

The Evaluation and Effectiveness of Regional Language Patient Information Leaflets for Persons with Chronic Kidney Disease

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ABSTRACT

Objectives: The objective of this study was to develop Chronic Kidney Disease Patient Information Leaflets (CKD-PILs) to test their understandability and assess their usefulness. **Materials and Methods:** Prospective observational research was carried out in a dialysis unit at renowned medical care for 9 months and 140 CKD patients enrolled in the study to evaluate prepared CKD-PILs. Patient Information Leaflets (PILs) is prepared by referring to various medical database and it's evaluated using computer-aided readability tools using the website "http://readabilityscore.com". Afterward, PIL was translated into a regional language and verified by a subject expert. The design and layout were analyzed using BADL criteria and user option tests. **Results:** Prepared CKD-PILs found to be good design and layout as per BALD and user opinion (BALD Assamese: 27, BALD English: 28; User opinion: 82.7% for Assamese PILs and 89.2% for English PILs). The mean scores on the knowledge evaluated using user testing methods and Disease management and lifestyle-related knowledge increased from 49.08±4.16 to 80.40±5.71 ($p<0.001$) and is statistically significant. **Conclusion:** The results showed significant improvement of their lifestyle and disease-related knowledge after the implementation of PILs. The Prepared CKD-based patient information leaflets have been found to be a good and effective educational tool for CKD patients.

Keywords: Pharmaceutical care, Patient Information Leaflets (PILs), Hemodialysis (HD), Chronic kidney disease, BALD, CKD-PILs.

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INTRODUCTION

Drug-related problems may be effectively managed via the use of pharmaceutical care programmers (interventions that often include assessing the appropriateness of the treatment, reconciling, and fostering adherence).^{1,2} Patients with chronic kidney disease who are not properly educated and who do not strictly stick to their prescribed treatment regimen have poor health outcomes. Most patients will forget maximum of the information what their doctors told them over the conversation.³ Knowledge preservation via the usage of printed materials would be very helpful. PILs are popular tools that advise patients and users about medications, illnesses, and healthy habits.^{4,5} PILs may be used to improve health classes. PILs are particularly helpful for patients who are dealing with long-term health issues such diabetes, hypertension, asthma, and COPD.^{6,7} PILs are often written in English. Despite the widespread habit of translating

PILs into Indian languages, readability cannot be assessed by conventional measures. Patients should be asked for their feedback on PILs to determine acceptability and usability.⁸

Chronic Kidney Disease (CKD) is defined as a decline in renal function (estimated glomerular filtration rate decreased to 60 mL/min/1.73 m²) or the development of symptoms of kidney damage (albuminuria 3 mg/mmol or abnormalities in urine volumes) that have adverse health effects.^{9,10} The estimated 850 million persons with CKD make it the 9th greatest cause of mortality worldwide. Dialysis or kidney transplantation helped 2.6 million Americans with ESKD in 2010, and that number is expected to rise to 5.4 million by 2030.¹¹ There is an increasing financial burden on governments, particularly in developing countries, due to the prevalence of Chronic Kidney Disease (CKD).¹² Thus, chronic kidney disease has been recognized as a non-communicable condition deserving of urgent global attention. New infections with COVID-19 and death rates were found to be higher in persons with CKD.¹³ Pharmacists are among the frontline healthcare providers providing essential services during this epidemic and health calamity. Patients undergoing hemodialysis for end-stage renal failure typically take 12 drugs and suffer from 6 co-occurring medical conditions.¹⁴ To prevent



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graft rejection and subsequent high medical expenditures, patients who have undergone organ transplantation are needed to take many drugs.¹⁵ Many people on dialysis have issues with their medications. The objective of this study was to develop Chronic Kidney Disease Patient Information Leaflets (CKD-PILs) to test their understandability and assess the usefulness of CKD-PILs.

MATERIALS AND METHODS

Study design

Prospective observational research was carried out in a dialysis unit at a renowned medical Center from 4th October 2021 to 19th July 2022 (9-Months). The human ethics committee at the university has approved this study (Approval no: AdtU/Ethics/PhD scholar/2021/010). 140 CKD patients agreed to take part in the research. Patient's ages, sex, and ethnicities were documented. It was decided not to include participants who had mental or learning difficulties. Block randomization methods are used to select participate from each group. Detail of the participant recruitment process is shown in Figure 1.

CONSORT Flow Diagram

Sample Size

The sample size was generated using the following method based on the change in patient awareness of user-testing scores from baseline to post-intervention scores.

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

$$\sigma = 12, Z_{1-\alpha} \text{ is } 1.96 \text{ (for } \alpha = 5\%)$$

$Z_{1-\beta}$ is 0.84 for power and $d = 5$.

σ is the mean of the two groups standard deviation

d is the minimum significant difference between the two groups.

The minimum sample required for this study is 47.

P-PILs preparation, validation, and translation

The patient information leaflets were prepared using by referring primary, secondary, and tertiary sources. The tertiary resources included textbooks on the nutritional value of Indian foods, pharmacotherapy textbooks, National Kidney Foundation guidelines, Kidney Disease Outcomes Quality Initiative Clinical Practice guidelines, Indian Association of Nephrology guidelines, and publications from the National Kidney Disease Education Program and the Renal Nutrition Forum.¹⁷⁻¹⁹ Main materials included many CKD articles, while secondary resources included databases like Micromedex, Up-to-date, Medscape, Medline, and Web MD. The leaflet's content and illustrations were double checked by a panel of experts consisting of 2 nephrologists and 4 academic pharmacists. PIL utilizing layout and design components were evaluated by Baker Able Leaflets Design

(BALD) criteria, and three adjustments were made according to the expert committee's instructions and readability score.²⁰ The final version of English PILs were translated into Assamese using a three-stage process consisting of forward translation, reverse translation, and patient testing.

Readability testing of P-PILs

Each modification of the PILs resulted in an increase in the readability as measured by the Coleman-Liau Index (CLI), Flesch Reading-Ease (FRE), Flesch-Kincaid Grade Level (FK-GL) and Automated Readability Index (ARI) scale factors. This readability score was obtained by using website "http://readabilityscore.com". The user-testing questionnaire was used to evaluate the readability of the translated CKD-PILs. 10 multiple-choice questions were developed using the information presented in the brochure for this round of user testing. The readability and validity of the survey were both examined. Patients in group were given a questionnaire during user testing to determine their base level of understanding of CKD, and then the leaflet was given to each participated patient. Afterwards, patients were given the same questionnaire to reassess their knowledge; this time, however, they were given 20 min to read. On satisfied the result, the translated PILs is administered to clinical study groups. A formula was used to assess participant participation and results.

$$\text{Response Evaluation} = \frac{\text{Total number of correct responses patient}}{\text{Total number of actual responses}} \times 100$$

Following the knowledge evaluation, patients were asked for their thoughts on the PILs content, layout, and design using a 4-question rating form with a 5-1 scale. Here are how the results should be interpreted Table 1:

User-testing and user-opinion testing using questionnaire

Prior to collecting patient feedback, we made our questionnaire for user testing and user opinion testing was valid and reliable by subgroup of patient's. An advisory panel verified the accuracy of the user feedback survey. Test the reliability opinion for prepared PILs carried out in a sub sample of 15 randomly chosen CKD patients enrolled in two groups (Assamese group and English group) and the test conducted for day. After statistics analysis of subgroup the same questionnaire are used to evaluate the final PILs.

Statistical Analysis

Among a sample of CKD patient demographic data was summarized using descriptive statistics, and pre ad post test scores for Assamese group and English group user data were calculated using a paired student *t*-test, with a $p < 0.05$ indicating statistical significance. IBM-SPSS version 21 software was used to analyze data.

RESULTS

Patient demographic data

There were 165 people in total receiving pharmacological treatment for CKD. There was total of 140 patients screened and were enrolled in the research, 25 patients exclude from the study out of 8 patients not meeting inclusion criteria and 17 patients declined to participate at initial screening. The demographic and physiological data of 140 patients was recorded in a standard form. Later from the study groups 2 patients lost follow in Assamese PILs group and 1 patient volunteer withdrawal from English group (Figure 1). Following permission from hospital administration, 68 patients were chosen for Assamese PILs, and 69 patients were chosen for English PILs validation. We gave CKD-PILs to the patients after obtained inform concern from all the participants. The selection of the patient's summaries in Figure 1. During patient selection, we prioritized a ratio of male to female patients (56.4% male and 43.6% female). Most patients had completed undergraduate education and were of intermediate socioeconomic background (41.8% male and 39.2% female). Table 2 shows the outcomes of the patient's socio-demographic information, and Table 3 describes the patient physiological variations.

Readability test

Readability of prepared English CKD-PILs was assed using website <http://readabilityscore.com>,²¹ and modified accordingly. Readability result of prepared PILs displayed in Figure 2.

Readability opinion for Assamese and English version of PILs

Readability opinion on design and content carried out in subsample of 30 patients (15 patients were evaluated using the Assamese version of the questionnaire, while the remaining 15 were evaluated using the English form of CKD-PILs). Both questionnaires had high levels of dependability, with ICCs ranging from 0.83 to 0.98. Results for both the Assamese and English versions are reported, with their corresponding ICC reliability values, 95% confidence intervals, mean, and standard deviations Table 4.

Design and layout assessment of PILs

Evaluation of the design and layout according to the BALD (Baker's Able Leaflet Design) Criteria. After three rounds of revisions, the final CKD-PILs BALD evaluation scores for the

Table 1: Table for Response evaluation of CKD-PILs content.

Content of the CKD-PILs	Score Range
Good	14-20
Average	9-14
Poor	Less than 9

English and Assamese versions of the leaflet were 28 and 27, respectively. Figure 3 shows the PILs score.

User-testing PILs

Patients were given the PILs brochure as per the CONSORT Flow Diagram (Figure 1). The total patient data analyzed after dropped out is 68 for Assamese CKD-PILs user and 69 for English CKD-PILs user. The mean scores on the knowledge evaluation used in the user testing increased from 48.74 ± 4.63 to 78.22 ± 6.21 ($p < 0.001$) in Assamese PILs user and 49.43 ± 3.68 to 82.57 ± 4.23 ($p < 0.001$) English PILs user. The overall mean knowledge improve was 49.08 ± 4.16 to 80.40 ± 5.71 ($p < 0.001$). Table 5 provides a summary of the results of user testing conducted on both the Assamese and English versions of leaflets. Leaflets were well received by their target audiences, with positive ratings for both readability and substance (Assamese=84.3% and English=82.9%). Tabulated in Table 6 below are summaries of the comprehensive user-opinion rating ratings for the Assamese and English versions of leaflets.

DISCUSSION

This study is the first of its kind to be conducted in north-east India on patients with CKD. Patient information leaflets have been studied in the past for a variety of medical conditions like Chronic Obstructive Pulmonary Disease (COPD), diabetes, hypertension, diabetic foot ulcer, rheumatoid arthritis, asthma, peptic ulcer, and Tuberculosis (TB) for their effectiveness in patient care.²²⁻²⁶ Similar kind of study conducted on HD patients in southern part of India and they found P-PILs are very effective tools for patients education.²⁷ Health literacy and adoption of the COVID-19 vaccination might be enhanced using readability assessments and the subsequent analysis of written materials.²⁸ To improve treatment and medication adherence and decrease

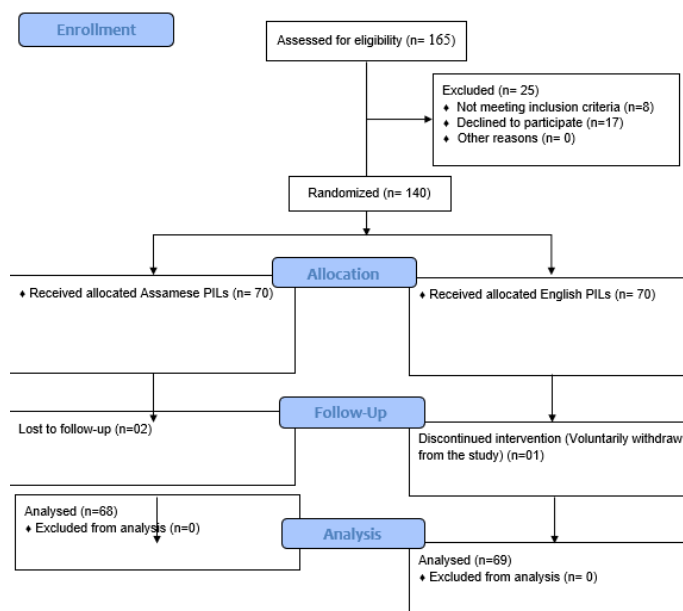


Figure 1: CONSORT Flow Diagram for patient recruitment.¹⁶

Table 2: Demography of the patient enrolled in the study.

Category		Sex			
		Male (n=56.4%)		Female (n=43.6%)	
		Count	Column N %	Count	Column N %
Education	Postgraduate	5	6.3%	1	1.6%
	Undergraduate	50	63.3%	35	57.4%
	12th Pass	24	30.4%	25	41.0%
	10th Pass	0	0.0%	0	0.0%
	PhD	0	0.0%	0	0.0%
Socio-economic	Upper	28	35.4%	29	47.5%
	Middle	33	41.8%	24	39.3%
	Lower	18	22.8%	8	13.1%
DM	Yes	33	41.8%	43	70.5%
	No	46	58.2%	18	29.5%
HTN	Yes	55	69.6%	43	70.5%
	No	24	30.4%	18	29.5%
Anemia	No	9	11.4%	6	9.8%
	Mild anemia	28	35.4%	20	32.8%
	Moderate anemia	42	53.2%	35	57.4%
	Severe anemia	0	0.0%	0	0.0%

Table 3: HD related physiological changes.

Category	Sex			
	Male		Female	
	Mean	Standard Deviation	Mean	Standard Deviation
Pre-HD-Weight	54.90	7.68	58.61	9.07
Post-HD-Weight	53.43	7.55	57.32	8.84
Pre-HD-Systolic-BP	149	13	157	13
Post-HD-Systolic-BP	141	19	155	22
Pre-HD-Diastolic-BP	80	7	80	6
Post-HD-Diastolic-BP	76	4	78	4
HD-Time (Hr.)	3.928	.253	3.689	.450
Hemoglobin level	10.51	1.12	9.48	1.05

health-risk behaviours, it is important to pay attention to patient and leaflet aspects that impact understanding of information in the PILs.²⁹ Patients should first consult their neighbourhood pharmacy for guidance on treating common illnesses. Patients may self-manage symptoms and evaluate the need for additional assistance with the use of the patient information sheet on common infections, which should be used in primary care and community pharmacies.³⁰ User testing is the most reliable approach for determining whether leaflets, in any language, are easily readable. The readability determined using formulae can only be used to the English version leaflets and readability of other language leaflets was until unknown. Readability formulas discovered

in the west were applied to Indian languages, although it was uncertain whether they were legitimate or readable. In addition to user testing, the research also gathered feedback from actual people who had used the leaflets. Most of the existing studies did not examine the user-opinion on the leaflets which the current research tried since they are one of the essential stakeholders in patient education. According to the findings of the research, over 82% of patients regarded the substance, readability, and design of the leaflets as satisfactory. It has been determined that the dependability of the current research in terms of user-testing and user-opinion of the questionnaire is excellent, and it is regarded as being very dependable.

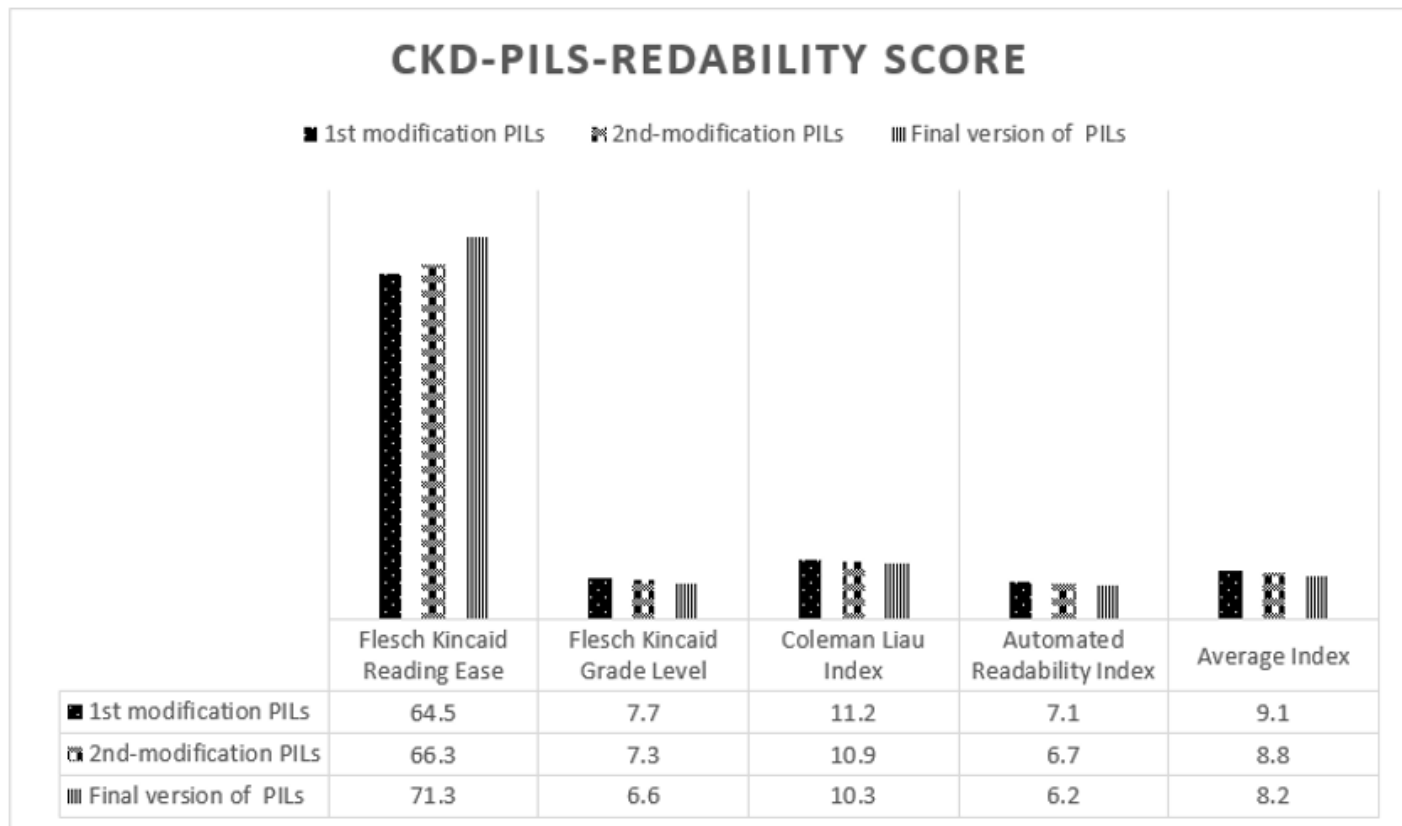


Figure 2: Readability score of prepared CKD-PILs.

Table 4: Readability pilot test for Assamese and English version of CKD-PILs content.

User opinion readability responses	Mean ±SD (D1)	Mean± SD (D7)	Mean difference ± SD	ICC	95% CI	P-value
Assamese (N15)	15.83± 1.48	16.17±1.77	0.34±2.35	0.93	0.86-0.98	P=0.047*
English (N15)	15.97±1.92	16.23±1.86	0.25±2.6	0.95	0.83-0.97	P=0.038*

*p value is less than 0.05 is statistically significant.

Table 5: PILs user-testing scores of Assamese and English version.

Languages	Pre-test Mean ±SD*	Post-test Mean ±SD*	Mean difference ± SD, (range)	95% CI	P-value
Assamese (N68)	48.74±4.63	78.22±6.21	29.48+5.55(23,24)	31.39-27.57	p<0.001 (Significant)
English (N69)	49.43±3.68	82.57±4.23	33.14+1.63(14,17)	33.7-32.5	p<0.001 (Significant)
Overall (N137)	49.08±4.16	80.40±5.71	31.31+4.46(23-25)	32.37-30.25	p<0.001 (Significant)

*SD: Standard division

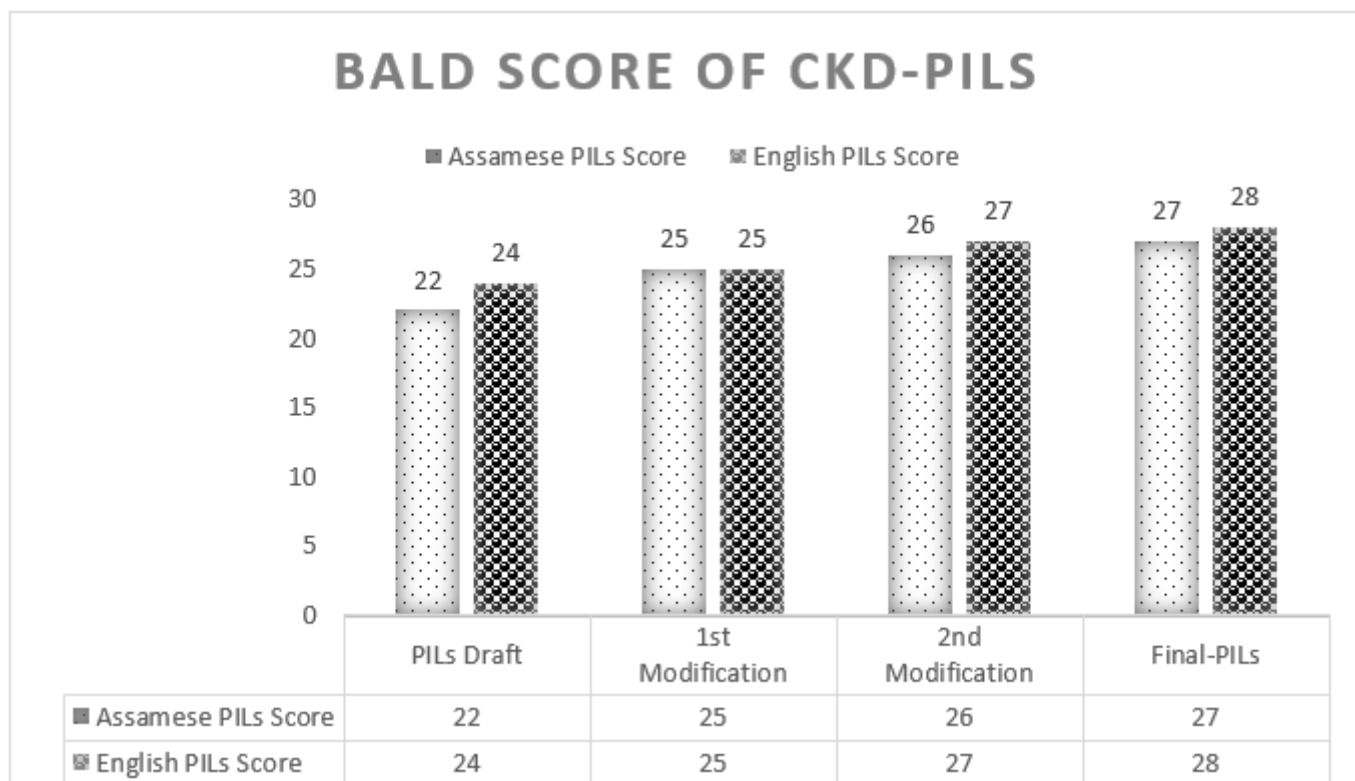


Figure 3: PILs score after 3 modified version.

Table 6: User rating of Prepared PIL.

Language		Count	Percentage %
Assamese (n=68)	Good	62	82.7
	Average	6	8.0
	Poor	7	9.3
	Total	75	100.0
English (n=69)	Good	58	89.2
	Average	4	6.2
	Poor	3	4.6
	Total	65	100.0

The post-intervention CKD-PILs knowledge-based user-testing scores increased significantly from the baseline scores (49.08 ± 4.16) to the post-intervention values (80.40 ± 5.71) with a $p < 0.001$. The overall content of PILs consider to be highly readable as per user rating and consider to be good (82.7% for Assamese PILs and 89.2% for English PILs). Leiria and Ros's (2003) investigation on the impact of pictograms in PILs on participants' memorization found similar advantages.³¹ Drug memory improved dramatically between pre-and post-intervention PIL studies conducted in a community pharmacy, from 30% to 65%. As reported by Carina et al., (1996).³² Evidence suggests that students' ability to correctly identify drug indications and side effects can improve

by as much as 67% when they receive both traditional classroom instruction and PIL. Studies with similar designs have shown that patient information leaflets had a significant impact on patients' knowledge, attitudes, and practices regarding diabetes, hypertension, asthma, COPD, peptic ulcer, and rheumatoid arthritis.^{22-24,26,33,34}

CONCLUSION

Patients' education is integral part of pharmaceutical care. The present study showed significant improvement in knowledge levels after reading the prepared CKD-PILs of Assamese and English version of leaflets. Patients also rated the leaflets content

are found to be readable (82.7% for Assamese PILs and 89.2% for English PILs). PILs design of each language was good as per user opinion and BALD criteria. The Prepared CKD-based patient information leaflets have been found to be an effective educational tool for patients.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

BALD: Baker's Able Leaflet Design; **COPD:** Chronic obstructive pulmonary disease; **CKD:** Chronic kidney disease; **CONSORT:** Consolidated Standards of Reporting Trials; **PILs:** Patient Information Leaflets; **HD:** Haemodialysis.

Ethical Approval Statement

The human ethics committee (approval no: AdtU/Ethics/PhD scholar/2021/010).

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