

Patient Information Leaflets: How Do Patients Comprehend and Understand Drug Information?

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Abstract

Pharmaceutical manufacturers are obligated by national drug regulations to provide package information leaflets (PIL), which is a patient-friendly form of the Summary Product Characteristics (SmPC). The main objective of this study was to evaluate whether and how these patients in Montenegro read PILs and to get insight into patients' opinions regarding comprehension and usefulness of said leaflets. The survey was conducted on randomly recruited patients at a private pharmacy in Podgorica, Montenegro. The survey was conducted in September 2019 on randomly recruited patients (>18 years of age) at the private pharmacy in Podgorica. Number of patients who read PILs, way and frequency of reading PILs, patients' opinions on clearness and usefulness of PILs. Of the 200 patients asked to participate in this research, 126 (63% response rate) filled out the questionnaire. The majority of the respondents thought that it is important to read the patient information leaflet (76.2%) and most of them (75.4%) reported that they always read the leaflet. Less than half of those who read the PIL read it thoroughly (47.9%). Around half of patients reported that the terms and expressions in leaflets are partially understandable (53.7%). After reading the leaflet, around a third of the patients often feel confused (28.1%) or anxious (32.5%). To improve the quality of the information, PILs need to convey the potential risk information in a language that is less fear-provoking.

Keywords: Patient information leaflet, Pharmaceutical manufacturers, Comprehension, Anxiety

INTRODUCTION

Pharmaceutical manufacturers are obligated by national drug regulations to provide package information leaflets (PIL), this is a version of the Summary Product Characteristics (SmPC) that is more patient-friendly. PIL includes details on clinical pharmacology, suggested dosage, mode of handling, and a sizable section on precautions, adverse events, and restrictions [1, 2]. The main aim of PIL is to instruct patients on how and when to use a medicine and to contribute to understanding the purpose, benefits, and risks of the medication prescribed, all to achieve successful therapy [3].

Although there has been considerable progress in the previous 10 years due to extensive studies on PIL, patients are frequently unhappy with the data that they are given and believe that the pamphlets are complicated, difficult to read, and poorly produced [4]. To date, a limited number of studies evaluated the percentage of patients who read the provided drug information [5-8]. A recent study looked at research published in the last eight years to determine the informational design and content that patients like in PILs so they can read, comprehend, and use them efficiently [9]. Studies focusing on design revealed that limiting

information and utilizing plain language improved patient comprehension and decreased the time required to find information [10, 11]. According to one research, eliminating negations enhanced patients' comprehension and the readability of leaflets [12]. It was also shown that information about side effects is often lengthy, confusing, and alarming to patients and that the leaflet should contain the action required if a side effect occurs [9]. As a result, patients may feel fear and anxiety after reading the PIL and might not continue with their therapy. Therefore, to provide

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well-written and useful PILs which will support the effective and safe use of medicines, it is of immense importance to understand patient’s requirements [9].

As information regarding patients' perceptions of PILs is missing in Montenegro, the main objective of this study was to evaluate whether and how these patients read PILs and to get insight into patients' opinions regarding comprehension and usefulness of leaflets.

MATERIALS AND METHODS

The survey was conducted in September 2019 on randomly recruited patients at a private pharmacy in Podgorica and it was performed in the Montenegrin language by a trained interviewer. The respondents were all Montenegrin-speaking adults (>18 years of age).

The investigators created the questionnaire and pretested it on twenty customers to make sure the questions were clear. The questionnaire consisted of 22 close-ended questions regarding the following topics: socio-demographic characteristics, source of the information about the drug that is used, reading PILs regularly, which sections of the leaflet were read, and if the information was understood and beneficial, and if the information changed how medicine was used. Completion of the questionnaire took up to 10 min.

Microsoft Excel 2016 (Microsoft Corp., Redmond, WA) was used to tabulate the results. Data pertaining to the study's goals were analyzed using descriptive statistics.

Additionally, a post hoc analysis utilizing the Chi-square test and Spearman's correlation coefficient was carried out to ascertain if the reading of leaflets was dependent upon a patient's age category, sex, and level of education category. All p-values less than 0.05 were considered significant.

RESULTS AND DISCUSSION

To the best of our knowledge, this is the first study performed in Montenegro investigating whether and how patients read medication leaflets, as well as its utility and clarity. A total of 200 patients were asked to participate in this research, however only 126 (63% response rate) of patients filled out the questionnaire. The gender distribution was almost uniform. More than half of the patients had a college education (Table 1).

Table 1. Sociodemographic characteristics of the respondents

Sociodemographic characteristics	Number (n)	Percentage (%)
Gender		
Male	64	50,8
Female	62	49,2

Age		
18-24	21	16,7
25-30	22	17,5
31-40	28	22,4
41-50	27	21,4
51-65	21	16,7
>65	7	5,6
Level of education		
Secondary school	50	39,7
Junior college	5	4,0
Degree	71	56,3

Most of the patients find information about the drug in leaflets (80.2%). Less than half of patients (38.1%) reported that the doctor or pharmacist is a source of information about the drugs they use (Figure 1).

A relatively small number of patients are aware that instructions for medicinal products can be found online on the website of the Agency for Medicines and Medical Devices of Montenegro (CALIMS). Similarly, the Belgian study that investigated the impact of the internet on the patient's search for information showed that the number of patients searching for leaflets on the Internet is quite limited and that the Federal Agency Medicines and Health Products (Belgian competent authority in charge of ensuring the quality, safety, and efficacy of medicines and health products) website is unknown to most internet users [6].

Where do you find information about the drug you take?

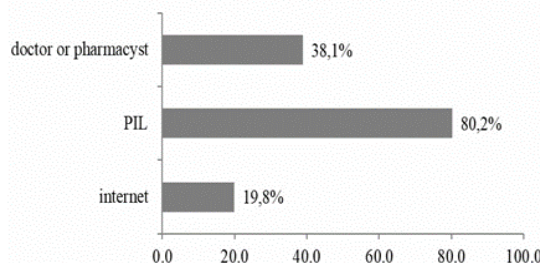


Figure 1. Source of information about the drug

Most of the patients (75.4%) reported that they read the leaflet always, while a small number of them indicated that they read the pil rarely (4.0%) or never (4.0%). Less than half of those who read the PIL, read it thoroughly (47.9%) (Table 2). Most of the respondents believed that it is important to read the patient information leaflet before starting with the therapy (96, 76.2%). Numerous studies have examined this topic, despite the paucity of new study data examining the true percentage of patients who read the leaflets. The survey conducted in Thailand via interviewing patients in outpatient clinics showed that 34.3% of the investigated patients always read leaflets, 59.0% sometimes, and 6.0% never read [5]. The study performed in Belgium showed that only one out of four participants read the full PIL when purchasing new medicine [6]. In similarity to our results, the study conducted in Saudi Arabia reported that the majority of patients (78,2%) read the instructions for

new drugs often or constantly [7]. The results of a Jordan study showed a majority of respondents (64%) always read the information leaflet for patients, 23.5% sometimes read it, and 12.5% never read it [8]. However, all these studies have different methodologies and populations examined, thus it is difficult to make a viable comparison.

Table 2. Frequency of reading PILs

Frequency of reading PILs	Number (n)	Percentage (%)
always	95	75,4
often	13	10,3
sometimes	8	6,3
rare	5	4,0
never	5	4,0
Way of reading PIL		
thoroughly	58	47,9
partially	7	5,6
only certain parts	56	48,3

Previous research has demonstrated that the most often cited explanation for not always reading the leaflet is that the doctor provides information regarding the medication [5, 7, 13]. Our results demonstrated that around a third of patients reported that doctors or pharmacists are the main sources of information about the drug they use, pointing out that the patient–physician interaction might be at stake. Communication problems between patient and physician can be explained by the fact that the influential position of the physician has been reduced, or that prior confidence has been betrayed due to the ease with which fresh information may be accessed online. This way of obtaining information might raise concerns, leaving the patient with doubts and concerns. As a result, the caregiver must not only select the appropriate course of treatment for each patient but also supply thorough information on the effectiveness and security of any given drug. Furthermore, it is the responsibility of the medical professional to make sure that patients' worry and anxiety resulting from misinterpreting PILs or additional sources of medication information are appropriately addressed to boost their self-assurance and therapeutic compliance.

The majority of patients consider that the quantity of information in leaflets is too large (96, 79.3%). A little more than half of them reported that it is not easy to find necessary information (63, 52.1%), although two-thirds of them (83, 68.6%) think that the information given in leaflets is very useful. Around half of the investigated patients reported that terms and expressions in leaflets are partially understandable (65, 53.7%). After reading the leaflet, around a third of the patients often feel confused (28.1%) and anxious (32.5%) (Table 3). Recent publications also pointed out that patients are often confronted with long texts and non-comprehensible medical terms [3]. Studies focusing on PIL design showed that the limitation of the information to one page and the use of plain language

principles improved comprehension and reduced the time to find the necessary information [10, 11]. Preference pertaining to the length of the leaflet differs- in some studies, patients prefer one-page formats, while in other studies they want more information [9]. It's necessary to produce PILs that have high readability scores. These leaflets could incorporate additional pictograms and vibrant images, potentially enhancing overall understanding.

Table 3. Understandability and usefulness of PILs

Quantity of information in PIL	Number (n)	Percentage (%)
too large	96	79,3
adequate	18	14,9
insufficient	7	5,8
Easy to find the information you need		
Yes	58	47,9
No	63	52,1
Information given in PIL		
Very useful	83	68,6
Somewhat useful	35	28,9
unnecessary	3	2,5
Terms and expressions in PIL		
Easy to understand	52	43,0
Partially understandable	65	53,7
Not understandable at all	4	3,2
After reading PIL, you feel confused		
always	9	7,4
often	25	20,7
sometimes	37	30,6
rare	30	24,8
never	20	16,5
After reading PIL, you feel anxious		
always	15	12,4
often	27	22,3
sometimes	41	33,9
rare	11	9,1
never	27	22,3

The majority (98, 81%) of the respondents think that drug interactions are very important data, however, 61.2% of them read the part referring to drug interactions. Most read parts of the PIL are how to take the drug (75.2%) and possible side effects (80.2%) (Figure 2). Our results are in line with previously published studies where the most often read parts of PIL were the section on side effects [6, 13], how to take drugs [13], and indications [6].

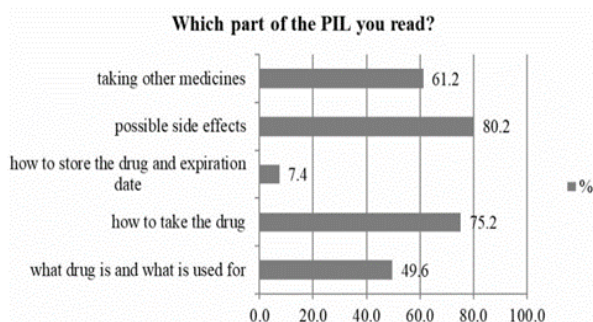


Figure 2. Which part of the PIL do you usually read?

Approximately half of the respondents (62, 49.2%) stop with the prescribed therapy after reading part of PIL referring to possible side effects, while a relatively small percentage (24, 22.5%) consult with the doctor or pharmacist before stopping with the therapy. Herber *et al.*'s findings showed that the way potential side effects and drug interactions are currently described to patients deters them and makes them feel afraid and anxious. This is primarily because statistical data is presented in an unsatisfactory manner, which makes it difficult to judge adverse effects and, as a result, lowers patient compliance with treatment [3]. Moreover, the most recent study has shown that information about the prevalence of side effects in PILs is deceptive and that a comparison of side effect rates with and without medication use, together with remarks about the causal relationship, can increase comprehension [14].

Women significantly more often read PILs ($p = 0.002$), it is much easier for them to find necessary information ($p = 0.023$) and they less often feel confused ($p = 0.025$). A higher degree of education is associated with a more frequent ($r_s = -0.277$; $p = 0.002$) and more detailed reading of PILs ($r_s = -0.189$; $p = 0.038$) as well as a better understanding of terms and expressions in the instruction ($r_s = -0.205$; $p = 0.024$). Age categories are not related to any of the issues in **Tables 2 and 3**. This was in agreement with the findings of other studies [14].

Competent authorities are advised to embrace enforceable national guidelines for structuring and overseeing written information presented in Patient Information Leaflets (PILs). Economically advanced nations have implemented guidelines and standards dictating the structure and content of PILs, aiming to enhance their overall comprehensiveness, readability, and clarity for patients [15]. Although the results of this study are valuable as guidance on creating PILs not only for patients in Montenegro but for the broader population, some weaknesses need to be mentioned. Our sample was limited to the city of Podgorica, the capital of Montenegro, which makes it difficult to extrapolate the results to the general population. Furthermore, the sample could have been biased toward particular patient demographics (such as those who frequently visit pharmacies in the early morning or the middle of the day). Since the likelihood cannot be ruled out, the study sample's

demographics must be diverse. Despite these limitations, our results have important implications for the prospective improvement of PILs.

CONCLUSION

More than three-quarters of investigated patients reported reading the leaflet always, however less than a half of them read it thoroughly. The majority of patients consider that the quantity of information in leaflets is too large, while for more than half it was not easy to find the necessary information pertaining to them. After reading a PIL, particularly the part referring to the side effects, around a third of the patients often feel confused and anxious. To improve the quality of information, Potential risk information should be communicated in PILs less frighteningly, and throughout the preparation process, more care should be taken to measure the emotional responses that patients have while reading risk information. To further boost the patient's confidence and adherence to the recommended therapy, the caregiver should also offer thorough information on the safety of the prescribed medication. This will help to guarantee that fear and anxiety brought on by a misunderstanding of PIL are taken into account.

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