

Public Attitude Toward Drug Technical Package Inserts in Saudi Arabia

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Objective: To examine public opinion in Saudi Arabia regarding the technical drug package insert (PI) as a source of information and to assess the need for potential changes to the existing format in favor of a more patient-oriented package insert (PPI).

Design: A cross-sectional survey was conducted from March through May 1998 by means of a self-administered questionnaire.

Setting: Eighty-four community pharmacies in Riyadh.

Participants: Two thousand twenty-nine customers entering community pharmacies in Riyadh were enrolled in this survey.

Results: Results of the survey showed that 88% of the respondents read the PI. The motives for reading the PI included the desire to know more about the medication (48.7%), to adhere to the prescription (21.7%), and to decide whether to take the medication (13.1%). From the list of information contained therein, respondents listed indications (47.1%) and adverse drug effects (46.6%) as the principal sections of interest. Respondents overwhelmingly endorsed the PI as a complementary source of drug information to the verbal instructions of the physician and the pharmacist. However, readers did criticize its detail, legibility, and poor graphic illustration. Respondents indicated their desire to see a concise PPI introduced, one that highlights only the most common adverse effects of a drug. It should be written in simple Arabic and include, whenever possible, illustrations to enhance comprehension.

Conclusions: The PI does not have the power to overrule the physician's or pharmacist's instructions. Since some patients may cease taking their medicines if they feel threatened by the adverse effects mentioned in the PI, precautionary statements should be prominently placed in the PI to explain the purpose of mentioning such information and what proper action should be taken by the patient.

J Pharm Technol 2003;19:209-18.

Despite the widespread use of prescription and OTC medications, patients' knowledge about their prescription medications is often inadequate.¹ Previous studies have shown that most patients do not take their medications precisely as prescribed.^{2,4} Cessation of drug therapy when patients apparently feel better, but before completing the full course, is a common finding. Such inappropriate use of medication may have resulted from a genuine lack of understanding and/or information about their disease state and its treatment regimen or simply

due to sheer complacency on the part of the patients. Most healthcare professionals agree that patients need unbiased, accurate information about the drugs they are taking.

Over the past decade, public health policy has been evolving, with increased options available to consumers to obtain information on their prescribed medications. Despite the fact that physicians and pharmacists are the preferred sources of information,^{5,6} healthcare professionals do not always ensure optimal knowledge transfer.⁷ In

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This study was supported by College of Pharmacy Research Center, grant number CPRC 50.

addition, information given verbally is likely to be either misunderstood or forgotten.⁸⁻¹⁰ Therefore, it is now widely acknowledged that patients do require a certain amount of information in order to use their drugs optimally.^{11,12}

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Advertisement of prescription and OTC medications is not allowed except in medical and pharmaceutical journals.

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In 1995, the FDA launched a 10-year program to ensure that 90% of all prescription drugs would have a package insert (PI) giving drug information and potential adverse effects. It was hoped this new PI would reduce medication errors.¹³ Information written on medication packaging or handed over by physicians or pharmacists as leaflets or patient-oriented package inserts (PPIs) were considered useful supplements.¹⁴⁻¹⁷

Saudi Arabia boasts more than 300 hospitals, with a capacity in excess of 45,000 beds, 2,329 healthcare centers, and almost 100 private clinics. These healthcare facilities are predominantly governmental, offering gratis service to all citizens. In addition, there are more than 3,000 private sector community pharmacies. Outside governmental hospitals, prescription and nonprescription medications are obtained from community pharmacies in their branded packages at the customers' expense. Self-medication is prevalent in Saudi Arabia, with many people obtaining their medications from community pharmacies.¹⁸ Furthermore, advertisement of prescription and OTC medications is not allowed except in medical and pharmaceutical journals. However, these regulations are not strictly enforced.

In Saudi Arabia, all medications available for use, whether OTC or prescription, are distributed exclusively through pharmacies in brand packages and include a PI. The PI consists of a technical transcript data sheet, primarily intended for physicians and pharmacists. The Drug Registration Act in Saudi Arabia requires that the PI data sheet must include information on description, clinical pharmacology, indications and usage, contraindications, warnings, precautions, teratogenicity, drug interactions, adverse drug reactions, overdose, dosage and administration, and storage instructions. In addition, the Drug Registration Act stipulates that all PIs must be written in both Arabic and English.

In the Saudi Arabian medication distribution system, technical information contained in the PIs prepared by

the individual pharmaceutical companies is approved by health authorities and targeted to healthcare professionals for dissemination to lay people without any additional effort or modification. Some of the PIs in Saudi marketed products show a wide variation in the amount of information provided when compared with US labeling.¹⁹ In the past, a similar situation existed in several European countries including Belgium when, in 1984, the Belgian health authorities decided to transform the traditional technical PI into a fully informative PPI written in lay language.²⁰ Vander Stichele et al.²¹ reported on the attitude of the Belgian public toward the PI as a medication information tool written in technical language and intended for healthcare professionals within an original drug-dispensing system. The PI was seen as a supplementary source of information instrumental to the physician-pharmacist-patient relationship, without the power to overrule the physician's or pharmacist's instructions. We decided to conduct a similar study to examine public opinion in Saudi Arabia on the technical drug PI as a source of information and to assess the need for potential changes to the existing format in favor of a PPI.

Methods

For the present study, Riyadh, the capital of Saudi Arabia, was divided into 5 zones (central, northern, southern, eastern, western) to ensure proper and equal pharmacy representation. One hundred community pharmacies were randomly selected from the Ministry of Health register. After explaining the purpose of the study to the pharmacist, permission was solicited to distribute the questionnaire inside the premises. Eighty-four pharmacies agreed to participate in the study, 10 refused, and 6 were closed.

The self-administered questionnaire contained 28 questions and was designed to address the following (Appendix I):

1. What were the characteristics of the study population (10 questions)?
2. What was the extent of actual use of the present PI by the public (4 questions)?
3. What were the motives for reading the PI (4 questions)?
4. How was this information source perceived (8 questions)?
5. What constituted an ideal PPI (2 questions)?

A pilot study was carried out to test the validity of the survey form and to ascertain the best time to collect data. Accordingly, several questions were reworded, instructions on completing the questionnaire were reviewed, and the best time for data collection was decided. Data were collected and recorded over a 4-hour period (18.00-22.00) on 1 working day of the week for each pharmacy. An earlier pilot study had indicated this time period to be one of the best public shopping periods in Riyadh. This approach would give reliable responses as the ques-

tionnaire was completed on the premises immediately following the transaction while details were still fresh in the customer's mind.

Data were collected over 3 months starting in March 1998, when all Arabic-speaking customers entering these pharmacies were approached, introduced to the study, and asked permission for time to complete the questionnaire regarding drug PIs without mentioning the objective of the study. Of 2,408 customers entering the community pharmacies (7-40 customers per pharmacy), 2,029 agreed to complete the questionnaire (84% response rate): 302 consumers refused (212 women) and 77 were excluded because they could not speak Arabic or were younger than 15 years of age.

Data were analyzed using the SPSS-PC+ statistical package. Data were also analyzed by cross-tabulation of the variables with the application of the χ^2 test to assess statistical significance. In addition, the technique of weighting was used to correct selection bias for gender, age, and educational level. The impact of this weighting method is limited; the main results of this study (the percentage of PI readers) decreased only from 88.3% to 83.6% for educational level, to 86.7% for age, and there was no change for gender. This indicates that the results obtained are validated by sample distortion.

Results

SAMPLE CHARACTERISTICS

Demographic characteristics of the respondents in the study sample (age, gender, nationality, social status, occupation, educational level) are summarized in Table 1. The ratio of male to female respondents was 1.9, and the mean age \pm SD was 30.2 ± 10.8 years. Elderly participants (>60 y old) constituted 1.9% of the sample surveyed, and university graduates accounted for 47.4%. The majority of respondents were Saudi nationals and the remainder were non-Saudis belonging to neighboring Arab countries.

AWARENESS AND USE OF THE PI

When respondents were asked whether they were aware of the PI, 1,888 (93.1%) answered affirmatively. Also, when they were asked for whom the PI is intended, 57% believed that the PI is intended for physicians and pharmacists as well as patients, 31% believed that the PI is for the benefit of the patients, and 11.2% thought that it is targeted at physicians and pharmacists only. Furthermore, when respondents were asked whether they read the PI, 88.3% of them claimed that they read it or ask somebody to read it for them (34% did so with each new drug; the remainder were only occasional readers).

Differences in the readership of PI by gender and age were similar. However, significant differences ($p < 0.05$)

were observed among the respondents with respect to educational levels. The higher the educational level of respondents, the greater the tendency to read the PI ($p < 0.05$).

Motives for Reading the PI and Topics of Interest

The readers of the PI responded positively to 4 predefined motives: to decide whether to take the medicine (233 respondents, 13.1%); to know more about their drug (867 respondents, 48.7%); to be able to adhere to the therapy (387 respondents, 21.7%), and to be reassured that they were taking the appropriate treatment (293 respondents, 11.3%). These respondents did not show any significant differences when analyzed with respect to gender or occupation. Age and educational level, however, appeared to have significant influence on readers' motives ($p < 0.05$). Furthermore, a high percentage of younger (49.5%), middle-aged (46.2%), and elderly respondents (39.1%) rated the variable "to know more about medication," as an important motive for reading the PI.

Topics that interested readers in the PI were indication (47%), adverse effects (46.6%), dosage and administration (27.1%), contraindications (21.8%), duration of therapy (17.7%), precautions (14.0%), drug interaction (10.9%), drug composition (8.3%), and mechanism of action (7.2%).

Table 1. Sample Characteristics

| DEMOGRAPHIC CHARACTERISTICS | SUBJECTS | | NATIONAL CENSUS* (%) |
|-----------------------------|----------|------|----------------------|
| | n | % | |
| Gender | | | |
| male | 1317 | 64.9 | 50.8 |
| female | 712 | 35.1 | 49.2 |
| Age | | | |
| <15 | 0 | 0 | 32.4 |
| 15-39 | 1666 | 82.1 | 41.2 |
| 40-59 | 324 | 16.0 | 17.2 |
| ≥ 60 | 39 | 1.9 | 9.2 |
| Nationality | | | |
| Saudi | 1398 | 68.9 | 64.9 |
| non-Saudi | 631 | 31.1 | 35.1 |
| Status | | | |
| married | 1152 | 56.8 | 56.7 |
| single | 818 | 40.3 | 39.7 |
| other | 59 | 2.9 | 3.6 |
| Occupation | | | |
| employed (public & private) | 881 | 43.4 | NA |
| student | 659 | 32.5 | NA |
| housewife | 278 | 13.7 | NA |
| self-employed | 151 | 7.4 | NA |
| retired | 21 | 1.0 | NA |
| other | 39 | 1.9 | NA |
| Education | | | |
| university | 962 | 47.4 | 16 |
| secondary | 603 | 29.7 | 16 |
| intermediate | 246 | 12.1 | 17.3 |
| primary | 106 | 5.2 | 20.3 |
| other | 112 | 5.5 | 30.4 |

NA = not available.

*National Institute for Statistics.

PROFESSIONAL ADVICE VERSUS PI CONTENT

In cases where the information obtained from health-care professionals was contradictory to that found in the PI, 48.9% of respondents indicated that they would seek further consultation with their physician, while 17.1% opted to resolve the matter by discussion with the pharmacist. Those who were inclined to ignore the information in the leaflet accounted for 21.4% of the respondents, while only 4.7% were willing to trust and follow the PI information. A further 6.1% of respondents reported that they would stop taking the medication altogether under these circumstances. The remainder were either undecided or would seek the advice of close family and friends before starting the drug (Table 2).

Analysis of data with respect to age, gender, and educational level revealed statistical differences among the 3 subgroups ($p < 0.05$). The response patterns relating to reading material on serious adverse effects in the PI (prescription or OTC drug) were similar. In case of prescription and OTC items, the percentages of respondents who would prefer to discuss the matter with their physician were 62.6% for prescription drugs and 34.3% for OTC items; percentages of those opting to discuss the matter with the pharmacist were 11.1% for prescription drugs and 26% for OTC items. In addition, 33.9% of participants were prepared to abandon OTC medication rather than prescription drugs (16%). Two to three percent of people would continue taking either category of medication at a lower dose level to minimize the reported adverse effects. Cross-tabulation of response data against gender and age of the respondents showed no significant trend ($p > 0.05$). On the other hand, statistically significant differences were found among respondents with different educational levels and occupations ($p < 0.5$).

The reaction of respondents when encountering details they did not understand in the PI was also investigated. Under these circumstances, the percentages of people who would seek further clarification from the pharmacist were 65.2% and 48.2% for OTC and prescription items, respectively. The corresponding figures for those who favored approaching the physician were

23.2% for OTC medications and 32.9% for prescription drugs.

Consumer Opinion of PI Content

Respondents' opinions of a list of 9 principal statements about drug information content of the PI are summarized in Table 3. The results showed that the majority of respondents (93%) agreed that the PI gives useful information. Seventy-eight percent of respondents felt that the PI provides information prior to drug use and 77.2% had agreed that the PI gives credence to what the physician says. Moreover, 76.3% of the PI readers agreed that it is reassuring to know that the PI could always be consulted. Most of the respondents (74.5%) acknowledged that the information contained in the PI is readable and understandable and 42% believed that the information is easy to remember. On the other hand, 59.4% of PI readers stated that the PI contains too much information. Sixty-three percent of the respondents disagreed with the statement that the PI is difficult to understand, and 51.7% disagreed that the PI discourages them from taking their medications. About 58% of consumers either were uncertain or disagreed that PI is easy to remember.

Characteristics of the Ideal PI

Table 4 lists the various criteria that respondents rated for the format of a new PI. The 7 principal features in their recommendations, rated in the order from most to least important, were: the PI should be written in lay language, should be written in Arabic, should contain the most important adverse effects, should contain all adverse effects, should be written in both Arabic and English, should be brief and concise, and should contain illustrations whenever possible.

Discussion

An overwhelming number of respondents were familiar with PIs. Since 1980, the laws governing community pharmacy practice mandate that medications be dispensed in their original brand packages with PIs.¹⁹ The large number of respondents who claimed to read the insert when taking medicines reflects people's intentions and not their observed behavior, and was closely parallel to the observations reported elsewhere.²¹ Other researchers have reported lower rates (44%).²² However, such high levels of PI readership do not necessarily reflect that all who read the leaflet derived lasting benefit (i.e., increased knowledge or modified behavior). Despite this, the high figure, coupled with the strong desire of the respondents who favored the introduction of a new PPI, may support the idea that verbal instructions traditionally given to patients by healthcare professionals are insufficient and re-

Table 2. Respondents' Reaction to Conflicting Sets of Information (Professional Advice vs. PI Content)

| REACTION | RESPONDENTS | |
|---|-------------|------|
| | n | % |
| What do you do when the PI contains information that conflicts with physician's instructions? | | |
| recontact the physician | 873 | 48.9 |
| follow physician's instructions | 382 | 21.4 |
| ask the pharmacist | 305 | 17.1 |
| stop taking the drug | 109 | 6.1 |
| follow PI instructions | 84 | 4.7 |
| make your own decision | 27 | 1.5 |
| seek advice from family and friends | 4 | 0.2 |

PI = package insert.

inforcement through the PPI is needed. In addition, the percentage of respondents in our study who favored the introduction of PPIs is similar to that reported in a British community.²¹

The results further provided some findings regarding the rating of PIs among other sources of information. The PI emerged to be an information source for the patient to refer to more than textbooks or other people. Furthermore, it is reassuring to know that only 4.7% of respondents will follow PI instructions if they contradict physician instructions. This apparently indicates that the PI does not overrule the physician. These results are similar to those reported in the Belgian study.²¹ However, the situation requires careful attention, since a further 6.1% of respondents would stop taking their medicine based on information in the PI.

Respondents reacted differently to reading a list of serious adverse effects in the PIs of both prescription and OTC medications. Such information was found not to be conducive to consumption of drugs. In addition, the higher proportion of the study population would prefer consultation with the physician rather than pharmacist concerning details of potential adverse effects mentioned in the PIs of prescription drugs. The level of such preference was, however, greatly narrowed with OTC medications. It was also noted that the percentage of people who were prepared to abandon their prescription drugs was less than that of those who would cease taking OTC preparations.

These findings highlight the traditional belief in physicians' knowledge. This belief is supported by a long-standing healthcare system dominated by physicians. Furthermore, consumers' trust in physicians is assisted by the poor public image of the community pharmacist in Saudi Arabia. For several reasons, including lack of

professionalism, commercial pressure on community pharmacy, and lack of enforcement of regulations governing pharmacy practice, this is a common perception.

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In case of contradictory information, 48.9% of respondents indicated that they would seek further consultation with their physician, while 17.1% opted to resolve the matter by discussion with the pharmacist.

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When respondents encountered difficulty in understanding the content of the PI, however, they approached the pharmacist more often than any other available source of drug information, including the physician. Also, a substantial number of readers said they would discontinue their medicines if the PI mentioned threatening adverse effects (16%), especially when the medication is OTC (33.9%). Similar results were reported in the Belgian population.²¹ Other survey participants reacted indifferently, taking no further action if they did not understand the in-

Table 3. Consumers' Opinions Regarding Content of the PI^a

| REACTION TO PI | STRONGLY AGREE | | AGREE | | UNCERTAIN | | DISAGREE | | STRONGLY DISAGREE | | AVERAGE ± SD SCORES (RANGE 1-5) | TOTAL NO. OF RESPONDENTS |
|---|----------------|------|-------|------|-----------|------|----------|------|-------------------|------|---------------------------------|--------------------------|
| | n | % | n | % | n | % | n | % | n | % | | |
| Hard to understand | 129 | 7.4 | 261 | 14.9 | 259 | 14.8 | 840 | 48.0 | 262 | 15.0 | 3.48 ± 1.14 | 1751 |
| Readable and understandable | 432 | 24.6 | 877 | 49.9 | 224 | 12.7 | 190 | 10.8 | 34 | 1.9 | 2.16 ± 0.98 | 1757 |
| Gives useful information | 851 | 48.7 | 774 | 44.3 | 86 | 4.9 | 22 | 1.3 | 14 | 0.8 | 1.61 ± 0.71 | 1747 |
| Easy to remember | 185 | 10.6 | 550 | 31.4 | 592 | 33.8 | 354 | 20.2 | 68 | 3.9 | 2.75 ± 1.02 | 1749 |
| Has too much information | 452 | 25.8 | 590 | 33.6 | 333 | 19.0 | 313 | 17.8 | 66 | 3.8 | 2.40 ± 1.16 | 1754 |
| Reassuring to know that one can always consult it | 512 | 29.1 | 831 | 47.2 | 246 | 14.0 | 136 | 7.7 | 35 | 2.0 | 2.06 ± 0.96 | 1760 |
| Discourages taking medication | 194 | 11.1 | 286 | 16.3 | 366 | 20.9 | 572 | 32.7 | 332 | 19.0 | 3.32 ± 1.26 | 1750 |
| Gives an idea before drug use | 606 | 34.3 | 772 | 43.7 | 237 | 13.4 | 131 | 6.5 | 22 | 1.1 | 1.98 ± 0.94 | 1768 |
| Produces credence to what the physician says | 498 | 28.3 | 861 | 48.9 | 257 | 14.6 | 119 | 6.8 | 24 | 1.4 | 2.04 ± 0.91 | 1759 |

PI = package insert.

^aThe average level of agreement was obtained by averaging responses according to the following scale: strongly agree = 1, agree = 2, uncertain = 3, disagree = 4, strongly disagree = 5.

formation on the PI, or even if the information was threatening. These findings highlight the importance of adding specific statement(s) in the PI to address the purpose of mentioning adverse effects, to ensure the patient of drug safety, and to describe the action to be taken if the patient feels threatened by such adverse effects.

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The particular sections of interest among the majority of PI readers were those devoted to indication and adverse effects, possibly suggesting their overall concern about medication efficacy and safety, respectively. The lack of interest in the other sections of the PI may be due in part to earlier provision of the relevant information by the physician or the pharmacist. Alternatively, these sections may have been perceived as irrelevant, as their contents are usually technical and not readily understood by laymen.

With respect to the public's rating scale of drug information, the PI was ranked third after physician and pharmacist, but far ahead of advice of family members and friends. That the physician headed such a list emphasizes the traditional trust in the healthcare professionals, but it also highlights the apparent lack of public awareness in the training and expertise of the pharmacist. The majority of respondents, particularly those with lower educational levels, clearly viewed the physician as the primary source of drug information. While this may be seen as projecting a positive image of the physician, it could also create or increase the degree of dependence on 1 particular member of the healthcare team. Our findings

are in agreement with earlier reports in which similar results have been described.^{23,24} The influence of patients' educational background on their perception of the physician's role in relation to drug information may have practical implications. Those with a poor level of education may demand that the physician spend more time explaining the disease state and its therapy to them, while this aspect of physician-patient dialogue may be minimal or absent altogether in those with higher educational background. In our study, the former group of patients appeared to be highly dependent on physicians for drug information. Furthermore, those with higher education have the ability to interpret information and easily access alternative sources of information.²³

In case of OTC medications, the majority of respondents appeared to rely heavily on the pharmacist to give them further clarification of vague or hard-to-understand details mentioned in the PI. This may be attributed to either the respondent's habit of self-prescribing or the fact that the medicines were taken as recommended by the pharmacist. Likewise, the pharmacist's availability and ease of accessibility could be another important factor. A study similar to ours indicated that patients contact pharmacists because of easy communication (49%) and accessibility (47%), whereas 98% of the patients who consult the physicians do so because they feel that physicians know much more about medications than do the pharmacists.²⁵ Few readers rated relatives and friends as important sources of information, although the influence of some friends and relatives on the other family members in using medicines seems to be important. These findings are in corroboration with those of the study in Belgium.²¹

When survey participants were faced with apparently conflicting information between the PI and that of the prescribing physician, the majority indicated that they would continue taking the drug with professional advice. This response rate is reassuring as it helps to highlight the fact that the PI serves as a complementary source of information and is not a substitute for professional advice from physicians and pharmacists. It is worth noting that adherence may be adversely affected in certain patients following exposure to overwhelming amounts of information or supposedly contradictory statements contained in the PI.²⁶

Table 4. Characteristics of the Ideal PPI

| REACTION | VERY IMPORTANT | | IMPORTANT | | LESS IMPORTANT | | NOT IMPORTANT | |
|-------------------------------------|----------------|------|-----------|------|----------------|------|---------------|------|
| | n | % | n | % | n | % | n | % |
| PPI should: | | | | | | | | |
| be brief and concise | 715 | 41.2 | 534 | 30.8 | 240 | 13.8 | 247 | 14.2 |
| be written in lay language | 1419 | 80.9 | 305 | 17.4 | 18 | 1.0 | 13 | 0.7 |
| be written in Arabic | 1283 | 74.0 | 321 | 18.5 | 83 | 4.8 | 47 | 2.7 |
| be written in Arabic and English | 796 | 46.6 | 450 | 26.3 | 298 | 17.4 | 165 | 9.7 |
| contain most important side effects | 1272 | 73.2 | 381 | 21.9 | 66 | 3.8 | 18 | 1.0 |
| contain all side effects | 845 | 48.4 | 436 | 25.0 | 340 | 19.5 | 126 | 7.2 |
| contain illustrations | 436 | 25.0 | 326 | 18.7 | 528 | 30.3 | 454 | 26.0 |

The respondents expressed further positive opinions regarding the PI. The PI is regarded as a useful source of information that is readable and understandable, is reassuring, and gives confidence in physician instruction. However, this positive attitude is hindered by the patient's uncertainty regarding the possibility that information contained in the PI is hard to understand and may discourage them from taking their medicines. These findings emphasize the importance of the PI for the patient and the need to improve the quality and the content of the PI, and encourage other countries to follow suit.¹³

It is also evident from this survey that the Saudi Arabian public would like to see some basic changes in both the content and format of the existing technical PIs. This, they feel, would make them more patient-oriented and improve their usefulness as a complementary tool to the verbal instructions of healthcare professionals. The changes recommended include the conciseness of the documents, simplicity of the language (particularly the Arabic section), and, whenever possible, the inclusion of illustrations to improve the readability and acceptance by all strata of society. Similar findings have been reported.²⁷ The results of this study highlighted the need for PPIs, and the current regulations should be changed to include PPIs.

This study has some inherent limitations. It was limited to community pharmacy premises rather than homes, since telephone and home interviews are not applicable in Saudi Arabian society. The high male-to-female ratio found in this study (1.9:1) is not a truly representative value for actual gender distribution in the population (1.2:1), but rather reflects the gender distribution of the community pharmacy customers at that given period of time. Additionally, young respondents and those with higher educational levels were over-represented and the elderly were under-represented. This is very likely a reflection of the unique Saudi social and cultural characteristic, where young men traditionally assume full responsibility and attend to the needs of spouses and other female relatives and the elderly, including shopping for pharmaceuticals.

Summary

The results of our study reflect how the general Saudi population — especially young adults — feels about technical PI within a system of its mandatory inclusion in all dispensed medication packages. The Saudi population reads the PI and perceives it to be a supplementary source of information on medication, although the leaflet is technical and intended for healthcare professionals. The readers of the PI criticized its details and poor graphic illustrations. Although readers appreciate the technical PI as a useful source of information, it does not have the power to overrule the physicians' and pharmacists' instructions. Sometimes the PI causes patients to abandon treatment or take less of the medicine if they feel threat-

ened by adverse effects mentioned in the PI. Precautionary statements should be prominently placed in the PI to explain the purpose of mentioning such adverse effects and what proper action should be taken by the patient. In addition, physicians must make themselves aware of the information on frequently prescribed drugs contained in the PI to avoid disseminating contradictory information to the patients. The information should be reviewed regularly to simplify the details. ≍

We acknowledge the support provided by the Research Center, College of Pharmacy, King Saud University, to accomplish this study.

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Appendix I. Survey Questions Pertaining to Attitudes Toward PIs in Saudi Arabia

Population

1. Sex _____ 2. Age _____ 3. Nationality _____ 4. Marital status _____
 5. Occupation _____ 6. Education level _____
 7. For whom is the medication intended?
 a. myself
 b. one of my family
 c. other (specify) _____
 8. Since when do you take this medication?
 a. for the first time
 b. less than 1 week
 c. a week to a month
 d. a month to 6 months
 9. Do you refer to a particular pharmacy every time you need medicine?
 yes _____ no _____
 10. How much do you spend monthly for purchasing medicines?

Extent of actual use of the present PI

1. How did you obtain your medication?
 a. by prescription
 b. pharmacist advice
 c. my own request
 d. some with a prescription, others without
 2. Are you aware of the existence of the PI?
 yes _____ no _____
 3. For whom, in your opinion, is the PI meant?
 a. physicians and pharmacists
 b. patients
 c. physicians, pharmacists, and patients
 4. For what kind of medicine do you read the PI?
 a. drugs that treat serious illness
 b. drugs that treat minor illness
 c. all drugs without exception
 d. I don't read the PI

Motives for reading the PI

1. Do you have any preference in reading the PI of drugs dispensed with prescription over those purchased without prescription?
 a. I read all without any preference.
 b. I read only PIs for drugs when dispensed with a prescription.
 c. I read only PIs for drugs purchased without a prescription.
 2. Under what circumstances do you read the PI?
 a. always
 b. only prior to taking new medicines
 c. in certain situations
 3. There may be a particular reason for reading PIs. In your opinion, for what purpose do you read it?
 a. to decide whether to take the medicine
 b. to learn more about my medicine
 c. to be sure that I am taking the appropriate treatment
 d. to be able to take the medicine exactly as it is prescribed
 4. While reading the PI, which topic do you usually like to read?
 a. how long to take the medicine
 b. what is in the medicine (composition)
 c. how to take the medicine
 d. side effects of the medicine
 e. how much to take
 f. disease for which the medicine is indicated
 g. circumstances in which the medicine should not be taken
 h. how the medicine acts
 i. other: please specify _____

How the information sources are perceived

1. When you are confronted with a conflict of information between the instructions of the physician and those of the PI for prescription medicines, you may decide to:
 a. follow physician instructions.
 b. follow the PI instructions.
 c. ask the pharmacist.
 d. recontact the physician.
 e. make my own decision.
 f. stop taking the drug.
 g. seek advice from family and friends.

(continued on page 218)

Appendix I. Survey Questions Pertaining to Attitudes Toward PIs in Saudi Arabia (continued)

2. When you are confronted with serious side effects in the PI for prescription medicines, you may decide to:
- continue taking the medicine.
 - recontact the physician.
 - take less of the medicine.
 - ask the pharmacist.
 - stop taking the medicine.
 - do something else (please specify) _____
3. When you are confronted with difficulty in understanding what is written in the PI, you may decide to:
- ask the pharmacist.
 - ask the physician.
 - consult a medical encyclopedia or medical textbook.
 - ask my family or friends.
 - ask no additional information.
 - do something else (please specify) _____
4. Where do you get your information on medications that are available without prescription? Rank the answers according to their importance starting from 1 (most important) to 9 (least important).
- the physician
 - the pharmacist
 - the PI
 - family and friends
 - my own experiences
 - books and newspapers
 - advertisements
 - broadcast and television programs
 - other
5. When you are confronted with a listing of side effects in the PI for nonprescription medicines, what do you do?
- continue taking the medicine
 - recontact the physician
 - take less of the medicine
 - ask the pharmacist
 - stop taking the medicine
 - other
6. When you are confronted with difficulty in understanding what is written in the PI, you may decide to:
- ask the pharmacist.
 - ask the physician.
 - consult a medical encyclopedia or medical textbook.
 - ask my family or friends.
 - ask no additional information.
 - other
7. In your opinion, to what extent do you perceive the following statements?
- | Reaction | Strongly agree | Agree | Uncertain | Disagree | Strongly disagree |
|--|----------------|-------|-----------|----------|-------------------|
| PI is hard to understand. | | | | | |
| PI is readable and understandable. | | | | | |
| PI gives me useful information. | | | | | |
| PI is easy to remember. | | | | | |
| PI has too much information. | | | | | |
| PI is reassuring. I always consult it. | | | | | |
| PI discourages me from taking medications. | | | | | |
| PI gives me an idea about the drug prior to its use. | | | | | |
| PI gives credence to what physician says. | | | | | |
8. In your opinion, how do you perceive the following statements?
- | Statement | Strongly agree | Agree | Uncertain | Disagree | Strongly disagree |
|---|----------------|-------|-----------|----------|-------------------|
| Physicians give sufficient information about the drugs they prescribed. | | | | | |
| Pharmacists give sufficient information about the drugs they dispensed. | | | | | |
- The constituents of an ideal PPI
1. Do you like the PI to be especially designed for the patients?
- yes _____ no _____
- If your answer is yes, try the following question:
2. In your opinion, what features of the PI are the most important?
- | Reaction | Very important | Important | Less important | Not important |
|--|----------------|-----------|----------------|---------------|
| should be brief and concise | | | | |
| should be written in lay language | | | | |
| should be written in Arabic | | | | |
| should be written in Arabic and English | | | | |
| should contain most important side effects | | | | |
| should contain all side effects | | | | |
| should contain illustrations | | | | |