

Medication package inserts' usefulness for Sudanese pharmacists and patients: pharmacists' perspective

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ABSTRACT

Background: Written medication information is important to health care professionals and patients, alike. Medication package inserts (PI) can prove useful sources for written medication information for pharmacist and patients. The main objective of this study was to evaluate the knowledge, attitude, and practice of the Sudanese pharmacists toward PIs.

Methods: A total of 120 randomly selected Sudanese community and hospital pharmacists, were addressed with a questionnaire of 14 free to answer closed-ended questions.

Results: Results showed clear dominance of the young (96.5%), females (63.3%) pharmacists population, whose majority (90.8%) had their undergraduates studies in Sudan. Majority (79.2%) of respondents was keen to read the PIs, and (75.8%) considered them as reliable written medication information sources and references. Correlation between respondents' reliability and reading of PIs was significant (**p=0.038). How to use medications (95%) their dose (92.5%), and compliance (67.5%), topped the medication information particulars provided by respondents to patients. Drug-interactions and side-effects (36.7%) were downplayed by the respondents. Only a small minority (21.7%) of respondents used to advise patients to read PIs. Majority (85%) of respondents believed that PIs were difficult for patients to understand. Their texts' language (68.2%), technical terminology (75%) and font size (10%) were cited as main barriers to understandability.

Conclusions: To secure usefulness of PIs, they shall be written in lay terminology of patients' native language. Pharmacists shall seek independent sources of medication information, advice and motivate patients to read PIs and keep them for ongoing reference.

Keywords: Information, Package inserts medication, Patients, Pharmacists usefulness

INTRODUCTION

The success of any treatment where pharmaceutical intervention is recommended largely depends on patients' adherence to the prescribed regimen. As prerequisites for an informed free consent (concordance), patients have to be involved in their treatment plans, as the patient is an important member of the health care team.¹ This necessitates the provision of an easily accessible, up-to-date, clear, understandable, balanced, comprehensible and useful

medication information that fits individual patients' needs.² This needed medications information, is usually available to patients in verbal, written and/or visual forms. The verbal form that is provided to patients by their health care providers is usually deficient, not comprehensive and can easily be forgotten.³

The medication package insert (PI), as a form of written medication information, is probably the most easily available, accessible and important to patients. Written

medication information is important to patients as it supports, complements and reinforces the verbal one, and can be kept for ongoing reference.⁴ Patients, themselves, prefer a combination of both verbal and written medication information.⁵ The PI, however, received a lot of criticism to its medication informational contents deficiencies, non-conformity, poor design, overall layout, legibility, readability, complexity, difficult technical terms, and the language, which ultimately make its readability, understandability, comprehensibility, satisfaction and usefulness, to the targeted audience, not convincingly serving the purpose. These PI discrepancies may lead to poor patients' adherence rates, medication errors and ultimately poor health outcomes, which are known to be quite costly to both the individual patients and their communities. Moreover, PIs provided by different manufacturers for the same generic name products many show disparities in their informational contents, as regulators do not strictly define and mandate those contents, but leave that to manufacturers and their commercial interests.⁶

Based on the above it was, accordingly, decided to conduct this study to evaluate and define, the knowledge, attitude and perception of the Sudanese pharmacists toward the usefulness of PI as a form of written medication information, to both the pharmacists and patients.

METHODS

A total of 120 Sudanese pharmacists (n=120), from both the private and public hospital and community pharmacies, from different pharmaceutical facilities in Khartoum and Gezira states, Sudan, were randomly selected. They were informed of the purpose of the study and requested to cooperate. Their verbal acceptance and practical participation by filling and returning the questionnaire was considered a free, informed consent.

A questionnaire consisting of 14 questions was developed and then piloted on (n=12) subjects for validation. The piloting helped making minor changes on the drafted questionnaire. The subjects of the piloting were not included in the study population. The first four questions of the final questionnaire were about the demographic characteristics of the studied pharmacists' group. The other ten questions were closed-ended questions meant to assess the knowledge, attitude and practice of the studied pharmacists about the various determinants of a useful medications' PIs for both the patients and pharmacists. Three pharmacy students from the faculty of pharmacy, University of Gezira, Wad Medani, Sudan; served as the interviewers after being well-oriented to the task. They successfully reached the selected potential participants, secured their verbal and practical agreement to participate, distributed and collected back the filled questionnaires. Moreover, 404 PIs for an equal number of different registered pharmaceutical products were randomly selected and screened

for the sole purpose of identifying the language(s) in which they were written.

RESULTS

Results showed that the overall average response rate percentage for all the 14 questions was 117 (97.5%). Demographic characteristics of the respondent's pharmacists showed a clear dominance of young (91.7%) respondents, whose majority were females (63.3%), majority (90%) and had their undergraduate courses in Sudan. 95 (79.2 %) of the respondent pharmacists were keen to read the PIs. A total of 91 (75.8%) of the respondents considered the PI as a reliable source of medications information. The bi-variant analysis using the Chi-square test revealed that the correlation of respondent pharmacist reading of PIs by their reliability on the PIs as references for medication information, was significant (**p=0.038), (Table 1).

Only a minority 26 (21.7%) of the respondents confirmed that they routinely advise patients to read the PIs. Out of the 120 respondent pharmacists 87 (72.5%) believed that patients have got the right to be fully informed of their medications. To

Table 1: Respondent pharmacists' reliability on package inserts as medication information reference by their act of reading them.

Rely on PI as a reference	Reading PI		Total
	Yes	No	
Yes	76	15	91
No	19	10	29
Total	95	25	120

PI: Package insert

	Value	df	p value
Pearson Chi-Square	4.30	1	0.038 S
N of valid cases	120		

S: Significant

Table 2: Reasons cited by the respondent pharmacists for poor patients' understandability of medication information in the PI.

	Frequency	Valid percent
The terms		
Yes	78	65
No	26	21.66
Missing	16	13.34
The language		
Yes	72	60
No	32	26.7
Missing	16	13.3
Total	240	100.0

PI: Package insert

understand medication information in the PIs, patients have to be familiar with the terms, language used and the text should be in a readable font size. Only 18 (15%) of the respondents agreed that patients can understand the medications' information in the PI text, whereas the majority 102 (85%) did not. The respondent pharmacists cited PIs texts' language, technical terminology and font size as main barriers to patients' understandability of medication information displayed in PIs Table 2.

The respondent pharmacists cited PIs' texts language and technical terminology as main barriers for its easy understandability by patients.

Many of the patients comeback to their pharmacists, after reading the PIs of their medications, to report about that they experienced side-effects and/or the effectiveness of their medicines. 64 (53.3 %) of the 118 respondent pharmacists confirmed that act. 54 (45%) did not confirm it. Pharmacists are supposed and are expected to provide patients with full and balanced medication information. A majority of respondent pharmacists 114 (95%) confirmed that, whereas a small minority of 6 (5%) did not.

Medication's use and dose topped the medication particulars provided by pharmacists to patients.

The big majority of the respondent pharmacists (91.7%) confirmed their belief in providing patients with adequate medication information.

Figure 1 shows the results of the screening of the randomly selected n=404 PIs, for registered pharmaceutical products, to identify the language(s) in which they were written.

The majority (60.39%) of the screened PIs were written in English, only. None were written in Arabic only (the native language). The balance of PIs, (39.61%) was written in both Arabic and English.

DISCUSSION

The result of the demographic characteristics of the respondent pharmacists showed an overall young population of respondents, whose majority had their undergraduate studies in Sudan. This could easily be explained by the fact that the period after the year 1995, had witnessed a big increase in the number of new schools of pharmacy in Sudan,⁷ and their admissions rates were multiples of the intake of the old faculties of pharmacy. When asked whether they read the PIs, the majority of respondents (79.2%) confirmed that they do. This might point to the availability and easy accessibility of PIs to pharmacists, doctors and patients. The majority (75.8%) of the respondent pharmacists, considered the PI as a reliable sources of medication information. The scarcity or even the downright lack of other independent sources of medication information especially in developing countries might explain this act. The respondent pharmacists' act of reading the PI was significantly correlated to their reliability

on PIs, as a reference for medication information (Table 1). This result matched the finding of other researchers from Palestine, Kuwait, and Nigeria.⁸⁻¹⁰ Though recommended by other researchers,¹¹ only a small minority (21.7%), of the respondent's pharmacists asserted that they advise their patients to read the PIs, before using their dispensed medications. The majority of the respondent pharmacists who do not usually advise patients to read the PIs, might be under the apprehension that, patients do not understand the medication PIs, and when they read them, they get intimidated by and apprehensive of the detailed descriptively reported side-effects,¹² which they usually overestimate.¹³ They might, as well, question the effectiveness of those medications which have much reported side effects.¹⁴ Add to that, they might out of intimidation, reduce the dose, stop the use of the medication, altogether based on indications displayed, and practice cross-treatment.^{15,16} Moreover, when the prescriber, sometimes, recommends the medication for an off-label indication, which usually is not included in the PI, the patient might think it is the wrong prescription and refuse to take it.

The patients' rights to be adequately and fully informed about their medications was endorsed by (72.5%) of the respondent pharmacists. Many international pharmaceutical organizations and authors called for that provision of clear, simple, balanced and understandable medication information to patients and considered it a professional responsibility of pharmacists as medication information should be valued same as the active ingredients of the medications.¹⁷

Barriers to understandability of medication information displayed in the PIs texts include the use of non-native language, medical, legal, and other professional jargons.^{18,19} As the majority of PIs for the registered pharmaceutical products in Sudan, were found to be written in English only, Figure 1 that might explain why the majority (85%) of the respondent pharmacists agreed that patients could find difficulty in understanding the written information in the PIs. The reasons cited and the rates reported by the respondent pharmacists, for the difficulty in understanding the medication information in PIs, were matching to the

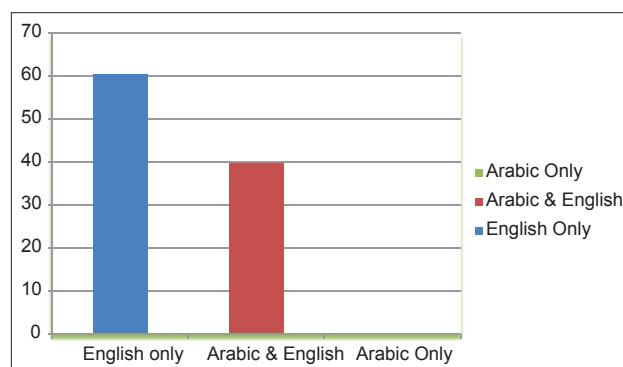


Figure 1: The language(s) in which the 404 screened package inserts were written.

findings and opinions of other authors.^{20,21} Though not up to the needed standards, the majority (70%) of the respondent pharmacists confirmed that they usually discuss medications benefits and risk with patients. This could be reflective of the needed professional responsibility trend. However, the trend of the respondent pharmacists (30%), who were not counseling their patients, though frankly against their basic professional responsibilities, was matching to the findings of other researcher.²² In our opinion that could be referred to the poor pharmacists' patient care training during undergraduate courses, poor communication skills, poor academic fitness, inadequate continuous professionals development, and lack of direct pharmacists' economical advantage (no counseling fees). Moreover, the assumption that the prescribers must have done the patient counseling, patients (passiveness) toward counseling, pharmacists lack of confidence, time constraints due in part to inadequate pharmacy staff, and lack of patients medical history records, might explain over and above, stand as additional reasons for the behavior of those (30%) of the respondents pharmacists who were not used to counseling their patients. According to this study results, the respondent pharmacists provided medication information to patients, [Figure 2], in the following ranking of importance pattern: How to use the drug (95%), dose instructions (92.5%), and compliance 81 (67.5%), food-drug interactions (64.2%), indications (52.5%), side effects (38.3%), and drug-drug interactions (36.7%). The provision, by the respondent pharmacists, of information to patients about medications' side-effects and drug-drug interactions gained the lowest percentages (38.3%) and (36.7%) respectively. Both may lead serious medication errors, potential hospitalization and may compromise the targeted patients' health outcomes.²³ Contrary to the findings of other researchers,²⁴ the respondent pharmacists may have thought that their discussion of medications' side-effects with patients might trigger patients' fears and/or anxiety, leading to decreased adherence of patients to their prescribed regimens. Patients always demanded thorough information about their medications side-effects and drug-interactions.²⁴

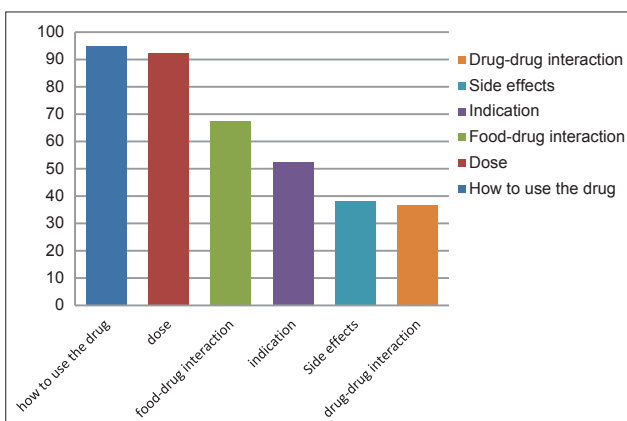


Figure 2: Medication information particulars (attributes) provided by the respondent pharmacists to patients.

As for drug-drug interactions, patients always showed interests in receiving information about them from the dispensing pharmacist.²⁵

CONCLUSIONS

Patients should be well informed about their medications as that are a basic human right. Slightly less than one-third (30%) of the respondent community pharmacists refrained from any degree of verbal counseling for patients about their medications thus shedding down their professional responsibilities. Most of the respondent Sudanese pharmacists were not inclined to counseling patients about the adverse effect of their medications (78.2%), possibly for fear of worrying or intimidating patients and consequently causing a decline in their adherence to prescribed medications. The written medications information in the PIs represented reliable reference of information about medications for (75.8%) of the respondent pharmacist. Respondent pharmacist shall advise their patients to read the PIs before starting use of their dispensed medications. Developer of medication PIs shall observe that they shall be written in patients' native language, with minimal technical terms and an appropriate font size of text (10-12 points). Patients' counseling by pharmacists may prove conducive to better adherence.

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