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RESEARCH ARTICLE

Survey of outpatients' use and needs of patient medicine information leaflets in Thailand

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Abstract

Background Patient information leaflets are important sources of medicine information. Regulations of patient information leaflet provision varies among country. Little is known regarding patients' behavior and expectation on use of patient information leaflets. *Objectives* To explore patients' use of either package inserts or patient information leaflets and to survey patients' expectations and needs on use of patient information leaflets and their associated factors. *Setting* Two university hospitals in Thailand. *Methods* Cross-sectional study using self-administered questionnaires distributed to outpatients over a 3-month period. Participants were selected through systematic random sampling. Logistic regression was used for data analysis. *Main outcome measure* Patient use of medicine information. Visual Analogue Scale scores for patient needs and their expectation of knowledge gains from using patient information leaflets. *Results* The response rate was 77.0%. Most respondents had received package inserts (91.3%) with 59.4% reporting that they sometimes read them. While most respondents had not previously known about patient information leaflets (75.9%), 97.3% reported that patient information leaflets would be useful. Respondents scored their needs and expected knowledge gains after reading patient information leaflets as 9.68 ± 0.97 and 9.64 ± 0.99, respectively. Previous experience with package inserts was associated with increased patient need scores ($p = 0.002$) and higher expected knowledge gains from use of patient information leaflets ($p = 0.037$). In addition, patients who had not previously known about patient information leaflets had higher expectations of knowledge gains ($p = 0.016$). *Conclusion* Overall, patients showed good behavior on reading package inserts. Although many patients were not previously aware of patient information leaflets, they realized the importance. Hence, patient information leaflets should be developed and provided to Thai patients.

Keywords Expectations · Expected knowledge · Medicine information · Patient needs · Package inserts · Patient information leaflets · Thailand

Impacts on practice

- Thai patients have limited access to patient information leaflets, hence they should be promoted as additional medicine information given to outpatients in routine practice.
- Patients are aware of the usefulness of patient information leaflets. Increased recognition of patient information leaflets should be encouraged in the wider population.
- Patients expect to gain knowledge from patient information leaflets. Therefore, healthcare professionals should provide patient information leaflets to patients in addition to verbal information.

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Introduction

Patients' knowledge about their medications is often inadequate [1]. Improved knowledge and understanding of medication use would result in increased patient safety [2, 3]. Healthcare professionals should compile the necessary information regarding prescribed medicines and provide it

to patients in order to promote rational use of medications [4]. Adverse drug reactions (ADRs) are one of the important drug-related problems on which healthcare professionals should advise their patients [5, 6]. If patients receive appropriate safety information related to their medicines, they may become aware of the safety implications [3]. This has the potential to reduce the seriousness of ADRs [3, 7]. However healthcare professionals have a large number of patients and limited time, they often only explain briefly to patients about medication use [8]. In addition, patients are often unable to remember information provided verbally [9]. Previous studies have suggested that patients retain only about 20% of the information given and that physicians' use of technical terms in their explanations often mislead patients [10–12]. However, when written material is included in counseling patients, they may remember up to 50% of the information [10]. Several studies have shown that verbal or written information improves patient knowledge about medications and increases medication compliance [13–15].

The package inserts (PIs) that accompany medicines provide information to help consumers gain accurate knowledge about the medicine in question. Nevertheless, PIs have been found to be difficult for patients to understand due to their excessive information, use of medical terminology and improper formatting of the documents [16]. In order to solve this problem, clearly written patient information leaflets (PILs) that make it easier to access and understand information about medications have been developed. In Thailand, the health authority requires pharmaceutical companies to provide PIs with every package of medicinal products, but PIs are not necessarily supplied to every patient during the dispensing process. Since PILs are voluntarily produced and supplied by pharmaceutical companies, there is a very limited number of available PILs for medicinal products dispensed in Thailand [17]. In contrast, many countries, especially those in the EU, the United Kingdom, USA, and Australia, have encouraged the production and use of comprehensible patient PIs and PILs, and have guidelines for the preparation and testing of PILs [18]. Nevertheless, PILs can still lack a user-friendly format that would better facilitate patient understanding [19]. In Thailand, healthcare professionals have many patients to take care of and have limited time to supply each patient with the necessary information regarding their medication. This suggests that providing these patients with effective PILs would be beneficial. There have been few studies exploring the needs and opinions of patients on the usefulness of PILs in Thailand. This study was designed to explore patients' use of either PIs or PILs and their expectations on use of PILs. It is expected that this study will contribute to the development of PILs that suit the needs of patients in this region.

Aims of the study

The purposes of this study were to explore patients' use of PIs and PILs, and to evaluate their needs and expectations on use of PILs, as well as to assess factors associated with these aspects.

Ethics approval

The study protocol was approved by the Khon Kaen University Ethics Committee for Human Research (Number HE591091).

Methods

Study design and setting

This study was a cross-sectional survey conducted in outpatient clinics at Srinagarind University hospital and Queen Sirikit Heart Center, the largest tertiary care settings in the northeast region of Thailand covering the highest density of inhabitants. Hence, patients visiting these hospitals have a wide variety of disease states and medication use. This study was carried out over 3-month period from January 1 to March 31, 2016.

Participants

Study participants included adults (age 18 years and older) who were able to complete the questionnaire, either by themselves or with support from relatives. The sample size was calculated based on the proportion of patients who required PILs. The proportion of patients who required information leaflets was 0.50 (based on 50% of patients from a previous study) [20] with an allowable error of 10%. The calculated sample size was 400. Thus, in order to ensure sufficient response, we distributed 500 questionnaires: 350 to patients at Srinagarind Hospital and 150 to patients at Queen Sirikit Heart Center.

Questionnaire development and testing

The self-administered questionnaire consisted of three sections. The first section was concerned with demographic data including age, gender, education level, occupation, health insurance status and medical history of participants. Section two collected the participants' experience of using PIs with closed and open questions and participants were encouraged to add their own thoughts, where appropriate. Section three

asked about the extent of the participants' needs on use of PILs using a visual analog scale from 0 (least need) to 10 (most need). The content validity of the questionnaire was tested by three experts using the index of consistency (IOC) technique in order to assess the consistency between each question, affirm the questions meet the study objectives, and check the appropriateness of wording. The IOC of the questionnaire was more than 0.5 in total and for each question, indicating sufficient consistency [21]. The face validity of the questionnaire was used in a pilot study with 15 patients to ensure that it was simple to read and understand.

Data collection

Self-administered questionnaires were distributed to patients directly at outpatient clinics. The researcher approached 649 patients seated in the waiting area to take part (149 declined to participate), using a systematic random sampling method to select patients. Every second patient seated in the waiting area was selected to be approached to participate. If the selected patient declined to participate, the next patient was approached. All 500 patients who agreed to participate in the study were given a questionnaire and letter to explain the aims of the study and informed consent was obtained from each patient. A sample PI and PIL of the same medication was provided with each questionnaire and differences between PIs and PILs in provided information content, language, format, application and targeted user, were explained to study participants by the researcher. The questionnaires were returned to the researcher directly after completion.

Data analysis

Data was analyzed using descriptive statistics together with Chi square tests or Fisher's exact test to compare subgroups for categorical data and an independent-sample *t* test or one-way ANOVA for continuous data. Multivariate logistic regression analysis was used to examine predictors or independent variables that might affect patients' needs of PILs and expected knowledge scores on use of PILs. A stepwise multiple linear regression model was built to assess the contributions of gender, age, education level, occupation, health insurance, number of comorbid diseases and number of medications, receiving PIs in the past, and previously known PILs. The results were judged statistically significant when *p* values were less than 0.05. Analysis was performed using IBM SPSS for Windows version 19.0.

Results

A total of 649 questionnaires were distributed at the two study centers and 500 completed questionnaires were collected (response rate 77.0%). Most of the respondents were female (54.8%, n = 274), with mean age 45.2 ± 14.04 years (range 19–81 years). The largest education category for respondents was a bachelor's degree (39.2%, n = 196) and 21.8% (n = 109) worked in private business. The majority of respondents had an average monthly income over 10,000 baht (52.2%, n = 261) indicating medium income. Over half of the respondents suffered from one or more comorbid diseases (58.8%, n = 294) and had taken concomitant medications (55.2%, n = 276).

Patients' use of PIs

Most respondents (98.4%, n = 492) indicated that they had received PIs (91.3%, n = 449), and 34.3% (n = 154) claimed to read them every time, 59.0% (n = 265) claimed to read them sometimes, and 6.0% (n = 27) claimed to never read PIs, mainly because their pharmacists give them the necessary information (88.9%, n = 24). Of the 419 patients that read PIs, (55.4%, n = 232) read them the first time they received their medication, (19.8%, n = 83) read them when they experienced potential side effects, and 23.4% (n = 98) read them when they were curious about the medication. Most patients who read PIs did not read the entire PIs, only reading some sections (73.5%, n = 308). The most often read sections were indications (88.3%, n = 370), instructions (81.6%, n = 342), and precautions (74.7%, n = 313). The remaining 26.0% (n = 109) respondents claimed to read all sections of PIs. After reading the PIs, 59.7% (n = 250) of respondents stated they felt more confident using the medicine, but 21.2% (n = 89) indicated that they still felt anxious. No factors were identified that significantly affected patient use of PIs.

Respondents indicated that their sources of information regarding medication were PIs (66.0%, n = 330), pharmacists (49.6%, n = 248), doctors (43.6%, n = 218) or the internet (42.4%, n = 212). A small number of respondents indicated that they received information from books, newspapers, or magazines (7.2%, n = 36) and 153 respondents (30.6%) indicated that they preferred to ask friends or family members.

Expectations and needs on use of PILs

Three-quarters of all respondents had never heard of PILs prior to the study (75.9%, n = 372). However, most patients reported that medication documentation was beneficial (97.3%). This study found that VAS score of the

patients' needs for receiving PILs was 9.68 ± 0.97 (score min–max = 4–10) and VAS score of their expected knowledge that they will gain from use of PILs was 9.64 ± 0.99 (score min–max = 4–10). The most common content for PILs required by the patients were indication of medicine (93.2%), instruction for use (92.0%) and precautions (89.1%). A majority of respondents (55.8%) commented that they would prefer to receive PILs when prescribed medicine, and 44.2% indicated that they should receive them along with the first dose in their regimen. Nearly two-third (62.9%) of patients reported that they would read PILs only when taking the first dose in their regimen, 19.1% reported that they would read PILs when they are curious about the medications, and 17.4% when they experienced side effects. Nearly all respondents (98.4%) supported the provision of PILs for all medications. Respondents expected that after reading PILs, they would still need advice from healthcare professionals (98.1%). Respondents also stated that their need for advice after receiving PILs remained unchanged (79.6%) and 14.2% reported reduced need. Most respondents (71.5%) said they would read PILs if they were available online. Only one statistically significant difference was found in expectations on use of PILs between patients who had received PIs and patients who had never received PIs in the past. Patients who had previously received PIs indicated statistically significantly greater need for medication precautions than those who had not ($p = 0.008$).

Factors related to patients' needs of PILs and their expected knowledge from PILs

The average score of patients' PIL needs was 9.68 ± 0.97 (from a total score of 10, range 4–10) and of their expected knowledge was 9.64 ± 0.99 (range 4–10). Respondents who had received PIs in the past had greater score of PIL need than those who had never received PIs ($p = 0.030$). Respondents who had never heard of PILs expected to gain more knowledge from PILs than those who had experience with PILs ($p = 0.036$). No other factors were found to be associated with patients' need scores and expected knowledge scores.

The factors related to score of need PILs and expected knowledge were examined using multivariate analysis. Respondents who had received PIs had greater need of PILs than those who had never received PIs ($p = 0.002$). Respondents who had received PIs expected to gain better knowledge from PILs than those who had never received PIs ($p = 0.037$). On the other hand, respondents who had previous experience or knowledge of PILs expected to gain less knowledge than those who had never heard of PILs ($p = 0.016$).

Discussion

This study showed that 91.3% of respondents had previously received PIs. This proportion is high presumably because the production and supply of PIs has been mandatory for all medications registered in Thailand since 1967 [22]. Hence, PIs have been widely distributed to Thai patients. The current study found that most respondents indicated they had received PIs but less than half of them claimed they always read PIs, which is consistent with previous studies indicating that patients read the leaflets 35–50% of the time [23, 24]. However, some previous study reported that 70% of patients read the PIs and about half kept them [25]. Most respondents in the current study read PIs both sometime and always. This suggests that PIs should be made simpler to increase patient understanding of medicines. However, some respondents indicated that they never read PIs because they received enough information from their pharmacists and doctors. This is consistent with previous studies that have indicated the importance of verbal explanations by healthcare professionals [26–28]. Thus, this suggests that both verbal information and written information are important ways that patients receive medicine information and they can complement each other.

The current study found that the majority of patients used PIs the first time they used a medicine, but this was slightly lower than the rates reported in previous studies [29, 30]. However, half of all patients in one of those previous studies reported they had never read PIs again after the first time [30]. Although PIs could help patients to review their medication for safety use, some respondents in our study read PIs only when they had experienced potential side effects. This finding was consistent with a previous study that showed the side effect topic was the section most commonly read by patients [31]. In addition, most of the patients in the current study did not read the whole PI, but only the specific content in which they were interested. Patients may not read the entire leaflet because the PIs provided in Thailand [32] might make patients confused or anxious regarding the use of their medication [24]. The sections of the PIs that were most often read by respondents in the current study were

indications, instructions, and precautions. This is likely to be because these sections describe how the medication is taken, as well as the expected benefits and possible side effects of the drugs [33–35]. The present study showed that patients used PIs as a source of medicine information at higher rate than they used healthcare professionals, internet, and other sources of medicine information. The result from this study is concordant with a previous study indicating that additional sources of information used by patients included drug information leaflets, internet and family [36].

Although PILs are available for patients internationally, there are reports of patients being dissatisfied with the quantity, quality, and content [5, 17]. Thus, PILs have been developed that are easy to read and understand, using fewer medical terms. We found that three-fourths of all patients who had received PIs had never heard of PILs. A previous study reported that nearly half of their respondents had previously received PILs and that many patients were unaware of their availability [20]. Since Thailand does not have a law governing pharmaceutical manufacturers' provision of PILs, drug companies provide this information voluntarily. Therefore, the amount of PILs distributed to patients is in this study was less than in the EU countries, where PILs are widely provided to patients. Compared with the large percentage of patients who had used PIs in our study, very few patients had used PILs. However, most respondents reported that PILs were beneficial. Our study found very high average scores of needs and expected knowledge from PIL use. This suggests that patients expected PILs to have an important role in providing information. They also reported a strong need to use PILs in order to gain more knowledge about the medicines. Hence, the Thai health authority should cooperate with drug companies to produce and distribute more PILs for patients.

We found that the expectations and needs on PIL content did not differ significantly between those who had received PIs in the past and those who had never received them, except with regard to medication precautions. Patients who had received PIs indicated a significantly greater requirement for this information ($p = 0.008$). This increased requirement was true for each topic, with the demand for information from patients who had received PIs higher than those who had never received them. This may be because patients who had received PIs in the past had the necessary experience to be able to suggest the kind of information they wanted [37]. A Previous study of Thai NSAID leaflets showed that half of all PIs lacked safety information including contraindications, precautions, and adverse drug reactions [17]. When considering factors affecting PIL need and expected knowledge, it was found that those who had received PIs had greater PIL need scores than those who had never received PIs. This may also be explained by patients with previous experience with PIs placing more importance on receiving drug information. Moreover, significantly higher numbers of patients who had never heard of PILs were expecting to gain knowledge from PILs. Therefore, our study suggests that Thai patients recognize the importance of providing PILs to enhance their appropriate use of medications.

Strengths and limitations of study

The study was performed at the largest tertiary care hospitals in northeast Thailand where a high number of medicines are provided to a wide variety of patients. Study participants were selected by systematic random sampling to reduce bias. However, as our study was conducted in two university hospitals, the findings may not be representative of the wider Thai population. Moreover, although the questionnaire explained the differences between PIs and PILs and provided real figure examples, respondents might still have difficulty distinguishing them.

Conclusion

Overall, patients had frequently used and read PIs. Although a high number of patients did not know about PILs, they expressed that they needed PILs and expected to gain more medication knowledge from reading PILs. Therefore, provision of PILs to Thai patients with comprehensible information about their medication should be promoted.

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Conflicts of interest The authors declare no conflicts of interest.

Appendix

See Tables 1, 2, 3 and 4.

Table 1 Characteristics of the study population who received package inserts and comparison of patient characteristics in relation to use of package inserts

Characteristic	Total N	No. of individual (%)		*p* value*
		Read (N = 419)	Don't read (N = 27)	
Gender (n = 446)				
Male	200 (44.8)	189 (45.1)	11 (40.7)	0.658
Female	246 (55.2)	230 (54.9)	16 (59.3)	
Age (n = 442)				
< 45	203 (45.9)	190 (45.3)	13 (48.1)	0.811
≥ 45	239 (54.1)	225 (54.7)	14 (51.9)	
Mean ± SD	45.19 ± 14.04	45.25 ± 13.88	44.74 ± 14.01	
Median (range)	45 (19–81)	46 (19–81)	45 (23–75)	
Education level (n = 445)				
Junior high school and lower	111 (24.9)	105 (25.1)	6 (22.2)	0.619
High school and diploma	128 (28.8)	118 (28.2)	37.0)	
Bachelor's degree and higher	206 (46.3)	195 (46.7)	11 (40.7)	
Occupation (n = 443)				
No career	47 (10.6)	45 (10.8)	2 (7.4)	0.584
Farmer	74 (16.7)	68 (16.3)	6 (22.2)	
Private company	100 (22.6)	94 (22.6)	6 (22.2)	
Government official	94 (21.2)	91 (21.9)	3 (11.1)	
Other	128 (28.9)	118 (28.4)	10 (37.0)	
Income (n = 441)				
≤ 10,000	208(47.17)	198 (47.7)	10 (38.5)	0.359
> 10,000	233(52.83)	217 (52.3)	16 (61.5)	
Health Insurance (n = 446)				
Universal Coverage#	282 (63.2)	262 (62.5)	20 (74.1)	0.481
Social security	67 (15.0)	64 (15.3)	3 (11.1)	
Other	97 (21.8)	93 (22.2)	4 (14.8)	
Comorbid diseases (n = 443)				
Yes	262 (59.1)	248 (59.5)	14 (53.8)	0.571
No	181 (40.9)	169 (40.5)	12 (46.2)	
Number of comorbid diseases (n = 425)				
≤ 1	337 (79.3)	319 (79.8)	18 (72.0)	0.354
> 1	88 (20.7)	81 (20.3)	7 (28.0)	
Concomitant medications (n = 394)				
Yes	249 (63.2)	233 (63.0)	16 (66.7)	0.716
No	145 (36.8)	137 (37.0)	8 (33.3)	

*Using Pearson Chi Square test

#Universal Coverage refers to the basic health insurance provided to all Thai citizens

Table 2 Comparison of expectations on use of PILs in patients who had and had not received PIs

Characteristic	No. of individual (%)		Total N (492)	*p* value*
	Had received PIs (N = 449)	Had not received PIs (N = 43)		
Know of PILs				
Knew	103 (23.0)	15 (34.9)	118 (24.1)	0.083*
Did not know	344 (77.0)	28 (65.1)	372 (75.9)	
Benefit of PILs				
Useful	434 (97.1)	43 (100)	477 (97.3)	0.526**
Not useful	3 (0.7)	0 (0)	3 (0.6)	
Not sure	10 (2.2)	0 (0)	10 (2.0)	
Content that PILs should contain				
Name	386 (86.4)	32 (78.0)	418 (85.7)	0.147*
Indications	418 (93.5)	37 (90.2)	455 (93.2)	0.509**
Precaution	404 (90.4)	31 (75.6)	435 (89.1)	0.008**
Instructions for use	413 (92.4)	36 (87.8)	449 (92.0)	0.359**
Overdose	215 (48.1)	17 (41.5)	232 (47.5)	0.416*
What to do when a dose is missed	254 (56.8)	21 (51.2)	275 (56.4)	0.489*
Side effects	344 (77.0)	30 (73.2)	374 (76.6)	0.583*
Contraindications	341 (76.3)	27 (65.9)	368 (75.4)	0.138*
Warnings	350 (78.3)	29 (70.7)	379 (77.7)	0.265*
Drug interactions	243 (54.4)	21 (51.2)	264 (54.1)	0.699*
Storage	257 (57.5)	22 (53.7)	279 (57.2)	0.635*
When PILs should be provided				
With the first dose	194 (43.7)	21 (50.0)	215 (44.2)	0.432*
Every time	250 (56.3)	21 (50.0)	271 (55.8)	
Need for advice from healthcare professionals				
Need	437 (98.4)	40 (95.2)	477 (98.1)	0.178**
No need	7 (1.6)	2 (4.8)	9 (1.9)	
Need for advice from healthcare professionals after receiving PILs				
Unchanged	354 (79.7)	32 (78.0)	386 (79.6)	0.385*
Decreased	61 (13.7)	8 (19.5)	69 (14.2)	
Not sure	29 (6.5)	1 (2.4)	30 (6.2)	
Time to start reading PILs				
With the first dose	274 (62.1)	29 (70.7)	303 (62.9)	0.142*
After the occurrence of side effects	81 (18.4)	3 (7.3)	84 (17.4)	
If curious	84 (19.0)	8 (19.5)	92 (19.1)	
Reading online PILs if they are available				
Yes	324 (72.8)	24 (57.1)	348 (71.5)	0.093*
No	104 (23.4)	15 (35.7)	119 (24.4)	
Not sure	17 (3.8)	3 (7.1)	20 (4.1)	

*Using Pearson Chi Square test

**Using Fisher's exact

Table 3 Comparison of patient characteristics in relation to PIL needs and expected knowledge

Characteristic	Need score[a]				Knowledge score[b]			
	n	Mean	SD	*p* value	n	Mean	SD	*p* value
Gender								
Male	217	9.76	0.88	0.122*	217	9.68	1.00	0.515*
Female	269	9.62	1.03		268	9.62	0.97	
Age								
< 45	228	9.73	0.89	0.342*	227	9.69	0.97	0.340*
≥ 45	258	9.64	1.03		258	9.60	1.00	
Education level								
Lower than Bachelors	254	9.68	1.00	0.885*	253	9.69	0.90	0.302*
Bachelor's degree and higher	230	9.69	0.93		230	9.59	1.07	
Occupation								
No career	49	9.65	0.91	0.724**	49	9.60	0.91	0.347**
Agriculturist	79	9.68	1.05		79	9.75	0.73	
Private company	106	9.68	0.96		105	9.67	1.05	
Government official	109	9.62	1.04		109	9.50	1.14	
Other	139	9.78	0.81		139	9.72	0.88	
Health insurance								
Universal coverage	302	9.67	0.99	0.462**	301	9.65	0.96	0.882**
Social security	74	9.81	0.76		74	9.59	1.13	
Other	110	9.63	1.04		110	9.65	0.95	
Comorbid diseases								
Yes	288	9.66	0.98	0.589*	288	9.62	0.96	0.564*
No	196	9.71	0.95		195	9.67	1.03	
Number of comorbid diseases								
≤ 1	366	9.70	0.93	0.728*	365	9.66	0.96	0.443*
> 1	95	9.74	0.78		95	9.74	0.68	
Concomitant drug use								
No	156	9.79	0.71	0.188*	156	9.65	0.90	0.251*
Yes	273	9.69	0.89		273	9.75	0.83	
Receiving PIs in the past								
No	41	9.17	1.57	***0.030****	41	9.30	1.43	0.111*
Yes	440	9.73	0.89		439	9.67	0.93	
Previously known PILs								
No	369	9.72	0.87	0.153*	368	9.71	0.85	***0.036****
Yes	117	9.55	1.23		117	9.44	1.32	

Bold-italic numbers refer to statistical significant at $p < 0.05$

*Independent *t* test

** One way ANOVA

[a]Need score: participants rated their need for PILs on a visual analog scale (min–max = 0–10)

[b]Knowledge score: participants rated the amount of knowledge they expected to gain from using PILs on a visual analog scale (min–max = 0–10)

Table 4 Factors affecting the score of PIL needs and expected knowledge (multiple linear regression)

Factor	b	SE_b	β	T	95% confidence interval		*p* value
					Lower	Upper	
Score of PIL needs							
Ever received PIs	0.455	0.147	0.148	3.089	0.166	0.745	0.002*
	Constant 9.310; $SE_{est} = \pm 0.82497$						
	$R = 0.148$; adjusted $R^2 = 0.020$; $F = 9.540$; *p* value = 0.002*						
Score of knowledge							
Ever received PIs	0.336	0.161	0.095	2.092	0.020	0.652	0.037
Ever known PILs	−0.255	0.105	−0.110	−2.417	−0.461	−0.048	0.016
	Constant 9.396; $SE_{est} = \pm 0.98070$						
	$R = 0.152$; adjust $R^2 = 0.019$; $F = 5.614$; *p* value = 0.004**						

b denotes *the variable estimate*

SE_b denotes *the standard error of the variable estimate*

β denotes *the standardized estimate*

*Adjusted for gender, concomitant drug, ever received PIs, ever known PILs

**Adjusted for ever received PIs, ever known PILs

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