understand the information provided^[40]. The mean BALD assessment score of English, *Kannada* and *Malayalam* leaflets was better than that of the leaflets prepared by the similar studies^[34,38,39,41]. One of the drug companies prepared 30 customer PILs in Australia and subjected them for readability and design characteristics. Results of this study showed that mean FRE score of all the PILs was 51 and mean BALD criteria score was 17, suggesting poor readability and design characteristics. It was also shown that a leaflet with good readability scores and design characters like pictograms, font sizes, space between sentences and paper quality will improve the patient's comprehension and acceptability^[40]. In the

present study, the inclusion of pictograms in PILs has helped the patients recalling capacity (such as causes of the disease, symptoms, diet and lifestyle modification). The same has been reflected in the results of user testing using a knowledge based questionnaire for diabetes and HTN. Patients enrolled in the study are with various educational backgrounds and with a history of various lengths of disease duration. Many patients are from school and pre-university educational levels. In a study reported by Bernardini *et al.*, the majority of respondents considered that the use of symbols and pictograms has been helpful in finding the required information^[43]. It would be interesting to establish if symbols or picture sequences can have a role in increasing the clarity and understanding of a specific message^[42]. The pictograms and symbols may significantly enhance readability and comprehension of the PILs. It is evident from this study that the post-interventional PILs knowledge-based user-testing scores have significantly improved mean baseline scores from 44.80 to 87.99 in diabetic patients and 63.19 to 90.13 in hypertensive patients. The pre- and post-interventional PIL study conducted in the community pharmacy has shown that the recall drug information has significantly improved from 30 to 65 %^[43]. The verbal advice along with PIL is shown to have improved knowledge levels in recognizing the uses and side effects of medications from 40 to 67 %^[44]. Similar studies conducted by others with PILs as an educational intervention have a significant impact on the KAP among the patients with diabetes, HTN, asthma peptic ulcer and rheumatoid arthritis^[38,45-47]. The impact of pictograms in PILs in recalling the information have shown similar improvement^[32,48]. Most of the published studies have not assessed the user-testing and user-opinion on the leaflets, which the present study attempts as they are one of the important stakeholders in patient education. The results of this study reveal that 57.5 % of diabetic and 67.5 % of hypertensive patients rated the leaflets content, legibility and design as good. The objective of the present study is to prepare good quality PILs and to follow the user-testing method as per European guidelines on the Indian population.

The information leaflets in the present study are in accordance with the standard readability and good layout and design criteria scores and in tune with the patients' education and comprehension. FRE and FK-GL scores rate have shown that the leaflet was 'fairly easily' readable. BALD scores have been evaluated for all the prepared leaflets and have shown that all of them have a good score. User-testing of

leaflets has imparted comprehensible awareness regarding the expectations and understanding of the end users and prepared leaflets have subjected to user-testing irrespective of the language. Leaflets with good layout and design have easily acknowledged by the end users. The present study has recorded a significant improvement in the knowledge levels after reading the validated leaflets. More than 60 % of the patients have rated the leaflets content, readability and design as good. It has also been observed that the patient education with information leaflets by the clinical pharmacist has shown significant improvement in the knowledge of diabetes and hypertensive patients towards their disease management, which showing the effectiveness of a PIL.

Conflicts of interest:

There are no conflicts of interest.

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