

# Assessment of Patient Information Leaflets Usefulness in Selected Chronic Diseases - A South Indian Based Study

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## ABSTRACT

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**Objective:** To develop and assess the usefulness of patient information leaflets.

**Methods:** Flesche Reading Ease (FRE) formula and Baker Able Leaflet Design (BALD) criterion and Ensuring Quality Information for Patients (EQIP) questionnaire was applied to assess readability, layout and design characters and information quality in the developed leaflets. Knowledge, Attitudes and Practices (KAP) questionnaire was applied to assess patient's knowledge at pre and post administration of leaflets. Patient Information Leaflet Usefulness Assessment Questionnaire (PILUAQ) was applied to assess the usefulness of leaflet.

**Results:** Readability scores of disease information leaflets was found standard (55%) to fairly easy (45%) and standard (15%) to easy (85%) for drugs. All leaflets met the design characteristics. The EQIP Score of the leaflets was found to be 71%. The post education KAP scores were significantly ( $P < 0.05$ ) improved in all patients and in all disease categories. PILUAQ results suggest that the leaflets were found useful.

**Conclusion:** The study concludes that developed PILs have met the good readability and design characteristics and EQIP score. PILs have improved the post PIL administration KAP scores and usefulness.

**Practice Implications:** Information leaflets should contain the adequate information, meet the readability and design characteristics and useful to the patients.

**Keywords:** Patient Information Leaflet, Readability, Layout and Design, PIL usefulness Assessment Questionnaire

## Introduction

Patient education has been defined as a systematic process of providing information, advice and behavioural modification techniques to improve the patient's ability to make informed decisions regarding their disease and medication.<sup>1</sup> Due to the increasing complexity of care, shorter hospital stays and a shift towards outpatient care there is a need for quality patient education. The main objective of patient education is to inform people about the disease, non-pharmacological and pharmacological prevention strategies and to improve understanding of disease management.<sup>2</sup> Patient education is also required to motivate patients to modify lifestyle factors that may contribute to deterioration of their current health status.<sup>3</sup> Due to high patient numbers, hospital doctors often give brief information to their patients regarding the disease and medication use. Patients may not retain such verbal information given by their doctors for longer time periods. Studies suggest that patients may retain only 20% of the information given by their doctors. However It has been observed that when verbal counseling is complemented with visual or written material, patients may remember up to 50%

of the information.<sup>4</sup> Print materials convey basic but essential information and therefore assist patients to update their knowledge at their convenience. Print materials can serve as valuable tools to educate patients and maximize their understanding. When used effectively, print materials enable patients to develop disease management skills and help them to manage their health better.<sup>5</sup>

Information is most essential for those who are diagnosed with chronic and complex diseases such as diabetes, hypertension, asthma, angina, rheumatoid arthritis, chronic kidney disease and peptic ulcer etc. This is because the effective management of these diseases necessitates a large component of self-care which includes changes in the diet, lifestyle modifications, medication adherence etc. Several studies have shown that lack of knowledge in patients with these diseases means that patients may not be able to manage their disease, due to inadequate information they receive.<sup>1,6</sup>

Educational level is an important parameter in the preparation of information leaflets because written information is helpful only if it can be read and understood by the patient.<sup>7</sup> Limited literacy is widespread but often a hidden problem. There are published reports highlighting the importance of good readability and design scores in information leaflet for improved acceptance by patient. It was also found that in an English speaking country like America, the majority of Americans have reading and comprehension skills below

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fifth grade level.<sup>8</sup> These facts must be given consideration while preparing print materials. Patients must have a basic understanding about the risks and benefits of their prescribed medicines to take them safely and appropriately. It is very important to provide quality information in the leaflet that not only meets the needs of the patients, but also satisfies the prescribers and other health care professionals.<sup>9</sup> Drug information on labels and inserts is a major source of knowledge for patients as they attempt to balance the risks and benefits of medications and use them safely. But this information is often difficult for patients to read and understand. Readability is an important criterion while developing the information leaflets. Standard readability formulas such as Flesch Reading Ease (FRE), Flesch Kincaide grade level (FKG) and SMOG formula are often used to assess the readability of developed information leaflets. Layout and design characteristics contribute to readability of information leaflets by patients.<sup>10</sup> The present study was conducted to evaluate the information quality, readability, layout & design characteristics of patient information leaflets for a range of selected diseases and medicines, and usefulness of the leaflets to patients with these diseases.

## METHODS

**Background :** The study was conducted at JSS Hospital, a 1200 bed South Indian tertiary care teaching hospital located in Mysore city. The daily out patients registrations are around 2400 with daily in patient admission of 250 patients. The study was a prospective study conducted for a period of nine months and was approved by the institutional ethics committee. The research pharmacist recruited the patients suffering with the selected chronic diseases from out-patient clinics of Medicine department. The pharmacists on OPD duty provided the medication counseling to the recruited patients and also provided the information leaflets.

**Preparation of patient information leaflets:** Pharmacists used text books, compendia and internet resources to prepare the leaflet content. An expert team including physicians and clinical pharmacists validated the information content to be given in the proposed leaflet. Linguistic experts from Central Institute of Indian Languages (CIIL), Mysore translated the leaflets to the locale language (Kannada) and back translation was also done for translation validation.

**Evaluation tools:** The quality of the information in the prepared leaflets was assessed by using a 20 item Ensuring Quality Information for Patients (EQIP) questionnaire [9]. Scoring of EQIP is done by using the given formula:

$$((\text{Yes} \times 1) + (\text{Partly} \times 0.5) + (\text{No} \times 0) / 20 - \text{Does not apply}) \times 100 = \% \text{ score}$$

Readability and layout of the prepared leaflets was assessed by using the Flesch Readability Ease (FRE) formula and Baker Able Leaflet Design (BALD) Criteria [11]. Flesch Readability

Ease (FRE) formula predict reading difficulty without the need for validation by sample of readers. The analysis is based on the average sentence length (in words) of selected samples and the average word length measured by syllables per 100 words of the sample. These two variables are combined to yield a Flesch Reading Ease Score (FRE).

$$RE = 206.835 - 1.015 SL - 0.846 WL$$

Where RE is the reading ease scores, SL is the average sentence length in words, and WL is the average word length measured as syllables per 100 words.

Baker Able Leaflet Design (BALD) criteria are used commonly to assess the layout and design of various patient package inserts (PPI). Baker Able stressed on length of line (50-80mm) separation between lines, (>2.8mm) unjustification of lines, Serif type face, type size (>12 point) indenting of first line, lower case titles, words in italics, (0-3 words) positive advice, standard headings, numbers in Arabic, boxed text (0-1 Box). Apart from these specifications, Baker Able added three more important criteria in the design of leaflet. They are number of colors used, (4 colors) amount of white space (% of page area, Eg. Cm2, >40%) and paper quality (>90 gsm).

A 5-Item Patient Information Leaflet Usefulness Assessment Questionnaire (PIL UAQ) was developed to assess the usefulness of the PILs. A 3 point Likert scale was applied to score the usefulness of the information leaflet. Maximum score is 10 and minimum score is 0 in the questionnaire.

A 10 item Knowledge, Attitude and Practice (KAP) Questionnaire was prepared and applied on enrolled eligible patients to assess the pre and post usefulness of the information leaflets on knowledge, attitudes and practices. Patients satisfying the inclusion criteria (adult, literate patients with minimum of secondary school education) were enrolled into the study after obtaining their written informed consent. Demographic details, medical history, medication details, and diagnosis were obtained in a suitably designed data collection form. At baseline the patient's knowledge, attitude and practices were assessed through the KAP questionnaire. Subsequently disease and medication related counseling was provided to the patients enrolled in selected disease categories and an information leaflet in Kannada was also provided regarding the disease and medications used for treating the disease. All the enrolled patients were followed up after a month from the date of enrolment and education. Post education knowledge, attitude and practice was assessed by reapplying the KAP questionnaire and usefulness of PIL was assessed using the PIL UAQ.

**Evaluation methods:** All the collected data was subjected for evaluation. A senior clinical pharmacist supported in the evaluation of data.

## RESULTS

**Information quality:** Quality information in EQIP questionnaire score was found to be 71.4% for the disease information leaflets and 71% for the medicines information leaflets.

**Readability & Design:** The readability and layout and design scores of developed information leaflets were found between standard (55%) to fairly easy (45%) for diseases and standard (15%) to easy (85%) for medicines. All leaflets met the design characteristics. The results are presented in table 1.

**Knowledge, attitudes and practices:** Significant improvement in KAP scores was observed in patients in selected disease categories who received information leaflets along with education. The details are presented in Table.2.

**Usefulness assessment:** The developed information leaflets were assessed for usefulness using PIL UAQ which is a 5 item questionnaire. The results suggest that 78.5 % of the study population found that the amount of information provided in the leaflets was adequate, and 48.5 % respondents found that the information provided was very useful. Regarding the readability of the leaflets, 63% of respondents stated that the leaflet was very easy to read and 52.5% respondents found that the content in the leaflet was easy to understand and 54 % found that the leaflet was very useful for them to understand their disease condition. The results are presented in table 3.

## DISCUSSION

It is well known that patients tend to forget most of the information given by their doctors once they leave the consultation room. Studies have also corroborated that written information complements verbal instructions and motivates patients to update their understanding at their leisure, and supports them to improve their medication adherence behavior.<sup>11</sup>

An ideal information leaflet should contain adequate health

**Table 1: Readability and design scores of disease information leaflets.**

| Disease                               | Flesch Reading Ease | BALD Mean score |
|---------------------------------------|---------------------|-----------------|
| Hypertension                          | 68                  | 25              |
| Peptic ulcer                          | 71.1                | 25              |
| Diabetes mellitus                     | 67.9                | 25              |
| Angina                                | 70.1                | 25              |
| Asthma                                | 65.8                | 25              |
| Chronic Kidney Disease                | 76.5                | 25              |
| Chronic Obstructive Pulmonary Disease | 70.8                | 25              |
| Gastro Esophageal Reflux Disease      | 63.2                | 25              |
| Rheumatoid Arthritis                  | 68.8                | 25              |
| Stroke                                | 70                  | 25              |
| Tuberculosis                          | 68.3                | 25              |

**Table 2: Readability and design scores of information leaflets on medicines.**

| Drug   | Fre Score | Bald Score |
|--|-----------|------------|
| Clopidogrel  | 73.2      | 25         |
| Warfarin   | 69.5      | 24         |
| Aspirin  | 73.8      | 25         |
| Aspirin+clopidogrel  | 72.5      | 25         |
| Atorvastatin   | 83        | 25         |
| <b>Drugs used in Rheumatoid Arthritis</b>  |           |            |
| Methotrexate   | 71.1      | 25         |
| Prednisolone   | 76.6      | 25         |
| <b>Drugs used in Hypertension &amp; Cardiovascular Diseases</b>                  |           |            |
| Amlodipine   | 73.7      | 25         |
| Atenolol   | 73.5      | 25         |
| Bisoprolol   | 73.4      | 24         |
| Digoxin  | 70.5      | 24         |
| Isosorbide   | 76        | 24         |
| Metoprolol   | 75.3      | 25         |
| Ramipril   | 76.5      | 25         |
| Carvedilol   | 73        | 24         |
| Diltiazem  | 75.1      | 24         |
| Prasugrel  | 77.8      | 25         |
| Ranolazine   | 74.6      | 24         |
| Trimetazidine  | 76.7      | 25         |
| Aspirin+Atorvastatin   | 76        | 25         |
| Amlodipine+Atenolol  | 71        | 25         |
| <b>Drugs used in Gastro Esophageal Reflux Disease &amp; Peptic Ulcer Disease</b> |           |            |
| Pantoprazole   | 76.8      | 25         |
| Rabeprazole  | 76        | 25         |
| Ranitidine   | 76.7      | 25         |
| Sucralfate   | 81        | 25         |
| <b>Drugs used in Diabetes</b>  |           |            |
| Glimepiride  | 60.5      | 25         |
| Metformin  | 69.1      | 25         |
| Metformin+ Glimepiride   | 63.2      | 24         |
| <b>Drugs used in Chronic Kidney Disease</b>                                      |           |            |
| Furosemide   | 70.9      | 25         |
| Hydrochlorothiazide  | 67.3      | 24         |
| Metolazone   | 71.1      | 25         |
| Spiranolactone   | 72.4      | 25         |
| Torsemide  | 73        | 24         |
| Torsemide+ Spiranolactone  | 70.8      | 24         |
| <b>Drugs used in Asthma &amp; COPD</b>   |           |            |
| Budesonide   | 73.5      | 25         |
| Formoterol   | 75        | 25         |
| Ipratropium  | 74.5      | 25         |
| Salbutamol   | 76.2      | 25         |
| <b>Drugs used to treat Tuberculosis</b>  |           |            |
| Anti Tubercular drugs  | 74.9      | 24         |

**Table 3: Demographic details of enrolled patients**

| Disease              | Age<br>(average) | Gender |        | Education level |           |                |            |
|----------------------|------------------|--------|--------|-----------------|-----------|----------------|------------|
|                      |                  | Male   | Female | Primary         | Secondary | Pre-university | University |
| Diabetes             | 55.8             | 55%    | 45%    | 59%             | 34%       | 2 %            | 5%         |
| Hypertension         | 59.4             | 51%    | 49%    | 66%             | 27%       | 3%             | 4%         |
| COPD                 | 59.6             | 96%    | 4%     | 60%             | 26%       | 6%             | 8%         |
| Asthma               | 53.4             | 40%    | 60%    | 50%             | 30%       | 10%            | 10%        |
| Tuberculosis         | 42.3             | 90%    | 10%    | 20%             | 40%       | 20%            | 20%        |
| GERD                 | 41.3             | 72%    | 28%    | 28%             | 14%       | 26%            | 28%        |
| Peptic Ulcer         | 50.2             | 80%    | 20%    | 45%             | 30%       | 15%            | 10%        |
| Stroke               | 54.15            | 75%    | 25%    | 7.5%            | 30%       | 7.5 %          | 15%        |
| CKD                  | 50.3             | 74%    | 26%    | 40%             | 36%       | 14%            | 10%        |
| Angina               | 53.4             | 65%    | 35%    | 35%             | 35%       | 15%            | 15%        |
| Rheumatoid Arthritis | 53.75            | 10%    | 90%    | 50%             | 15%       | 20%            | 15%        |

related information, be easily readable and have good design characteristics which assist patient learning. Researchers in previous studies have noted that PILs are generally prepared by highly educated people and the information given is typically complex, which may lead to patients finding it difficult to comprehend.<sup>7</sup> Thus it is essential to subject the prepared content for readability assessment. A readability formula is a simple method to predict the reading grade level required to comprehend written materials and documents. The FRE formula is commonly used to assess readability. Any leaflet which scores more than 70 out of 100 is considered as fairly easy to read.

In the present study, five (45.45%) information leaflets in the disease category scored more than 70, and the remaining six (54.54%) were in the range of scores which are also considered as acceptable scores. The low score of these six leaflets is due to complex medical terminology that cannot be

**Table 4: KAP scores in selected diseases**

| Disease              | KAP score  | KAP score | Significance |
|----------------------|------------|-----------|--------------|
|                      | Before PIL | After PIL |              |
| Diabetes             | 20         | 71        | p=0.000002   |
| Hypertension         | 21         | 76        | p< 0.05      |
| COPD                 | 24.6       | 74.75     | p<0.05       |
| Asthma               | 24.48      | 82.68     | p=0.00000002 |
| Tuberculosis         | 24         | 80.5      | P<0.05       |
| GERD                 | 28.2       | 79.56     | p=0.00000002 |
| GERD                 | 28.2       | 79.56     | p=0.00000002 |
| Peptic ulcer         | 21.66      | 82.41     | p<0.05       |
| Stroke               | 23.16      | 79.42     | p=0.0000007  |
| CKD                  | 26.8       | 79.3      | p<0.05       |
| Angina               | 27.35      | 84.28     | p< 0.05      |
| Rheumatoid Arthritis | 25.4       | 82.3      | p=0.00000002 |

**Table 5: Scores of PIL Usefulness Assessment Questionnaire**

| Questions                               | Number answered | Average |
|---|-----------------|---------|
| <b>Amount of information</b>            |                 |         |
| Too much                                | 39              | 19.5 %  |
| Adequate                                | 157             | 78.5 %  |
| Too little                              | 4               | 2%      |
| <b>Usefulness of the information</b>    |                 |         |
| Very useful                             | 97              | 48.5 %  |
| Useful                                  | 91              | 45.5 %  |
| Not useful                              | 12              | 6 %     |
| <b>Readability of the leaflet</b>       |                 |         |
| Very easy                               | 126             | 63 %    |
| Easy                                    | 72              | 36 %    |
| Very Difficult                          | 2               | 1 %     |
| <b>Understandability of the content</b> |                 |         |
| Very Easy                               | 85              | 42.5 %  |
| Easy                                    | 105             | 52.5 %  |
| Very Difficult                          | 10              | 5 %     |
| <b>Usefulness of the PIL</b>            |                 |         |
| Very useful                             | 108             | 54 %    |
| useful                                  | 61              | 30.5 %  |
| Not useful                              | 31              | 15.5 %  |

replaced with an easy word. In case of medication PILs, 34 medications PILs achieved easy to comprehend scores, and the remaining leaflets achieved standard scores (FRE Score 60-70). The low FRE score for medication information leaflets was partly due to complex drug names which contain many syllables that reduce the readability score. A report published in the American Medical Association Journal (1995) noted that 42% of the respondents were unable to comprehend information material. This indicates the need for making leaflets easily readable. To use simple words in the preparation of leaflets, a dictionary of medical and lay terms in the local language would be valuable.

The Baker Able Leaflet Design (BALD) criteria were applied to assess the design characteristics of the PILs. As per the BALD criteria, a leaflet scoring in the range of 20-25 (32 is the total score) is considered to have good layout and design characteristics. All the PILs developed for the present study scored between 24-25 and met the BALD criteria.

Leaflet design is an important quality of a good information leaflet. As per Kitching,<sup>12</sup> line length between 50-89 mm long, separation of lines by 2.5 mm, serif type face with 12 font size, and pictograms improve the design characteristics and patient satisfaction. Thus efforts were made to prepare well-designed leaflets meeting the BALD criteria.. Incorporation of pictograms in the PILs helped the respondents to recall the information such as causes of the diseases, symptoms, diet and lifestyle modification. The same was reflected in patient responses while answering the KAP questions.

Patients enrolled in the study had a mixed educational background. Many patients were from school and pre university educational levels. Most of the patients were farmers or from business. The pre and post education scores were analyzed with the time gap of one month. Analysis of KAP pre and post education suggests that a significant improvement in post KAP scores occurred in all disease categories. This suggests the positive influence of information leaflets when complemented along with oral instructions. In a study conducted by Hawkey and Hawkey, it was observed that patients with gastrointestinal diseases who received information leaflets found that, the leaflet was helpful in recalling the disease related information and side effects of medicines.. A significant improvement in knowledge scores was observed in patients who received information leaflets compared to patients who did not received the leaflet.<sup>13</sup> In another randomized control study conducted by Carre et al to study the influence of patient information leaflets on knowledge attitudes and practices in COPD patients, the findings have suggested the positive influence on the final KAP scores supporting the usefulness of leaflets on KAP improvement.<sup>14</sup>

The influence of confounding factors such as age, education and gender on KAP scores was also studied. Participants with pre university and university education levels showed a greater positive impact on Knowledge, Attitude and Practice regarding disease management and lifestyle modifications. Same was reflected in KAP scores of various diseases. Increased age of the participants has shown a negative impact on results, possibly a result of age related memory impairment and multiple disease states.

The developed information leaflets were assessed for usefulness using the PILUAQ which is a 5 item questionnaire. The results of PILUAQ suggest that 78.5% of the study population found the amount of information provided in the

leaflet was adequate. About 48.5% respondents found information provided was very useful and 63% of respondents stated that the leaflet was very easy to read. About 52.5% respondents found that the content in the leaflet was easy to understand and 54% found that the leaflet was very useful to them in understanding about their disease condition. Usefulness assessment is a psychological parameter assesses the individuals' acceptance of PIL using various criteria. A position paper published by the Co-ordination group on Mutual recognition and Decentralised applications (CMDh), an European agency suggests that the developed PILs should be subjected for user testing to optimize the leaflet for content and design elements and identification of key messages for safe and effective usage [15]. In a UK based study, the usefulness of an information leaflet in coronary heart disease (CHD) was assessed. The majority of respondents (94%) said the content was useful for them and their family members in controlling the disease state. This finding supports need for assessment of usefulness of PILs to the patients.<sup>16</sup>

## CONCLUSION

Patient information leaflets can contribute to better patient understanding of chronic disease and its treatment. Information leaflets developed by pharmacists can play an important role in improving patient understanding not just of medications, but of disease conditions. It was also observed that pharmacist provided patient education together with information leaflets had a significant ( $p < 0.05$ ) impact on knowledge, attitude, and practice of the patients towards their disease management. The developed leaflets were found to be very useful by patients.

## PRACTICE IMPLICATIONS

To be useful, patient information leaflets must meet criteria associated with quality of information, readability, layout and design. The quality of information should be updated on a yearly basis and patients with the disease should provide feedback on the usefulness of information. A dictionary of medical terms translated into lay terms in local languages is needed.

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## REFERENCES

1. Ferran Pellise, P Sell. Patient information and education with modern media. The spine society of Europe patient line. *Eur Spine J* 2009;18(3):S395-S401.
2. Finset A. Patient education and counselling in a changing era of health care. *Patient Educ Couns* 2007; 66:2-3.
3. Chris F. What are the goals of patient education? *West J Med.* 2001;174:173-4.
4. Kenny T, Wilson RG, Purves IN, Clark J, Newton LD, et al. A PIL for every ill? Patient information leaflets (PILs): a review of past, present and future use. *Family Practice* 1998; 15:471-79.
5. Shrank WH, Avorn J. Educating patients about their medications: The potential and limitations of written drug information. *Health Affairs* 2007; 26:731-40.
6. Hill J and Bird H. The development and evaluation of a drug information leaflets for patients with rheumatoid arthritis. *British Society for Rheumatology* 2003; 42:66-70.
7. Baker SJ. Who can read Consumer Product Information? *Australian Journal of Hospital Pharmacy* 1997; 27(2): 126-31.
8. Mallet L, Spruill WJ. Readability Evaluation of Nine Patient Drug Education Sources. *American pharmacy* 1988; NS28 (11): 33-6.
9. Moul B, Franck LS, Brady H. Ensuring quality information for patients: development and preliminary validation of a new instrument to improve the quality of written health care information. *Health Expect.* 2004 Jun;7(2):165-75.
10. Adepu R, Nagavi BG. Patient information leaflets design and Readability. *The Pharma review* Dec 2003:135-43.
11. DA Fitzmaurice and JL Adams. A systematic review of patient information leaflets for hypertension. *J Human Hypertension.* 2000;14: 259-62.
12. Kitching JB. Patient information leaflets – the state of art. *J R Soc Med* 1990;83:298-300.
13. G M Hawkey and C J Hawkey. Effect of information leaflets on knowledge in patients with gastrointestinal diseases. *Gut* 1989;30:1641-6.
14. Philippe CC, Nicholas R, Françoise N et al. The effect of information leaflet upon knowledge and awareness of COPD in potential sufferers *Respiration* 2008;76:53-60.
15. Position paper on user testing of patient information leaflet. *CMDh/234/2011.*, 2013.
16. Paul Wilson, Amanda J S, Ian Watt, Liz Newbronner and Chris Acton. Involving patients in effective health care. , 2013.