

Computer-Assisted Evaluation of Patient Information Leaflets (PILs) for Chronic Kidney Disease Compared with Marketed PILs

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Abstract

Printed educational materials play an important part in the treatment of disease. The patient may use them as a reference at home or to enhance knowledge. The goal of this study was to use standard approaches, such as Baker Able Leaflet Design (BALD) and readability score, to the evaluation of patients' opinions on Patient Information Leaflets (PILs) for chronic kidney disease. Participants were enrolled randomly, and some were taken at a convenient time. The study spanned 1 year in a hospital in Assam, India. We compiled our Patient Information Leaflets (PILs) by referring to various sources of information and translating them into the Assamese language. With the help of the BALD assessment strategy and user rating, we compared our PILs with available PILs on the website and marketed them. The prepared leaflets scored "above standard" in BALD and readability evaluations, indicating that they are above the industry standard. Since their average score was greater than 25, the layout and design. This shows that the issue is important from the patient's perspective, which may encourage them to read the PILs. Even though a larger percentage of Indian consumers cannot read or write English, many PILs are still written in the English language. Without considering the patient's reading levels and ensuring proper style and design, PILs may not be understood or used. Every company has to take this into account when creating leaflets and, at the absolute least, in some of the most important local languages in which PILs must be published.

Keywords: Patient information leaflets, BALD, CKD, Computer-assisted readability

INTRODUCTION

Patient information leaflets (PILs) are provided by the manufacturer in a standard format and include the same types of information for each medicine. Most patients find it difficult to recollect information that has been regularly presented by their physicians over a long period. The use of printed materials will prove to be an effective approach to memorizing knowledge of medicines. PILs are a kind of instructional material that is widely recognized and used to educate patients and users about ailments, treatments, and lifestyle modifications. PILs have the potential to be used as a complement to health education. PILs are the most beneficial tools for individuals suffering from chronic diseases such as diabetes, hypertension, asthma, Chronic obstructive pulmonary disease (COPD), and chronic kidney disease (CKD) [1]. PILs are often accessible exclusively in English. Even though some PILs are translated into Indian languages, the readability of these PILs cannot be judged using the standard procedures accessible in English. To determine product acceptance and end-user opinion, it is critical to analyze the readability of PILs and apply them to user testing in patients [2]. The purpose of this research was to create PILs for chronic obstructive pulmonary disease (COPD), evaluate their readability based on user feedback, and determine the utility of PILs for such conditions. Include

patient education materials to ensure that patients fully grasp their ailments, treatments, and prescribed lifestyle modifications. Medication non-adherence is common, has a negative influence on patients' quality of life and survival chances, and is expensive to treat. Adherence is a complex behavior that can be divided into three parts: initiation (when the patient takes the first dose), implementation (the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen from initiation to the last dose), and persistence (the amount of time until the patient stops taking the prescribed medication). Adherence is a complicated

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behavior that may be split into three categories. Patients who only partially follow their doctor's advice naturally worry about what to do if they miss or are unable to take one of their regular medications.

Chronic kidney disease (CKD) significantly adds to the global disease burden since it is both a risk factor for and a symptom of other risk factors and illnesses such as cancer and cardiovascular disease (CVD) [3]. During the 2019 coronavirus pandemic, chronic kidney disease (CKD) has been linked to a bad prognosis (COVID-19). Despite the clinical and public health importance of CKD, research has been confined to all phases, multimorbidity, or the general population utilizing national-level data. The pandemic's consequences might be classified as direct (through infection) or indirect (by changes in health care, economic hardship, and behavioral factors) [4]. People with CKD and other underlying diseases are immediately influenced by baseline risk, which is defined by age, gender, the presence of multiple illnesses, and other sociodemographic variables. Previous investigations on COVID-19 in CKD had a limited sample size, mostly focused on advanced CKD, and overlooked critical co-morbidities [5]. All these difficulties must be addressed (either most common in CKD or related to the risk of COVID-19 mortality). There are few clinical risk stratification strategies relevant to persons with CKD or at risk of developing CKD, and those that do often fail to account for the disease's fluctuating severity over time. A more exact assessment of baseline risk in CKD patients may influence individual and population-based approaches to CKD prevention and therapy, as well as integrated chronic disease management [6].

A Knowledge, Attitude, and Practice survey is a kind of survey that is separated into three sections: knowledge, attitude, and practice. Questions about knowledge, attitudes, and practices show not just commonalities in health-related facts, attitudes, and behaviors, but also each person's perspective on the condition. Most misconceptions may be traced to these many elements. Chronic illness management requires not just medical therapy, but also long-term behavioral changes. Individuals with chronic diseases must fully understand their issues before initiating therapy. Effective patient counseling increases patient compliance by strengthening the patient's understanding of his or her illness, as well as any required lifestyle and medication changes. The pharmacist has a tremendous degree of responsibility when it comes to counseling patients with chronic diseases. The pharmacist who conducts counseling should be well-informed and a competent communicator who is capable of both verbal and nonverbal communication

MATERIALS AND METHODS

The PILs for CKD was prepared using various source of information and translate into the local language (Assamese). Already available PILs are gathered at random from websites and community pharmacies. A total of 4 PILs regularly used

by customers were gathered and appraised using the readability scale and BALD evaluation technique. All the leaflets were assessed by various readability scale formulas and rated accordingly. BALD criteria of leaflets with a total score of 25 or more are deemed 'above standard,' whereas leaflets with a total score of 22 to 25 are regarded as standard. However, leaflets with a score of 21 or less are regarded as bad. Then the prepared PILs are compared with marketed PILs. Assessment of readability and design was carried out for prepared PILs. A customer satisfaction survey was conducted for the prepared PILs following the marketed PILs after signing the informed concern form. The study was approved by the Institutional ethics committee. The demography of the surveyor was recorded in a standard format.

Preparation of PILs

Primary, secondary, and tertiary resources were used to create the patient information pamphlets. Textbooks on the nutritional values 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 Renal Nutrition Forum were among the tertiary resources [7-9]. The secondary resources included databases like Micromedex, Up-to-date, Medscape, Medline, and Web MD, while the main materials included numerous HD papers. An expert team comprised of two nephrologists and two academic pharmacists verified the leaflet's text and pictograms [10]. The three revisions were performed following the expert committee's instructions, and the readability score and the leaflet were created after evaluating the layout and design aspects of PILs employing. The design approach for Baker Able Leaflets.

Assessment of PILs

Readability scales are used for the assessment of readability scores and compared with marketed PILs. The readability score was obtained using the domain "http://readabilityscore.com" [11]. The results obtained from this website are summarized in **Table 1**.

Assessment of Design and Layout

The Baker-Able Leaflet Design (BALD) approach is used to evaluate the layout and design of the leaflets. The scores are determined by the length of the line, the space between the lines, the letter font size, and the letter font style. Graphics utilized, percentage of white space, and paper quality A document with a score of 25 or above is regarded to have an excellent layout and design. The presentation is critical in terms of reading and comprehension [12]. The text should be in suitably big print and readable. To differentiate, different colors and font sizes might be employed. Clear disclosure of negative impacts, for example, increases message comprehension [13].

The Baker-Able Leaflet Design (BALD) Method is used to evaluate the layout and design of the leaflets. The scores are determined by the length of the line, the spacing between the lines, the letter font size, the visuals used, the percentage of white space, and the paper quality. A document with a score of 25 or above is regarded to have a strong layout and design [13]. The presentation is quite important in terms of reading and comprehension. The text should be legible and inappropriately big print. Different colors and font sizes may be utilized to differentiate. Clear listing of negative impacts; for example, increase message comprehension.

RESULTS AND DISCUSSION

A total of 188 users participated in the PILs assessment. PILs are distributed among the user randomly and their output is collected in survey form. The median age of the user male 45 ± 3.5 and Female 37 ± 5.6 . The demography of the user is represented in **Table 1** below. The readability score was assessed for all 5 leaflets and represented below in **Table 2** and found that the prepared PILs is usually readable by the user compared to marketed PILs the user-based rating was obtained and found that our PILs are very good in term of contents and can be used as counseling tools (**Figure 1**). BALD criteria were assessed for the prepared PILs and market PILs. Our PILs design and layout were found to be above standard and represent in **Table 3**.

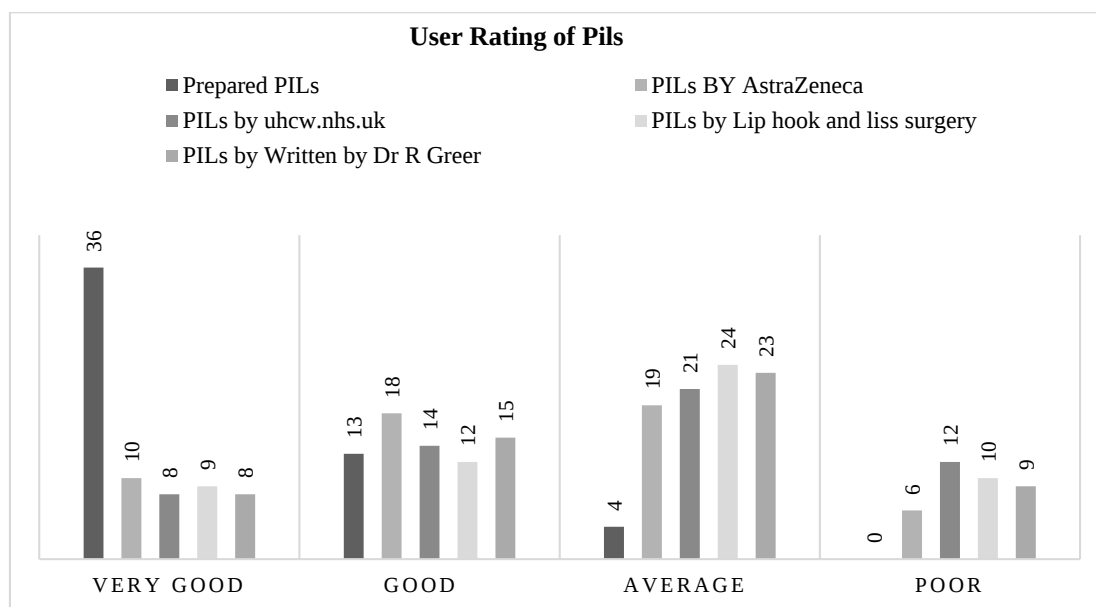


Figure 1. User-based-user rating based on PILs contents.

Table 1. The demography of the PILs user.

Sl. No	Education Qualification	Male	Female	Socioeconomics Statues	Male	Female
1	Postgraduate	14	6	Upper	19	23
2	Undergraduate	48	59	Middle	65	61
3	12th Pass	24	30	Lower	11	9

Table 2. The readability score was assessed for all 5 leaflets.

Scoring Method	Prepared PILs	PILs by Written by Dr. R Greer	PILs by lip hook and liss surgery	PILs by uhcw.nhs.UK	PILs BY AstraZeneca
Flesch Reading Ease	83.36	82.88	64.89	67.34	59.6
Flesch-Kincaid Grade Level	3.04	2.97	6.07	5.63	6.07
Gunning Fog	5.21	5.26	8.18	7.95	8.18
SMOG	6.82	6.79	8.76	8.57	8.76
Automated Readability Index	6.5	1.84	5.56	4.87	5.56
Coleman-Liau Index	9.33	4.28	9.27	8.44	9.27

Table 3. The design and layout of PILs according to the BALD method

Leaflets	BALD Score	Levels
Prepared PILs	26	Above standard
PILs BY AstraZeneca	25	Above standard
PILs by uhcw. nhs. uk	24	Standard
PILs by Lip hook and liss surgery	24	Standard
PILs by Written by Dr. R Greer	27	Above standard

The PILs were carefully analyzed in this study to discover how the use PILs results in the knowledge of CKD presented and communicated with participants throughout the patient's counseling process and to evaluate the usefulness and quality of created PILs [14]. According to the BALD criterion evaluation, the prepared PILs are sold above standard among the four PILs. The majority of PILs described here have a high readability score and use active channels of dissemination that are of high quality, with academic publications being the most prevalent. Information on when results would be revealed and whether patients would stay anonymous was less often supplied.

It was surprising to realize that almost one-third of the PILs in our sample did not specify how potential volunteers may learn about CKD. When developing PILs for chronic diseases, it is critical to focus on the user [15, 16]. To make PILs more valuable for prospective participants, have participant representatives assist to develop them and emphasize how patient feedback will or has been included in research data sharing.

In the Indian pharmaceutical industry, PILs are still typically produced in English, even though a bigger number of customers are illiterate in English. PILs that are created without considering the reading level of the customers, as well as the correct layout and design, may fail to fulfil their intended objective. This is a key consideration for every firm when generating leaflets and, at the very least, in some main local languages in which PILs must be written.

Though consumers with postgraduate degrees were able to assess the leaflets quickly, consumers with graduate degrees or higher school education were unable to rate the leaflets accurately, indicating that these leaflets are not appropriate for Assam, India. This is because most of the people here have a high school diploma or a graduate degree.

PIL research in our study demonstrated that the generated PILs are very standard and readily understandable by users. As a result, this research found that the provided PILs are effective patient education aids.

CONCLUSION

The BALD method's design and layout ratings did not correspond to the perceptions of the customers surveyed. This

is because the customers were either highly qualified, such as graduates, or had just a high school degree and were unable to read English well. Only consumers with a college degree can comprehend the PILs issued by pharmaceutical corporations. This research suggests that many pharmaceutical businesses (leaflet suppliers) do not consider the reading level of the user, which may result in the intended purpose not being met. According to the Indian system, there is a requirement to create PILs with high readability scores. PILs may be built with more pictograms and colorful images, which may result in improved comprehension. Companies should also investigate the possibility of producing pamphlets in the country's native language.

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