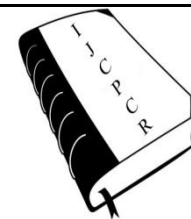




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**DEVELOPMENT AND VALIDATION OF PATIENT INFORMATION  
LEAFLET FOR DIABETIC AND HYPERTENSIVE PATIENTS IN  
RURAL AREA OF ERODE DISTRICT, TAMILNADU.**

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**ABSTRACT**

It was a Prospective Study conducted in the local community of Erode, Tamil Nadu. Study population consist of 105 participants including professionals, Non-professional and patient will be included during the phase of evaluation of the PIL. It is nine months (Jan 2019 – Sep 2019). The study has equal proportions of samples from clinicians, pharmacy teachers, working pharmacists, nurses, social workers, lay persons and patients with both diabetes and hypertension. Social workers, lay persons and patients who are working as health care professionals were excluded. Sample patient information leaflet was prepared and analysed for the study. The analysed data was fed in MS Excel and the result was drawn using graphical method. Readability and lay out of the developed leaflets will be analysed by using Flesh Readability Ease (FRE) formula, Flesch-Kincaid Grade level and SMOG Formula. Validity of the information will be evaluated using ensuring quality information for patient (EQIP) method.

**Key words:** Hypertension, Diabetes Mellitus, SMOG index, Flesch Kincaid formula, Health-related quality of life.

**INTRODUCTION**

Diabetes mellitus (DM) is a group of metabolic disorders characterized by high blood glucose levels. People with persistent high blood glucose levels are at higher risk to develop micro- and macrovascular complications, resulting in increased health-care costs, higher mortality, and reduced quality of life (QoL).[1] According to the recent census of International Diabetes Federation (IDF), it was estimated that in 2017, there were 451 million people living with diabetes worldwide. In 2045, it is expected to increase to 693 million.[2] Over the past decade, the prevalence of diabetes was drastically

raised in low- and middle-income countries compared to that in high-income countries. This rise in the global prevalence of diabetes posed a great challenge to health-care system. India is a lower-middle economy country, which ranks in the top second in global diabetic population. According to IDF, in 2015, 69.2 million cases were reported in India.[3] The prevalence of diabetes was increasing in India, initially diabetes was considered as a rich man's disease but now the scenario has changed as everyone was getting diabetes because of changes in lifestyle, sedentary occupation, and irregular food

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habits.[4]

Pharmacist-provided diabetic care services have been recognized as a cornerstone for improving the knowledge, medication adherence, clinical outcomes, and health-related quality of life (HRQoL) in various settings across the world.[5] Evidence on the effect of pharmacist-mediated counselling in the management of type II DM was lacking in rural settings of India. Most of the available evidence reinforced the involvement of pharmacist in achieving normal glycemia. There was a lack of evidence about the role of pharmacist in diabetes-associated long-term complication by controlling modifiable risk factors such as blood pressure, lipid profile, and body mass index (BMI). [6]

Hypertension is an important public health challenge because of the associated morbidity and mortality caused by cardiovascular diseases and the cost to society. Hypertension is very common chronic disease in rural, urban and semi urban areas of today's world, which needs continuous monitoring and treatment throughout the life [7].

Hypertension nearly affects 26% of adult population worldwide. By 2025 it is projected that 29% of the world's population (1.56 billion adults) will have Hypertension, in 2000 over 972 million adult populations were estimated to have hypertension. Indian population accounts for 66 million Hypertensive patients (34 million are in urban areas and 32 million in rural areas) [8,9]. In India, the prevalence of Hypertension reports was increasing rapidly, in the urban, i.e.25% of adults, and gradually even in rural areas, i.e.10% of individuals are affected. This indicates that medication nonadherence is the multifaceted problem, responsible for increasing the important medical and public health issues like worsened therapeutic outcome, higher hospitalization rates and increased health care costs [7]. Uncontrolled B.P accounts for 7.1 million deaths worldwide each year [9]. It doubles the risk of cardiovascular diseases including stroke, congestive heart failure, coronary heart disease, renal failure.

### **Pharmacist-directed patient counselling**

In intervention group, pharmacist provided a face-to-face counselling regarding knowledge on diabetes, self-monitoring of blood glucose, regular check-up of systolic blood pressure (SBP), body weight, and serum cholesterol levels. The pharmacist also gave counselling regarding non-pharmacological management strategies such as diet control, exercise therapy, and early identification of symptoms of hypoglycaemia (blurred vision, rapid heartbeat, sweating, fatigue, headache, dizziness, trouble thinking, seizures, and coma) and its management. At the end of the counselling, all patients were educated regarding antidiabetic medications, their indications, adverse effects, contraindications, warnings/precautions, drug interactions, pregnancy risk factors, and storage. In the counselling

session, the pharmacist also attempted to improve medication adherence in patients with diabetes by tailoring the medication administration time and dosage according to patient need. They were also educated regarding the importance of medication and dietary adherence and complications (microvascular, macrovascular, and diabetic foot) of nonadherence. Intervention group patients participated in all three counselling sessions: baseline, first, and second follow-up, whereas control group received usual care given by physician.

Pharmacists can contribute to positive outcomes by educating and counselling patients to prepare and motivate them to follow their pharmacotherapeutic regimens and monitoring plans [10]. Patient Information Leaflets (PILs) are produced by either manufacturer or pharmacists for the benefit of the patients and are universally accepted as the most important tool to educate the patient. Illiteracy remains a pervasive problem that compromises quality health care, limits understanding of health information, and potentially leads to poor health outcomes. The use of pictorial aids enhances patients understanding of how they should take their medications, particularly when pictures are used in combination with written or oral instructions [11].

Preparation of Patient information Leaflet: A patient Information Leaflet was prepared. The leaflet contains information about high blood pressure, its risk factors, symptoms, hypertensive complications, dietary and life style modifications that hypertensive patients need to be followed.

## **AIMS AND OBJECTIVES**

### **AIM**

To develop and validate the patient information leaflet (PIL) on the disease and treatment aspects of patients with both type 2 diabetes mellitus and hypertension.

### **OBJECTIVES**

- To develop patient information leaflet for patients who have type 2 diabetes
- mellitus and hypertension.
- To assess the readability and design of the PIL using standard methods
- To evaluate the validity of the information contained in the PIL.

## **MATERIALS AND METHODS**

### **STUDY DESIGN**

A Prospective Study was conducted in the local community of Erode, Tamil Nadu.

### **STUDY POPULATION**

105 participants including professionals, Non-professional and patient will be included during the phase of evaluation of the PIL.

## STUDY PERIOD

Nine months (Jan 2019 – Sep 2019)

## STUDY CRITERIA

- Inclusion Criteria:

Equal proportions of samples from clinicians, pharmacy teachers, working pharmacists, nurses, social workers, lay persons and patients with both diabetes and hypertension will be included.

- Exclusion Criteria:

Social workers, lay persons and patients who are working as health care professionals will be excluded.

## STUDY TOOLS

Sample patient information leaflet was prepared and analysed. The analysed data was fed in MS Excel and the result was drawn using graphical method. Readability and lay out of the developed leaflets will be analysed by using Flesch Readability Ease (FRE) formula, Flesch-Kincaid Grade level and SMOG Formula. Validity of the information will be evaluated using ensuring quality information for patient (EQIP) method.

## RESULTS

A minimum of 105 participants including clinicians, pharmacy teachers, working pharmacists, nurses, social workers, lay persons and patients will be included during the phase of evaluation of the PIL as in table 1. Number of participants were included from each category is 15. Percentage response were obtained from each category. High response was given by Social workers and patients. (80.5%) Total response was found to be 76.10%.

Patients were grouped according to their educational status as in table 2. The majority of the patients have only primary education [10]. Number of patients selected was 15.

There are 20 quality criterions in EQIP questionnaire. The 1<sup>st</sup> quality criterion “Have clearly stated aims and achieve them” got high score. The quality criterion “Contains details of other sources of information” got the least score. Out of 20 criteria given by EQIP, nine got a score range of more than 90%, Three received a score of less than 50% and Eight were within the range of 50 – 90%.

The majority of the patients are in age group above 64. (11). Number of Patients selected was 15. Three of the patients were in age group of 50-64. One patient included in the age category of 35-49.

The majority of the Lay persons have above High school education (13). Number of Lay persons selected was 15.

To find the association of EQIP score with different group of samples, Chi square test was used. The following null hypothesis was stated.

$H_{01}$ : There will not be any significant association of readability score with different group of samples.

Data in table 7 shows that the  $\chi^2$  value (20.647) for readability score with different group of samples was greater than the table value at 0.05 level of significance and the p value (0.002) found was less than 0.05. Hence the null hypothesis was rejected and research hypothesis was accepted for this variable. Therefore, there was a significant association of EQIP score with different group of samples.

Data in Table 8 shows that Hypertension has found greater Flesch reading ease score Compared to diabetes. Hypertension have 76.4 and diabetes have 70.5.

Data in Table 9 explains the ranges of flesch reading ease. It starts from 90-100 to 0-30.

Each range have a particular description of style like Very easy to Very difficult.

90-100 shows a very easy description style. Likewise,80-90-Easy,70-80-Fairly Easy,60-70-Standard, 50-60-Fairly difficult,30-50-Difficult,0-30-Very difficult.

Conversion of Flesch reading ease to an appropriate grade was shown in Table 10. It starts from 5<sup>th</sup> grade to a college graduate level. The FRE score is from 90-100 to 0-30. 5<sup>th</sup> grade shows FRE value of 90-100. Similarly,6<sup>th</sup> grade-80-90,7<sup>th</sup> grade-70-80, 8<sup>th</sup> to 9<sup>th</sup> grade - 60-70,10<sup>th</sup> to 12<sup>th</sup> grade (high school)-50-60,13<sup>th</sup> to 16<sup>th</sup> grade (college level)-30-50, College graduate-0-30.

Table 11 shows flesch Kincaid values of diabetes and hypertension. The leaflet of diabetes has higher Flesch Kincaid value (4.9). Hypertension has a Flesch Kincaid value of 4.4. Both of them have Fourth grade level.

Table 12 shows SMOG Index values of diabetes and hypertension. The leaflet of diabetes has higher SMOG Index value (5.9). Hypertension has a SMOG Index value of 5.3. Both of them have Fifth grade level.

Flesch reading values are obtained for Diabetes and hypertension by manual method as in Table 13. Hypertension (73.91%) has higher score compared to diabetes (72.28%). Both of them have a “Fairly easy” description style.

Table 14 shows the Flesch Kincaid values of Diabetes and Hypertension. Out of these values Hypertension has got higher Flesch Kincaid value (4.6). Diabetes secured 4.3. Both of them have Fourth grade level.

Table 15 shows the SMOG Index values of Diabetes and Hypertension. Out of these values, both of them have got a SMOG Index of 6. It indicates Sixth grade level.

Table 16 shows comparison of Flesch reading values obtained from manual method and from text readability consensus calculator. Score obtained for diabetes by manual method (72.28%) is higher compared to the score obtained from text readability consensus calculator (70.5%). But for Hypertension highest score is obtained from text readability consensus calculator

(76.4%). From manual method Hypertension has only “Fairly easy”. The mean scores obtained was 71.39% for Diabetes. Hypertension scored 75.15%.

Table 17 shows that higher value obtained for diabetes is from text readability consensus calculator. But Hypertension obtained higher score from manual method (4.6).

73.91% For both leaflets description of style obtained was

Both leaflets have fourth grade level. The mean scores for Diabetes were 4.7 and Hypertension Secured 4.5. Table 18 shows that for both diseases higher SMOG index values are obtained from manual method. Grade level is fifth grade for both diabetes and hypertension. Mean scores for diabetes was 5.95 and for Hypertension was 5.6.

**Table: 1 Percentage response to EQIP of study participants. (n=15)**

S.No	Participants	Percentage Of participants (n%)	Response (%)
1.	Clinicians	15(14.28)	71.83
2.	Pharmacy teachers	15(14.28)	73.5
3.	Working pharmacists	15(14.28)	75.5
4.	Nurses	15(14.28)	74.6
5.	Social workers	15(14.28)	80.5
6.	Lay persons	15(14.28)	76.33
7.	Patients	15(14.28)	80.5
	Total	=105	=76.10

**Table: 2 Distribution of patients based on educational status (n=15)**

Educational status	No. of patients	Percentage
Primary	11	73.33
High school	2	13.33
Above high school	2	13.33

**Table 3: Scores assigned for each quality criterions of EQIP**

EQIP Criterions	Assigned score (%)
Have clearly stated aims and achieve them	95.71
Written using everyday language. Explaining unusual or medical words or abbreviations	95.2
Written using short sentences	85.2
Written so that it personally addresses the reader	92.85
Written so that the tone is respectful	69.52
Design of information satisfactory	89.52
Contains easy to understand illustrations, diagrams or photos that are relevant to the subject of the information	66.66
Presented in a logical order	86.19
Contain a space to make notes	43.33
Contain contact details for health care	94.76
Contain the date information was produced	17.14
Contain name of person or department that produced information	95.2
Indicates whether information was produced with assistance from users of service	56.66
Contains reference to quality of life issues	82.38
Uses generic names for medications or products, or identifies brand names as such	91.428
Contains details of other sources of information	15.71
Describes the purpose	93.33
Describes the benefits	90
Describes risks and side effects	92.8
Describes alternatives	62.85

**Table 4: Age distribution of Patients(N=15)**

Age group	No. of Patients	Percentage
35-49	1	6.66
50-64	3	20
>64	11	73.33

**Table 5: Distribution of Lay persons based on educational status (n=15)**

Educational status	No: of Lay persons	Percentage
Primary	13	86.66
High school	1	6.66
Above high school	1	6.66

**Table 6: Feedback strategy on EQIP of patient information leaflets**

Specifications	Frequency (%)	Recommendations
76 and above	56	Continue to stock; review in two to three years.
51-75	49	Continue to stock; review in one to two years.

**Table 7: Association of EQIP score with different group of samples. n= 105**

Group	Score		$\chi^2$ value	df	Table value of $\chi^2$	p value	Inference
	≤ 75	>75					
Clinicians	10	5	20.647	6	12.592	0.002	S*
Nurses	10	5					
Pharmacy teachers	9	6					
Working pharmacists	9	6					
Social worker	2	13					
Lay persons	6	9					
Patients	2	13					

$\chi^2$  at 0.05 level of significance

S\* - Significant

**Table 8: Analysis of Flesch reading ease by using text readability consensus calculator**

S.NO	Disease	Flesch reading Ease	Description of style
1	Diabetes mellitus	70.5	Fairly easy
2	Hypertension	76.4	

**Table 9: Interpretation of flesch reading ease score**

S. No	Reading Ease	Description of style
1	90-100	Very easy
2	80-90	Easy
3	70-80	Fairly easy
4	60-70	Standard
5	50-60	Fairly difficult
6	30-50	Difficult
7	0-30	Very difficult

**Table 10: Conversion of FRE into an appropriate grade**

S.No	Grade level	FRE
1	5 <sup>th</sup> grade	90-100
2	6 <sup>th</sup> grade	80-90
3	7 <sup>th</sup> grade	70-80
4	8 <sup>th</sup> to 9 <sup>th</sup> grade	60-70
5	10 <sup>th</sup> to 12 <sup>th</sup> grade (high school)	50-60
6	13 <sup>th</sup> to 16 <sup>th</sup> grade (college level)	30-50
7	College graduate	0-30

**Table 11: Analysis of Flesch Kincaid value by using Text readability consensus calculator**

S. No	Disease	Flesch Kincaid	Grade level
1	Diabetes mellitus	4.9	Fourth grade level.
2	Hypertension	4.4	

**Table 12: Analysis of SMOG index by using Text readability consensus calculator**

S. No	Disease	SMOG Index	Grade level
1	Diabetes mellitus	5.9	Fifth grade level.
2	Hypertension	5.3	

**Table 13: Analysis of Flesch reading ease by manual method**

S. No	Disease	Flesch reading Ease	Description of style
1	Diabetes mellitus	72.28	Fairly easy
2	Hypertension	73.91	

**Table 14: Analysis of Flesch Kincaid by using Manual method**

S. No	Disease	Flesch Kincaid	Grade level
1	Diabetes mellitus	4.3	Fourth grade level
2	Hypertension	4.6	

**Table 15: Analysis of SMOG Index by using Manual method**

S.No	Disease	SMOG Index	Grade level
1	Diabetes mellitus	6	Sixth grade level
2	Hypertension	6	

**Table 16: Comparison of Flesch reading ease**

S. No	Disease	Flesch reading 1	Flesch reading 2	Mean	Description of style
1	Diabetes	72.28	70.5	71.39	Fairly easy
2	Hypertension	73.91	76.4	75.15	

**Table 17: Comparison of Flesch Kincaid values**

S. No	Disease	Flesch kincaid1	Flesch Kincaid 2	Mean	Grade level
1	Diabetes	4.3	5.1	4.7	Fourth grade level

**Table 18: Comparison of SMOG index values**

S. No	Disease	SMOG index 1	SMOG index 2	Mean	Grade level
1	Diabetes	6	5.9	5.9	Fifth grade level
2	Hypertension	6	5.3	5.6	

## DISCUSSION

A Prospective Study was conducted in the local community of Erode, Tamilnadu to develop and validate the patient information leaflet (PIL) on the disease and treatment aspects of patients with both type 2 diabetes mellitus and hypertension. A minimum of 105 participants including professionals, Non-professional and patients are included during the phase of evaluation of the PIL. The study carried out for a period of 9 months. Equal proportions of samples from clinicians, pharmacy teachers, working pharmacists, nurses, social workers, lay persons and patients with both diabetes and hypertension are included. social workers, lay persons and patients who are working as health care professionals are excluded.

Readability and lay out of the developed leaflets were analysed by using Flesch Readability Ease (FRE) formula, Flesch-Kincaid Grade level and SMOG Formula. Validity of the information was evaluated using ensuring quality information for patients (EQIP) method. Association of EQIP score with different group of samples, Chi square test was used. P value was also found. The specifications include 76 and above and 51-75. The individual responses of participants were taken into consideration for testing the usability of the leaflets. 56 participants gave a response of 76% and above. 49 gave response of 51-75%.

Data in table shows that the  $\chi^2$  value (20.647) for readability score with different group of samples was

greater than the table value at 0.05 level of significance and the p value (0.002) found was less than 0.05. Hence the null hypothesis was rejected and research hypothesis was accepted for this variable. Therefore, there was a significant association of EQIP score with different group of samples.

Similar results have been described in a study on “Preparation and readability assessment of patient information leaflets for diabetic foot ulcers”. The Study aims to develop and to assess the readability of PIL for diabetic foot ulcer. Physicians were validated the content of the leaflet. Layout and design features of the PILs were assessed by using Baker Able Leaflets Design (BALD) method. PILs prepared had ideal readability score and layout design. The leaflet’s estimated FRE and FKGL scores rate showed that it was fairly easily readable. (J. Hill et al.2018), conducted a study on “The development and evaluation of a drug information leaflet for patients with rheumatoid arthritis”. The Study aims to develop and assess the effectiveness of a drug information leaflet (DIL) for D-penicillamine (DPA) and determine whether additional verbal information provides enhanced benefit. The reading study showed that 12% of the sample had difficulty reading and so the DPA DIL was designed to be easy to read using the Flesch Reading Index. (Kathryn Fullmann et al. 2017), conducted a study on “Readability and Suitability of COPD Consumer Information”. The Study aims to perform an appraisal of the consumer information provided in COPD inhaler monographs. Twenty-six inhalers with a COPD indication were evaluated. Medication information sections were rated as “difficult to read” or “hard” and 85% (22/26) had a reading level above grade 8. Sonal Sekhar M et al. (2017), conducted a study on “Development and Evaluation of Patient Information Leaflet for Diabetic Foot Ulcer Patients”. The Study aims at developing PILs for DFU

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patients and investigating its validation. The developed PILs met the criteria of fairly easy readability and good layout design. The user-opinion of the majority of patients reported the PIL content, legibility, and design as good. The Pictogram-based PILs(P-PILs) was found to be an executive PE tool in DFU patients.

## CONCLUSION

Patient information leaflets with good quality and designed with more pictograms and colourful pictures may help 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 study had standard readability score and layout design. FRE scores shows that It had a “Fairly easy” description style. FK-GL grade level and SMOG index shows that the leaflet was easily understood by 9 to 10-year-old students. Ensuring Quality Information for Patients (EQIP) questionnaire was applied to assess layout and design characteristics and information quality in the developed leaflets. The information leaflet developed in the present study had good quality.

It can be concluded that the leaflet developed for Diabetes and Hypertension can be used as a source of patient information and can be circulated among the patients to provide education and counselling but it should be reviewed within one to two years.

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