

Development and Validation of the Patient Information Leaflet for Pregnant Women

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ABSTRACT

Objective: The objective of the study is to prepare, validate and analyze the user understanding of the pictogram-based leaflet. **Methods:** The patient information leaflet (PIL) was prepared by referring to national and international guidelines. It was reviewed by an expert committee for content and layout. The readability of the PIL was assessed using the Flesch readability ease (FRE) score and Flesch Kincaid Grade Level score (FK-GL), while the layout was validated using Baker Able leaflet design (BALD) criteria. In addition, a pre and post-test study of user-testing and user-opinion methods were employed to validate both English and Kannada versions of PIL. **Results:** The FRE, FKGL, and BALD score of the final version of the prepared leaflet was found to be 70.5, 5.8, and 31, respectively. The user testing scores of PIL were improved from pre-test score of 62.5 ± 9.26 to post-test score of 88.5 ± 6.99 with $P < 0.0001$. The overall patient education materials assessment tool for printable materials score assigned by study participants was found to be good 32 (80.32%) and average 8 (20%). **Conclusion:** This study showed that the use of well-developed and validated leaflet as an effective educational tool for patient education may have a positive impact on knowledge and attitude of pregnant women toward the antenatal care for better pregnancy outcomes.

Keywords: Baker Able leaflet design, Flesch Kincaid grade level, Flesch readability ease, Patient education materials assessment tool for printable materials score, Patient information leaflet

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INTRODUCTION

Antenatal care (ANC) can be defined as the care provided by skilled healthcare professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby during pregnancy. The information provided to a pregnant woman during ANC visits is an important part of her journey and central to the overall quality of her experience of pregnancy.^[1] Hence, there is a need to improve and monitor the information we provide to the women attending ANC centers and make sure that the information provided to them is concise, relevant, accurate, and is in an everyday language. It should give the women confidence so that their overall experience of their pregnancy is improved, and the outcome is favorable.^[2]

Women in low- and middle-income countries like India often have less personal autonomy and less access to information about their health.^[3] Many of them travel long distances to access healthcare facilities and have inhibitions regarding the healthcare system and the quality of care provided. The limited number of trained healthcare providers to educate and counsel these women is another lacuna in the overall ANC system.^[4] In such circumstances, the clinical pharmacists can lend a helping hand to the obstetric care team by developing the appropriate patient information leaflets (PILs), which can be easily understood by the patients. The proper designing and validation of PIL is a core component of health education in ANC.^[5,6] Hence our study aimed at improving the information provided to the pregnant women, who visited the obstetrics and gynecology department of a tertiary care hospital in Bangalore by designing a suitable PIL for them.

METHODS

Study Design, Setting and Patients

A quasi-experimental study was carried out to evaluate the PIL by 40 pregnant women. This study was part of a large study aimed

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at determining the impact of complications of pregnancy on fetomaternal outcomes. The present study was approved by the Institutional Ethical Committee (IEC) on 12 November 2016 (VIPS/IEC/2016-07). Written consent was obtained from the pregnant women, who were willing to participate in the study. These subjects' demographic details and obstetric history were recorded on a specially designed form. The study was carried out in two phases (i.e.) Phase I comprises of preparation and translation of PIL, while Phase II comprises of validation of PIL.

Phase I: Preparation and translation of PIL

The Pictogram-based PIL was developed using information from various international and national guidelines on nutrition, exercise, and lifestyle changes during pregnancy. Recommendations such as Essential nutrition actions and ANC module by the World Health Organization, dietary guidelines for Indians by the National Institute of nutrition, and national health portal guidelines for pregnancy were used.^[7-10] In addition, information was obtained from the resources such as Mayo Clinic and obstetric textbooks. The leaflet was designed as per standard guidelines using the information from the above sources. Later, it

was reviewed by an expert committee comprising of dieticians, physiotherapists, gynecologists, and clinical pharmacist for content and layout. Based on the recommendations of the committee, changes were made to the leaflet. Once the English leaflet was finalized, it was then translated into the local language, i.e., Kannada.

Phase II: Validation of PIL

The English version of the leaflet was validated for readability and layout. Readability was assessed using Flesch readability Ease (FRE) score and Flesch Kincaid Grade Level (FK-GL), Gunning Fog, The Coleman-Liau Index, The SMOG Index and Linsear Write Formula score, while the layout was validated using Baker Able Leaflet Design (BALD) criteria.^[11]

User-testing and User Opinion Test

The formulae available for assessing readability and layout cannot be employed in validating PIL of local language. Hence the readability of both the English and Kannada version of PIL was assessed using the user-testing method. In this method, the questionnaire was administered to 40 pregnant women for assessing their baseline knowledge. Later, the PIL was given to the same subjects and they were asked to read and go through it. On completion of reading, the questionnaire was re-administered to the same pregnant women to reassess their knowledge. Finally, the response was evaluated using the following formula.

$$\text{Response evaluation} = \frac{\text{Total number of correct responses}}{\text{Total number of actual responses}} \times 100 \quad (1)$$

In addition, the user opinion on the PIL content, layout, and design was assessed using the patient education materials assessment tool for printable materials (PEMAT-P) questionnaire. The above-recruited subjects were also handed over with PEMAT-P questionnaires of Kannada or English version as per their choice and requested them to answer. The understandability and actionability of PIL were assessed using the below formulae.^[12]

$$\text{Understandability} = \frac{\text{Total Points}}{\text{Total possible points}} \times 100 \quad (2)$$

$$\text{Actionability} = \frac{\text{Total Points}}{\text{Total possible points}} \times 100 \quad (3)$$

Sample Size

The minimum sample size of the study was calculated using the following formula.^[5,6] It was found to be 40 subjects.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2 + 2}{d^2} \quad (4)$$

Where,

Mean of the two standard deviations (σ) = 10

$Z_{1-\alpha/2}$ for α (5%) = 1.96

$Z_{1-\beta}$ for 80% power = 0.84

Minimum significant difference in the two groups ($d=5$).

RESULTS

Socio-demographic details of the study subjects

The socio-demographic characteristics of the participants. Of the 40 subjects included in the study, majority of the participants (57.5%) were between the age group 18-25 years. Among the participants, 22(55%) had multigravida, 65% belonged to the lower middle socio-economic status. All the study subjects had a minimum of school education in Table 1.

Readability scores of the leaflet

The Flesch Reading Ease score for the English version of leaflets was 70.5 indicating that it can be easily understood by 13-15-year-old students. Flesch -Kincaid Grade Level score was 5.8, Gunning Fog score was 8.9 indicating a reading level suitable for eighth grade and by high school freshman which is also indicated by The Coleman-Liau Index of 9. The smog index was 6.6 and Linsear Write Formula score was 5, which also indicated that the PIL can be easily understood by seventh grade and fifth grade subjects respectively, as summarized in Table 2.

User testing scores of PIL

The overall user testing knowledge assessment mean scores significantly improved from 62.5 to 88.5 at $p < 0.0001$, as described in Table 3.

User-opinion (PEMAT-P) scores of PIL

The detailed user-opinion (PEMAT-P) scores of PIL of Kannada and English versions of the leaflet are described in table 4 which shows that Kannada and English leaflet user opinion score was good for 57.5% and 22.5% respectively. The overall user opinion score was good (80.32%), as shown in Table 4.

DISCUSSION

Our target population was pregnant women, who came for their first antenatal visit to our study site and their gestational age was < 12 weeks. The mean age of the study population was 25.05 ± 3.86 years. The study population were all married and lived in a similar geographic area. Among the 40 subjects, 18 (45%) had first pregnancy (primigravida) and 22 (55%) had more than one pregnancy [Table 1].

The ANC given to pregnant women becomes a key determinant for better pregnancy outcomes. There were several lacunas that were identified in the proper performance of ANC. First, the health education and counseling given to pregnant women during their ANC visits were inadequate. Secondly, the leaflet used for counseling were not appropriately validated, which may result in poor understanding by the study population.^[13] However, in the clinical setup, the healthcare workers are not able to allot enough time for educating the pregnant women, that may be either due to high patient floating or due to excess time involved in screening the complications of pregnancy. As a result, most caregivers provide health education orally. While, the information provided orally tends to be misunderstood, forgotten or lost in translation. Therefore, there is a dire need to supplement the oral instructions along with a PIL, which may help the pregnant

women in better understanding and recalling the information provided by their clinician. Hence in our study, we tailored the health educational leaflet for the target population, in order to ensure better understanding of their specific needs.

The PIL designed for our study had a Times New Roman font, with the font size of 11 and point driven illustrations, which were created specifically for the leaflet. The readability of the leaflet was validated using the FRE and FK-GL score and were found to be 70.5 and 5.8, respectively [Table 2]. The FRE score of a leaflet between 70 and 79, indicates that the document is "fairly easy" to read, and since our leaflet had acquired a 70.5 score, it can be inferred that it

is easily understood by our study subjects.^[11] On the other hand, the reading age of a leaflet can be calculated by adding 5 to the FK-GL score.^[5] The FK-GL score of our leaflet was 5.8 and the approximate reading age was found to be 10–11 years. In India, unmarried women being pregnant is quite uncommon and the minimum age to marry is 18 years. Furthermore, the literacy rates among urban women in Karnataka was found to be 77.97%, as per 2011 statistics.^[14] By taking into account the above considerations, we can conclude that our PIL was easily understood by the pregnant women attending the study site for their ANC. In addition, other readability scores such as Gunning Fog score, Coleman-Liau index, SMOG index, and Linsear Write Formula were also assessed for our leaflet indicating that the English version of leaflet was easily understandable. While the Baker Able design BALD score of our final version leaflet was found to be 31, any leaflet with a BALD score of >20 is referred as a "good design."^[15]

These readability scores and baker-able score are available only to validate the English leaflets but fail to validate the leaflets in regional languages.^[11] Hence, to validate both the English and Kannada version of our PIL, user testing method was employed similar to that used by Sekhar *et al.* and Mateti *et al.* study.^[5,6] The results of our study were consistent with the above-mentioned studies, where the overall mean user-testing scores significantly improved from 62.5 (pre-test) to 88.5 (post-test) with a $P < 0.0001$ ^[5,6] [Table 3].

In addition to the user-testing method, the current study also employed a PEMAT-P questionnaire for obtaining user opinion about the design, layout, understandability, and actionability of the PIL.^[12] The English version of the questionnaire was translated into the Kannada language in order to obtain feedback about the Kannada version PIL. The average PEMAT-P score for the leaflet was found to be 20.30 ± 1.25 . About 80.32% and 20% of the study subjects rated the leaflet as good and average respectively [Table 4].

In general, women become more conscious when they are pregnant. They seem to have an interest, ability, and motivation to think about the information provided in the PIL, which aids in improving the understanding of one's own health status. Hence, the quality of the PIL content is important. Hence, in the current study, the quality of the PIL was tested by the committee of health care professionals prior to use by the participants.

CONCLUSION

The cover page of the leaflet should be eye-catching, and the font, color, and illustrations should be tailored to pregnant women, which should also be scientifically convincing. This study showed that patient education through a validated leaflet can become an effective educational tool and is shown to have a positive impact on the knowledge gain and attitude of the pregnant women towards their pregnancy management, which may aid in attaining better pregnancy outcomes.

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Table 1: Socio-demographic details of the study subjects

Socio-demographic characteristics	No. of subjects, n (%)
Age	
Age group (18–25 years)	23 (57.5)
Age group (26–35 years)	17 (42.5)
Age group (36–45 years)	0
Parity of pregnant women	
Primigravida	18 (45)
Multigravida	22 (55)
Educational status of pregnant women	
Primary school education	0
Middle school education	1 (2.5)
High school education	10 (25)
Intermediate	14 (35)
Graduate	14 (35)
Post-graduate	1 (2.5)
Socio-economic status (Kuppuswamy scale)	
Upper	5 (12.5)
Upper middle class	5 (12.5)
Lower middle class	26 (65)
Upper lower	4 (10)
Lower	0

Table 2: Readability scores of the patient information leaflet

Readability Scores	Value
Flesch Reading Ease score	70.5
Flesch-Kincaid Grade Level	5.8
Gunning Fog	8.9
The Coleman-Liau Index	9
The SMOG Index	6.6
Linsear Write Formula	5

Table 3: User testing scores of PIL

User testing scores	Pre-test scores	Post-test scores	P-value
Kannada	60±8.52	88.33±5.77	<0.0001*
English	63.57±9.51	88.57±7.55	
Overall	62.5±9.26	88.5±6.99	

*Statistically significant at $P < 0.05$

Table 4: User-opinion (PEMAT-P) scores of PIL

Type of leaflet	No. of subjects
Kannada	
Good	23 (57.5)
Average	6 (15)
Poor	-
English	
Good	9 (22.5)
Average	2 (5)
Poor	-
Overall PEMAT-P score	
Good	32 (80.32)
Average	8 (20)
Poor	-

PEMAT-P: Patient education materials assessment tool for printable materials score

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