



Patients' Information Leaflets: Its' Influence on Ophthalmic Patient Education and Medication Compliance

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Authors' contributions

This work was collaboration among all authors. Author SK conceived the idea, designed the study, wrote the protocol, and wrote the first draft of the manuscript. Authors SO and GAK were involved in the design of the study, performed the statistical analysis, managed the analyses of the study performed the statistical analysis and managed literature searches. Authors SA and KAF managed the literature searches and data collection. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To investigate the influence of patient information leaflets on Ophthalmic patients' education and medication compliance.

Study Design: Hospital-based cross- sectional survey.

Place and Duration of Study: Department of Optometry, School of Physical Sciences, UCC, Cape Coast, Ghana, between September 2012 and May 2013.

Methodology: A semi - structured questionnaire with sections on patient demographics, patient information leaflets impact on therapeutic education, and medication compliance, was administered to 400 ophthalmic review patients in three eye care facilities in Central Region of Ghana. Patient information leaflets (PILs) of common ophthalmic medications

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prescribed in these eye centers were also reviewed and assessed on their readability using the Rudolph Flesch's readability ease calculator. Obtained data was analyzed using SPSS version 19. Pearson's Chi-square statistical analysis was used to test for significant association between variables.

Results: Of the 400 ophthalmic patients, 140 (35%) were males and 260 (65%) females. The mean age was 50.2 ± 19.5 . Patients had varying opinion on the purpose for the PIL: 228 (57 %) thought the PIL only gives instructions on the use of the medication; 108 (27%) did not know why the PIL have been provided. The remaining 64 (16%) provided no response. There was significant association between higher educational level and reading of the leaflet ($P < 0.001$). The kind of ophthalmic condition one suffered had a positive influence on reading the PIL ($\chi^2 = 28.594$, $P < 0.001$). A greater proportion of the patients (88.04%) said various components of information on the leaflet were beneficial in ensuring compliance to therapy. All the PILs from the five different companies (where medication were obtained for retail) had very low readability score (0-29) except some PILs of topical analgesic drug. The low readability score indicated that the text was difficult to comprehend; the reason for which most patients did not read the leaflets. Most patients 91 (99%) who read the PILs indicated that they were beneficial but were difficult to understand.

Conclusion: Ophthalmic patients' opinion on patient information leaflets was reasonably good and had a positive influence on patients' medication compliance. It however, did not have much influence on patient education due to low readability and comprehensible.

Keywords: Rudolph Flesch's readability ease calculator; drug information; medication compliance; medication package insert.

1. INTRODUCTION

The Patient Information Leaflet (PIL) is a patient friendly account of the outlined characteristics of a drug written by the manufacturing pharmaceutical company. It usually has information specific to the drug such as indication for use, dosage, side effects, interactions with other drugs, and contraindications, [1,2]. Self-care requires that patients have sufficient but high quality medication information on which to base their decision-making. However, when medicines are purchased over the counter, interaction between the patient and the healthcare professional may be limited making written information important for effective therapy and safe use of medicines [3,4]. For many patients, the PIL is the only written information about their medication available to them [5,6].

There are lots of information on drugs available from many different sources to the user. However, these information may not always be intelligible, reliable, authoritative, up to date, and available to patients [4,7]. Unlike other sources of information, the PIL is well scrutinized to provide valid and up to date information. Information in all PILs are reviewed and approved by the Medicines and Healthcare products Regulatory Agency before being supplied with medicines [6].

The provision of information to patients by healthcare providers requires effective communication; primarily by discussion. Verbal information will only be useful if it is provided in a manner intelligible to the receiver, and at a pace the recipient can digest [7]. PILs however, allow patients to digest information at their own pace, and serve as reference

materials for therapy. Studies have shown that medication compliance is significantly dependent on the quality of information available (in informing their decisions) to patients [8].

Although the PIL supplements the limited information given by healthcare providers regarding patients' medication usage, and serves as a reference material [9], it comes with its challenges such as; densely typed leaflet, difficulty in reading font, and content comprehension difficulty. As a result, PILs have been of little value to most patients as it fails to educate them [10].

It is against this backdrop that this study sought to investigate ophthalmic patients' opinion of patient information leaflet; its readability and comprehensibility, its influence on patients' adherence or reluctance to medication intake, its contribution to patients' education, and to investigate which ocular disorder prompts patients to read the PIL. This would help inform public health interventions in eye care.

2. METHODOLOGY

2.1 Study Site

The Central Regional Hospital, Bishop Ackon Memorial Christian Eye Center both in Cape Coast and Our lady of Grace Hospital, Breman Asikuma were selected for the study. These eye care centers, all in the Central Region of Ghana, were chosen because they were the largest (with the full complement of eye care staff) of the 16 eye care facilities in the region [11]. The records from the hospitals indicate an average of 8000 patients' attendances per annum.

2.2 Study Population

The study population was ophthalmic patients reporting to the eye care facilities for review. These patients, who were regular visitors for at most three months prior to the study, were interviewed individually as and when they come in to seek eye care.

2.3 Inclusion/Exclusion Criteria

All review patients aged 18 years or older (who were prescribed with ophthalmic medication) and revisiting within three months after their first visit to the health care facilities were eligible for the study. Review patients who had been visiting the care facility for more than three months after their maiden visit were excluded to avoid recall bias.

2.4 Sample Size Determination

Purposive sampling technique was used. The minimum sample size for the survey was determined as quoted by Glenn [12].

$$N_0 = Z^2 pq / e^2$$

Where;

- N_0 is the sample size.
- Z^2 is the abscissa of the normal curve that cuts off an area α at the tails ($1 - \alpha$ equals the desired confidence level, e.g., 95%).
- e is the desired level of precision.

- p is the estimated proportion of an attribute that is present in the population.
- q is $1-p$.

Therefore assuming that 50% of the patients who come to the eye center will be available for the survey, taking a confidence level of 95% and a sampling error of 5% minimum sample size computed was 384.12. However, the sample size was adjusted to 400 respondents. An average of 133 participants was selected from each care facility as the annual records of attendance were about equal.

2.5 Study Design

The study was a hospital-based cross-sectional survey. Data was collected using a semi-structured questionnaire. The questions asked were in three sections. Section A; featured items on age, gender, educational level and occupation of the respondents. Section B; contained items like the number of times patient had visited the eye center in the last three months, patients' knowledge of the eye condition he or she was suffering, the number of years he/she has had the condition, the name of the drugs given and the information which was provided to the patient by their eye care providers concerning the disease, and the drugs prescribed. Patients were also asked of their perception of the PIL and whether they read it or not. Section C; contained items such as the reasons why they read or did not read the PIL, information they looked out for, whether the content was easy to understand, and if the information helped them to adhere to the prescribed medication or it scared them from taking their medication. Readability of the PILs was assessed with the Rudolph Flesch's readability ease calculator [13].

2.6 Data Analysis

The data gathered from the study was analyzed using Statistical Package for Social Sciences version 19. The responses were coded and fed into the SPSS database. Descriptive results were expressed as frequencies, percentages, and means \pm SD. Pearson's Chi-square statistical analysis was used to test for significant association between variables. $P \leq 0.05$ was considered significant.

2.7 Limitation of the Study

The sampling technique used in this study was not representative enough to allow for extrapolation to the population.

3. RESULTS

3.1 Demographics

A total of 400 participants, [140 (35%) males and 260 (65%) females] met the inclusion criteria for this study: 188 (47%) were ≥ 60 years, 126 (31.5%) were adults (36-59 years), 86 (21.5%) were young adults (18-35 years). The mean age was 50.2 ± 19.5 . Three hundred and ten patients (77.5%) had some level of formal education i.e. 160 (40%) had basic, 97 (24.3%) had secondary and post-secondary education (nursing training, teachers training, technical school and senior high school) while 53 (13.2%) had tertiary education. Ninety (22.5%) however had no formal education whatsoever. In terms of occupation, 80 (20.0%)

pensioners, 75 (18.75%) farmers, 74 (18.5%) Traders, 40 (10.0%) teachers, and 50 (12.5%) students were sampled. There were 81 (20.25%) artisans.

3.2 Visitation to Eye Care Facility

Many of the patients i.e. 190 (47.5%) had visited the eye center twice in the last three months. The mean visit was 2.10 ± 1.0 . More females, 260 (65%) visited the facility than males, 140 (35%).

3.3 Patients' condition and Reading of PIL

One hundred and ninety two patients (48%) knew the ocular disorders they were suffering. However, the majority of patients 208 (52%) just reported to the eye centers as scheduled and receive their medications, but did not know precisely the kind of conditions they were suffering from. Among the participants who knew their condition; 87 (45.3%) had cataract, 50 (26.0%) glaucoma, glaucoma suspects were 5 (2.6%), 16 (8.3%) had refractive errors of different kinds. Conjunctivitis constituted 7.8% (15) while those with various eye conditions like keratitis, pain in the eye, hyphema, and optic neuritis, collectively were 19 (9.9%).

The probability that one's disease condition would prompt the reading of the PIL was evaluated. Sufferers of chronic conditions such as cataract, refractive errors and glaucoma were more likely to read the PILs than others (Table 1).

Table 1. Ocular condition and the likelihood of reading the PIL

	B	SE	Df	P value
Cataract	1.562	0.496	1	0.002
Glaucoma	0.503	0.490	1	0.304
Glaucoma suspect	0.164	0.998	1	0.869
Refractive error	0.934	0.680	1	0.169
Conjunctivitis	0.359	0.631	1	0.570
Others	0.241	0.403	1	0.549

B = binomial distribution, SE =standard error, Df is the degree of freedom,

3.4 Information in Medication Package

Although 392 (98%) patients reported to have received verbal information on their medication application procedure, only 2% reported to have received information other than medication application procedure i.e. how to store it. Three hundred and seventy six, (94%) patients confirmed that there were PILs in their medication packs with only 24 (6%) indicating otherwise. Patients had varying views on the purpose for the PILs: 228 (57%) thought the PILs only gave instructions on the use of the medication; 108 (27%) did not know why the PILs were provided. The remaining 64 (16%) provided no response. Although majority of patients had one opinion or the other on the purpose for the PIL, only 92 (23%) ever read it. Of the 308 (77%) who never read the PIL, 130 (42.21%) attributed it to lack of formal education, 121 (39.3%) said they do not see its importance, while 45 (14.61%) attributed this to small font size of PILs' text, among others (Table 2).

Table 2. Reasons given by the 308 ophthalmic patients who never read the PIL

Reasons	Frequency
Lack of formal education	130(42.21%)
I don't see its importance	121(39.29%)
Small font size of PIL text	45(14.61%)
Causes Anxiety	2 (0.65%)
Others	10(3.229%)

3.5 Patients' Benefits from Reading the PIL

Of the 92 (23%) who read the PILs, 34 (36.9%) were interested in the information on indications to confirm what the health care provider had given, 22 (23.9%) looked for medication composition, while 18 (19.6%) were interested in the medication side effects. Eight (8.6%) were interested in the mode of action of the drug, 4 (4.4%) looked for information on contraindications and precautions, and 3 (3.3%) look for the manufacturers another 3 (3.3%) expiry date. Eighty five, (92.4%) found all information they were looking for. That notwithstanding, 7 (7.6%) did not find some of the information they were looking out for. All the patients except one of the 92 (99%), found information in the PIL beneficial. Regarding the benefits of the PIL, 85 (92.4%) indicated their opinion: many 23 (27.0 %) said it educated them on the side effects of the drug while 19 (22.3%) said it educated them on the how to use the drug effectively. Other benefits included provision of extra information about the drug, sustained confidence in the health care professional and the drug given, etc (Table 3).

Table 3. Benefits of PIL as indicated by ophthalmic patients

Benefit Derived	Frequency (%)
Education on side effects	23 (27.0)
Education on usage of drug	19(22.3)
Provision of extra information	13 (15.3)
Education on drug composition	8 (9.4)
Education on contraindication	6 (7.1)
As a reference material	6 (7.1)
Education on precaution	6 (7.1)
Sustenance of confidence in practitioner	4 (4.7)

3.6 Impact of PIL on Effective Communication

Forty six (50%) of the patients who read the PILs indicated their levels of reassurance the information gave them: 3 (7%) said the information was not reassuring, 37 (80%) said the information in the leaflet was quite worrying, while 6 (13%) said the information in the leaflet was highly worrying.

3.7 The PIL and Patient Medication Compliance

Out of the 92 (23%) patients who reported on medication compliance, 20 (21.7%) indicated that the composition of the drug shown on the information leaflet made them comply with their prescribed medicines while 1(1.1%) patient reported non-compliance due to information on drug composition. Twelve (13.0%) complied with their medication while 1 (1.1%) patient

was reluctant in taking the medication because of the information on the mechanism of the drug's action.

Thirty seven (40.2%) complied with their medication because the drug's indication(s) marched their disease conditions while 3 (3.3%) did not comply because their condition did not match the indication(s) on the leaflets. Out of 8 (8.7%) patients' who responded to contraindication(s) on compliance, half said they did not comply. Some 3 (3.3%) patients complied with their medication because of the notes on adverse effect but 2 (2.2%) did not comply after reading notes on adverse effect. After reading precaution notes from the PILs, all 5 (5.4%) patients complied with medication.

3.8 PIL Readability and Comprehensibility

Of 92 (23%) patients who read the PIL, 50 (54.4%) said the diction was difficult to understand as it was made up of lots of medical terms. Another 5 (5.4%) said the information was in another language other than English while 37 (40.2%) had said the font size were small thus making reading difficult. It was observed that (Table 4) majority of the leaflets had scores between 0-29 indicating that the wording of the leaflets was very confusing.

Table 4. Readability scores of the PILs from five different companies

Drug	Company 1	Company 2	Company 3	Company 4	Company 5
Anti-glaucoma	30.8	24.8	30.6	38.6	34.0
Anti-inflammatory	27.0	27.8	18.6	18.7	7.5
Anti-allergic	22.7	62.4	36.8	-	-
Antibiotic	35.8	20.6	17.7	9.6	45.5
Artificial tears	48.8	45.7	-	-	-
Analgesic	49.2	26.7	74.7	-	-

(-) means there was no available medication from the designated company.

4. DISCUSSION

4.1 Demographics

The study was a hospital-based cross-sectional survey of ophthalmic patients of mean age 50.2 ± 19.5 . The age distribution for participants was extensive which augured well for the study. The number of participants increased progressively from young adulthood to the late adulthood (elderly). It is postulated that ageing is associated with limitations to regenerative abilities and are more prone to diseases, syndromes and sickness [14]. The common diseases such as cataract and glaucoma reported by the patients were more linked to senility therefore the increased trend from early adulthood through to the elderly population [15]. The level of formal education among the patients was high i.e. 77.5%. Chi square analysis showed a significant association ($P < 0.001$) between educational level and reading of the PILs. Closely linked with educational attainment is the issue of literacy. These two interrelated factors have been identified as very crucial in health maintenance as they influence the ability to access information and maneuver in literate environments [16,17]. Occupations were varied and statistical analysis revealed no significant association ($P > 0.05$) between occupation and reading of PILs in this study, although there is a reported interaction between type of occupation and reading of PILs [18].

4.2 Visitation to Eye Care Facility

In terms of hospital visits, the mean was 2.10 ± 1.0 implying that participants were not first timers. This affirms the possible use of an ophthalmic medication prior to the conduct of this study. The frequency of visit to a health care facility has been hypothesized to be associated with patients' satisfaction and compliance with physicians' advice, though this study ascertained no such relationship ($P < 0.05$) [19]. Females visited more than the males. Although females visited the eye center more than males, this was not statistically significant ($\chi^2 = 0.971$, $P = 0.965$, $df = 5$). This could be due to chance as the proportion of female (52.3%) to male (47.7%) in the Region was high (2010 population census) [20]. Females have been known to be more concerned with their health than males [21] which could have accounted for the higher number of females who visited the eye care facilities for review.

4.3 Patients' Condition and Reading of PIL

The patients' conditions studied in this hospital based survey were consistent with WHO ranking of the major causes of blindness and visual impairment in the world [22]. On knowing his/her condition, the patient develops the interest in learning more about the condition e.g. its morbidity and treatment, which might be found in the PIL [1]. Lack of awareness and inadequate information on the part of sufferers of these conditions can be managed if the attitude of reading the PIL is encouraged [23]. Patients should therefore be encouraged to take interest in their health conditions by healthcare practitioners. There was a significant association between the patients' condition and reading of PILs (Table 1). Patient suffering from chronic diseases such as HIV/AIDS are likely to read the PIL [24]. This could be due to the fact that these patients tend to be much concerned about their continuous use of medication and its effects on their health. A similar trend was observed in this study as persons suffering from cataract, refractive error and glaucoma were more likely (Table 1) to read the leaflet. This supports the assertion that sufferers of chronic diseases are more likely to read the PILs.

4.4 Information in Medication Package

The fact that only 2% of the ophthalmic patient's reported to have received information other than that pertaining to medication application procedure gives an indication that little or no information is given by the health care provider other than that pertaining medication application procedure. This assertion by the patients' has several implications, which may include insufficient information from healthcare providers, misunderstanding on the part of the patients' or patients' forgetfulness [25].

Twenty four (6%) indicated that there were no PILs in their medication packages. Nevertheless, the PIL is a legal requirement [26]. This finding suggests there is a lax in the enforcement of the law requiring the PILs to be packaged with medications by pharmaceutical companies.

It has been documented that most people have variable views about the PILs regarding; the information it provides, its comprehensibility, and its usefulness in promoting compliance [27]. This study's assessment of patients' view on the reason for the PILs indicated similar varying opinions. The majority reported that the PILs provide instructions on drug use; few reported not having any knowledge on the reason of the PILs. Though few people reported not knowing the reason for the PILs in this study, the number is higher compared to that

reported by Walter et al. study [27] and could be attributed to the relatively high levels of illiteracy and personal attitude [28]. The high proportion of illiterate patients has been identified especially in developing countries [29].

Although several reasons such as; information given by the health care provider was enough, and seeking further information meant challenging the credibility of the eye care professional, not seeing the importance of the PIL; were given for not reading the PIL, patients should be educated on the usefulness of the PIL. Illiterates could ask educated individuals to read it to them. Drug manufacturer could adopt alternative strategies such as the use of pictograms to enhance PIL comprehensibility. It is part of the responsibility of health care delivery teams to help educate the patient on the therapeutic management of their conditions [30]. Article 59 (3) of the amended European Union's medicine law, Directive 2001/83/EC, requires that medication package inserts be legible, clear and easy to use and that readability test results should reflect this [31,32]. In line with this a general font size of at least 12 pt is recommended. Nevertheless PILs from medicines frequently used by visually impaired patients should contain font sizes of between 16 and 20 pt [33]. Law enforcement agencies should therefore step up effort to ensure this is done.

4.5 Patients' Benefits from Reading the PIL

All the patients except one of the 92 (99%), found information in the PIL beneficial (Table 3). Reports that patients forget more than 50% of the information given to them by their health care givers augment the importance of PILs in assisting to overcome this difficulty. This is because the PILs serve as reference materials patients can refer to [34-36]. It is also obvious that they helped to overcome the challenge of inadequate information received from health care givers.

4.6 Impact of PIL on Effective Communication

Communication is a key process in health care provision. It does not only provide the foundation for diagnosis and treatment, but is also closely associated with therapeutic outcomes. Patients can be left unhappy with the amount of information they receive as the information given is often misunderstood or forgotten. 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 about their medications and disease [37]. Patient information leaflets are widely used by diverse health organizations and professionals as part of patient education or health promotion efforts, in support of preventive, treatment and compliance objectives [38]. Booklet helps patients in their self-management decisions in providing information about self-management and guidance on when it is important to see a doctor [39,40]. Quality client education requires use of either educational materials appropriate for the measured reading level of clients or alternatives to written materials. It was observed in the study that majority of the patients responded the information in the PILs was beneficial and that it served as a guide and also informed them of the side effects of their medicines.

4.7 The PIL and Patient Medication Compliance

Twenty three percent (23%) of patients who reported on medication compliance after reading the PILs only 0.3% reported non-compliance indicating the significant effect of the PIL on patient medication compliance. Article 59(1) of Council Directive 2001/83/EC [41]

requires the leaflet to be drawn up in accordance with the summary of product characteristics (SPC). The drug composition information on the leaflet is the qualitative and quantitative composition which includes information on the active substance and the excipient used. This specification encourages compliance among patients as it assures them of the identity, strength, quality, and purity of the medication [42].

There is dearth of information on the impact of patients' knowledge of the mechanism of action of their medication's contribution to compliance. However, it could be hypothesized that educational implications on drug consumers have translational effect on informed decision and subsequent adherence to treatment regimen. In patient centered medicine, the patient is central in medical decision making about his/her care. Information pertaining to therapeutic indication places meticulous emphasis on the importance of informed consent which allows complete informed medication compliance discretion [43].

The greatest rate of noncompliance is associated with information derived from contraindication [44]. Knowing the adverse/undesirable effects of drugs in therapy has been reported to cause fear and panic in patients on such therapy. Although not all documented adverse effects happen in all individuals, patients should know them to be able to realize the effect as it comes up for adverse drug effect reporting [45].

4.8 PIL Readability and Comprehensibility

The readability score is a predictive index for comprehensibility hence the higher the readability score, the easier it is to understand the content of the PILs. Despite the various advantages of the PILs such as educating the drug consumer, health promotion effect, improvement of patients' compliance, improvement of patients' understanding and aiding in recall of the things they have been informed earlier by physicians, the wording of the leaflets was difficult to understand as indicated by the generally low readability scores recorded in this study [46]. This might have been the reason for most patients not reading the patient information leaflet (Table 2). These low readability scores recorded required a more academic and scientific reader to comprehend [47]. To improve patients' understanding, especially patients without any formal education, the use of pictorial aids in the leaflets would be very helpful, particularly when pictures are used in combination with oral instructions [48]. However, it is noteworthy to indicate the score (74.7) for company 3's leaflets for analgesics (not other medications from same company) were fairly easy to understand.

5. CONCLUSION AND RECOMMENDATIONS

Ophthalmic patients' opinion on patient information leaflets was reasonably good and had a positive influence on patients' medication compliance. It however did not have much influence on patient education due to low readability and comprehensibility.

It would be recommended that pharmaceutical companies include pictogram and modify the language in writing the PIL in order to improve patients' understanding of the PILs. Health care providers should advocate reading the leaflet and promote it as a useful resource tool and Government institutions such as the food and drug administration and standards board responsible for enforcing laws on PILs should step up their activity.

CONSENT

The research aims at eliciting the views of users on the influence of patient information leaflet on patient education and compliance in ophthalmic practice. There is no discomfort that would be associated with the participation in this research. All information obtained in this study will be kept confidential and would be used for academic purpose only. Participation is entirely voluntary.

ETHICAL APPROVAL

All authors hereby declare that permission was sought from heads of the various facilities where the study was conducted. Each participant signed a written informed consent after the nature, objectives and significance of the study had been made known to them. Participation was entirely voluntary and participants were at liberty to withdraw at any stage of the study. Confidentiality of their responses was ensured and the study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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