

DRUG INFORMATIONAL VALUE OF PATIENT PACKAGE INSERT (PPI): A SAMPLE STUDY IN PALESTINE

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قيمة المعلومات الدوائية الموجوده النشرات الدوائية الخاصة بالمريض والمرفقة بالدواء: عينة من فلسطين

ملخص: الهدف من هذه الدراسة هو معاينة رأي المرضى للنشرات الدوائية المرفقة بعلبة الدواء و مناقشة النواحي القانونية والعملية المعمول بها في فلسطين. تمت الدراسة على 371 مريضاً. أكثر من نصف العينة (51.7%) يقرأون النشرات الدوائية ولكنهم يجدونها غير واضحة أو تثير مخاوفهم. حوالي 44.5% من العينة لا يقرأون النشرة الدوائية و 3.8% لا يجدون أو لا يعرفون عن النشرة الدوائية. هذه الدراسة تبين أهمية تجديد القوانين الخاصة بنشرات الأدوية المرفقة للمريض مع الدواء من حيث التصميم أو اللغة وتبين هذه الدراسة أيضاً أهمية استحداث النشرات الإلكترونية التي يمكن أن تلائم وضع المريض بصفه خاصة أكثر من النشرات الدوائية العامة. وأخيراً فان الدراسة تبين أهمية أن يقوم الصيدلي والطبيب بالتنقيف الدوائي للمريض.

Abstract: The primary aims of this study were to investigate the attitude of the Palestinian public to patient package insert (PPI) and to evaluate the practical and legal issues of PPI in Palestine. Three hundred and seventy one (371) patients were verbally interviewed using a yes or no questionnaire that examine their attitude toward the information presented in (PPI). More than half of the patients (51.7%) said that they read the (PPI), but either find it vague or raise their fears and concerns. A second group of patients (44.5%) said that they do not read the (PPI). A third group (3.8%) said that they do not find or do not know about the PPI. This study emphasizes the need for a pharmacy legislation regarding PPI design and language, introduction of electronic pharmacy labeling and finally better patient-pharmacist communication to educate patients about over-the-counter (OTC) and prescription only medications (POM).

Key Words: Drug information, PPI, Electronic labeling, Patient education.

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Introduction and Aims

In recent years the general public has become increasingly aware of health matters, and many people wish to know more about the medicines they receive from doctors or buy from community pharmacies. The physicians must be the primary source of information for the patient regarding his disease and prescribed medications. The patient package insert (PPI) is intended to give secondary additional information about the product, the disease and the correct use or application of the drug ^(1,2). For self-prescribed over-the-counter (OTC) medications, both the pharmacist and the PPI become an important source of information for the patient. The PPI has been shown to influence the rate of compliance in some types of patients. The patients who read the PPI were found to be more likely compliant if the information in the leaflet were supportive to the physician's / pharmacist's explanations about the disease and the drug ⁽³⁾. Another detailed study conducted by Professor C. F. George's team in Southampton ⁽⁴⁾ showed that the detailed patient's leaflets resulted in some increase in patient's knowledge and satisfaction, but no effect on medication compliance in chronic therapy.

In USA, the late 1960s witnessed the emergence of the patient package insert (PPI) to be associated with prescription drugs ⁽⁵⁾. The Palestinian Pharmacy Practice law requires that all medicines should be supplied with a patient information leaflet (package insert) to be written in Arabic as well as another language ⁽⁶⁾. The medications in community pharmacies in Palestine are almost exclusively available by branded unit-of-use, with a product insert inside every package. This informative insert is directed toward the users and must give full and comprehensible information about the drug. However, the Palestinian law does not give advice about the type of information, design and the wording about the drug to be presented to the patient. In other countries, the pharmacy law, for example, suggests that PPI should include symbols and special features for drugs intended to be used by pediatric or pregnant patients ⁽⁷⁾. In Palestine, the bulk of pharmaceutical sale in community pharmacies is dependent on the local five pharmaceutical companies. This study explores the attitude of the Palestinian public toward patient package insert. This study also identifies the positive and negative aspects of patient's drug information leaflet from a legal and practical point of view.

Method and Design

Personal verbal interviews were carried out on three hundred seventy one (371) randomly selected patients attending a community pharmacy center in West-Bank / Palestine. Every third patient entering the pharmacy center was verbally asked to participate in the study by answering questions regarding his attitude toward PPI. Out of approximately three hundred and ninety customers who were asked to participate in the study, three hundred seventy one (371) agreed to participate indicating a responding rate of more than 95%. The interviews were made over a period of three months. Two hundred and sixty two (262/371; 70.6%) patients of the sample were taking prescription (non-OTC) medications while one hundred and nine (109/371; 29.4%) patients were purchasing over-the-counter medications (OTC) like analgesics, flu or cough products from the community pharmacy center which participated in the study. The POM were dispensed based on new prescriptions that were issued by physicians in private or governmental clinics. The selection of patients rather than prescription was made. The selection of patients was made on the basis of every third patient entering the pharmacy regardless of the nature of the prescription. The criterion for distinction of POM and OTC medications was based on the drug list of OTC medications found in the “Textbook of Non-Prescription Medications”.

Results

Three hundred and seventy one patients were verbally interviewed. The age distribution of the patients is seen in Table 1. Eighty two patients (22%) were above 60 years, one hundred and ninety one (51.4%) patients belong to the age category (40 – 60 years) and the rest of the patients (26.6%) were below 40 years of age.

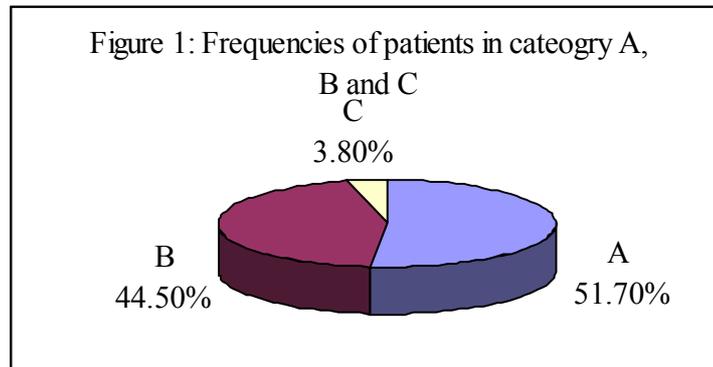
Table 1: Age distribution of patients that participated in the study.

Age Category (years)	Percentage
> 60	22%
40 – 60	51.4%
< 40	26.6%

Analysis of the data regarding patient’s attitude toward the information presented in the patient package insert (PPI) is shown in figures 1-4. The data is presented as category (A) and category (B), where category (A) represents

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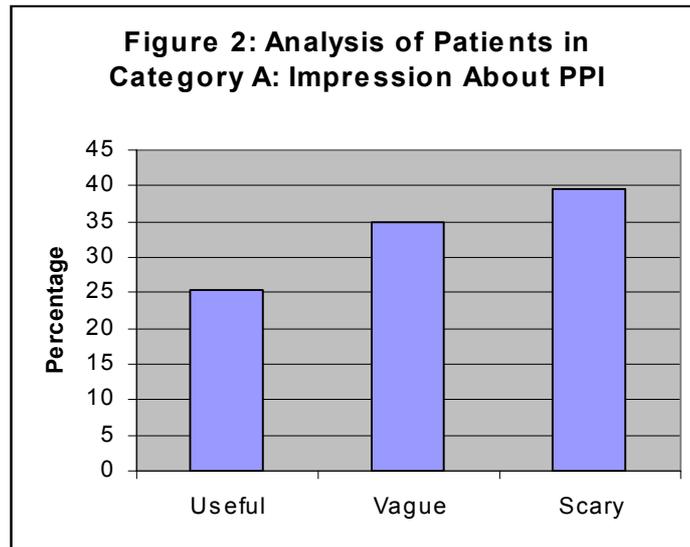
patients who read the PPI while category B represents patients who do not read the PPI. The percentage of patients in category (A) was 51.7% and those in category (B) was 44.5%. A third category (C) with a percentage of 3.8% who claims that they either do not find a PPI in the product or they do not know about such a leaflet. The frequencies of patients in category A, B and C are seen in Figure 1.



Category A: read PPI; Category B: don't read PPI; Category C: don't find PPI.

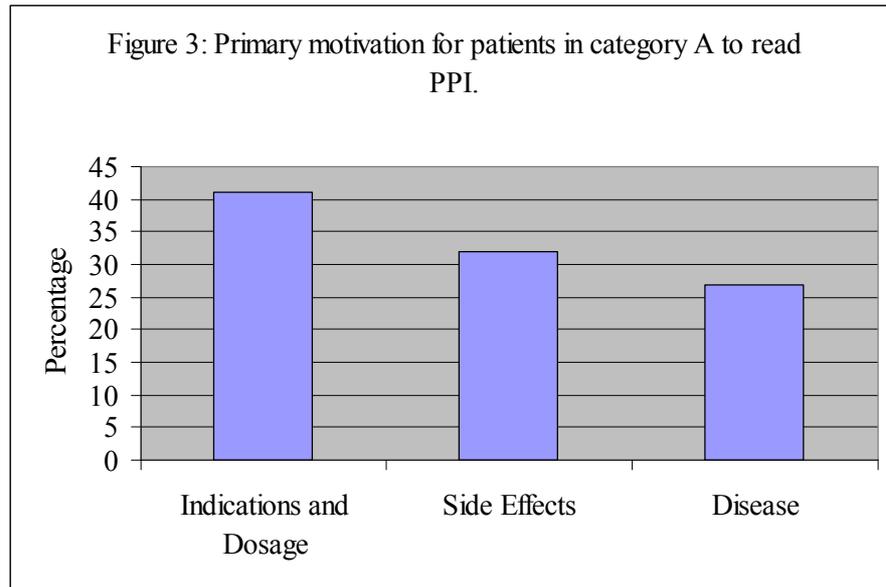
Category A: Those who read the PPI

- 1) Among those patients who read the PPI, forty nine patients (25.5%) said that they found the PPI useful or very useful and provided them with new information while, sixty seven (35%) patients found the PPI to be vague, un-useful and that they could not find the needed information readily. A third group, seventy six (39.5%) patients said that the PPI was scary and raised their concerns and they had to talk to their pharmacists or doctors about the information found in the PPI. The attitudes of the patients in category "A" toward the information presented in PPI is shown in Figure2.



- 2) When asked about their primary reason and motivation to read the PPI, seventy nine patients (41.1%) of patients in category A said that they do so to learn more about the indications and dosage of their medications, sixty one (31.8%) patients do so to learn more about possible side effects, adverse reactions and possible special warnings, and fifty two (27.1%) patients do so to learn more about their disease.

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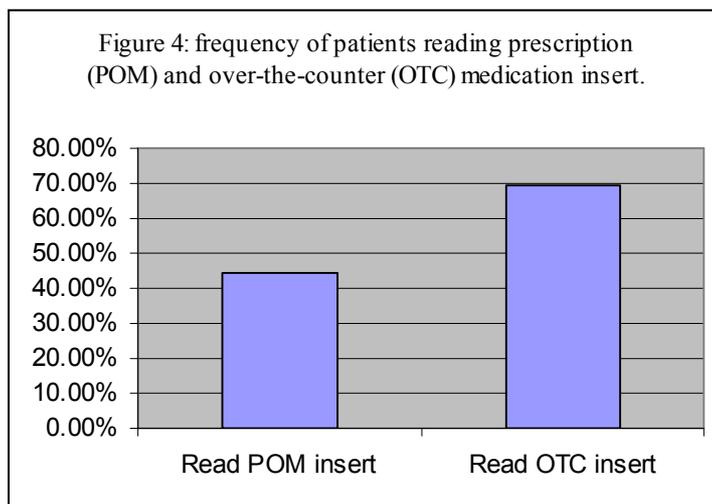


Category B: Those who do not read the PPI

1) Among those who do not read the PPI in category B (44.5%); eighty nine patients (54%) patients said that they would read the PPI if they were advised to do so by their doctor or pharmacist.

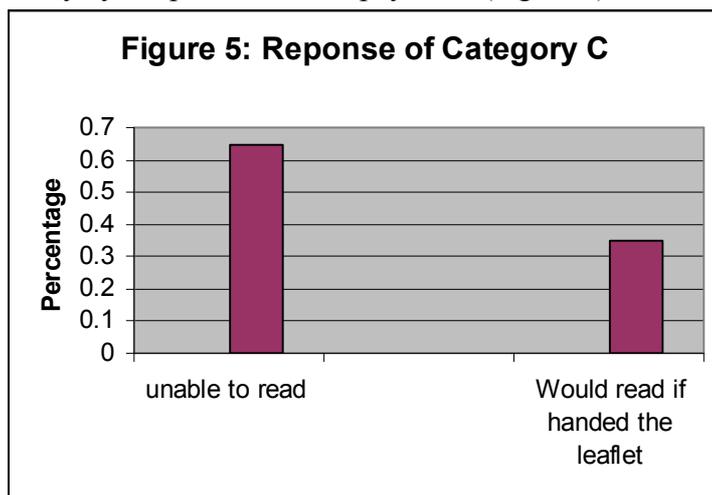
Prescription only medications (POM) versus the (OTC) medications

1) Among those patients who take prescription medications, one hundred and sixteen patients (44.3%) said that they read the package leaflet while seventy six patients (69.7%) of those who were purchasing over-the-counter medications read the PPI as seen in Figure 4.



Category C: Those who don't know or don't find the PPI

Of the whole sample studied, fourteen patients (3.8%) claims that they do not know about such leaflet or they usually don't find it in the box. When asked if they would read the leaflet if given to them directly, most of them (64.7%) said that they do not have basic education and wouldn't read the leaflet. The rest of the patients (35.3%) said they would try to read the leaflet if handed to them directly by the pharmacists or physician (Figure 5).



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Discussion and Conclusions

More than half (52%) of the patients in the Palestinian community usually read the PPI. The primary motivation for most of those patients to read the package leaflet was to know more about indications, adverse effects, dosage and dosing guidelines, contraindications and medication shelf-life. Unfortunately, one third of those patients who read the leaflet neither understand the leaflet easily nor find the needed information readily. For example, most patients indicate that the term “ To be taken as directed” is found in most PPI even those for OTC medications. Another 40% of those patients who read the PPI were afraid to use the medication because of the technical language of the leaflet especially in the warning section. For example, some inserts for drugs that are prescribed during pregnancy include the term “Consult your physician if you are pregnant”. Another example is that some PPI might have detailed effects of the drug on pregnancy while the drug is intended for male patients. Nevertheless, the PPI was still considered to be a good tool for education and drug information in 25% of the patients who read the PPI.

This study is the first of its type in Palestine, however, a small Norwegian study based on telephone interview, found that 48 per cent of patients had not found or could not remember having seen a leaflet in the package. The level of awareness was higher among patients on short course therapy than those on long term treatment ⁽⁸⁾. A series of American studies from the 1970s found that 50 to 72 per cent of patients read the package inserts ⁽⁹⁾.

The need for an improved PPI in Palestine is necessary because of the large sale of OTC medications. The data shows that for the self-prescribing OTC medications, the community pharmacist must verbally educate the patients regarding the drug and its correct use since the results show that 69.7% of those type of patients do not read the leaflet. Various types of brochures, leaflets and supplemental materials ought to be available in community pharmacies for patients. A study has suggested that more patients will read leaflets if they are handed to them personally, as patients will perceive the leaflet as having more personal relevance ⁽¹⁰⁾. In the US and Australia, computer-generated labels are the chosen method of leaflet delivery ⁽¹¹⁾. In contrast to package inserts, these computer-generated leaflets can be personalized and thus irrelevant information can be omitted and only age-

specific dose and precautions information are included leading to a shorter and relevant leaflet. Another major advantage of electronically generated leaflets is that they can be instantly updated regarding dosing or precautions⁽¹²⁾. This computerized system of labeling and delivery can replace the PPI in Palestine but it needs the introduction of automation and internet service to community pharmacies.

Although the PPI is mandatory by the Palestinian pharmacy practice law, but still there are some few drugs especially ophthalmic and nasal drops that do not have a package leaflet as a PPI. The Palestinian pharmacy practice legislation ought be modified to include detailed information regarding the product. For example, colors, pictures, symbols, and/or diagrams must be recommended. Many studies have shown that symbols and pictograms in the patient package insert helps the patient understand and use the drug correctly⁽¹³⁾. Also, there is a need to review and re-write the language of most PPI in the Palestinian market to make them easily readable and not to contain unnecessary or over-estimated language especially in the side effect section.

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