

Short Communication

DEVELOPMENT AND VALIDATION OF PATIENT INFORMATION LEAFLET FOR HEART ATTACK PATIENTS

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Received: 09 Mar 2016 Revised and Accepted: 20 Jun 2016

ABSTRACT

Objective: To prepare a validated heart attack patient information leaflet and to educate and promote the patient knowledge regarding the disease, lifestyle modification, and medication.

Methods: The patient information leaflet was prepared by referring to the various literature. The content of the leaflet was validated by ensuring the quality information for patient's method. Baker able leaflet design has been applied to develop the layout and design of the PILS and readability by Flesch readability score.

Results: The mean validity score by EQIP method achieved for the leaflet was 84.9%. Flesch readability score is 72.4. Scoring for the leaflet's layout and design criteria based on baker able leaflet design method was 24. The overall knowledge assessment means score was statistically significant with *P value 0.000.

Conclusion: The validated heart attack PILs found to be effective in patients self management.

Keywords: Heart attack, Patient information leaflet, Knowledge assessment

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Chronic diseases are the dominant contributors to the global burden of disease and CVD is the largest contributor to worldwide disease. Coronary heart disease is a major cause of death and disability in developed countries. Acute coronary syndrome is a leading cause of death in the world. India has the highest proportion of the burden of cardiovascular diseases, for example, the proportion of CVD death reports for 35 to 64 y is 41% in South Africa, 35% in India, 28% in Brazil, 12% in the US [1]. The world health organisation estimates there will be about 20 million CVD deaths in 2015 accounting 30 percentages of worldwide [2]. Coronary heart disease is a chronic illness that is best managed when positive health behaviors become integrated into long term lifetime habits. Nearly half of patients with a history of heart disease have poor knowledge about the symptoms of a heart attack and do not perceive themselves to have an elevated cardiovascular risk. A lack of knowledge about cardiac symptoms and low perception of risk factors contributes to prolonged delay admission.

Low health literacy affects outcomes and may influence the effectiveness of interventions. Without paying attention to the challenges of limited health literacy, improvements in chronic disease management is not possible. Providing patients with information about their disease and treatments is an important aspect of chronic disease care. The provision of high quality information is a legal responsibility of health care institutions and professionals [3].

Verbal communication often fails because the information may be misunderstood or forgotten. Health education can be effective with information leaflets. Patient information leaflets are universally accepted material to educate patients about the medication, disease and lifestyle modifications like diet and exercises. [4].

The prospective, interventional study was done in Department of Cardiology, PSG hospitals for six months. The population included for content validation were doctors, pharmacist, nurses, heart attack patients, students from pharmacy, nursing & medical. In our study, we excluded who are not willing to participate. The study tools we included Baker able leaflet design, Flesch readability scale, content validation-EQIP method. The patient information leaflet was prepared for heart attack patients, where the leaflet contains information about disease condition, diagnosis, risk factor, causes, management and prevention of heart disease. The PIL was validated for its layout and design, readability

and contents. Internationally accepted baker able leaflet design [BALD] criterion is used for good design characteristics of the information leaflet. The Flesch readability ease formula is used to assess the readability of the patient information leaflet. Patient information leaflet content was validated by using EQIP method. EQIP is a questionnaire based survey, which comprises of 15 questions based on various criteria. The study was submitted to the institutional human ethical committee and got approved.

Statistical Package for Social Sciences [SPSS], Version 16.0 for Windows, was used for analyzing results. Paired t test, was used for finding an association between first validation and second validation scores. P value was found to be 0.000. Since *P<0.05, Statistical Significance. Patient information leaflet for heart attack was prepared by referring various literature. The leaflet contains information about disease condition, diagnosis, risk factor, causes, management and prevention of heart disease. Patient information leaflet was validated for it

- Layout and design
- Readability
- Content

According to baker able leaflet design method the score of our leaflet was found to be 24 and consider as standard in second validation was depicted in table 2.

A well designed information leaflet with good readability score helps patient to understand the content given in the leaflet which may in turn improve their knowledge, attitude and practice towards their disease management. The readability assessment of patient information leaflet is based on a Flesch readability ease formula.

In the initial phase of leaflet development, the mean readability score was found to be 50 which is in fairly difficult to read and later on with the suggestion we received the leaflet was modified and a fair increment of score was observed and is 72.6. This score shows the view of an easy readability of the leaflet.

Leaflet along with a questionnaire was given to approximately 70 participants. Participants include doctors, pharmacists, nurses,

students (medical and pharmacy) and patients. Responses were obtained. Among the 70 candidates participated, 10 candidates (doctors) gave the highest response of 62.3%, 10 (nurses) of them shows the response of 62%, 58% responses was given by 12 (students) candidates, 56% response was acquired from 15 (teachers) candidates, then 15 (pharmacists) candidates gave the

response of 54.2% and 8 (patients) candidates gave the response of 45.4%. From all of the above, the least % per response obtained was 45.4% from 8 (patients) candidates and then finally the mean validity score achieved for the leaflet was 56.32% were depicted in table 3. According to EQIP method, the score of the leaflet shows that it requires a review and need to replace within one to two years.

Table 1: Scoring for the leaflet's layout and design criteria based on BALD method at the first validation

Design characteristics	3 points	2 points	1 point	0 point
Lines 50 to 89 mm long				No
Separation between lines				<2.2 mm
Lines unjustified			No	
Serif type face		Yes		
Type size		10-11		
First line indented				No
Italics		0 words		
Positive advice		Positive		
Headings stand out		Yes		
Numbers all Arabic				No
Boxed text			0-1 box	
Pictures		In between		
Number of colours	4			
White space			20-29%	
Paper quality	>90gsm			

In baker able leaflet design method the score of our leaflet was found to be 21 and consider as standard in first validation was depicted in table 1.

Table 2: Scoring for the leaflet's layout and design criteria based on BALD method at the second validation

Design characteristics	3 points	2 points	1 point	0 point
Lines 50 to 89 mm long				No
Separation between lines				
Lines unjustified			No	
Serif type face		Yes		No
Type size	12 points			
First line indented			Yes	
Italics		0 words		
Positive advice		Positive		
Headings stand out		Yes		
Numbers all Arabic				No
Boxed text			0-1 box	
Pictures		In between		
Number of colours	4			
White space		30-39%		
Paper quality	>90gsm			

Table 3: Percentage response of participants (First validation)

No of participants (n=70)	Percentage response
10 (Doctors)	62.3%
15 (Teachers)	56%
15 (Pharmacist)	54.2%
10 (Nurses)	62%
12 (Students)	58%
8 (Patients)	45.4%
Total = 70	Mean =56.32%

As a response to the questionnaire the participants suggested that the pictures that included in the leaflet should be even more relevant, detailed information on diet and exercise, need information on adverse drug reactions, add website address/link to learn more about the conditions and also to include the address and contact numbers of the hospital health care professionals. These suggestions were considered and the leaflet was modified and again provided to the participants.

In the second phase of the study the above suggestions were considered and the leaflet was modified and again provided to the participants. Among the 70 candidates participated, 10 (doctors) candidates gave the highest response of 90%, 15 (teachers) of them shows response of 88%, 85% response was given by

12 (students) candidates, 83.3% response was acquired from 10 (nurses) candidates, then 15 (pharmacists) candidates gave the response of 82.40% were depicted in table 4.

From all of the above, the least % per response obtained was 81.2% from 8 (patients) candidates and then finally the mean validity score achieved for the leaflet was 84.9%. The leaflet was found to be standard through EQIP method.

Table 4: Percentage response of participants (Second validation)

No of participants (n=70)	Percentage response
10 (Doctors)	90%
15 (Teachers)	88%
15 (Pharmacist)	82.40%
10 (Nurses)	83.3%
12 (Students)	85%
8 (Patients)	81.2%
Total = 70	Mean =84.9%

First validation the baker able leaflet design score of our leaflet was found to be 21 followed by the second validation which was changed

according to the suggestion from first validation. The second validation score was found to be 24 respectively. The mean baker able leaflet design score for leaflet prepared by Uday Venkat Mateti *et al.*, 2015 [4] was found to be 28 which was found is higher than our study results. In the initial phase of leaflet development, the mean readability score was found to be 50 which is in fairly difficult to read and later on with the suggestion we received the leaflet was modified and a fair increment of score was observed and is 72.6. This score shows the view of an easy readability of the leaflet. When comparing the leaflet prepared by Raymol Thomas Roy *et al.* 2015 [5] which had a score of 69.9 for readability, our study showed a better readability score. According to EQIP method, the score of the leaflet shows that it requires a review and need to replace within one to two years. The mean validity score achieved for first validation was 56.32%. As a response to the questionnaire the participants suggested that the pictures that included in the leaflet should be even more relevant, detailed information on diet and exercise, need information on adverse drug reactions, add website address/link to learn more about the conditions and also to include the address and contact numbers of the hospital health care professionals. These suggestions were considered and the leaflet was modified and again provided to the participants. The mean score for second validation achieved for the leaflet was 84.9%. The leaflet was found to be standard and review after two to three years. Vigneshwaran, E, *et al.* 2012[6] conducted a content validation for an HIV/AIDS leaflet in which the EQIP score was found to be higher score of 68.23 and 68.45 by clinical nurses and patients. In all the groups (doctors, pharmacist, nurses, public and patients) P value was found to be 0.000. Since $P < 0.05$, showed Statistical Significance. Therefore, a significant difference in scores between first validation and second validation.

The PIL met easy readability based on Flesch readability score and attained standard design criteria based on baker able leaflet design criteria. Content validation was performed based on EQIP. From the initial validation, it was found that leaflet needs review in one or two years. We further modified the patient information leaflet according to the suggestions provided by various participants and finally developed into a standard leaflet that needs review in two to three years. The validated patient information leaflet has been found to be an effective educational tool in heart attack patient.

Small sample size was the limitation of the study.

CONFLICT OF INTERESTS

Declared none

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How to cite this article

- Andhuvan Gandhi. Development and validation of patient information leaflet for heart attack patients. Int J Pharm Pharm Sci 2016;8(8):381-383.