

RESEARCH ARTICLE

# Reported knowledge and practices towards the proper use of patient information leaflet among university students

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## Abstract

**Background:** A patient information leaflet (PIL) is a valuable tool that can convey basic information about the disease conditions and the recommended medication enabling both the patients and the health care professional to get rapid, easy, and precise access to the treatment process. **Objective:** To evaluate the level of knowledge and practices for appropriate and useful use of PIL among final-year medical and non-medical undergraduate university students in Baghdad, Iraq. **Method:** A descriptive, cross-sectional study was conducted among final-year undergraduate university students with different academic disciplines, including medical (pharmacy, dentistry) and non-medical disciplines (law, media) in Baghdad, Iraq, using a structured questionnaire to evaluate the level of knowledge and practices towards the proper use of PIL. **Result:** A total of 384 students enrolled in this study and the majority were medical students (59.1%). The proportion of non-medical students who read the PILs was lower than that of medical students (82.2% vs. 91.6%,  $p < 0.0001$ ). According to participants' responses, 84.6% ( $p = 0.03$ ) of the medical students stated that reading PIL was useful for accurate medication use, while 60.5% of the non-medical students reported that the language of PIL was difficult to understand. Instructions for proper medication intake were significantly higher among the medical students (78%,  $p < 0.0001$ ). **Conclusion:** An acceptable level of knowledge along with several different practices toward the proper use of PIL while taking medicines was reported among medical and non-medical undergraduate university students.

## Introduction

Health literacy is the degree of individual capacity to obtain and understand basic health-related information and services which are required to make appropriate health decisions (Nielsen *et al.*, 2004). Poor or impaired health literacy is described as a struggle to understand and efficiently act on different health-related information regarding different disease conditions and treatment plans, along with the patient information leaflet (PIL) and prescription warning labels. Low literacy level, particularly in elderly patients with polypharmacy, might be a principal cause of improper medication use, poor adherence, and ineffectiveness of medications, causing a high incidence of adverse drug reactions (ADRs) and other drug-related problems, frequent hospitalisation, and poor health-related outcomes (Davis *et al.*, 2006a; Davis *et al.*, 2006b; Wolf *et al.*, 2006; Ngoh, 2009).

Printed materials, including patient information leaflets (PIL) are considered valuable tools that can convey basic information about the disease conditions and related medications, particularly for chronic and complex diseases, enabling both the patients and the health care professional to get a rapid, easy, and precise access about the treatment process (Wilson *et al.*, 1992). PIL is a standard template of technical documents provided by drug manufacturers which are included in every medicine package with contents that are unbiased, and evidence-based. The main purpose of these documents is to offer written information and increase knowledge regarding therapeutic indications, proper dose administration, pharmaceutical dosage forms, warnings, and precautions regarding drug contraindications, potential ADRs, drug interaction, safe drug use in specific patient groups, proper drug storage and handling, and drug manufacturer-related information.

The PIL is a highly trusted and well-organised regulated drug information source compared to other sources. The contents must provide a set of authentic, unbiased, and comprehensible information, and be presented in a clear, well-readable way without ambiguous language for maximal understanding to both the patients and the healthcare professionals. The sentences should also not be too long. Highly emphasises avoiding medication errors and motivating patients to use medicines only with medical counselling and advice thereby enabling the proper and safer use of medicines (Gibbs *et al.*, 1989; Nicolson *et al.*, 2009). Furthermore, an important consideration should be applied to the overall layout, design, and font size of the PIL since labels with too small font, strenuous to read or ambiguous might make the patient experience difficulties in reading clearly and contribute to medication errors (Spadaro *et al.*, 1980; Bernardini *et al.*, 2001; Adepu & Nagavi, 2003; Judy *et al.*, 2003). Undoubtedly, healthcare professionals are responsible for educating patients about their medicines. A study by Ramia and team (Ramia *et al.*, 2017) reported that one-third of the study participants reported reading the PIL always and very often, and up to 17% and 21% reported reading the leaflet rarely and never, respectively.

University-age participants, whether medical or non-medical, represent an integral part of the community as they are highly educated and get access to information regarding their health which might be influenced by media and internet engines. Meanwhile, medical students will be future healthcare providers and would try to implement their health knowledge into practice settings. This could promote their responsibility towards optimising therapy and proper medication use while avoiding drug-related problems. To the best of our knowledge, earlier studies are lacking reporting the knowledge and practices towards the proper use of patient information leaflets in the Iraqi community. Accordingly, the present study aimed to evaluate the knowledge and practices towards the proper use of PIL among final-year undergraduate university students with different academic disciplines, including medical and non-medical disciplines in Baghdad, Iraq.

## Methods

### **Study design and participants**

This descriptive, cross-sectional study was carried out at Asool Al-Deen University College, Baghdad, Iraq from February to April 2019 through a random sample selection of participants. The study was approved by the Clinical Research Ethics Committee of the Pharmacy Department, Asool Al-Deen University College,

Baghdad, Iraq (002/05/01/2019). A total of 430 participants were approached during this study, however, 384 participants completed all the items of the questionnaire giving a response rate of 89.3% based on Cochran's sample size formula within  $\pm 5\%$  precision and 95% confidence level for a large population whose degree of variability is not known.

Inclusion criteria included final-year undergraduate students of both genders from different academic disciplines, including medical (pharmacy, dentistry) and non-medical (law, media). The students who revealed readiness to participate in this study were supplied a written informed consent along with verbal information regarding the aim of the study. Furthermore, all participants were informed that participation is voluntary, and they were assured of their anonymity and confidentiality of response. Those who dismissed participation or with an incomplete response for the items of the questionnaire were excluded.

### **Questionnaire design and implementation**

The structured questionnaire was developed and customised to suit the objective of the study after an extensive and comprehensive literature review in a well-known database. The questionnaire was translated from English to the Arabic language to accommodate every participant. The structured items of the questionnaire were assessed for rephrasing, reformatting, and relevance. Furthermore, several academic experts and community pharmacists tested the final drafted questionnaire for content validity. In addition, a pilot part of the study was tested for around 5% of the sample size ( $n=19$ ) to process the question's uncertainty and to figure out reliable data which were excluded from the final statistical analysis.

The final version of the questionnaire included 24 questions divided into three parts. The first part consisted of five items and included participants' demographic characteristics (age, gender, academic discipline, and college) and medical characteristics (current medication therapy, whether prescription-only medicines (POM), over-the-counter medications (OTC), and herbal drugs). The second part (eight items) gathered data to assess the perceptions of knowledge and proper use of the PIL, each answered on a four-point Likert scale (1=strongly disagree, 2=disagree, 3=agree, and 4=strongly agree) which was categorised into a two-point classification. The third part consisted of 11 items that evaluated the participants' practices and reasons for using PIL. The questionnaire was distributed at the end of the scheduled classes. The study aim was described in an introductory letter provided with the questionnaire which demanded

nearly ten minutes out of the class time to complete and was collected immediately after completion, while all the questionnaire information was used in analyses.

### Statistical analysis

Microsoft Office Excel 2013 and SAS (Statistical Analysis System- version 9.1) were used for data analysis. Descriptive data were presented as numbers, percentages, and means (standard deviations) to describe the study population. The score and the results depended on the four-point Likert scale rating. However, to ease running the statistical analysis, the authors categorised the four-scale into two-scale. Responses to the questionnaire based on the Likert scale rating were also presented as percentages. Chi-square test was applied to analyse the comparisons between proportions of the groups regarding the items of the questionnaire utilised for the assessment of the perceptions towards the level of knowledge and practices for proper use of patient information leaflets. The level of statistical significance was considered at  $p < 0.05$ .

## Results

The demographic findings of the study participants are presented in Table I, with a mean age of  $22.9 \pm 2.3$  years. Almost more than half of the participants were females (58.6%). Regarding the academic discipline, most of the participants were medical students (59.1%), (34.9%) represented pharmacy, and (24.2%) dentistry while the non-medical students represented (40.9%), (21.1%) represented law and (19.8%) media. A total of 76.8% of the participants were on current medication therapy, and a nearly equal proportion of the participants received POM (43.2%) and OTC (42.7%), as shown in Table I.

The proportion of non-medical students who read the PIL was lower than that of medical students (82.2% vs. 91.6%,  $p < 0.0001$ ). A total of 84.6% of the medical students stated that reading PIL was useful to use medications more accurately in comparison to 75.8% of the non-medical students ( $p = 0.03$ ). Although statistically non-significant ( $p = 0.28$ ), 83.3% of the medical students reported that reading PIL was also useful to use medications more safely compared to 79% of the non-medical students. Similarly, 71% of the medical students stated that they need some advice about using their medications from the pharmacists after reading PIL in comparison to 64.3% of the non-medical students ( $p = 0.17$ ). Nearly, the participants from both groups reported that PILs reading did not make them confused or hesitate when using medications (78% vs. 79%,  $p = 0.81$ ), respectively, as presented in Table II.

**Table I: Demographic characteristics of the study participants**

Variables	Number (n)	Percentage (%)
<b>Gender</b>		
Males	159	41.4
Females	225	58.6
<b>Academic discipline</b>		
Medical	227	59.1
Non-medical	157	40.9
<b>Academic college</b>		
Pharmacy	134	34.9
Dentistry	93	24.2
Law	81	21.1
Media	76	19.8
<b>Current medication therapy</b>		
Yes	295	76.8
No	89	23.2
<b>Classes of current medication therapy*</b>		
POM	166	43.2
OTC	164	42.7
Herbal	5	1.3

Data present in number and percentage: n, %; \* Sum of the numbers does not equally indicate the total number of study participants as they taking more than one medication

On the other hand, regarding the overall readability of PIL, including language, font size, and colour, 60.5% of the non-medical students reported that the language of PILs makes it difficult in understanding compared to 33% of the medical students ( $p < 0.0001$ ). However, regarding the PIL font size, 66.1% of the medical students reported that the font size makes it difficult in reading the PILs in comparison to 35% of the non-medical students ( $p < 0.0001$ ). Nearly, both the medical and non-medical students reported that the PIL colour did not make it difficult in reading the PILs (83.7% vs. 82.8%,  $p = 0.81$ ), respectively, as shown in Table II.

Table III presents the practices and reasons for using PIL, although statistically non-significant, nearly both the medical (71.8%) and non-medical students (74.5%) ( $p = 0.55$ ) reported that proper storage conditions of the medicines were the primary reason for using PIL. Instructions for proper medication intake were significantly higher among the medical students (78%) compared to the non-medical students 53.3% ( $p < 0.0001$ ). Proper dosage intake by 63.9% of the medical students was a second reason for using PIL in comparison to 49.7% of the non-medical students ( $p = 0.005$ ). Similarly, information about the presence of medication side effects by 63.9% of the medical students compared to 47.8% of the non-medical students was one more reason for using the PIL ( $p = 0.001$ ).

**Table II: Reported Knowledge about the usefulness of the patient information leaflet among the study participants**

Variable	Academic discipline		p-value
	Medical students	Non-medical students	
	Total n=227 n (%)	Total n=157 n (%)	
<b>Did you read PIL during the last year?</b>			
Yes	208 (91.6)	28 (82.2)	<0.0001
No	19 (8.4)	129 (17.8)	
<b>Does PIL help you use medications more accurately?</b>			
Agree/Strongly agree	192 (84.6)	119 (75.8)	0.03
Disagree/Strongly disagree	35 (15.4)	38 (24.2)	
<b>Does PIL help you use medications more safely?</b>			
Agree/Strongly agree	189 (83.3)	124 (79)	0.28
Disagree/Strongly disagree	38 (16.7)	33 (21)	
<b>Do you need some advice about using the medication from the pharmacist after reading PIL?</b>			
Agree/Strongly agree	161 (71)	101 (64.3)	0.17
Disagree/Strongly disagree	66 (29)	56 (35.7)	
<b>Does PIL reading make you confused or hesitate when using medications?</b>			
Agree/Strongly agree	50 (22)	33 (21)	0.81
Disagree/Strongly disagree	177 (78)	124 (79)	
<b>Does the language cause a difficulty in understanding the PIL?</b>			
Agree/Strongly agree	75 (33)	95 (60.5)	<0.0001
Disagree/Strongly disagree	152 (67)	62 (39.5)	
<b>Does the font size cause a difficulty in reading the PIL?</b>			
Agree/Strongly agree	150 (66.1)	55 (35)	<0.0001
Disagree/Strongly disagree	77 (33.9)	102 (65)	
<b>Does the colour cause a difficulty in reading the PIL?</b>			
Agree/Strongly agree	37 (16.3)	27 (17.2)	0.81
Disagree/Strongly disagree	190 (83.7)	130 (82.8)	

Data present in number and percentage: n, %; PIL: Patient information leaflet; Responses based on a 4-point Likert scale: 1= strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree; Significant at p<0.05

**Table III: Reported practices for using patient information leaflet among the study participants**

Variable	Academic Discipline		p-value
	Medical students	Non-medical students	
	Total n=227 n (%)	Total n=157 n (%)	
Disease condition	87 (38.3)	60 (38.2)	0.99
Allergy/drug sensitivity	122 (53.7)	81 (51.6)	0.67
Proper medication information	80 (35.2)	42 (26.8)	0.07
Proper dosage intake	145 (63.9)	78 (49.7)	0.005
Proper treatment duration	79 (34.8)	68 (43.3)	0.09
Proper storage conditions	163 (71.8)	117 (74.5)	0.55
Information about the avoidance of inappropriate combination of drugs	62 (27.3)	24 (15.2)	0.005
Proper time intake of medication	53 (23.3)	31 (19.7)	0.05
Information about the presence of medication side effects	145 (63.9)	75 (47.8)	0.001
Information about the presence of possible medication contraindications	89 (39.2)	39 (24.8)	0.42
Information for proper medication intake	177 (78)	84 (53.5)	<0.0001

Data present in number and percentage: n, %. Significant at p<0.05

A total of 27.3% of the medical students in comparison to 15.2% of the non-medical students reported that information about the avoidance of inappropriate combination of drugs is another reason for reading the PIL ( $p=0.005$ ). Other practices and reasons for using PIL

are presented in Table III. Figure 1 also illustrated the practices and reasons for using PIL among the study participants for the medical students (pharmacy, dentistry) and non-medical students (law and media).

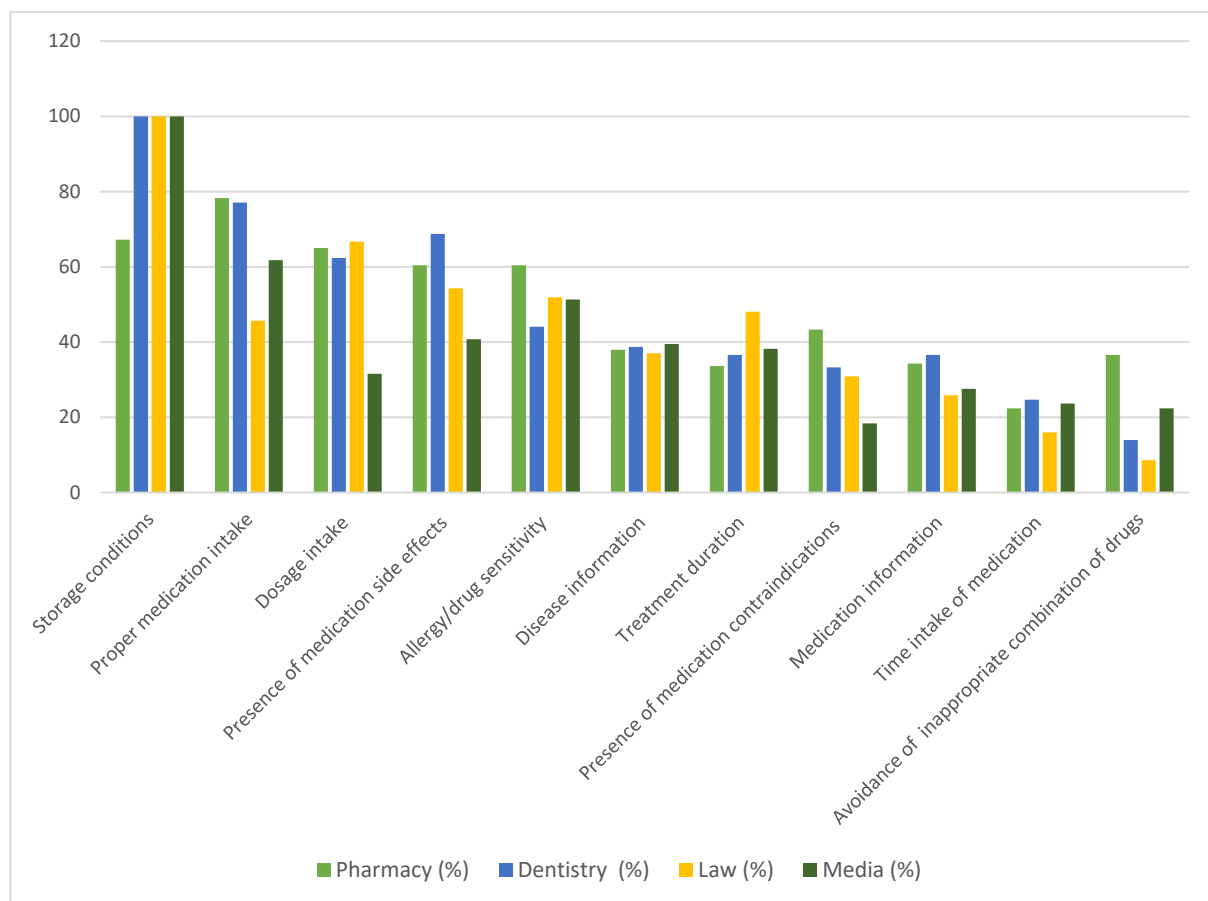


Figure 1: Practices and reasons for using patient information leaflet among the study participants

**Discussion**

It has been observed that an integral part to ensure correct, safe, and optimal medication use is through the provision of PIL and patients’ self-education about medications which must be accompanied by optimal reading and comprehension of the materials (Koo *et al.*, 2006). In the present study, most of the study participants from the pharmacy discipline were females who expressed willingness to participate in this study because this group of medical students are learning the fundamentals of PIL application during their undergraduate pharmacy studies. Earlier evidence also coincided with the findings of our study which reported that females, younger and well-educated populations are more likely to take the advantage of healthcare services, seeking more health and medical information, along with a better ability to observe and record

disease symptoms and related health problems (Bertakis *et al.*, 2000; Koo *et al.*, 2003;). The findings of the present study concur with the assertion concerning gender and level of education. A study by Shiyanbola and team (Shiyanbola *et al.*, 2014) found that women are more attentive to the prescription warning labels, while a study by Wolf and team (Wolf *et al.*, 2010) found that men reported a significant poor liability to the information of the warning labels.

The study revealed common and comparable knowledge and practices toward the use of PIL among university students with different academic disciplines. This was observed in several outcomes, including a lower proportion of reading PIL by the non-medical students compared to the medical students. These comparable outcomes might be described in part by the different knowledge and background between the medical and non-medical students. A study conducted

in the United Kingdom by Raynor and team (Raynor *et al.*, 2000) through a telehealth interview, revealed that 40% of the participants read the PIL. Other studies showed a higher proportion by Nathan and team (Nathan *et al.*, 2007) as well as Koo and team (Koo *et al.*, 2015) to evaluate patients' use of PIL, reported that almost two-thirds of the study participants read the PIL for new drugs.

In the present study, most of the respondents reported that reading PIL was useful for medication use both more accurately and safely, paying particular attention to all information about their medications, also, reading the PIL did not make them confused or hesitate when using medications. This is related to the fact that the written information of PIL might increase medication knowledge regarding indications, proper dosage and administration, contraindications, warnings, precautions, potential ADRs, drug interaction, proper storage, and handling. This is in accordance with an earlier study which reported that almost all (99%) of the participants found the reading of PIL very useful (Nathan *et al.*, 2007), while the participants in the study by Svarstad and team (Svarstad *et al.*, 2005) reported reading PIL was slightly useful.

Patient counselling is an integral part to raise the patient's understanding of PIL, mostly for patients with poor health literacy. The pharmacist could play an essential role in optimising medication pharmacotherapy, providing personalised pharmaceutical care, and proper medication and healthy lifestyle counselling to improve patient-related outcomes. This might be conducted through the provision of appropriate education about the patient's health status along with the risk of disease complications. Providing such kind of education in simple and clear communication ensures rational and safe medications use (Al-taie *et al.*, 2018; Al-taie *et al.*, 2020; Mohammed *et al.*, 2020). The findings of this study reported that most of the study participants, particularly the medical university students needed some advice to use their medications more properly even after reading PIL in comparison to the non-medical students. This might be related to the higher level of responsibility and seeking more knowledge about medicines and their proper use among medical university students, suggesting that this group of participants is more apt to receive drug information and recommendations from the pharmacists compared to the non-medical students. A study by Shiyabola and authors (Shiyabola *et al.*, 2014) found that 61.2% of the participants thought the counselling provided by the pharmacists could further simplify understanding the information of the PIL. Therefore, it is important to

raise the patient's understanding of PIL using convenient, simple, and brief language.

PIL colours play a potential role to highlight instructions for proper drug use since the use of colours is proposed to help patients find important drug information, improve the PIL semblance, and to clarify the logo of the product manufacturer. Meanwhile, nine points Didot is the common front size and font used in PIL respectively, this size is considered too small, and patients would prefer either 10 or 11 points Didot, while the PIL should be presented in a more detailed, schematic, and concise way (Alshogran *et al.*, 2018). In the present study regarding the overall readability of PILs, including language, font size, and colour, most of the non-medical students reported that they find the language of PILs difficult to understand compared to the medical students. The high level of language dissatisfaction reported among the non-medical students indicates that those participants may have low health literacy about PILs, and drug uses. Bernardini and team (Bernardini *et al.*, 2001) in a study to assess the patients' attitudes towards some typographical aspects of the PIL, such as colour, layout, and font size, reported that most of the participants complained about the very small print size and colours of the PILs in proportion with a low level of education. In another study by Shiyabola and team. (Shiyabola *et al.*, 2014) as well as Wolf and team, (Wolf *et al.*, 2011) it was reported that participants with low health literacy found the PILs overwhelming and difficult to understand, thereby did not majorly focus on the information of the warning labels compared to those with high health literacy.

Regarding the reasons for using PIL, all the study participants reported that the most common reason for this source was to get more information about proper medication storage conditions. This is because improper storage without effective preservation and proper storage conditions could accelerate the degradation of medicines and advance expiration, resulting in more medicine adverse drug reactions (Huang *et al.*, 2019), particularly in areas with hot climates like Baghdad province. A high proportion reported by the medical students in comparison to the non-medical students regarding the following reasons: instructions for proper medication intake on a full or empty stomach and with water or other fluid, proper dosage intake, information about the presence of medication side effects and information about the presence of possible medication contraindications. Most probably, the medical knowledge gained by the medical students during their academic study might act as a solid driving factor to have more competent practice about the proper use of PILs.

Like the findings of our study, Alshogran and team (Alshogran *et al.*, 2018) in a study conducted in Jordan to evaluate the prevalence, patterns, and attitudes toward self-medication use among university students. The study found that there was a comparative level of awareness about reading the PILs, particularly more prevalent among the medical students every time the participants bought a new medicine pack. Earlier reports found that the physician's provision of drug information might be one of the most common reasons for not always reading the PIL. However, newly prescribed drugs or some medication regimens can be complex. Therefore, neither the physicians could adequately discuss the different aspects of the medicines and treatment plans with the patients, nor could the patients hold such information about their medication therapy during a short clinic visit. Accordingly, the patients could follow the suboptimal amount of information either directly from the pharmacists or by reading the PILs (Tarn *et al.*, 2006; Nathan *et al.*, 2007). A principle and key strategic objective to boost the practice of PIL reading is to improve the awareness and understanding of these information sources. This considerably can be carried out by the pharmacists in the community setting since they play a great potential role within the multidisciplinary healthcare system as medicine experts, and have incessant and plain contact with the patients. This can be considered through effective communication and conducting educational sessions regarding medication and health knowledge among different population groups, including university students and the public.

This current study has some limitations that must be pointed out. First, the study included only one university in Baghdad city without the consideration of other universities in other parts of Iraq. Second, the survey was self-reported, and this may have contributed to the inconsistent understanding of questions among students. Third, the study outcomes were based on the participants' reports and perspectives which might lead to a recall bias. Fourth, the study did not assess patients' understanding of the leaflet information they read or its effect on patients-related outcomes. Finally, most students who expressed willingness to participate in this study were from the pharmacy discipline. Given these limitations into account could be of high interest for further studies to evaluate the proper use of PIL among further university students or even the public.

## Conclusion

In conclusion, a passable level of knowledge and practice toward the proper use of PIL was revealed among university students, though it was more highly reported among medical than non-medical students. There is also a difference in the patterns followed by the university students for the practices while taking medications after reading the PIL. The results could suggest a significant role for healthcare providers, including pharmacists to improve students' awareness alongside getting more involved in in-patient education about the proper use of PIL.

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## Conflict of interest

No conflict of interest is to be declared.

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