

Development, Quality and Readability Assessment of Patient Information Leaflet for Diabetes Mellitus

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Abstract

Introduction: Patient health education through information leaflets plays a very important role in the understanding about diseases, drugs and lifestyle modifications in diabetes mellitus.

Aim: To develop and assess the quality and readability of patient information leaflet for diabetes mellitus.

Methods: patient information leaflet for diabetes mellitus was developed by referring to various online resources such as 'Diabetes UK (NHS Lanarkshire)' and other medical websites. The content of the developed leaflet was validated by the physicians and specialist doctors. Feedback from the experts was used to design and modify the leaflet. Readability was checked online by using the website 'www.readability-score.com' and calculated Flesch Reading Ease (FRE) and Flesch-Kincaid grade level (FK-GL). Baker Able Leaflet Design (BALD) Criterion and Ensuring Quality Information for Patients (EQIP) questionnaire was applied to assess layout and design characteristics and information quality in the developed leaflets.

Results: Readability scores by using FRE and grade level by FK-GL was found to be 63.9% and 7.8 which shows that the leaflet was found to be 'standard' and easily understood by 13- to 15-year-old students. The BALD score was 27 rated as 'above standard' and the EQIP score of the leaflet was found to be 70%.

Conclusion: The information leaflet developed in the present study had good quality and standard readability score and layout design. The FRE scores and FK-GL grade level shows that the leaflet was easily understood by 8th and 9th grade school levels.

Keywords: Diabetes mellitus; Patient information leaflet; Readability; Layout and design

Introduction

Diabetes mellitus is a chronic disease leading to short and long-term complications which will affect patients physical, psychological and social well being.

Uncontrolled blood glucose leads to damage of end organs such as kidney, heart, brain and eyes leading to frequent hospitalization, morbidity and mortality. It also increases the healthcare expenditure and negatively affect the patient's quality of life [1,2].

The incidence, prevalence and hospital admissions due to diabetes mellitus are on the rise worldwide with significant impact on the individual and the society. Several studies have reported the positive impact of clinical pharmacist delivered education and counselling including diet and lifestyle modifications on clinical outcomes and improved quality of life in patients with diabetes mellitus. Diabetes control and complication trial (DCCT) and United Kingdom prospective diabetes study (UKPDS) studies have clearly showed that optimal glycaemic control can delay the onset and progression of diabetes mellitus and associated complication [3].

Patient health education plays a very important role in the successful management of chronic diseases. It is defined as 'the process by which healthcare professionals and others impart information to patients that will modify their health behaviours or improve their health status' [4]. Health education can be effective with audiovisual aids. It helps to simply unfamiliar concepts; brings about understanding where the words fail; reinforce learning by different means and provide a dynamic way of avoiding monotony. There is strong evidence that patients overall satisfaction with the treatment will increase if they are supplied with education material with comprehend information and clinical advice. Providing education material on disease, drugs, diet and lifestyle modifications improves not only satisfaction but also patient adherence to treatment recommendations and improves knowledge, attitude and practices to enable patients to self manage the disease [5]. This helps in achieving better therapeutic outcomes and improved quality of life in patients with diabetes mellitus.

Unfortunately most often, patients with diabetes mellitus were not adequately educated regarding the disease. Therefore, providing education through information leaflets could be considered as a way of supplementing health education. But evidence suggests that the readability, layout and design characteristics of health information leaflet matter most while communicating the information for the patients [6]. Standard readability formulas such as Flesch Reading Ease (FRE), Flesch Kincaide grade level (FKG) and simplified Measure of Gobbledygoo (SMOG) formula are often used to assess the readability of developed information leaflets. In the FRE test, higher scores indicated that the content was easier to read, whereas lower scores indicated that the content were difficult to read. The SMOG grade is a readability measure that estimates the years of education required to fully understand a piece of writing. Baker Able Leaflet Design (BALD) method was used to assess the layout and design of the information leaflets. The present study was aimed

to develop, and assess the patient's information leaflets on diabetes mellitus for quality, readability, layout & design characteristics.

Materials & Methods

It was a prospective study carried out in Justice K S Hegde Charitable Hospital, Mangalore for a period of seven months from July 2015 to January 2016. Patient information leaflet was prepared according to the European Commission Guidelines by referring to various diabetes model leaflets which were available from various online sources such as 'Diabetes UK (NHS Lanarkshire)' and other medical websites. The search was also supplemented by gathering information from National Diabetes Education Program and Centre for Disease Control and Prevention (www.cdc.gov/diabetes/prevention) [7]. The developed information leaflets were evaluated for their content and readability before delivering to the patients. The content of the leaflet was validated by physicians and specialist doctors. Recommendations suggested by the experts were incorporated and leaflets were designed accordingly.

Assessment of the quality of the information

The quality of the information in the prepared leaflets was assessed by using a 20 item Ensuring Quality Information for Patients (EQIP) questionnaire. Scoring of the EQIP is done by using the given formula [8].

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

Assessment of FRE score for readability

Readability and layout of the developed leaflets was analysed by using the Flesh Readability Ease (FRE) formula and Baker Able Leaflet Design (BALD) Criteria [6,8]. FRE formula is considered as one of the oldest and most accurate simple approach to assess the grade level of the reader. The readability of the prepared leaflets was calculated using FRE formula.

Flesch Reading Ease Readability Formula is:

$$RE = 206.835 - (1.015 \times ASL) - (84.6 \times ASW)$$

Where RE = Readability Ease

ASL = Average Sentence Length (i.e., the number of words divided by the number of sentences)

ASW = Average number of syllables per word (i.e., the number of syllables divided by the number of words)

The reading scores on FRE scale are 0-100. The scores between 90 and 100 are considered easily understandable by an average 5th grader, between 60 and

70 are considered easily understood by 8th and 9th graders and scores between 0 and 30 are considered easily understood by college graduates. The scores between 60 and 70 is largely considered acceptable.

Flesh – Kincaid grade level

The grade level is calculated with the following formula:
 $FK\text{-}GL = 0.39 (\text{total words}/\text{total sentences}) + 11.8 (\text{total syllables}/\text{total words}) - 15.59$

Baker Able Leaflet Design (BALD) Method

This method is used to assess the layout and design characteristics of the information leaflets. The scores are based on the length of the line, distance between the line, letter font size, graphics used, percent of white space and paper quality. A total score of 25 or more considered as the document with good layout and design.

Results

Assessment of quality: Quality information in EQIP questionnaire for the developed patient information leaflet for diabetes mellitus was found to be 70%.

Assessment of readability: During the preparation of leaflet, readability was assessed by calculating the FRE and FK-GL scores by using the website 'www.readability-score.com' [9]. After assessment leaflets were modified and readability scores were reassessed for improvement after each modification. In the present study, mean FRE score achieved was 63.9 and FK-GL grade achieved was 7.8. These scores suggest that the readability of the information leaflet is 'standard' and the grade level indicates the leaflet is easily understood by 13 to 15 year old students. The Flesch/Flesch – Kincaid readability tests score is shown in the following (Table 1).

Readability formula	Grade
Flesch – Kincaid grade level	7.8
Flesch – Kincaid reading ease	63.9
Gunning fog score	10.2
SMOG index	7.7
Automated readability index	7.5
Coleman – Liau index	11.7
Average grade level	9

SMOG: Simplified measure of gobbledygook
 Table 1: Flesch/Flesch – Kincaid readability tests score.

Assessment of layout and design characteristics: BALD criteria were applied to assess the layout and design

characteristics of the developed information leaflets. According to BALD assessment leaflet showed a total score of 27 (maximum score is 32) which rates the design and layout of the information leaflet as 'above standard'. The Baker Able Leaflet Design (BALD) Assessment Tool is shown in the following (Table 2).

Design characteristics	3 points	2 points	1 point	0 point
Lines 50-89 mm long			Yes	No
Separation between lines	>2.8m m	2.2-2.8mm		<2.2 mm
Lines unjustified			Yes	No
Serif typeface		Yes		No
Type size	12 point	10-11point	9 point	< 9 point
First line indented			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 count not replace	In between	In between	None or superfluous
Number of colours	4	3	2	1
White space	> 40%	30-39%	20-29%	<20%
Paper quality	>90 gsm	75-90 gsm		<75 gsm

Table 2: Baker Able Leaflet Design (BALD) Assessment Tool.

Discussion

Diabetes mellitus is a chronic disease that requires lifestyle modifications and self care practice for the effective management in addition to drug therapy. The increased incidence has drawn the attention of the healthcare professionals to the need of effective

management programmes. Researchers have shown that patients forget or fail to assimilate much of information discussed during their medical consultation. Most of the time the consultations are usually short and plenty of evidence exists that patients don't receive the information they want and need. Providing patient health education through information leaflets and other materials can play an important part in reinforcing information provided by the clinicians and thereby lead to more appropriate and effective use of health care services [10,11].

The designed and validated information leaflet covered various important aspects of diabetes mellitus such as definition, symptoms, risk factors, diagnosis and monitoring, diabetic diet plan, exercise, complications, signs of hypoglycaemia and their management and control and management of diabetes mellitus.

An ideal information leaflet should contain adequate health related information and should be easily readable with good design and layout characteristics that will help in patient understanding and using them. Unfortunately, evidence suggests that the design of health information leaflet is poor [12]. A properly developed and designed leaflet can have a deep and lasting effect on target audience. This highlights the need of testing the readability of all educational material before it is presented to patients [13]. A readability formula is a simple method to predict the score and reading grade level required to comprehend written materials and documents. The FRE formula is commonly used to assess readability, which measures textual difficulty, indicates how easy a text is to read. The FRE scale measures readability ranges from 90-100 (very easy to read) to 0-30 (very difficult to read). The developed patient information leaflets for diabetes mellitus had FRE score of 63.9, which is considered as 'standard' and largely acceptable. The printed word on the leaflet is unique, has a high degree of acceptance, credibility and it can be passed from person to person without distortion. The pictograms and graphic illustrations printed on the leaflet helps to simplify unfamiliar concepts and helps in reinforcing adherence and strengthening their role in disease management. It has an advantage of considering as provision for translating effective information and highly effective method of increasing the patient knowledge there by involving them in decision-making process. The information on the developed and designed leaflet can have a deep and long lasting message on the patient and can be passed from one to another without distortion. Gunning fog index calculates the years of formal education wanted to understand the text on a first reading. It is mainly used to verify whether the intended

audience can read the text easily. Texts for wide audience generally require fox index less than 12. Our study showed a score of 10.2 represents that it is readable and more understandable by the wide range of audience. SMOG index readability formula measures the years of education a person needs to fully understand a piece of writing. The calculated score of 7.7 is equivalent to 7th and 8th grade reading level in the United States. Automated readability index is a readability test used to assess the understand ability of a text. A grade level of 7.5 corresponds to the typical reading level of a 14 year old in the United States. Coleman Liau index to gauge the understand ability of a text. The FK-GL score of 7.9 is equivalent to 8th and 9th grade reading level in the United States.

A leaflet with good design and layout characteristics such as font size, use of pictograms, sentence length and separation between the lines will enhance the acceptability of the patient information leaflets. The use of pictorial aids along with the written or oral instructions enhances patients understanding about their disease, symptoms, diet, lifestyle modifications and the medications to be taken in controlling them [14,15]. As per the BALD criteria, a leaflet scoring between 2 and 25 (total score 32) is considered as having good layout and design characteristics. The developed patient information leaflet in the present study scored 28 and met the BALD criteria.

The quality information for the developed patient information leaflet for diabetes mellitus was found to be 70%. This clearly shows that the developed leaflet clearly states aims and achieves them by using simple 'everyday' language, written in short sentences so that it personally addresses the reader with respectful tone. The quality also ensures that the design of information is satisfactory, contains easy-to-understand illustrations with diagrams and pictograms that are relevant to the subject of the information presenting in a logical order along with the contact address for health care services. The developed quality information leaflet also describes the purpose, benefits, risk and side effects and other relevant information about the diseases.

Conclusion

Patient information leaflets with good quality and designed with more pictograms and colourful pictures may helps in better understanding about the diseases and improved patient compliance. Information leaflet developed by the pharmacist plays a very important role in its effective management of diseases including drugs,

diet and lifestyle modifications. The information leaflet developed in the present study had good quality and standard readability score and layout design. The FRE scores and FK-GL grade level shows that the leaflet was easily understood by 13 to 15 year old students easily understood the leaflet.

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References

1. Eva T, Valentina PR, Alojz T, Stephen L, Arja I (2013) An audit of Diabetes-dependent quality of life (ADDQOL) in older patients with diabetes mellitus type 2 in Solvenia. *Value in Health Regional Issues* 2(2): 248-253.
2. Pichon-Riviere A, Irazola V, Beratarrechea A, Alcaraz A, Carrara C (2015) Quality of life in type 2 diabetes mellitus patients requiring insulin treatment in Buenos Aires, Argentina; a cross-sectional study. *Int J Health Policy Manag* 4(7): 475-480.
3. Adepur R, Rasheed A, Nagavi BG (2007) Effect of patient counselling on quality of life in type-2 diabetes mellitus patients in two selected south Indian community pharmacies: A study. *Indian J Pharm Sci* 69(4): 519-524.
4. Roy RT, Sekhar MS, Rodrigues GS, Rajesh V (2013) Preparation and readability assessment of patient information leaflets for diabetic foot ulcers. *J Soc Health Diabetes* 1(2): 79-81.
5. Renuka P, Pushpanjali K (2013) Leaflet preparation and validation procedures. *Universal Journal of Public Health* 1(3): 110-114.
6. Adepur R, Swamy MK (2012) Development and evaluation of patient information leaflets (PIL) usefulness. *Indian J Pharm Sci* 74(2): 174-178.
7. <http://www.cdc.gov/diabetes/prevention/index.html>
8. Elizabeth MM, Rajiah K, Sharma KK (2013) Consumer's perception on design and layout of consumer medical information leaflets on obesity and lipid lowering drugs. *Journal of Clinical and diagnostic research* 7(12): 2800-2802.
9. <http://www.readabilityformulas.com/free-readability-formula-tests.php>.
10. Hill J, Bird H (2003) The development and evaluation of a drug information leaflet for patients with rheumatoid arthritis. *Rheumatology* 42(1): 66-70.
11. Moul B, Franck LS, Brady H (2004) Ensuring quality information for patients: developing and preliminary validation of a new instrument to improve the quality of written health care information. *Health Expectations* 7(2): 165-175.
12. Ramesh A, Poornima D (2014) Assessment of patient information leaflets usefulness in selected chronic diseases- A south Indian based study. *Ijopp* 7(1): 23-28.
13. Arul KKSG, Yohannan JK, John J, Palanisamy S, Jacob S (2009) Development and implementation of patient information leaflet on hypertension and to assess its effectiveness. *Int J Pharm Tech Res* 1(3): 712-719.
14. Garner M, Ning Z, Francis J (2012) A framework for the evaluation of patient information leaflets. *Health Expectations* 15(3): 283-294.
15. Mateti UV, Nagappa AN, Attur RP, Bairy M, Nagaraju SP, et al. (2015) Preparation, validation and user-testing of pictogram-based patient information leaflets for hemodialysis patients. *Saudi Pharmaceutical Journal* 23(6): 621-625.

