

# Development and Evaluation of Patient Information Leaflets (PIL) Usefulness

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## Adepu and Swamy: Usefulness of Patient Information Leaflets

A prospective study was conducted to develop, validate and assess the usefulness of the patient information leaflets for selected diseases among the patient population. Flesch readability ease score, Baker Able leaflet design criteria were applied to develop the patient information leaflets. The leaflets were validated for both content and translation. Eligible patients meeting the study criteria were enrolled in the study. Suitably designed knowledge, attitude and practice questionnaire was administered at base line followed by patient education complimented with an information leaflet. After a month, knowledge, attitude and practice questionnaire was administered once again to assess the influence of education and usefulness of patient information leaflets on knowledge, attitude and practice scores. The mean readability score of the information leaflets is 80 and Baker Able leaflet design criteria score is 22. Post

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education knowledge, attitude and practice scores were significantly ( $P < 0.0001$ ) improved in all the enrolled patients in all disease. The study concludes that patient education complemented with suitably designed information leaflet has greater impact on knowledge, attitude and practice of the patients towards their disease management.

**Key words:** Layout and design score, patient information leaflets, readability score

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<sup>[1]</sup>. 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<sup>[2]</sup>.

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<sup>[3]</sup>. A Study conducted by Joseph *et al.* has shown that, patients wanted information leaflets and were more concordant with their medication, when they received information leaflet from their health care professional<sup>[4]</sup>. Another study conducted by Gibbs *et al.* in Southampton showed that well designed patient information leaflets improved the patients' acceptance and the satisfaction<sup>[5]</sup>.

The important elements while designing an information leaflet to be considered are literacy and individual's comprehension level. In an English speaking country like United States of America (USA), many researchers have reported that most Americans of 14 years of age or older cannot read better than a seventh grade student<sup>[6]</sup>.

Studies have shown that the qualities required for preparing a patient information leaflet (PIL) are, information should be authentic and unbiased, 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. Flesch reading ease (FRE) score is commonly used to assess readability of a written text<sup>[7-9]</sup>. An internationally accepted Baker Able leaflet design (BALD) criterion is used for good design characteristics of an information leaflet<sup>[10-11]</sup>. A well designed information leaflet with good readability scores help patients to understand the content given in the leaflets which may in turn improve their knowledge, attitude and practices towards their disease management<sup>[12-14]</sup>.

For the study purpose, PIL on diseases such as diabetes mellitus, hypertension, asthma, peptic ulcer, and angina were developed referring to standard text books and compendia. The readability of the prepared leaflets was calculated using FRE formula.  $FRE = 206.84 - 0.85W - 1.02S$ . Where W = Number of syllables per 100 words, S = Number of words in an average sentence.

The reading ease scores on FRE scale are 0-100. If the score of a written text is less than 60, the document is considered to be difficult to read by the general public. The ideal PIL should have a readability score of more than 80.

Layout and design of the information leaflets were assessed by BALD criteria. Length of the line, space between the lines, letter type, font size, indenting, pictograms, box type text, use of colors, paper quality are the features used to assess the leaflet layout and design characteristics in BALD criteria.

Content in the designed information leaflets was validated by a team of clinical pharmacists and physicians at JSS Hospital. The content in the information leaflets was translated in to Kannada, the local language with the help of a language expert at Central Institute of Indian Languages (CIIL), Mysore.

Patients visiting to the JSS Hospital outpatient pharmacy with the selected diseases were informed about the study and those who met the study criteria and willing to give the written informed consent were enrolled in to the study. Demographic details of the enrolled patients were documented in a suitably designed patient profile form. At base line, patient's knowledge, attitude and practices were assessed using knowledge, attitude and practice (KAP) questionnaire. Structured patient education was provided to all the patients complemented with the information leaflets in Kannada for the selected diseases. After one month, KAP questionnaire was administered once again on all the enrolled patients. The study was approved by the Institutional Research and Ethical Committee.

Unpaired Student "t" test was applied ( $P < 0.001$  is considered as significant) to assess the impact of patient education and usefulness of patient information leaflets on KAP using Instat 3 statistical software.

PIL for five chronic disorders such as hypertension, diabetes mellitus, asthma, peptic ulcer disease and angina were developed. The mean readability score of the PILs was found 80 on FRE scale. BALD criteria were used to evaluate the layout and design characteristics of the PIL. The mean BALD score

**TABLE 1: READABILITY, LAYOUT AND DESIGN CHARACTERISTICS OF THE PILS OF THE SELECTED DISEASES**

Disease	Flesch reading ease (FRE) score	Mean BALD scores
Hypertension	82	23
Peptic ulcer	81	23
Diabetes mellitus	84	22
Angina	74	21
Asthma	79	21

FRE = Flesch Reading Ease (FRE) Score, BALD = Baker Able leaflet design criteria

of the PIL is 22. The readability scores and design scores of the patient information leaflets are presented in Table 1. Mean age of the patients enrolled in diabetes was 52 y, in hypertension 49 y, in asthma 35 y and in angina 54 y. Majority subjects enrolled in to the study are males (155) compared to females (63). All the patients enrolled are educated. Among them more than 20% of the patients are having high school education and 14% of the patients are possessing university degree. The demographic details of the patients enrolled in to the study covering all the diseases are presented in Table 2. The mean pre education KAP scores and post education KAP scores of the patients were analyzed using the unpaired student t test. A significant improvement in post education KAP scores was observed in the study population. The results are presented in Table 3.

Patient counseling is defined as providing information regarding the disease, medications, diet and life style change to patients or patient's representatives in lay man language<sup>[15]</sup>. Structured patient education supported with patient information leaflets will have a greater improvement in patient's understanding about the disease management<sup>[1-5]</sup>. A good patient information leaflet should have desirable readability characteristics for easy comprehension and understanding the content<sup>[16]</sup>.

In order to assess the readability of designed patient information leaflets, about 40 formulas were recognized worldwide. Most of them are derived statistically and considers language variables such as word complexity and sentence length to calculate the readability<sup>[9]</sup>. A readability formula is a simple method to predict the reading grade level required to comprehend the written materials and documents<sup>[17]</sup>. More commonly,

**TABLE 2: DEMOGRAPHIC DETAILS OF THE PATIENTS ENROLLED IN TO THE STUDY**

	Diabetes mellitus	Hypertension	Asthma	Peptic ulcer	Angina
Age (in years)	52.7±9.7%	49.1±7.2%	35.2±6.6%	37.4±11.5%	54.7±9.2%
Gender					
Male	45 (80.35%)	37 (71.15%)	31 (62%)	26 (65%)	16 (80%)
Female	11 (17.65%)	15 (28.84%)	19 (38%)	14 (35%)	04 (20%)
Education					
Primary	3 (5.3%)	2 (3.84)	3 (6%)	2 (5%)	1 (5%)
High school	26 (46.42%)	29 (55.76%)	20 (40%)	17 (42.5%)	15 (75%)
PUC	14 (25%)	14 (26.92%)	16 (32%)	13 (32.5%)	3 (15%)
University	13 (23.21)	7 (13.46%)	11 (22%)	8 (20%)	1 (5%)
Disease history					
6-12 months	25 (42.85%)	12 (23.07%)	18 (36%)	26 (65%)	8 (61.53%)
12-24 months	18 (32.14%)	15 (28.84%)	21 (42%)	10 (25%)	10 (30.76%)
Above 24 months	13 (23.21%)	25 (48.07%)	11 (22%)	4 (10%)	4 (7.6%)

**TABLE 3: PRE AND POST EDUCATION KAP SCORES OF THE ENROLLED PATIENTS**

Disease	Pre-education KAP mean±SD	Post-education KAP mean±SD	P-value
Asthma	53.25±9.74	88.25±8.31	P<0.0001
Angina	51.90±12.24	88.40±3.86	P<0.0001
Diabetes mellitus	44.89±19.18	88.89±4.76	P<0.0001
Hypertension	51.40±9.99	82.00±6.45	P<0.0001
Peptic ulcer disease	35.90±12.24	51.90±12.24	P<0.0001

KAP = Knowledge, attitude and practices. SD = Standard deviation, P<0.0001 is considered as highly significant

FRE, Flesch KinKaid Grade Level (FKGL) and SMOG formulas are used to assess the readability. FRE and FKGL formulas are available in Microsoft word. To calculate FRE, FKGL using the computer, the text of the PIL should be typed in word document, and then using the tool bar click on readability, the calculated readability scores of the document appear on the screen. Any leaflet scores more than 70 out of 100 score is considered as fairly easy to read. In the present study, mean readability scores of the PILs were found as 80. These scores suggest that, the readability of the information leaflet is very easy. More the readability easiness more will be the acceptance of the PIL by the client. Readability easiness in PIL can be increased by using simple English words<sup>[18]</sup>.

A leaflet with good design characteristics such as font size, use of pictograms, sentence length etc will improve the acceptability of the PILs<sup>[19]</sup>. BALD criteria were applied to assess the design characteristics. As per the BALD criteria, a leaflet scoring between 20 and 25 (The total score is 32) is considered as having good layout and design characteristics. PILs developed in the present study scored more than 20 and met the Bald Criteria.

In an Australian based study, 30 customer product information leaflets produced by manufacturers were subjected for readability and lay out design characteristics. The results suggest that, mean FRE score was 51 and mean BALD criteria score was 17, suggesting poor readability and design characteristics. The same study suggests that a leaflet with good readability scores and design characters like, space between sentence, font sizes, pictograms, and paper quality has an impact on patient's comprehension and acceptability<sup>[11]</sup>.

In India, the literacy rate is less than 50% and the level of English understanding may be 4<sup>th</sup> grade level. Thus due care was taken in designing the

information leaflets with good readability and design characteristics. In the present study incorporation of pictograms in PILs helped the respondents recalling capacity (such as causes of the diseases symptoms diet and lifestyle modification). The same was reflected in answering KAP questions in various diseases.

Patients enrolled in the study were with mixed educational backgrounds and with various lengths of disease duration. Many patients were from school and pre university educational levels. Most of the patients were from agriculture and business category. A significant improvement in KAP scores was observed in all categories of the patients after the patients were counseled and complimented with patient information leaflets. In most of the studies, it was found that the structured verbal advice along with patient information leaflet has a significant effect on patient awareness, knowledge about disease and medicines.

Hill and Bird developed and evaluated drug information for patients with rheumatoid arthritis. The results of the study indicates that a significant improvement (P<0.001) was observed in knowledge of patients regarding the drug (D-penicillamine), at the study exit compared to study entry, suggesting the influence on information leaflets in knowledge levels<sup>[19]</sup>. Livingstone *et al.* in their study conducted in community pharmacy observed that patients when counseled with PILs, 65% of patients could able to recall the information about their drugs compared to 30% of patients before the education and PIL about their drugs<sup>[20]</sup>. Gibb's *et al.* have demonstrated that verbal advice complimented with a PIL greatly enhanced the knowledge level of 67% patients in recognising the uses and side effects of medications after the education compared to 40% of patients at the entry level<sup>[5]</sup>.

Leia and Ros studied the effect of pictograms in leaflets in recalling the information. Results of the present study have shown that the pictograms improved the comprehension of more complex information<sup>[21]</sup>. The findings of the above studies supports the findings of the present study showing an influence of leaflets complimented with education in improving awareness about their disease, signs and symptoms and other life style modifications.

The information leaflets in the present study met the minimum readability and design criteria scores

meeting the patients' education and comprehension. It was also observed that pharmacist provided patient education with information leaflets has a significant ( $P < 0.0001$ ) impact on KAP of the patients from diabetes mellitus, hypertension, asthma, peptic ulcer and angina towards their disease management showing the usefulness of patient information leaflet.

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