An investigation on patient attitudes toward package inserts and their accessibility in Iran

Parisa Ahmadi, Shirin S Badri, Amir H Zargarzadeh

Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

Background: Package inserts (PIs) can be a source of information for patients, especially when clinicians do not provide adequate consultations to the patients. Therefore, for the first time, we investigated the state of PIs in Iran and evaluated patients' attitude toward PI. **Materials and Methods:** In this descriptive study, conducted in a major teaching pharmacy in Isfahan, Iran, in 2016, 100 patients who presented a prescription were interviewed randomly and all medications in their medication bags were examined. The main outcome measures were whether or not the dispensed medications were accompanied by a PI and the behavior of patients in reading these PIs. **Results:** From the 237 medication items investigated, 129 (54.4%) were dispensed with a PI. Eighty-four percent of patients read the PIs and only 19% stated reading a non-Farsi PI. The level of education was the only significant factor related to reading the PI ($P = 0.02$). Reading the side effects was the main reason for reading the PI (64%). PIs were considered useful by 83% while 25% kept PIs as a source of drug information. Experience of fear to take the medication after reading the PI was reported by 47%. **Conclusion:** About half of medications were dispensed along with the PI. Although the majority of patients report reading the PIs and consider them useful, confidence in using the medicine may be diminished after reading the PI. Patients with higher education read the PIs the most.

Key words: Package insert, patient information leaflet, patient package insert, pharmacy practice

INTRODUCTION

For correct and rational use of medications and increasing patient adherence, patient education is warranted.[1] Pharmacists and physicians are expected to teach patients about their medications. Lack of communication with patients by both pharmacists and physicians has been cited as one of the factors in increasing medication errors and nonadherence to medications. Despite pharmacists' and physicians' responsibility for counseling patients on their medications, in many settings, this responsibility is not performed well. Therefore, many patients must seek information from other sources.[2]

There are three kinds of written patient medication information materials: package insert (PI), consumer medication information, and medication guide.[1] In most parts of the world such as Iran, the only written medication information every patient receives is the PI prepared by the manufacturer.[3] At the time of registration of a drug in Iran, a sample copy of a PI must be submitted to the Iranian Food and Drug Administration.[4]

After distribution of a PI, another important point is that whether a patient reads and uses the information or not. Especially in developing countries, patients may not be able to access a health-care facility easily, especially in the rural areas.[5] Self-medication is prevalent in Iran which necessitates having sufficient knowledge about medications by the patients.[6]

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Address for correspondence: Prof. Amir H Zargarzadeh, Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hezar Jerib Ave., 81873 Isfahan, Iran.
E-mail: zargarzadehamir@gmail.com

Farsi is the common language spoken in Iran, while English is the second language taught in the schools. Although the majority of the PIs with imported medications come in the English language, there are some written in a non-English language. No Farsi translation accompanies these medications either.

Since the importance of patient accessibility to PIs is quite evident in Iran, investigating the practice of pharmacies in providing the PIs to patients and the reading behavior of patients regarding the PIs can be helpful. Therefore, for the first time, we investigated the state of PIs in Iran and evaluated patients' attitude toward PI.

The results of this research would help policymakers reach new decisions on the format and availability of PIs in Iran.

MATERIALS AND METHODS

This cross-sectional descriptive two-phase study was conducted in January–March of 2017. We interviewed one hundred patients of Imam Sajjad Pharmacy, a major teaching pharmacy, affiliated with Isfahan University of Medical Sciences (IUMS) College of Pharmacy and checked their medication bags for containing PIs. The sample size of one hundred was determined by the formula which is used frequently for the descriptive type research. $z = 1.96$, in addition to $P = 0.5$, and $d = 0.1$ were chosen. Since we did not have prevalence data, the value of 0.5 was used for the P value. The formula is as follows: $N = z^2_{1-\alpha/2} \times p\,(1-p)/d^2$. The inclusion criterion for selecting the patients was any person whose prescription was filled for at least one item. The exclusion criteria were those patients who provided unreliable information (the researcher did not feel confident about the information the patient provided) or lack of patient consent to participate in the interview. The researcher solicited oral consent of patients for entering into the study. The study was conducted in a single pharmacy which is the pharmacy prototype, and the patients were selected randomly, one out of every five patients. Medication bag was examined first for the presence of PI for each medication and then a short interview took place with the customer. The data collection instrument was developed by the researchers and was tested with a pilot of 20 patients. The second author conducted the interviews. She was positioned in a place in the pharmacy far from the pharmacist in charge who was responsible for dispensing the medications. She would check the medication bag of each patient first for existence of PIs and then asked questions related to the PIs and the demographics of the patients. The data were recorded and later on entered into Excel Software version 2013. Parametric and nonparametric statistical tests such as Student's *t*-test, Chi-square, Fisher's exact, and Man–Whitney statistical tests were performed depending on the parameter measured. The

Investigational Review Board of IUMS granted a permission to conduct this study under the permit number 395935.

This study had two phases as described above.

Interview with the patients
A data collection instrument was designed to capture the demographic information of the patients such as age, gender, level of education, presence of chronic disease, mother tongue, and whether the person interviewed was the patient or the caregiver. The following questions were asked from the customer in the interview:
1. Do you usually read the PI in each medication package?
2. Would you read the PI even if the insert is in another language other than Farsi?
3. What parts of the PI do you read most?
4. Do you find the information contained in the PIs useful?
5. Do you regularly store the PIs as a source of drug information?
6. Have you ever become fearful after reading the information in the PI?

The researcher avoided the use of leading questions and behaved in such a manner to appear nonthreatening to the patients.

Medication bag examination
All the medications in the medication bag of each customer were examined for the presence of PI. The researcher examined the shelves of the pharmacy to seek whether the PI was provided by the manufacturer in the original container or the pharmacy personnel discarded the PI before dispensing the medication.

RESULTS

One hundred patients were interviewed and their medication bags were checked for the presence of PI.

Interview with the patients
Patients' age ranged from 20 to 77 years. The mean ± standard deviation was 41.1 ± 11.7 years.

The demographic characteristics of patients were summarized in Table 1.

The majority of patients (64%) cited the side effect section of the PI as the most frequent part which is read. Direction for use was the second most common section read by the patients (19%). Only 4% read the entire PI.

Patients' characteristics who read the PI are seen in Table 2. Level of education was significantly related to reading the PI ($P = 0.02$). A Mann–Whitney U-test

Table 1: Demographic characteristics of interviewees

Parameter	Quantity (%)
Age (years)	
20-35	38 (38)
36-50	41 (41)
>50	21 (21)
Relation of the interviewee to the patient	
Patient (self)	36 (36)
Caregiver	64 (64)
Gender	
Female	48 (48)
Male	52 (52)
Education level	
No education (illiterate)	3 (3)
Below high school diploma	19 (19)
High school diploma	42 (42)
College/university	36 (36)
Mother tongue	
Farsi	93 (93)
Other than Farsi	7 (7)
History of chronic disease	
Yes	39 (39)
No	61 (61)
Do you read the PI?	
Yes	84 (84)
No	16 (16)
Do you read non-Farsi PI?	
Yes	19 (19)
No	81 (81)
Have you experienced fear of taking the medication after reading the PI?	
Yes	47 (47)
No	53 (53)
Do you find the PI useful?	
Yes	83 (83)
No	17 (17)

PI=Package insert

was used to detect the significance. Others were not statistically significant.

Among those who read the PIs, the majority (90.5%) find the PIs useful ($P < 0.001$) and less than half (48.8%) stated that they become fearful of taking a medication upon reading the PI; however, there was no statistical significance ($P = 0.41$). Out of 64 patients who cited the side effect section of the PI as the reason for reading a PI, 34 (51.1%) had experienced fear of taking a medication upon reading the PI.

All those who stated reading a Non-Farsi PI had at least a high school diploma ($P = 0.002$).

Medication bag check

Altogether, 237 items were investigated in the 100 medication bags of patients.

As seen in Table 3, the majority of medications were prescription-only medicine (POM) and were dispensed in the original package. As seen in the table, 108 of medications were not accompanied with a PI in the medication bag of the patient. Once checked by the investigator, we found that 49 of these medications were not supplied with a PI by the manufacturer. The rest (59% or 24.9%) were not dispensed by the pharmacy despite the inclusion of PI in the original containers. In other words, the pharmacy had thrown away the PIs for those medications for reasons not apparent to the authors.

A Mann–Whitney U-test was used to detect the significance of education on whether the PIs were read or not by the patients. In further analysis using a Chi-square test, we did not find any significance ($P = 0.25$) between a medication having an over-the-counter (OTC) status and having a PI. However, the Fisher's exact test showed a significant relationship between being dispensed in the original container and dispensing with a PI ($P < 0.001$).

Among the 237 medications, we found only 3 medications in the bulk form dispensed out of their original bulk containers in a small paper envelop. These medications did not have any PI dispensed with them despite the manufacturer providing the PI with the original container.

DISCUSSION

A PI can provide complementary information to a patient. Accessibility to PIs is important and may fill up the gaps existing in the information provided by the physician or the pharmacist. In our study, 84% of patients claimed that they read the PIs. This percentage varies among other countries such as Belgium (89%), Saudi Arabia (88%), Italy (83.5%), England (82%), Denmark (79%), Turkey (78.2%), Ghana (76.3%), Palestine (74.3%), the USA (70%), Australia (64%), and Israel (51.5%).[7-17] These data show that the majority of patients read the PIs either in full or partially. However, it does not seem to be a correlation between reading the PIs with the industrialization or economic prosperity of a country. High percentage of participants in our study reading the PIs may be due to the existence of higher education in this population.

We did ask for the reasons of reading the PIs. Seeking information about the side effects of the medication was the main reason for reading the PI. Other articles have reported similar findings.[7,11,15,18,19]

Nineteen percent of respondents stated that they read the English PIs if accompanied by the medication, although the majority of patients prefer to read the PIs in their native language.[14,20] We believe that higher level of education in our participants may be a reason for their willingness to

Table 2: Characteristics of interviewees who read the package insert

Parameter	Quantity (%)	P
Age (years)		
20-35	31 (81.6)	0.64
36-50	35 (85.4)	
>50	18 (85.7)	
Relation of the interviewee to the patient		
Patient (self)	30 (83.3)	0.89
Caregiver	54 (84.4)	
Gender		
Female	43 (89.6)	0.14
Male	41 (78.8)	
Education level		
No education (illiterate)	0 (0)	0.02
Below high school diploma	14 (73.7)	
High school diploma	38 (90.5)	
College/university	32 (88.9)	
Mother tongue		
Farsi	77 (82.8)	0.28
Other than Farsi	7 (100)	
History of chronic disease		
Yes	33 (84.6)	0.89
No	51 (83.6)	

PI=Package insert

Table 3: Characteristics of the medications found in the bag

Parameter	Quantity (%)
Type of medication	
POM	222 (93.7)
OTC	15 (6.3)
Blister or bulk*	
Blister	162 (68.3)
Bulk	18 (7.6)
Other†	57 (24.1)
Dispensed in original container	
Yes	170 (71.7)
No	67 (28.3)
PI dispensed by the pharmacy	
Yes	129 (54.4)
No	108 (45.6)

*Bulk: Those medications in tablet or capsule dosage forms which were originally supplied in a nonblister form; †Other: Those medications including ampoules, drops, and multidose bottles which were not in either original blister package or bulk form. OTC=Over-the-counter; POM=Prescription-only medicine; PI=Package insert

read a non-Farsi (English) PI. All together, we suggest that all PIs whether they are imported or manufactured locally should be translated to the main language of that country as more people would tend to read them.

There are conflicting published reports about the relationship between reading a PI and some of the demographic variables of patients or their caregivers. In our study, we did not establish any significant association between likelihood of reading a PI and sex, mother tongue, chronic disease, age, and the identity of the interviewee (either the patient or his/her caregiver). However, some studies have shown that females tend to read the PI more than males.[14,19,21] On the other hand, other published studies do not report any significant association between sex and likelihood of reading the PI.[15,17,22] Chronicity of comorbid conditions was not reported to be associated with the reading of PI.[14] Regarding age of the interviewee, other studies like ours have not shown any association to reading a PI.[14,15,17] The elderly tend not to use the modern drug information sources and rely mostly on the interpersonal contacts with health-care personnel.[21] Therefore, it is important that health-care team members pay special attention to the elderly to assure of the safety of medication use.

The only parameter that we found an association with reading the PI was the level of education. It seems that higher educated people tend to read the PIs more. People with high school diploma and university education tend to read the PIs more than those with lower levels of education. Similar results have been reported by other researchers.[2,13,17] In the US, the literacy level suggested to design the PIs is to be in the 6th–8th reading levels.[23] We believe that in Iran, we need standards as well to help with more effective PIs given the level of literacy of the population. Other parameters not measured in this study such as health literacy, occupational status, patient coping style, and health status of the patient can all affect the likelihood of reading the PIs.[24]

In our study, about one-fourth of patients stated that they would store the PIs as a drug information source for future use. In lieu of a large number of medications stored in Iranian households[25] and lack of PIs, one may suggest that the majority of patients either do not receive the PIs from the pharmacies or throw away the PIs and do not consider the PIs as a source of medication information. It is suggested that pharmacists spend time to review the PIs with the patients and remind them of the beneficial use of the PIs as a source of medical information.[15]

Experience of fear after reading a PI is another important finding of this study that we found in 47% of our patients. Furthermore, close to half of the patients who read the side effect section of the PIs mostly have experienced fear of taking the medication. Similarly, other published articles have shown this experience of fear after reading the PIs.[7,19,26,27] Increase in anxiety and loss of confidence in the medication after reading the side effects of the PIs have been reported leading to nonadherence in the form of discontinuing the medication prematurely or changing the dose of the medication without the physician approval.[11,26]

Majority of our patients (83%) found the PIs useful. Similar results from other studies have been reported as well.[7,14,15]

According to our results, the positive feeling of the patient toward the PI may lead to reading of the PI by the patient. Therefore, physician or the pharmacist talks about the usefulness of the PIs can lead to creating a positive feeling encouraging the patient to read the PI.[13] Interestingly enough, only 8% of patients are encouraged to read the PIs by their health-care members.[28]

On examining the bags, less than half of the medications were not accompanied with a PI. As in the result section, close to one-fifth of these medications did not have a PI to begin with, that is, the manufacturer had not provided a PI in the original container. Therefore, two problems seem to exist. One is the pharmacy personnel that may throw away some of the PIs while dispensing. The second problem is the manufacturer that does not supply the PI with some of its products.

It seems that if the bulk- or blister-packed medications are dispensed in their original package, the likelihood of reaching the PI to the patient increases. During the partial dispensing of medications, the pharmacy personnel may throw away the PI at the time of dispensing. It could also be due to an inappropriate behavior by the pharmacy personnel because they may not value the importance of the PI to the patient.

In this study, any product outside the official OTC list of medications which is prepared by the Iranian Ministry of Health and Medical Education is considered POM. In the bags checked, we found only 15 OTC medications. Only ten (almost two-thirds) of these medications had a PI supplied by the manufacturer. From these 15 medications, only 6 medications were dispensed with a PI to the patient. The others apparently had been thrown away by the pharmacy personnel before dispensing. Hence, a great percentage of our true OTC medications do not have a PI when reached to the patient. On the other hand, since many POM medications in Iran are dispensed to the patients without a prescription,[2] the likelihood that patients do not receive the PI increases even more.

CONCLUSION

Since majority of patients find PIs useful, finding ways to improve their accessibility seems to be of paramount importance. Closer control by the Iranian food and drug administration (FDA) is necessary to ensure the availability of the PIs in the original packages. Furthermore, new regulations must be approved on the contents of these PIs and whether these PIs are prepared for the patient or the health-care professional. In addition, regulations for the pharmacists and pharmacy personnel must be written emphasizing the importance of PIs and dispensing them along with the medication itself. For the importing companies, new regulations must be prepared to make them translate the PIs to Farsi language. Future studies must be performed to examine the effectiveness, understandability, and design of PIs in Iran.

Although PIs frequently used by patients to obtain information relating to the medicine, confidence in using the medicine may be diminished after reading the PI.

Conflicts of interest
There are no conflicts of interest.

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