



## Study to Assess the Utility of Cloze test in Readability Assessment of Patient Information Leaflets in English and Indian Languages

Surulivelrajan M<sup>1</sup>, Mathew Joy<sup>1</sup>, Suhaj A<sup>1\*</sup>, RajeshV<sup>1</sup>, Mohan K Manu<sup>2</sup>

<sup>1</sup> Dept.of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal University, Manipal.

<sup>2</sup> Dept.of Pulmonary Medicine, Kasturba Medical College & Hospital, Manipal University, Manipal.

### ARTICLE HISTORY

Received: 11.08.2013

Accepted: 16.09.2013

Available online: 10.11.2013

### Keywords:

Patient Information Leaflet, Cloze test, readability.

### \*Corresponding author:

Email : a.suhaj@gmail.com

Tel : +91-8202922403

### ABSTRACT

Patient education is one of the major management strategies for curing or preventing the progression of many diseases. Patient Information Leaflets (PILs) are major patient counseling aids. Readability is an important issue of communication with PILs and there is a need to assess the readability of tools prepared in Indian languages. Patient Information Leaflet for tuberculosis was prepared in English language. The prepared leaflets were then translated to Malayalam and Kannada. Cloze test was identified as a possible test for assessing readability of leaflets in English, Kannada and Malayalam. Cloze test was performed in 16 volunteers for each language. Layout and design of the leaflet was assessed using BALD assessment. The results showed that an increase in scores with increasing length of regularly deleted words in Cloze test. Kannada leaflets were found to be easier with increasing regularly deleted words whereas in Malayalam sixth word removal did not improve scores. Volunteers participated in Cloze test for all versions of leaflets, scored above 60%, which is considered to be readable and understandable by readers. BALD assessment score for the designed PILs for English, Malayalam and Kannada were 30, 27 and 28 respectively. Cloze test was able to discriminate between tough and easier versions of leaflet irrespective of the language. It can be concluded that the cloze test might be useful in assessing the readability of Indian language leaflets. BALD scores were assessed for all the prepared leaflets and showed that all of them had better score.

### INTRODUCTION

Communication between health care providers and patients is an important aspect of patient care process. Proper communication helps to improve overall outcome of healthcare process. Even though the consultation is regarded as the cornerstone of medical practice, there has been accumulating evidence that the communication process is often unsatisfactory for patients [1]. It is well known that patients forget or misunderstand much of what is discussed during a consultation. This was identified as early as 1972 and seems to be an ongoing challenge for physician patient relationship.

The studies showed that on average patients had forgotten half of what the doctor had told them with in 5 minute of leaving the consultation room. In general people may only retain about 20% of what they hear, but this may increase up to 50% if there is additional visual or written input [2]. Though there are patient

education materials on video, audio, and in internet modes, the 'humble leaflet' remains the most widely used methods for conveying health related information [3]. Over the last few decades a voluminous literature has been accumulated regarding the use and characteristics of printed health education materials or 'Patient Information Leaflets' (PILs) [4]. Lack of information has been identified as a major factor for the patients not taking their medicines as the prescriber intends. Patients for whom medication is prescribed must understand how to take each drug correctly. Patient counseling and the provision of educational material in the form of PILs have been shown to be effective in improving patients' knowledge, compliance and the awareness of their potential side-effects [5].

Readability can be defined as: "...the efficiency with which a text can be comprehended by a reader, as measured by reading time, amount recalled, questions answered, or some other quantifiable measure of a reader's ability to process a text..." [6].

There are more than 50 formulae intended to predict the level of reading ability needed to understand a particular piece of prose [2]. In 1953, Taylor proposed using deletion tests called Cloze tests for measuring an individual's understanding of a text. Cloze testing is on the theory that readers are better able to fill in the missing words as their reading skills improve. A Cloze test uses a text with regularly deleted words and requires the subjects to fill in the blanks. The percentage of words correctly entered is the Cloze score [7].

Readability is an important issue of communication in healthcare. There are requirements in some countries to provide patient information leaflets with suitable readability levels to the consumers. Readability issues have to be studied in corroboration with the opinion of end users. PILs are generally available in English. Various methods are available to evaluate the readability of those PILs. Even though in some cases PILs are translated into Indian languages, their readability cannot be assessed using standard formulae available for English. There is a need to identify some methodology to evaluate readability of PIL in Indian vernacular languages. It is also equally important to subject prepared leaflets to user testing in patients who can read local languages for assessing its acceptability by them. The present study was planned to assess the utility of cloze test in assessing the readability of tuberculosis prepared in English and some Indian languages like Kannada and Malayalam.

## METHODOLOGY

The study was planned as prospective study with participation of volunteers to validate the developed patient information leaflets. Institutional ethics committee's approval was obtained before commencement of the study. Based on the available literature and drug data bases a patient information leaflet on tuberculosis was prepared. The content was validated with the help of experienced physicians and clinical pharmacists.

Readability assessment was carried out using FRE & FK-GL scoring system. Based on the scores of these assessments, the contents were improvised to attain better readability scores. The leaflets were translated into local languages like Kannada and Malayalam after attaining optimal readability scores with English leaflets. To check the consistency of translated material, translated leaflet was then back translated to English from Kannada and Malayalam by language experts. The back translated and original versions of leaflets were reviewed by a set of two experts to find out the difference between the versions.

Volunteers who were willing to participate were enrolled into the study after getting their consent. Volunteer who doesn't know any of the three languages mentioned were excluded from the study. These volunteers were provided with various versions of the leaflets prepared and asked to answer standard questions from their understanding of the leaflets.

Cloze test was identified as a suitable test for assessing the leaflets irrespective of the language. Performance of Cloze test involves preparing various versions of leaflet with missing words. The words were removed in particular sequence like removal of either fourth, fifth or sixth words in sequence to assess the level of comprehension with these leaflets. Cloze tests results were compared to find out the version which was easy to comprehend. When the words were removed from the leaflets each version had different number of word removals from each version and for each language. So, all the leaflets had different totals to score. Cloze test scores were calculated as percentages based on the total score for the specific version. After cloze tests,

the leaflets were modified further to improve the comprehensibility of the leaflets. The prepared leaflets were finally assessed using BALD scoring system to assess the layout and design of the leaflets [8]. Modifications like Font, alignment, Use of pictures and use of good quality paper were carried out for best BALD score. The process of development and validation of leaflets is presented in the figure 1.

## RESULTS

The PIL was prepared based on various literatures and subjected to readability assessment tests and used for further cloze tests with the help of volunteers.

### *Assessment of readability using FRE and FK-GL scores*

Readability of the leaflet was assessed using FRE and FK-GL scores. After assessment leaflets were modified to improve the readability scores and assessed further after modification. The best FRE score achieved was 78.1 and FK-GL score achieved was 4.5. Both scores rate the leaflet as "fairly easy".

### *Translation of leaflets to Malayalam and Kannada and Validation of translated material*

The prepared English leaflet was translated to Malayalam and Kannada languages. Back translation process carried out for the validation also resulted in a leaflet with similar to the original version. Comprehension assessment by language experts also showed that the prepared leaflets had better comprehension.

### *Performance of Cloze test in three languages among volunteers*

English, Malayalam and Kannada leaflets were subjected to Cloze test. For performance of Cloze test three sets of leaflets like the fourth word removal, fifth word removal and sixth word removal were prepared. These leaflets were tested in volunteers. The results are presented

#### *Cloze test scores*

Cloze test scores of all volunteers in all three languages were documented. English language scores were 75.48% for the 4<sup>th</sup> word removal version, 78% for the fifth word removal version and 82.32% for the sixth word removal version. The scores improved with increasing order of word removal series. Malayalam Cloze test scores of all volunteers were 66% for the 4<sup>th</sup> word removal version, 68.37% for the fifth word removal version and 60.57% for the sixth word removal version. The scores of 5<sup>th</sup> word removal series were higher compared to the 4<sup>th</sup> word removal, but the scores of 6<sup>th</sup> word removal was less than that of the 4<sup>th</sup> word removal.

Kannada Cloze test scores of all volunteers were 76.83% for the 4<sup>th</sup> word removal version, 81.25% for the fifth word removal version and 84% for the sixth word removal version. The scores improved with increasing order of word removal series. Results of Kannada cloze tests showed results similar to that of English cloze tests. The results are presented in Table. 1.

### *Assessment of BALD score and necessary modifications*

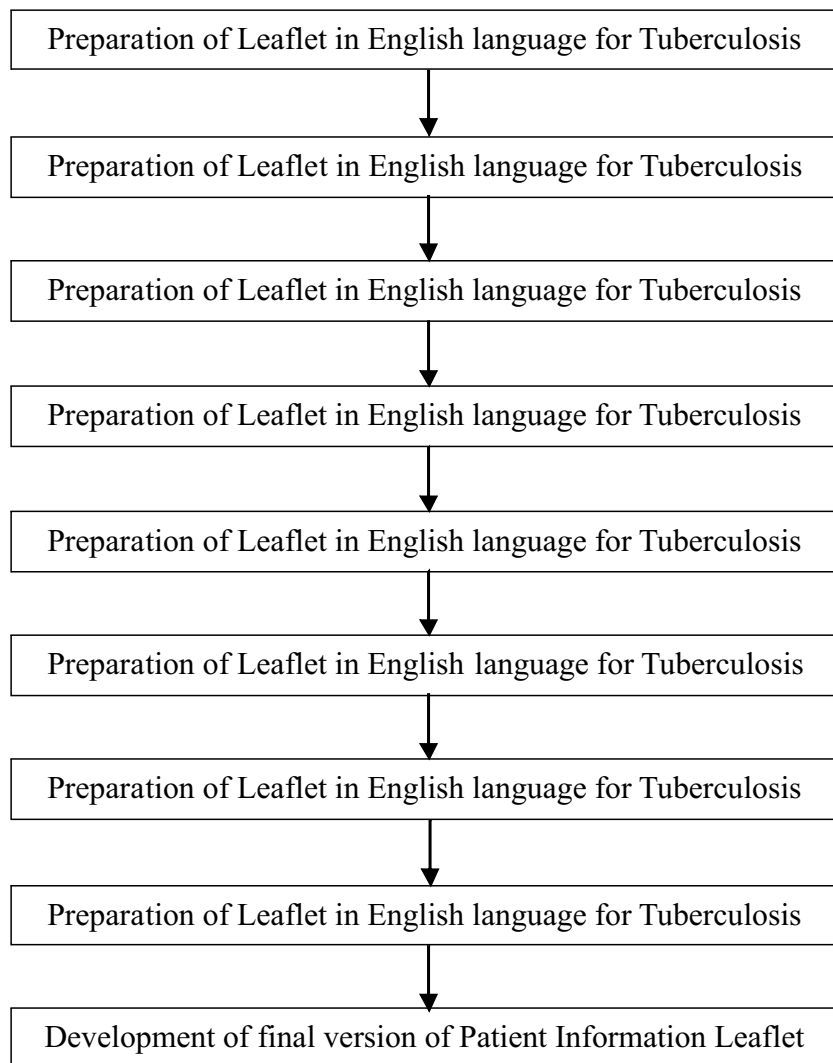
Baseline BALD score was assessed for the leaflet and modifications were made in layout and design of the leaflet and relevant pictures were included to improve the score. The final BALD assessment score for Designed English was 30. The maximum possible BALD assessment score is 32. Similarly BALD assessment score for Designed Patient Information Leaflet for Malayalam and Kannada was 27 and 28 respectively.

**Table 1:** Individual scores of 4th, 5th and 6th word removal versions of all languages. Performance of Cloze test in three languages among volunteers

Volunteer No.	English			Malayalam			Kannada		
	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>
1	25	18	28	19	19	16	33	21	24
2	26	17	25	19	17	16	30	25	24
3	18	19	25	14	21	17	27	21	26
4	20	15	19	20	22	15	26	27	28
5	21	23	24	19	16	14	27	30	22
6	18	18	23	20	20	14	27	22	21
7	23	20	26	17	19	14	27	19	24
8	22	24	26	16	11	19	25	22	24
9	18	20	24	18	21	19	29	24	25
10	17	21	25	15	19	13	26	21	23
11	18	23	23	21	27	16	25	23	22
12	17	18	21	16	26	16	28	21	27
13	22	18	25	20	20	16	31	21	19
14	21	16	25	14	18	19	24	25	29
15	15	20	23	22	16	13	27	22	21
16	13	22	20	17	22	15	28	24	27
<b>Average score</b>	19.63/ 26	19.50/ 25	23.88/ 29	18/ 27	19.83/ 29	15.75/ 26	27.5/ 36	23/ 28	24/ 28
<b>Score in percentage</b>	75.48	78	82.32	66	68.37	60.57	76.83	81.25	84

**Table 2:** BALD Assessment scores

BALD Assessment	Designed leaflet Score	Conventional leaflet Score
English	30	9
Malayalam	27	12
Kannada	10	10

**Fig 1:** Representative flow-chart depicting preparation and validation of PIL

The BALD assessment scores for Conventional leaflet of English, Malayalam and Kannada was 9, 12 and 10 respectively. BALD Assessment scores are shown in table 2.

## DISCUSSION

Patient information leaflet is remaining one of the important channels of communication as it helps to recollect all the information after the meeting with the health care provider and also it is easy to access unlike other forms of advanced tools like computer and internet based audio-visual aids increasingly used in health care communication [9, 10].

India is a country of many languages and preparing leaflet in every official language with sensibilities of each population group is a major challenge. In India few studies have been carried out regarding the readability and layout aspect of available leaflets and these studies have reported that majority of the available leaflets have poor readability scores and as well as poor layout design [11, 12]. Similar reports are available from other countries also reported that leaflets available at their countries were also prepared for higher grade school level rather than lower school level comprehension. In a study by Estrada et al, it has been reported that 88% of leaflets were written at 9th grade

education level or higher level. This study was planned to assess the utility of cloze test in evaluation of readability of patient information leaflets irrespective of the language it was prepared. [13].

The leaflet for Tuberculosis was prepared and assessed for readability using FRE and FK-GL scores which were in the category of 'fairly easy' after final modification. This level of readability is generally considered to be easy for the patient to understand the contents of leaflet. No other conventional readability tool could be applied to the leaflets which are translated to Indian languages. When this leaflet was translated to Malayalam and Kannada, no standard readability tests could be applied to them as the sentence structure and usage of these languages are different from English. FRE and FK-GL calculates readability based on sentence length and number of polysyllables. These tests assume polysyllables are difficult to understand whereas this might not be true in our languages. More over if the whole passage to be tested is typed in reverse still FRE assigns similar readability scores [6]. This raises the issue of using sentence length formulas to calculate readability.

Translated leaflets were prepared and validated for



consistency. The results showed English and translated leaflets were similar in terms of content. Malayalam and Kannada leaflets were based on the fairly readable English leaflet and it can be assumed that these leaflets might have similar readability. But this assumption needed to be tested. Cloze test was found to be suited for testing leaflets in Indian languages as it uses entirely different approach for testing readability based on comprehension.

Cloze test was performed in volunteers for all three language leaflets. This Cloze test was carried out in volunteers as reports are available that testing of patients' health literacy may stigmatize a patient being tested [14]. The demographical analysis showed that graduates participated more in the study although they were not the target group for final usage. People with lower school level qualifications were somewhat reluctant to participate in the study. Cloze test included series of word removal from fourth word to sixth word removal. These tests showed increase in scores with increasing length of regularly deleted words. The standard procedure is to remove every fifth word but in this study it was attempted to remove fourth word and sixth word to study their effect on comprehension. Malayalam and Kannada showed different results with increasing regularly deleted words which could not be understood. Kannada leaflets were found to be easier with increasing regularly deleted words whereas in Malayalam sixth word removal did not improve scores. Volunteers tested with all versions of leaflets scored above 60% which is considered to be readable and understandable by readers [7]. BALD assessment for designed leaflet as well as conventional leaflet was performed for English, Malayalam and Kannada. Overall BALD assessment scores for Designed leaflets were high compared to Conventional leaflet. User testing was carried out with volunteers to assess the readability, comprehension and as well as their opinion on layout-design. Most of the volunteers aged between 20 to 40 years of age. Most of them were graduates. Scores for content assessment before reading leaflet and after reading leaflet was found to be significantly different demonstrating the applicability of leaflet in improving volunteers' knowledge on Tuberculosis. These results showed the usefulness of leaflets. The improvement observed was significant in case of conventional and as well as designed leaflet. But the overall scores were better than conventional leaflets in case of designed leaflet for Kannada and Malayalam languages. When surveyed for opinion on layout and design, designed leaflets were rated significantly higher than conventional leaflet. Moreover volunteers participated in the study wanted to have a copy of leaflets for them whereas no such requests came for the conventional leaflet. This shows the preference of volunteers and this will predict how the actual usage of leaflet will be there once it is given to patients. It was 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 [15]. When perception of volunteers on layout and design of leaflets were tested, it was found that there is no significant difference in perception on well designed leaflets across all languages. Similarly when conventional leaflets are tested there was no significant difference among leaflets across the languages. This shows that irrespective of the language people's opinion remains same regarding the layout and design of leaflets. A well designed leaflet always rated higher than conventional leaflet. Use of pictures was appreciated both by volunteers and patients. In a study, it was reported most respondents considered the use of symbols and pictograms helpful in finding the required

information [16]. It would be interesting to establish if symbols or picture sequences could have a role in increasing the clarity and comprehensibility of a specific message. Moreover when educational level of leaflet users are low, the pictograms and symbols might significantly augment readability and comprehension of leaflets.

The study showed that testing readability and comprehension in Indian languages is possible. Cloze test was useful in evaluating prepared leaflets in Kannada and Malayalam. User testing of the leaflets is considered as important component of patient leaflet evaluation and recommended by many agencies. These user testing studies gave an idea about the comprehension of leaflets in local languages and also the preference of users on the design and layout of leaflet [17, 18]. The Cloze tests were carried out in 48 volunteers in each language group. It was carried out for 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> word removal. The tests with other versions of word removal such as 7<sup>th</sup> word and 8<sup>th</sup> words might have given a clear insight how far cloze test can help in readability assessment of Indian language leaflets. Most of the study subjects especially volunteers were graduates or further highly qualified and this might seriously hinder the generalizability of the results and the sample size for volunteers and patients was smaller.

## CONCLUSION

PILs were prepared in English and translated into Indian languages like Kannada and Malayalam. English leaflet was subjected to conventional readability and layout assessment tests. Readability of Kannada and Malayalam leaflets was tested using Cloze test. Cloze test scores showed certain versions of Cloze test were comprehensible to patients. Cloze test result showed that this test could pick up readability difficulties of the leaflets. BALD scores were assessed for all the prepared leaflets and showed that all of them had better score. User testing of PILs in volunteers and in patients showed that prepared leaflets were readable and also acceptable to patient in terms of layout-design component. The score of volunteers and patients for the content assessment showed that the leaflets were good enough to impart the needed knowledge to volunteers and as well as patients. When opinion on layout and design was assessed, well designed leaflet received better scores than the conventional leaflet.

It can be concluded that cloze test might be useful in assessing the readability of Indian language leaflets and further studies are also needed to validate the findings of this study. User testing of leaflets has given clear insight regarding the expectations and understanding of the end users and prepared leaflets should be subjected to user testing irrespective of the language. Leaflets with good layout and design were easily accepted by end users.

## ACKNOWLEDGEMENT

The authors wish to acknowledge the Staff of Manipal College of Pharmaceutical Sciences and Kasturba Hospital for their inputs, and also, Manipal University, Manipal, India for having provided with the necessary support.

## REFERENCES

1. McCann S, Weinman J. Empowering the patient in the consultation: a pilot study. *Patient Education and Counseling*, 1996; 27:227-234.
2. Kitching JB. Patient information leaflets -the state of the art. *Journal of the Royal Society of Medicine*, 1990; 83:298-300.

3. Anonymous. The humble leaflet. Available at: <http://www.katesharpleylibrary.net/x0k7h7>. Accessed on: 02 Oct 2013.
4. Gal I, Prigat A. Why organizations continue to create patient information leaflets with readability and usability problems: an exploratory study. *Health Education Research*, 2005; 20(4):485-493.
5. Gupta U, Sharma S, Sheth PD. Improving medicine usage through patient information leaflets in India. *Tropical Doctor*, 2005; 35:164-166
6. Marnell G. Measuring Readability-Part 1: The spirit is willing but the Flesch is weak. *Southern Communicator*, 2008;15: 18.
7. Dubay WH. The principles of readability. *Impact Information* [Online].2004; Available at: <http://www.impact-information.com/impactinfo/readability02.pdf>. Accessed on: 7 Jan 2013.
8. Baker SJ. Who can read Consumer Product Information? *Aust J Hosp Pharm*, 1997; 27: 126-131
9. Frederikson LG, Bull PE. Evaluation of a patient education leaflet designed to improve communication in medical consultations. *Patient Education and Counseling*, 1995; 25:51-57.
10. Kenny T, Wilson RG, Purves IN, Clark J, Newton LD, Newton DP, Moseley DV. 'A PIL for every ill? Patient information leaflets (PILs): A review of past, present and future use. *Family Practice*, 1998;15(5):471-479.
11. Adepu R, Nagavi BG. Assessment of Readability, Layout and Design of selected patient information PILs. *Indian Journal of Pharmaceutical Education*, 2004; 38: 93-97.
12. Rajesh V, Jisha BK, Arul KSG, Surulivelrajan M. Assessment of Readability and Layout-Design of Patient Information Leaflet by Standard methods and Patient perception in a Tertiary care hospital in South India. *Indian Journal of Hospital Pharmacy*, 2008;45:62-66.
13. Estrada CA, Hryniewicz MM, Higgs VB, Collins C, Byrd JC. Anticoagulant Patient Information Material Is Written at High Readability Levels. *Stroke*, 2000; 31:2966-2970.
14. Paache-Orlow MK, Wolf MS. Evidence does not support clinical screening of literacy. *J Gen Intern Med*, 2007; 23:100-102
15. Dickinson D, Raynor DK. Ask the patients-they may want to know more than you think. *BMJ*, 2003; 327:861
16. Bernardini C, Ambrogi V, Perioli L, Tiralti MC, Fardella G. Comprehensibility of the package leaflets of all medicinal products for human use: a questionnaire survey about the use of symbols and pictograms. *Pharmacological Research*, 2004; 41:679-688
17. European Commission Guideline on the readability of the labeling and package leaflet of medicinal products for human use. Brussels 2009: European Commission.
18. Sless D, Wiseman R. *Writing about medicines for people: Usability Guidelines for Consumer Medicine Information* (2nd edition). Canberra, 1997, Australian Government Publishing Service.