

Medications package inserts' usefulness to doctors and patients: Sudanese doctors perspective

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ABSTRACT

Background: Written medication information is important for both doctors and patients. In the developing countries, the medication package inserts (PIs) represent the most available and easily accessible source of written medication information. The main objective of the present study was to assess the knowledge, attitude, and practice of Sudanese doctors toward written medication information in the PIs, and its usefulness for both doctors and patients.

Methods: Four hundred (n=400) doctors were randomly selected and addressed with an open to answer the questionnaire composed of fifteen questions (n=15).

Results: A big majority (95.7%) of the respondents considered the medications' PIs, which they regularly read (93.2%), as a reliable and useful source of medication information in their prescribing. Only a minority of the respondent doctors (43.6%) used to advise their patients to read the PIs, whereas a majority (62.4%) of respondents believed that patients might find difficulty in understanding written medication information in the PI. The majority (61.3%) of respondent used to rely on pharmacists to provide patients with the needed medication information. The majority of the respondents (82.2%) used to inform their patients about the possible medication side effects. Respondents ranked medications' dose (79.5%), how to use it (77.3%) and information about side effects (73%) on top of patients' medication information most needed particulars.

Conclusion: Doctors should give more attention to their patients' medication information specific needs, advice and motivate them to read the PIs before using their medications.

Keywords: Sudanese, Doctors, Medication, Information, Package, Inserts

INTRODUCTION

Doctors in developing countries lack easy access to independent medication information.¹ The pharmaceutical industry, through its various promotional activities, represents their main source of medication information.² The medication package insert (PI) and the medical representatives represent an easily accessible and useful source of medication information for both patients and doctors.³ The Sudanese regulatory authorities themselves stipulated that the PIs be written for the prescriber and patient, thus primarily targeting doctors with PIs.⁴

Patients receive information about their medications, both prescription and over – the – counter, from their health care

providers, in verbal form and from the PIs as a written form. The verbal medication information that patients receive from their health care providers, is incomprehensive, deficient, tends to be easily forgotten, misunderstood or not understood.⁵⁻⁸

Accordingly, patients have to be provided with written medication information. The PIs represent an accessible and an important source of written medication information, which they can read at their convenience and keep for ongoing reference, thus complementing and reinforcing the verbal one, but not replacing it.^{9,10} The main objective for this study was to assess the knowledge, attitude, and practice (KAP) of Sudanese doctors towards medication PIs, as easily accessible, available written medication source

of medication information, and its usefulness to themselves and patients, alike.

METHODS

An open to answering the questionnaire is consisting of 15 questions was used to assess the KAP of 400 doctors, randomly selected from public and private medical facilities in Khartoum and Gezira states, Sudan, about the written medication information in PIs. The questionnaire was pre-tested and piloted, on a representative sample of the study subjects (doctors) consisting of 40 doctors in a multi-departmental hospital for contents and reliability, prior to commencing the main study. This number was not included in main study population. The piloting helped introducing minor change in the questionnaire setup and language. The studied doctors (n=400) were informed of the purpose of the study and its possible positive impact on health outcomes. Their cooperation was also requested verbally and in a six lines memo on the top of the first-questionnaire page. Their agreement to participate in the study was secured, and their practical participation was considered as informed consent. Three-pharmacy students, from the faculty of pharmacy, the university of Gezira, who were well informed about the objectives of the study, well trained and acquainted with the techniques and manners of addressing the doctors, distributing, following up and collecting back the filled questionnaires. To rule out any possible bias, the researchers did not involve themselves in this part of the study. In addition, 440 PIs were randomly selected and screened to define the languages in which they were written.

RESULTS

Descriptive, as well as correlated methods of data were processing, were adopted in analyzing the questionnaire results. Data were analysis was carried out in an organized sequence that stated the doctors, KAP on the PIs. The results about the demographic characteristics of the respondent doctors showed that the exclusive majority of the respondents, 366 (91.5%) were young (age group 20-39 years), while their gender showed a slight dominance of females group 214 (53.5%). Khartoum State encompassed 287 (71.75%) of the respondent doctors while those practicing in Gezira State were 109 (27.25%). Three hundred and seventy (92.5%) of the respondent doctors had their undergraduate studies in Sudan, while only 26 (6.5%) had it abroad. Among the respondents doctors; 348 (87%) had a maximum of 10 years of medicine practice. The medical officers 237 (59.25%) were the majority, followed respectively by the registrars 80 (20%), house officers 56 (14%) and the specialists 23 (5.75%). When asked whether they read the medications PIs, an overwhelming majority of the participant doctors, 370 (92.5%), confirmed that. They also confirmed that PIs were important and useful to them in their prescribing decision, 354 (88.9%). The respondent doctors, conferred

importance to some medications information particulars, to patients, over other attributes. Results were as per, Table 1. Only a minority of 148 (37%) of the respondent doctors felt that patients can understand the written medication information in the PI. While the majority of the respondent doctors 242 (61.3%) did not. Table 2 shows the results of the screening of the PIs for the languages in which they were written. The majority (60.39%) of the screened PIs were written in English only, while those written in both English and Arabic were (29.61%). None were written in Arabic alone (the native Sudanese language). A majority (93.5%) of the respondent doctors, believed it was important to provide adequate medications information to patients. However, only a minority (43.5%) of them used to advise their patients to read medications PIs. The correlation between the doctor’s advice to patients to read the PIs of their medications by increased understandability of patients to the medication information in PIs text,

Table 1: Respondent doctors’ ranking of medication information particulars, according to their importance to patients.

Medication information particulars considered of most important to patients	Frequency	Percentages of doctors agreeing to the importance of information particulars	Percentages of doctors disagreeing to importance of information particulars
Dose	318	79.5	20.5
How to use the drug	309	77.3	22.7
Adverse effects	292	73	27
Contraindications	237	59.3	40.7
Missed doses and management (in case)	219	54.7	45.3
Importance of compliance	212	53	47
Indications	193	48.3	51.7
Precautions	184	46	54
Drug-interactions	169	42.3	57.7

Table 2: Language(s) in which the screened PIs (404) texts were written.

Language in which PI is written	Frequency	Percentage of age of total
English only	244	60.39
English and Arabic	160	39.61
Arabic only	Zero	0
Total	404	100.0

English language is a foreign language for Sudanese.
PI: Package insert

proved to be significant ($p=0.000$) (Table 3). A fairly considerable majority (60.5%) of the respondents did rely on and, trusted the pharmacists to provide their patients with the needed, necessary medication information about their prescribed medicines. The majority (81.75%) of the respondent doctors asserted that they used to inform their patients about the possible side effects of the medications they prescribe for them. The majority (89.25%) of the respondent doctors believed that informing their patients about their prescribed medications might improve their safe use and adherence to prescribed medications' regimens. The correlation between respondent doctors beliefs in informing patients about their medications by improved patients' safe use of those medications proved to be non-significant (Table 4).

Table 3a: Doctors' advice for patient to read PI by increased patients' understandability of medication information in PIs.

Doctor's advice to patients to read PIs	Patients understandability of medication information in PI		Total
	Yes	No	
Yes	97	76	173
No	51	170	221
Total	148	246	394

PI: Package insert

Table 3b: Chi-square tests.

	Value	df	p value
Pearson Chi-square	45.04	1	0.0000
Number of valid cases	394		

**Correlation proved significant, * $p=0.0000$

Table 4a: Doctor's advice for patient to read PI, by safe use of medications.

Doctor's advice to patients	Patients, safe use of medications		Total
	Yes	No	
No	200	22	222
Yes	157	15	172
Total	357	37	394

PI: Package insert

Table 4b: Chi-square tests.

	Value	df	p value
Pearson Chi-square	0.16	1	0.69
Number of valid cases	394		

Correlation proved to be non-significant ($p=0.69$). Understandability of medication information may fail to trigger and maintain behavior (Safe use of medications)

DISCUSSION

The medications' PIs and the medical representatives were considered among the most frequently used sources of medication information by physician and pharmacists.^{1,2,11,12} This might explain why the majority of the respondent doctors were keen to read the PIs.

Moreover, the majority of the respondents who considered the medication information provided in the PIs as useful in their prescribing decision might be because they lacked easy access to independent and up-to-date information about medications, which is scarce or even sometimes downright lacking, in developing countries.^{1,13}

When the studied doctors were asked: which medication information attributes (particulars) they consider most important to patients? Their answer was as per Table 1. The results were almost matching to those reported by other researchers.¹⁴

The respondent doctors were expected to give patients' adherence to their prescribed medications' regimens, a prime consideration among the medication particulars most important to patients. However, only a small majority (53%) of the respondent doctors endorsed that. this result represented a serious issue and concern, as adherence is important to both patients and their communities, in terms of the targeted health outcomes and the cost to both patients and their communities.^{15,16} According to, other researchers,¹⁷ this overlook to medication adherence, might be referred to the low physicians' awareness and recognition of the importance of adherence. Not only that, but physicians are supposed to take more active roles in securing adherence by providing balanced medication information to patients, in excellent communication pattern, motivating, guiding and strongly advising them to be adherent, if the targeted health outcomes were to be reached.⁶

The majority of the respondent doctors did not use to advise their patients to read the PIs, before using their prescribed medications This result matched the findings of other researchers.^{18,19} If doctors advise their patients to read the PIs of their medication, patient would probably do so.²⁰

The reasons why the respondent doctors were not comfortable with advising patients to read the PIs, might be related to the detailed side effects profile displayed in the PIs in a highly defensive tone, which they might have thought would intimidate patients, and might negatively affect patients adherence.²¹ From the other side, other researchers reviews did not prove that the provision of written medication information to patients, would ever be harmful to patients.²²

The bi-variant analysis (Table 3) showed that, when doctors advised their patients to read the PIs, patients' understanding of the information in the PIs increased significantly **($p=0.000$).

This should encourage doctors and pharmacist, alike, to advise their patients to read PIs, and accordingly acquire more medication information and understanding that may help them deal with their medications more safely and appropriately.

The majority of the respondent doctors (61.5%) asserted that patients may not understand the information in the PIs. The PI's text language, technical terminology and font size were cited by other researchers as barriers to that understandability.²³⁻²⁶

Language barriers

As the majority (60.39%) of the PIs in Sudan, were written in English only (Table 2) language can stand as a real barrier for patients understanding of the medication information in PIs. Many researchers²³⁻²⁶ advised that to facilitate patients' understandability of the medication information in the PIs, they must be written in the targeted population own native language(s); as that might be more conducive to understandability and consequently more better dealing with the written medications information.

Medical Jargon and technical terms used in classical PIs texts, could also stand as barriers to PIs' texts understanding,²⁴ others advised that medication information should be presented in simple and understandable terminology, in the users' official languages.

Readability of the written information in the PIs could also affect understandability of a given text. Understandability and comprehensibility of any written text, in addition to other factors, are very intimately linked to its readability. The high general illiteracy, in Sudan, and a low-health literacy that is expected to follow may hinder the proper understandability and the handling of the information about medications, quite much.²⁷

A clear majority of the respondent doctors confirmed their reliance, and trust on pharmacists in providing patients with medication information. Many researchers reported that the pharmacists were not only drug experts, but are practically relied on, to varying degrees, by doctors to provide patients with the needed medications information and services.^{28,29} Other researchers, confirmed that (87.9%) of their studied Sudanese doctors, agreed that pharmacists were expected to be knowledgeable drug experts, and (81.8%) of them, expected pharmacists to educate patients about the safe and appropriate use of their medications.³⁰

Other researchers reported that only (33%) of physicians' discussions with patients were about side effects,⁸ however, a high majority of the respondent doctors in this study confirmed that they used to inform their patients about the side effects of their prescribed medications. The importance of providing patients with information about their medications' side effects was endorsed by a big group

of researchers.^{7,31}

As reported by other researchers,²² patients taking medicines need sufficient information to help them use the medicines safely and effectively, to understand the potential harms and benefits, and accordingly make informed decisions about taking them. Another group of researchers,^{32,33} reported that patients particularly expect all the information-related to adverse effects (Risks) and do not agree to give this discretion to physicians.

CONCLUSIONS

The written medications information in the PIs represented a reliable source and reference of medication information for the respondent Sudanese doctors in their prescribing practice. Respondent doctors used to inform their patients about the possible side effects of the prescribed medications, but rarely advised them to read PIs, before using their prescribed medications. They considered information about medications' dose, how to use the medication, and information about its side effects as the most important medication information particulars to patients. Doctors should advise and encourage their patients to read the medication PIs, treat their medication informational contents objectively, and keep them for ongoing reference.

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