

DEVELOPMENT AND EVALUATION OF A PATIENT INFORMATION LEAFLET FOR TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT

Objectives: This study aimed to develop and evaluate the patient information leaflets (PILs) for type 2 diabetes mellitus (T2DM) patients.

Methods: The PILs were prepared in English by referring to primary, secondary, and tertiary resources. Readability of the PIL was assessed using the Flesch reading ease (FRE) test, Flesch-Kincaid grade level (FKGL), and user readability methods. User opinion on PILs content and design was obtained from T2DM patients (n=40). The Baker Able Leaflet Design (BALD) method was used to assess the layout and design characteristics of the PILs.

Results: The FRE and FKGL readability scores were 62.9 and 6.6, respectively. The BALD criteria scores for English and Nepali PILs were 29 and 25, respectively. The overall user testing readability mean scores were significantly improved from 47.5 to 97.25. 90% of T2DM patients rated the PILs as good design and content. Most of them were housewife female patients (mean age 57.725) with a primary level of education and belonged to the upper-lower class of socioeconomic status.

Conclusion: The developed PILs met the standard criteria for easy reading and comprehension. The majority of them had a good opinion on the content and design of the PILs.

Keywords: Patient information leaflets, Type 2 diabetes mellitus, Patient counseling, Readability.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the fastest-growing public health burdens, leading to an increase in mortality and morbidity globally. It is characterized by hyperglycemia due to an imbalance in carbohydrate, protein, and fat metabolism; as a result, there are absolute or relative deficiencies in insulin secretion and action or both [1-3]. It is the major public health burden in middle and low-income countries and the fifth leading cause of mortality in high-income countries [4]. Globally, the prevalence of diabetes was estimated as 9.3% (463 million people) in 2019, and this is estimated to rise to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045 [5]. T2DM is the most common type of diabetes, which is seen among 95% of the diabetic population and is associated with positive macrovascular and microvascular complications, including retinopathy, stroke, nephropathy, myocardial infarction, neuropathy, and limb amputation, which mitigates the health-related quality of life [6-9]. The prevalence of DM was found to be 8.5% in Nepal, and the prevalence of DM and related risk factors such as obesity and overweight has increased in South Asia, including Nepal [10]. Factors such as decline in nutrition quality, reduction in physical activity, increase in sedentary behaviors, excessive consumption of white rice, sweets, processed foods, excessive abdominal fats, and low socioeconomic status are the main reasons for the increasing prevalence of T2DM and related risk factors in South Asian populations [10,11]. Medication adherence can improve the quality of life, so it is crucial for enhancing the effectiveness of treatment for T2DM patients. Adherence includes assessing the medication regimen and implementing counseling regarding exercise, diet, and lifestyle modifications. Hence, age, gender, number of prescribed medicines, availability, costs, socioeconomic status, and awareness level of the patients can influence adherence. Non-adherence can increase the adverse effects and treatment

failure [12]. Several factors contribute to non-adherence, which include out-of-pocket expenditure, literacy, and lack of awareness, inadequate family or community support, polypharmacy, unequal distribution of health providers between urban and rural areas, cultural norms, and forgetfulness [13]. A patient information leaflet (PIL) is a globally recognized counseling aid in providing information for managing chronic diseases. It can provide written information regarding disease, symptoms, risk factors, medicines, complications, lifestyle modification, and other health-related information to enhance patient adherence in medication therapy [14].

Good readability, design, and layout are important components for designing PIL, where user testing is done to assess the readability of the PIL to ensure that the information provided is legible, easy to understand, and clear so that patients can understand the important information in the PIL. This can improve the knowledge, attitude, and practice of the patients. Here, internationally accepted Baker Able Leaflet Design (BALD) criteria were employed for good design characteristics of the PIL [15]. Since T2DM is a major problem in Nepal and the key challenge is patient non-adherence and lack of knowledge, this study aimed to develop and evaluate a culturally and linguistically adapted PIL for T2DM patients and perform its readability test.

METHODS

Study design

An experimental pre- and post-design evaluation of PILs within the intervention group without a control group was carried out as part of a study on the impact of patient counseling on clinical outcomes in T2DM patients. Ethical approval was obtained from the Nepal Health Research Council (Ref.no.1898) and the Institutional Ethics Committee LPU (Ref. no. LPU/IEC-LPU/2025/1/13). The study was conducted in the

outpatient department of the Internal Medicine Department of Gandaki Medical College Teaching Hospital and Research Center from June 2024 to February 2025. The sociodemographic details such as age, gender, educational status, economic status, occupation, duration of diabetes mellitus, and co-morbidities were collected from the patients with written informed consent. The socioeconomic status of the patients was calculated using the Kuppaswamy socioeconomic scale in the context of Nepal [16].

Inclusion criteria

- Willing to participate in the study
- Able to speak and read Nepali/English languages
- Diagnosed with type 2 diabetes for >6 months
- Age ≥40 inclusive, any gender
- HbA1c of ≥ 6.5%
- On stable diabetes therapy for >3 months.

Exclusion criteria

- Pregnant or planning to become pregnant in the next 12 months
- Severe hearing or visual impairment
- Significant psychiatric illness, renal disease, hepatic disease, or other disease that impaired the ability to complete the study
- Type I diabetes mellitus patients.

Sample size

The sample size was calculated on the basis of the change in patients' knowledge of user-testing scores from baseline to post-intervention scores using the following formula [17].

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{d^2} + 2$$

Where, $\sigma=10$, $Z_{1-\alpha/2}$ is 1.96 (for $\alpha=5\%$), $Z_{1-\beta}$ is 0.84 for 80% power and $d=5$.

σ is the mean of the two standard deviations.

d is the minimum significant difference between the two groups. =33.36, this value comes from the process of calculation.

Anticipating attrition rate=15%

The sample taken for this study is 40

Initially, PILs are prepared in English by referring to primary, secondary, and tertiary resources. Various research articles related to T2DM were referred to as primary resources [7,9,11]. Secondary resources included up-to-date [18], Medscape [19], and WebMD [20]. The tertiary resources include a standard book, Clinical Pharmacy, and Therapeutics [21]. Information on the disease, risk factors, symptoms, diagnostic criteria, diet, lifestyle, commonly prescribed medications, and the importance of regular checkups was included in the PILs. The content of PILs was validated by the expert committee consisting of three doctors, three academic pharmacists, and one dietician using the Lawshe method, where the content validity was assessed by three criteria: Essential, useful but not essential, and not essential [22]. The questions for the user testing questionnaire (UTQ) and user opinion questionnaire (UOQ) were prepared with slight modifications from the references of various articles [23,24]. The experts also validated the PIL contents in terms of relevance, clarity, and simplicity. The necessary changes in PILs were made based on the suggestion of the expert committee before assessing the readability. PILs' design, and layout were developed using BALD criteria. The BALD criteria scores were calculated based on the font size, indenting, separation between lines, alignment, box type text, number of colors, use of pictures, and good-quality paper. As per the BALD criteria, a PIL score between 20 and 25 (maximum score is 32) is considered a good layout and design [10,11,13]. The prepared and validated PILs in the English version were translated into the Nepali language, using the forward and backward translation methods.

Before collecting patient feedback, the reliability of the UTQ and UOQ was assessed. For this, the test-retest methodology was used to measure the external consistency of UTQ and UOQ. By administering the same

UTQ and UOQ twice to the same individuals, the Intra-class Correlation Coefficient (ICC) was calculated to evaluate test-retest reliability. The UTQ and UOQ were examined in a subpopulation of 10 randomly selected T2DM patients. To assess reliability, they were issued the Nepali version of PILs twice, spaced a week apart. Similarly, internal consistency of the UTQ was evaluated by calculating Cronbach's alpha value. The author performed the user tests and UOQ on the basis of one to one face to face structured sets of interviews in 40 T2DM patients.

Assessment of readability

The readability of PILs was assessed using the Flesch-Kincaid Grade Level (FKGL) and Flesch Reading Ease (FRE) test, and a UTQ [25]. UTQ was developed based on the content of PILs. It includes 10 validated multiple-choice questions. The baseline knowledge of 40 T2DM patients (using Nepali language) who visited the outpatient department of the Internal Medicine department of the hospital during the study period was assessed using UTQ after informed consent. After determining the baseline knowledge, the patients were allowed to read the PILs for 20 min, then a post-test was performed using the same UTQ to reassess the knowledge. The user testing response evaluation was assessed using the following formula:

$$\text{Response evaluation} = \frac{\text{Total number of correct responses}}{\text{Total number of questions}} \times 100$$

After user testing, user opinions on PIL's content, design, and layout were obtained from patients. For this, five user opinion questions were prepared. The scores for this questionnaire ranged from 4 to 1. The interpretation of user opinion scores assessment is as follows: [26]

- If the score is >14–20, the content, design, and layout of the PIL are considered good
- If the score is 9–14, the content, design, and layout of the PIL are considered average
- If the score is <9, the content, design, and layout of the PIL are considered poor.

Statistical analysis

The test-retest reliability of the user-testing and user-opinion questionnaire was evaluated by calculating the ICC among randomly selected T2DM patients. An ICC ≥0.9 has been considered highly reliable, while an ICC between 0.7 and 0.89 has been considered moderately reliable, and an ICC <0.7 has been considered having low reliability. The data were entered in an MS Excel sheet 2007 and transferred into Statistical Package for the Social Sciences version 27. Descriptive statistics has been used to summarize the data, and the user-testing data of baseline and after 20 min, scores were analyzed using "paired student t-test" with "p"<0.05 considered as statistically significant.

RESULTS

Development and validation of leaflet and questionnaire

A panel of seven experts focused on the 15 key topics encompassing the definition, types of T2DM, risk factors, symptoms, diagnostic criteria, commonly prescribed medicines, symptoms and management of hypoglycemia, management of hyperglycemia, management of T2DM, types of complications, things to do and don't for diabetic foot care and things to do and don't to enhance medication adherence related to T2DM in the PIL. The PIL for T2DM patients was represented in Fig. 1. The PIL mainly focused on increasing the knowledge of T2DM patients on risk factors, symptoms, antidiabetic medicines use, types of complications, management of T2DM, self-care of the foot, and information to enhance medication adherence.

While assessing the content validity of UTQ, the experts had chosen the essential, very relevant, very clear, and very simple in all the items as a result, the mean content validity ratio for UTQ was 1.

User-testing and user-opinion testing using a questionnaire

The validity and reliability of the user testing and UOQ were done in a subsample of 10 randomly chosen T2DM patients. All the patients

PATIENT INFORMATION LEAFLET ON TYPE 2 DIABETES MELLITUS

**Effective Management
is Possible !!**

1. What is Diabetes Mellitus?

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by increased blood sugar levels.

2. Types of DM

There are mainly four types of diabetes: Type 1 DM, Type 2 DM, Type 3 (specific types of diabetes), and gestational diabetes mellitus (GDM).

3. How Common is Type 2 Diabetes?

Type 2 diabetes develops mainly in people older than the age of 30, but it is now seen in children and young people as well. It is more common in people who are overweight or obese or having family history of DM.

4. Risk Factors

4.1 Modifiable risk factors

4.2 Non-modifiable risk factors

5. Symptoms

6. Diagnostic Criteria for Type 2 DM

Test	Normal Glycemia (mg/dl)	Pre diabetes (mg/dl)	Diabetes (mg/dl)
Fasting plasma glucose (FPG)	<100	100-125	≥126
2-hour plasma glucose (Post Prandial)	<140	140-199	≥200
Random plasma glucose	<140	-	≥200
Glycated Hemoglobin (A1C) Test	<5.7%	5.7-6.4%	≥6.5%

7. Commonly Prescribed Antidiabetic Medicines

Tablets: Oral Route

Class	Generic name	Time of administration
*Sulfonylureas	Metformin	After meal
**Sulfonylureas Second generation	Glimperide, glipizide, gliburide	30 Mins before a meal
Thiazolidinedione	Pioglitazone	No regard for meals
α-glucosidase inhibitors	Acarbose voglibose	With meals
DPP-4 inhibitors	Linagliptin Sitagliptin	No regard for meals
SGLT2 inhibitors	Empagliflozin Dapagliflozin	No regard for meals
Combination	Linagliptin+metformin	With meal
	Sitagliptin+Metformin	With meal
	Glimepiride+Metformin	With meal

Injection: subcutaneous route

8. Hypoglycemia

Insulin*	Time of administration
Insulin, Regular (NPH) 40 IU/ml, insulin 30/70, insulin 50/50, insulin Glargine 300/70, insulin mixed preparation 30/70, 50/50	Administer within 15 minutes before a meal
Insulin Glargine 100 IU/ml	Injected subcutaneously once daily at any time of day, but at the same time every day.
Insulin Analogs	Within 5 to 10 minutes of eating

For most people with diabetes, hypoglycemia is seen when their blood sugar level is below 70 milligrams per deciliter (mg/dl).

Hypoglycemia can happen if you:

- Skip a meal
- Exercise too much without eating enough
- Drink too much alcohol
- Take other medications that can lower blood sugar
- Take too much medication

9. Symptoms of Hypoglycemia

10. Management of Hypoglycemia

Repeat until the blood sugar level is >= 70mg/dl

11. Hyperglycemia

The common reasons for high blood sugar levels in diabetic patients are:

- Miss the dose
- Stress
- Eat too many sugary foods
- Not exercising enough
- Insulin resistance

12. Management of Type 2 DM

High blood sugar levels in T2DM can be managed by following these ways:

- Medications:** Take antidiabetic medicines as prescribed by your doctor and do regular follow-up visits
- Lifestyle Changes**

2.1 Diet: Diabetes plate method for the Nepalese population

Some Diet Tips

Consistently eat at the same time every day and do not skip or delay the meals

Eat six small meals in a day

- Fill half of your plate with non-starchy vegetables
- Fill one-fourth of your plate with lean protein food
- Fill one-fourth of your plate with carbohydrate
- Choose water or zero calorie drinks.

Foods to be Taken	Foods to be Avoided
Non-starchy vegetables: cabbage, cauliflower, tomatoes, onions, spinach, radish, carrot, eggplant, asparagus, mushrooms. Fresh fruits: strawberries, oranges, apricots, pomegranates, apples, peaches, grapes, avocado. Carbohydrate: brown rice, wheat, popcorn, potato, yogurt, potatoes, sweet potatoes, pumpkins. Lean Protein: Fish, chicken, tofu, beans, lentils.	oily foods, junk food, red meat, packed fruits, sweets, jam, cake, Vanaspati ghee, sugary biscuits, chocolates, ghee, animal fats, sugary drinks, tobacco, and alcohol.

2.2 Weight Loss:

Maintain a weight reduction of at least 5% of initial body weight

2.3 Exercise:

At least 150 minutes of moderate aerobic exercise per week

3. Self-care:

- Check Blood glucose at least once a month and HbA1c level every 3 months
- Optimizing weight, waist, blood pressure, lipid profile
- Getting regular eye exams, dentist visits,
- Checking feet daily for sores, cuts, redness, or swelling
- Getting at least 7 hours of sleep each night
- Stress management

13. Types of Complications

Poorly managed T2DM can cause acute or chronic complications. Acute complications can cause hypoglycemia, and chronic complications can affect the following organs:

Eye: Blurred vision

Kidney: swelling in the hands, feet, and face, fatigue, nausea, vomiting, and darker urine

Brain: numbness or weakness in the face, arm, or leg, trouble in speaking

Heart: pain in the chest, difficulty in breathing, High blood pressure

Hands and Feet: Reduced ability to feel pain or temperature changes, tingling or burning feeling, Sharp pains and muscle weakness

THE DOS & DON'TS FOR DIABETIC FOOT CARE

DIABETIC FOOT CARE DOS	DIABETIC FOOT CARE DON'TS
Check your feet daily for sudden skin changes, cut blister hard and fungal infection.	Use over the counter medication to treat corns and warts.
Wash your feet daily in lukewarm water, using a mild soap.	Wear anything tight around your legs such as tight socks or knee highs.
Moisturize your feet daily and avoid applying moisturize in between toes.	Ever go barefoot, even indoors
File any build-up of hard skin or corns	Put hot water bottles or heating pads on your feet
Cut toenails straight across and file edges with a nail file.	Sit or cross your legs for long period of time
Wear fresh clean socks and well fitting shoes everyday.	Smoke, smoking decrease circulation and healing and significantly increase the risk of amputation.
Check that there is nothing in your shoes before wearing them.	Wear over the counter insoles they can cause blister if they are not right for your feet

Information to increase medication compliance

DO	DON'T
* Take Metformin Tablet after meals to reduce stomach upset Take medicine as per the medicine chart	**Skipping meals, exercising for too long, or drinking alcohol while taking this medication to reduce the risk for hypoglycemia
*Rotate injection sites, such as the abdomen, buttocks, upper legs, or upper arms.	Take any other medication (o) like homoeopathic, Ayurveda, without consulting a doctor
Stay in touch with your doctor, and report the side effects of the drugs immediately.	Stop or overdose on your prescribed medication without any consultation
Confirm the exact dose, frequency, and duration of each medication with your pharmacist, and visit on time for the refill of medications	Do not skip your follow-up visit

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Fig. 1: Patient information leaflet for type 2 diabetes mellitus

have chosen the Nepali version of the PILs. The ICC reliability of the UTQ and the user opinion testing questionnaire were 0.909 and 0.873, respectively. The Cronbach's alpha value of internal consistency of the UTQ of 40 respondents was 0.710, which was acceptable. After statistical analysis of the subgroup, the same questionnaire was used to evaluate the final PILs (Table 1).

Socio-demographic details of the patients

Forty patients took part in the study. The mean age of the patients was found to be 57.725±6.59 years. Out of 40 patients, the majority of them were female (75%) and were housewives (52.5%). The patient demographic information is shown in Table 2.

Leaflet design and readability score

PILs' design and layout scores were obtained by the BALD criteria, where the scores of the PILs were 29 for English and 25 for Nepali, respectively (Table 3). Serif typeface was absent in the Nepali language PIL because it is less common in digital use. The Nepali language is written in the Devanagari script, which involves complex conjuncts and vowel signs. Unlike English language, Nepali language does not have capital letters so the concept of lower case title does not directly apply.

The readability of the English PIL was determined using FRE/FKGL scores. The leaflet was revised 3 times to achieve an optimum FRE/

Table 1: Test-retest reliability of user testing questionnaire

PIL Nepali language (n=10)	Test 1 (Day 1) (Mean±SD)	Test 2 (Day 7) (Mean±SD)	ICC value
User testing questionnaire	5.00±0.666	4.8.0±0.788	0.909
User opinion testing questionnaire	17.8±1.03	17.6±0.84	0.873

SD: Standard deviation, ICC: Intra-class correlation coefficient. The user testing and user opinion questionnaire set were reliable. The mean and standard deviation of the UOQ (Mean±SD) are 17.6±0.84

Table 2: Demographic details of T2DM patients

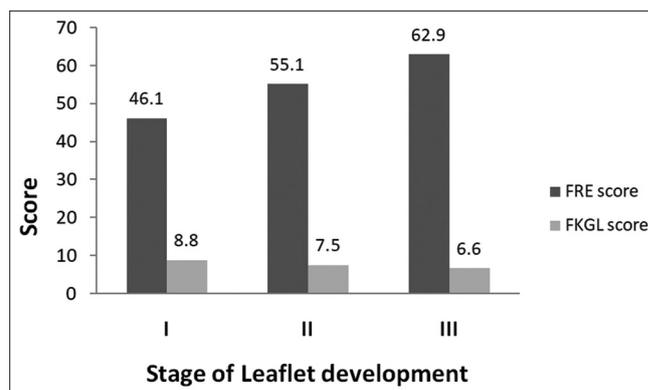
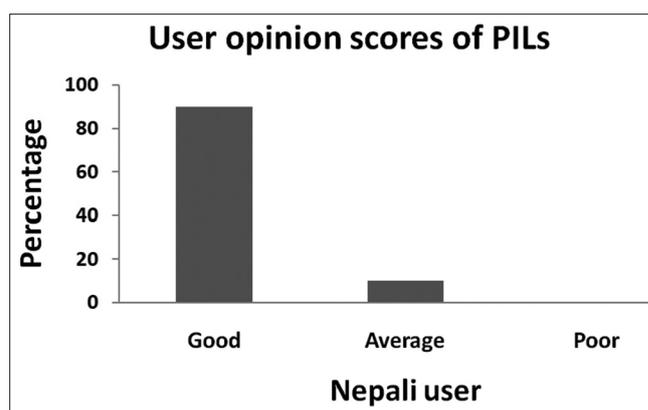
Demographic details	No. of patients (%)
Age, mean±SD	57.7250±6.59
Gender	
Male	10 (25)
Female	30 (75)
Educational status	
Primary	31 (77.5)
Secondary	4 (10)
College	5 (12.5)
Socioeconomic status	
Lower middle	10 (25)
Upper lower	27 (67.5)
Upper middle	3 (7.5)
Total	40 (100)
Diabetic family history	
Yes	12 (30)
No	28 (70)
Co morbidity	
Only T2DM	3 (7.5)
Hypertension	8 (20)
Hypertension+hyperlipidemia	17 (42.5)
Hypertension+hypothyroidism+hyperlipidemia	1 (2.5)
Hyperlipidemia	6 (15)
Hyperlipidemia+hypothyroidism	1 (2.5)
Hyperuricemia	1 (2.5)
Hypothyroidism	3 (7.5)
Total	40 (100)
Family type	
Joint	27 (67.5)
Nuclear	13 (32.5)
BMI	
Normal weight (18.5–24.9)	7 (17.5)
Overweight (25–29.9)	18 (45)
Obese ≥30	15 (37.5)
Cast	
Brahmin	16 (40)
Chetri	3 (7.5)
Dalit	9 (22.5)
Janajati	12 (30)
Duration of DM (year)	
≤1	13 (32.5)
2–5	6 (15)
6–10	11 (27.5)
>10	10 (25)

T2DM: Type 2 diabetes mellitus, SD: Standard deviation, BMI: Body mass index, DM: Diabetes mellitus. Mean±standard deviation of the patients' age was 57.7250±6.59

FKGL score, which improved after each revision. The final English version of the leaflet scored 62.9 on the FRE test and 6.6 on the FKGL test, which indicates that the PIL can be understood between grade levels 7–8. Scores of over 60 on the FRE test and fewer than 8 on the FKGL test indicate ease of reading and understanding (Fig. 2).

User testing scores

The overall pre- and post-user testing mean scores for the knowledge assessment significantly increased from 47.5 to 97.25 (Table 4).

**Fig. 2: Readability assessment of patient information leaflets****Fig. 3: User opinion scores of the patient information leaflets. The 90% of the respondents rated well for the PILs.**

User opinion score

Overall, 90% of patients rated the PILs as good, and the remaining 10% gave it an average rating (Fig. 3).

The change in readability score stage-wise after each modification of the content of PILs indicates that patients with primary-level education can easily read and understand the PILs.

The PILs were prepared with good layout and design since the BALD scores were >20.

The mean and standard deviation of the UOQ (Mean±SD) are 17.6±0.84. The 90% of the respondents rated well for the PILs.

DISCUSSION

Patients can only remember a certain amount of information from a doctor's appointment. Hence, the written health education materials, such as PILs, play a crucial role in providing the health-related information to the patients in topics such as disease conditions, risk factors, complications, medications, diet, lifestyle modification, and the importance of regular checkups. PIL is considered a cost-effective aid to educate the patients [27]. This study focused on developing the PILs for T2DM patients in the Nepali language so that patients can read easily, understand the content with no confusion, and remember by seeing relevant pictures along with the content. Moreover, the study also evaluated the knowledge of the patients and their opinions regarding the PILs.

As per the FRE score, the PIL content's readability was standard and can be understood by the primary grade education level of Nepal. In the present study, most of the patients belong to the primary level of education (77.5%), so all the enrolled patients can read and understand the content. The higher the readability, the better the understanding of the PILs by the patients [15]. PILs having written information and

Table 3: Baker Able Leaflet Design score of PILs

Design characteristics	3 points	2 points	1 point	0 point	English	Nepali
Lines 50–89 mm long			Yes		1	1
Separation between lines	>2.8 mm	2.2–2.8 mm		<2.2 mm	3	3
Lines unjustified			Yes	No	1	1
Serif typeface		Yes		No	2	0
Type size	12 point	10–11 point	9 point	<9 point	3	3
First Line Indented			Yes	No	0	0
Titles lower case			Yes	No	1	0
Italics		0 words	1–3 words	≥4 words	2	2
Positive advice		Positive		Negative	2	2
Headings standout		Yes		No	2	2
Number all Arabic			Yes	No	1	1
Boxed text			0–1 Box	>1 Box	0	0
Pictures	Words count not replace	In between	In between	None or superflours	3	2
Number of colors	4	3	2	1	3	3
White space	>40%	30–39%	20–29%	<20%	3	3
Paper quality	>90 g	75–90 g		<75 g	2	2
Total					29	25

PILs: Patient information leaflets. The PILs were prepared with good layout and design since the BALD scores were >20.

Table 4: User testing scores of PILs at pre-test and post-test

Type of users (n=40)	Pre-test (Mean±SD)	Post-test (Mean±SD)	p-value
Nepali	47.5±2.42	97.25±0.678	<0.001

SD: Standard deviation. User testing scores showed a significant increase in knowledge of T2DM patients after using the PILs (p<0.001)

supporting pictures have improved the patients' awareness regarding the disease condition, medication, and lifestyle modification [28]. Therefore, appropriate pictures have been used in the PILs to make the PILs more understandable.

The BALD score of 20 or more is considered a PIL with a good layout and design (Total score is 32) [15,26]. The layout and design of the developed PILs in English and Nepali versions were ≥25. In this study FRE/FK-GL method and UTQ were employed to assess the PILs' readability. User testing is more reliable than the assessment by the online formula method because PILs in any language could be assessed [29]. In addition to this user opinion regarding the design and layout of the PILs was also evaluated. It was found that the majority of them (90%) accepted that the PIL was of good quality. The ICC values for the UTQ and UOQ were >0.909 and 0.873, respectively, and were considered reliable. The study proved that the post-intervention user-testing scores significantly improved from 47.5 to 97.25 (p<0.001) with the use of PILs. Similar studies done in various diseases such as diabetic foot ulcer, hemodialysis patients, psychosis, coronary heart disease, cancer, diabetes, and hypertension have also supported the findings that use of PILs improves the knowledge of the patients [15,17,24,26,30,31].

CONCLUSION

It is concluded that the prepared leaflets were readable and acceptable to patients in terms of layout design components and significantly improved patient knowledge on T2DM. Thus, the study strongly suggests that the developed PIL had a significant impact on patient knowledge, and the user test was considered a standard tool for validating multi-language PILs.

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AUTHOR'S CONTRIBUTION

Dr. Neha Sharma designed the study protocol, contributed to the critical revision of the manuscript, and supervised the study. Ms. Bindu Malla

collected the data and wrote the manuscript. Dr. Tirtha Lal Upadhyaya contributed to designing the PIL, statistical analysis, and interpretation of data.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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REFERENCES

- Dhakal G, Prasad Malla K, Malla B. Correlation of serum urea, creatinine and urinary microalbumin in type 2 diabetic patients in western, Nepal: A cross sectional study. *Int J Heal Sci Res.* 2023;13(3):11-7. doi: 10.52403/ijhsr.20230303
- Dhyani S, Butola M, Sautha V, Jakhmola V. Resent advances in treatment approaches for diabetes mellitus and related complications: A review. *Int J Appl Pharm.* 2025;17(2):12-30.
- Kumari KV, Fatima MK, Sultana F, Chakradhar T, Quadri MM. A study to evaluate the effect of empagliflozin on cardiovascular and renal outcomes of patients with type 2 diabetes mellitus at a tertiary care hospital in Telengana. *Int J Pharm Pharm Sci.* 2025;17(3):10-5.
- Tripathy JP. Burden and risk factors of diabetes and hyperglycemia in India: Findings from the global burden of disease study 2016. *Diabetes Metab Syndr Obes.* 2018;11:381-7. doi: 10.2147/DMSO.S157376, PMID 30104893
- Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the international diabetes federation diabetes Atlas, 9th edition. *Diabetes Res Clin Pract.* 2019;157:107843. doi: 10.1016/j.diabres.2019.107843, PMID 31518657
- Abouammoh NA, Alshamrani MA. Knowledge about diabetes and glycemic control among diabetic patients in Saudi Arabia. *J Diabetes Res.* 2020;2020:1239735. doi: 10.1155/2020/1239735, PMID 32215269
- Hening WN, Sartika RA, Sauriasari R. Effect of hospital pharmacist counseling on clinical outcomes of type 2 diabetes mellitus outpatients. *J Res Pharm Pract.* 2019;8(3):155-61. doi: 10.4103/jrpp.JRPP_19_67, PMID 31728347
- Kumah E, Afriyie EK, Abuosi AA, Ankomah SE, Fusheini A, Otchere G. Influence of the model of care on the outcomes of diabetes self-management education program: A scoping review. *J Diabetes Res.* 2021;2021:2969243. doi: 10.1155/2021/2969243, PMID 33688505
- Wang W, Geng L, Sun C, Li H, Wang J. Efficacy of pharmaceutical care in patients with type 2 diabetes mellitus and hypertension: A randomized controlled trial. *Int J Clin Pract.* 2022;2022:7681404. doi: 10.1155/2022/7681404, PMID 35685555
- Shrestha N, Karki K, Poudyal A, Aryal KK, Mahato NK, Gautam N, et al. Prevalence of diabetes mellitus and associated risk factors in Nepal: Findings from a nationwide population-based survey. *BMJ*

- Open. 2022;12(2):e060750. doi: 10.1136/bmjopen-2022-060750, PMID 35193925
11. Pardhan S, Upadhyaya T, Smith L, Sharma T, Tuladhar S, Adhikari B, et al. Individual patient-centered target-driven intervention to improve clinical outcomes of diabetes, health literacy, and self-care practices in Nepal: A randomized controlled trial. *Front Endocrinol.* 2023;14:1076253. doi: 10.3389/fendo.2023.1076253, PMID 36742401
 12. Wahyuni AS, Marwa D, Oktasari SR, Yulianti T, Nugraheni AY, AL-Samea RA. Determination of factors affecting medication adherence in type 2 diabetes mellitus patients in a tertiary hospital: Case-control study. *Int J App Pharm.* 2025;17(2):126-31. doi: 10.22159/ijap.2025.v17s2.20
 13. Sahoo J, Mohanty S, Kundu A, Epari V. Medication adherence among patients of type II diabetes mellitus and its associated risk factors: A cross-sectional study in a tertiary care hospital of eastern India. *Cureus.* 2022;14(12):e33074. doi: 10.7759/cureus.33074, PMID 36721541
 14. Rajpurohit S, Musunuri B, Mohan PB, Vani LR, Bhat G, Shetty S. Development and evaluation of patient information leaflet for liver cirrhosis patients. *Clin Epidemiol Glob Heal.* 2023;24:101436. doi: 10.1016/j.cegh.2023.101436
 15. Sekhar MS, Mk U, Vyas N, Rodrigues GS. Development and evaluation of patient information leaflet for diabetic foot ulcer patients. *Int J Endocrinol Metab.* 2017;15(3):e55454. doi: 10.5812/ijem.55454, PMID 29201075
 16. Joshi SK, Acharya K. Modification of Kuppuswamy's socioeconomic status scale in the context of Nepal, 2019. *Kathmandu Univ Med J (KUMJ).* 2019;17(65):1-2. PMID 31734669
 17. Mateti UV, Nagappa AN, Attur RP, Bairy M, Nagaraju SP, Mallayasamy S, et al. Preparation, validation and user-testing of pictogram-based patient information leaflets for hemodialysis patients. *Saudi Pharm J.* 2015;23(6):621-5. doi: 10.1016/j.jsps.2015.01.022, PMID 26702256
 18. UpToDate. Available from: https://www.uptodate.com/contents/initial-management-of-hyperglycemia/in/adults/with/typediabetesmellitus?search=dm%20type%20&source=search_result&selectedtitle=1%7e150&usage_type=default&display_rank=1 [Last accessed on 2025 Jan 30].
 19. Available from: https://emedicine.medscape.com/article/117853overview?&icd=login_success_email_match_fpf [Last accessed on 2025 Jan 30].
 20. WebMD. Available from: <https://www.webmd.com/search?query=diabetes+mellitus+type+2> [Last accessed on 2025 Jan 30].
 21. Elizabeth A, Hackett SNJ. Jackson. Diabetes mellitus. In: Walker R, Whittlesea C, editors. *Clinical Pharmacy and Therapeutics.* 5th ed. London: Elsevier Limited; 2012. p. 685-708.
 22. Gilbert GE, Prion S. Making sense of methods and measurement: Lawshe's content validity index. *Clin Simul Nurs.* 2016;12(12):530-1. doi: 10.1016/j.ecns.2016.08.002
 23. Le NK, Turnbull N, Van Dam C, Khiewkhern S, Thiabrithi S. Impact of knowledge, attitude, and practices of Type 2 diabetic patients: A study in the locality in Vietnam. *J Educ Health Promot.* 2021;10:72. doi: 10.4103/jehp.jehp_712_20, PMID 34084819
 24. Poojari PG, Pai K, Khan SA, Shenoy S, Bhandary PV, Shetty S, et al. Development, validation, user testing of patient information leaflet to improve awareness of metabolic side effects in patients on atypical antipsychotics. *Clin Epidemiol Glob Heal.* 2024;29:101763. doi: 10.1016/j.cegh.2024.101763
 25. Good Calculators. Available from: <https://goodcalculators.com/flesch-kincaid-calculator> [Last accessed on 2025 Jan 30].
 26. Vinay BC, Shastry CS, Kodangala S, Mateti UV, Bhat K. Development and validation of patient information leaflet for coronary heart disease patients. *Perspect Clin Res.* 2021;12(2):83-6. doi: 10.4103/picr.PICR_58_19, PMID 34012904
 27. Sirimalla S, Mateti UV, Shenoy P, Shetty S. Health education for chronic kidney disease patients not on dialysis through the pictorial patient information leaflet. *J Pharm Technol.* 2023;39(6):274-80. doi: 10.1177/87551225231198988, PMID 37974594
 28. Van Beusekom MM, Grootens-Wiegers P, Bos MJ, Guchelaar HJ, Van Den Broek JM. Low literacy and written drug information: Information-seeking, leaflet evaluation and preferences, and roles for images. *Int J Clin Pharm.* 2016;38(6):1372-9. doi: 10.1007/s11096-016-0376-4, PMID 27655308
 29. Renuka P, Pushpanjali K. Leaflet preparation and validation procedures. *Univ J Public Heal.* 2013;1(3):110-4. doi: 10.13189/ujph.2013.010310
 30. Nandakumar UP, Joel JJ, Shetty J, Shastry CS, Krishna Bhat CH. Preparation, validation and user-testing of patient information leaflet on cancer. *Pharm Hosp Clin.* 2021;56(1):12-7. doi: 10.1016/j.phclin.2020.07.012
 31. Vooradi S, D Acharya L, Seshadri S, Thunga G, Vijayanarayana K. Preparation, validation and user-testing of patient information leaflets on diabetes and hypertension. *Indian J Pharm Sci.* 2018;80(1):118-25. doi: 10.4172/pharmaceutical-sciences.1000336