ATTITUDES OF SUDANESE PATIENTS AND THEIR PERCEPTION ON THE IMPORTANCE, UTILITY, READABILITY AND UNDERSTANDABILITY OF PACKAGE INSERTS

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ABSTRACT

Package inserts (PIs) provide additional written information about medications to patients, physicians and pharmacists. The aims of this study were to assess the acknowledgment of the importance and attitudes of patients towards PIs, to define whether the PI represents a reliable, useful and satisfactory source of information for patients and to assess the degree of accessibility of the PIs by patients. One thousand patients both Khartoum and Wad Medani cities were surveyed by means of a standardized pretested questionnaire. Approximately, 74% of patients claimed that they read medicines’ PIs. Almost 94% of patients who read PIs reported that they found them useful for better use of medications. Almost 70% and 65% of patients respectively believed doses and adverse effects as the most important information they required from PIs. Only 10.2% of patients reported that physicians and/or pharmacists advised them to read the PIs of drugs before using them. The decision of the patients whether to read the PIs seemed to be affected by both age and educational level. More than half of the sample (50.4%) reported that they faced some difficulties in understanding information included in PIs. Most patients claim to make use of information provided in PIs. However, half of them cannot understand much of this information and are not satisfied with them.
current state of the PIs’ use urges modifications of the language used and the information included in PIs. Also spreading awareness to rationalize the use of PIs is equally important.

**KEYWORDS:** Package inserts, Sudanese patients, Readability, Understandability, Attitudes.

**INTRODUCTION**

Patient package inserts, one of the potential sources of written information, is a document approved by the Food and Drug Administration (FDA) that contains scientific information about pharmacokinetics, pharmacodynamics, molecular structure, indications, risks, and benefits of the specific drug.\(^1\)\(^,\)\(^2\) Many patients wish to be informed in detail about their treatment by the healthcare providers.\(^3\) In most cases, the physicians do not give the information the patient needs.\(^4\) Many healthcare providers rely on a verbal explanation, but this has been shown to be ineffective.\(^5\),\(^6\) The need for more information, failure to provide information, lack of information and forgetting or misunderstanding of the verbal information, all are reasons for providing information about medicines in a written form.\(^2\)

Providing written information to patients has proved to increase their knowledge of how to use the medications and their effect.\(^4\),\(^7\) Therefore, provision of appropriate information in a suitable form is crucially important.

In the 1980s, the FDA acknowledged that the information included in the package insert had become so lengthy, detailed, and complex that it was difficult for health practitioners to find specific information and to distinguish critical information from less important ones. As a result, the FDA developed a new package insert format.\(^1\)

Many factors are believed to influence the patients’ attitude towards package inserts, including health literacy, educational level and age of the patient. In the United States, a study showed that elderly patients have particular difficulty reading and understanding drug labeling. In a survey of older hospitalized patients prior to discharge, only forty (40%) reported no problems in reading their drug labels, and even fewer reported that they had a clear understanding of the instructions.\(^2\)

Improving patients’ ability to understand and make appropriate decisions depended on both improving their literacy and improving the quality of information they are given.\(^8\)

Studies by Guinn\(^9\) had asserted that increased knowledge does not necessarily lead to behavioral change e.g. adherence. However, many researchers could point to possibly
increased compliance following the provision of written information.\cite{5,10} On the other hand, it was thought that written information may have negative consequences on the receiving patient. However, many studies have proved otherwise.\cite{5,7,11,12}

The Sudanese patient population faces difficulties in the readability and comprehensibility of the written information included in the PIs. This might be due to the fact that most PIs are written in English or in pure scientific language. Several observations have pointed that prescribers and pharmacists do not usually advise patients to refer to PIs for any information about drugs. Also there is general consensus among doctors and pharmacists that PIs contain information that might not be suitable for patients.

**METHODS**

A cross-sectional questionnaire based survey was conducted during the period of 1\textsuperscript{st} May 2010 - 2\textsuperscript{nd} July 2010. All adult patients who were in the randomly visited public areas and wishing to participate in the study were included. All patients who had intellectual disabilities were excluded. The questionnaire was piloted on 100 patients (10\% of the sample) to assure its validity. Some modifications were made and the piloted questionnaires were not included in the study sample. The pretested standardized questionnaire addressed one thousand (1000) members of the general public who were randomly distributed in both Khartoum (75\%) and Wad Medani cities (25\%).

Questionnaires contained nineteen (19) questions. Four (4) questions addressed the demographic characteristics of the studied group. Twelve (12) questions were closed ended and meant to disclose whether patients knew that each drug contained a PI, whether patients read the PIs, understood the information provided in PIs, found this information useful, whether they received adequate information about drugs from both physicians and/or pharmacists and if they have been advised to read PIs. Also patients were asked whether verbal information provided was forgettable, whether they changed doses or stopped taking drugs depending on their understanding of information provided in PIs, or whether they recommended a drug for another patient depending on information they obtained from PIs. Three (3) open-ended multiple choice questions were designed to address the reasons behind difficult understanding of information provided in PIs, type of information about drugs they considered most important and whether they preferred to receive this information verbally or in writing.
The collected data was tabulated and designed in such a way to be processed and analyzed using Statistical Package for Social Sciences (SPSS 14). Correlations were emphasized using the Chi-square test and p values < 0.05 were considered significant.

**RESULTS**

**Sample characteristics**

Demographic characteristics of the respondents in the study sample (age, gender, residence and educational level) are shown in the (table 1). The percentage of the male respondents was 63.4% and 36.6 % were females.

The first question was about the awareness of patients about the existence of a PI in every drug pack; 94.7 % said that they knew that and 5.3 % said they did not aware. This awareness is found to be highly affected by the educational level of the respondents but not their ages.

In order to check the favorable way for the patients to receive the information about medication, 18.4 % preferred to have it verbally, 29 % preferred it written and 60.1 % preferred the both ways.

**Attitude of patients towards PIs**

About 74.4 % of respondents claimed that they read the PIs of drugs, while 25.6% ignored them. In addition, the participants said only 10.2% of physicians and/or pharmacists advised them to read the PIs of drugs before using them.

This study showed that the decision of the patients to read the PIs was affected by both age and educational level Since P_ value is less than 0.05 in cross tabulation.

**Utility of the PIs to the patients**

About 93.6% of patients who read the PIs found that information provided were useful to them for better use of medications.

**Understandability**

About half the respondents (50.4%) who claimed reading PIs agreed they faced difficulties in understanding the information provided; according to the following reasons: the language used (51.9%), technical terms contained (58.3 %), font size (29.7%), too much content (33.1%), and other reasons (16.3%).
Drawbacks

The patients were asked two questions to assess whether their attitude after reading PIs was associated with drawbacks. About (42%) of patients said that; depending on the written information they found in PIs they sometimes advise others to use the drug they read its PI. When they asked if they had ever reduced the dose or stop the medication after reading the PIs, 39.8% of patients answered positively.

There was a high significant relation between the educational level of the patients and the ability to understand the written information provided in the PIs since P-value is less than 0.05.

The study also showed that there was no significant relation between the educational level and the decision of the patient to either stop the medication or cross-prescribe it to another patient.

Types of information most important to patient

Patients were asked about which type of information considered most important to them and the percentages were as follows: indications (56.4%), dose (70%), adverse effects (64.6%), contraindications (52.9 %), precautions (38%), drug interactions (41.4%) and warnings (47.1%).

Alternative sources of information

When patients were asked whether they found enough information about drugs from health care providers who prescribe or dispense their medications, almost 41% of the respondents said that the physicians provide them enough information while about 58.6% of the respondents reported that they found enough information from the pharmacist.

Table (1): Demographic characteristics of study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Categories</th>
<th>Number (N)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>628</td>
<td>63.4 %</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>362</td>
<td>36.6 %</td>
</tr>
<tr>
<td>Age (years)</td>
<td>14-29</td>
<td>687</td>
<td>69.2 %</td>
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<tr>
<td></td>
<td>30-44</td>
<td>197</td>
<td>19.8 %</td>
</tr>
<tr>
<td></td>
<td>45-60</td>
<td>95</td>
<td>9.6</td>
</tr>
<tr>
<td></td>
<td>&gt; 60</td>
<td>14</td>
<td>1.4 %</td>
</tr>
<tr>
<td>Residence</td>
<td>Khartoum</td>
<td>680</td>
<td>68.1 %</td>
</tr>
<tr>
<td></td>
<td>Wad Medani</td>
<td>318</td>
<td>31.9 %</td>
</tr>
<tr>
<td></td>
<td>Illiterate</td>
<td>18</td>
<td>1.8 %</td>
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</table>
DISCUSSION
A small proportion of the study group (5.3%) was found to be unaware of the existence of PIs within every drug package. This emphasizes the role of physicians and pharmacists to encourage the patients to read PIs. However, only 10.2% of the participants reported that physicians and/or pharmacists advised them to read PIs. This low number of the healthcare providers who advise their patients may be due to the lack of trust in these PIs as reliable sources of information. Some doctors and pharmacists may believe that it is difficult for the patients to understand the information included. There is also a fear from some drawbacks that may rise from the use of medications after reading the PIs. In a fairly old study, Ascione and Raven \[12\] found that 75% of doctors did not want patients to be told about the potential side effects of their medication, feeling that it may be harmful to do so. The data from studies of written information strongly contradicts this since a review by Morris \[13\] showed that only one out of eight studies produced evidence of increased side-effects. Also many studies have shown that forewarning patients about side-effects does not result in fewer adherences and in some cases can actually enhance adherence. \[14\]

Our findings about patients reading PIs (74.4 %) which is significantly related to both age and educational levels of respondents are consistent with findings in other studies in Saudi Arabia and Israel. \[15, 16\] However, such high levels of PIs readership don't necessarily reflect that all who read PIs get the lasting benefits. About 60% of patients prefer both ways, verbal and written, to be informed about their medications. This is consistent with other researches which proved so and recommended providing patients with written information besides the verbal counseling given by healthcare providers. Also it is well known that patients forget or misunderstand most the verbal information that discussed during consultation. \[6\] One study showed that, to some extent, patients had forgotten half of what the physician had told them within 5 minutes of leaving the consultation room. \[4\] Also people may only retain about 20% of what they hear, but this may increase to 50% if there is written input. \[18\]

Almost, 50% of sample who read PIs faced some difficulties to understand the information. Illiteracy which is high in Sudan might greatly affect the understandability of patients alongside with health knowledge and motives that drive patients to read PIs. There is a high

<table>
<thead>
<tr>
<th>Education</th>
<th>Basic</th>
<th>80</th>
<th>8.0 %</th>
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</thead>
<tbody>
<tr>
<td>Secondary</td>
<td>387</td>
<td></td>
<td>39.0 %</td>
</tr>
<tr>
<td>University</td>
<td>460</td>
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<td>46.3 %</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>49</td>
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<td>4.9 %</td>
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illiteracy rate in Sudan which is according to (Council of Minister, CBS 2004) to be more than 50%.\textsuperscript{17} The educational level of the population is significantly related to understandability as proved in many studies.\textsuperscript{15, 16} Other factors which affect patients’ understandability related to PIs include the language used in PIs, the presence of high technical terms not understood by patients and other factors related to typing format and font size. Concerning the language, it is observed, in Sudan, that it is a main obstacle in understandability of patients to information. The act or law of medicines and poisons in Sudan requires that the drug is supplied with PIs that are written in Arabic and/or English language. This in turn leads to marketing of drugs with PIs that are written in English only, bearing in mind that the spread of English language in the Sudanese population is not wide. Also, Arabic in which some of the PIs are written is classical Arabic or what is known as Modern Standard Arabic which is also not well understood, as spoken native Sudanese Arabic is different. The Arabic medical terminology used in written text is different even among different Arab countries. Moreover, the scientific terminology in which the PIs are written is difficult to understand. It may be more easily fitting for physicians and pharmacists.

Understandability of the written text of the PIs is also highly dependent on its readability. Readability and legibility of written material for public audience should be prime concerns for the writer. Patients may be ashamed of their inadequate literacy level or skills and may never tell anyone that they cannot read or understand medication information.\textsuperscript{19}

Transfer of the prescription to other patients and ceasing the use of a medication are some of the drawbacks that may appear when patients use PIs. A high percent (42%) were found liable to advise others to use a drug after reading its PI. Also it is found that 39.2% would stop their medicines due to information in PIs. This is much higher than in Saudi studies (6.1%) and the situation requires careful attention.\textsuperscript{16} A Belgian study proved that PI does not overrule the physician, in cases of contradiction between the physicians advises and information in PIs.\textsuperscript{16, 20}

CONCLUSION
PIs represent a reliable and satisfactory source of information about medications for most patients. Most of patient report that they make use of the information provided in the PIs, but nearly half of them cannot understand much of this information. This appears to be the main reason why patients are not satisfied with current PIs. The current state of the PIs use urges
modifications of the laws regarding the language used and the information included as well as spreading the awareness to rationalize the use of PIs.

REFERENCES
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