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Sudanese patients' knowledge, attitude and perception regarding written medication information in package inserts

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ABSTRACT

Medication package inserts are the most available and accessible sources of written medication information to patients. To assess the Sudanese patients' knowledge, attitude and perception towards written medication information in package inserts. One thousand (1000) patients were addressed with a questionnaire composed of nineteen (n=19) questions. The demographic characteristics of the respondents, showed dominance (89%) of young, males (64.4%), with high educational level. Respondents were keen to read package inserts (71.1%). Respondents' reading was significantly correlated to their age and educational levels (p 0.005, 0.000) respectively. Written medication information was difficult to understand for (35.3%) of respondents. Language (18.2%), technical terminology (20.4%), and font size (10.3%), were cited as the main barriers for understanding. Doctors and pharmacists provided verbal medication information to patients in (40.8%), and (57.8. %) of encounters, respectively. Respondents most needed medication information particulars were how to use it, side effects and contraindications. Respondents practiced medications cross - treatment, stopped and/or decreased medication dose after reading package inserts. Those practices were significantly correlated to respondents' reading of package inserts (p 0.028 and 0.034) respectively. Package inserts texts' language, technical terminology, were main barriers for patients' understandability of written medication information.

Key words: written, medication, information, patients, package inserts, usefulness.

INTRODUCTION

Both prescriptions only and over-the counter pharmaceuticals, represent major players in the management of different diseases, or ailments, complained of by patients to the different members of the healthcare team, mainly the physicians, pharmacists and nursing staff [1] Patients who are doomed to use these medications should, accordingly, be well informed and involved in the agreement on the choice and handling of these medications (concordance), if treatment is to succeed and meet its desired health outcomes. [2] The patient should be considered an important member of the healthcare team**.** The ideal Source of written medication information to patients has to be: - accurate, reliable, easily accessible, in understandable language, sufficiently informative, striking a balance between treatment benefits and risks, and practically useful. It should be provided with the intention of complementing and reinforcing the verbal medication information, but not to replace it. Verbal medication information is usually and commonly provided to patients, by their responsible healthcare providers. The overall level of the verbal medications information in terms of magnitude, quality, clearness, and understandability, varies quite considerably. The verbal information is criticized for, its deficiency, difficult understandability and comprehension. In addition the verbal message alone is easily forgotten, [3] and the amount of verbal information correctly recalled, is strikingly small. [4] It also is sometimes not understood or misunderstood. [5] It is criticized for leaving the knowledge and authority in the hands of the healthcare provider, does not help the patient to refer to information, and he/she may even forget it. [6, 7] Accordingly, patients must be provided with written medication information. The importance and benefits of providing patients with written information about medications is well documented in the literature.

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[8] it is thought that written information may have negative consequences on the receiving patients. [9] However, some other studies had proved otherwise.[10] Moreover, some other researchers had asserted that, no studies had ever proved that the provision of written medication information is harmful to patients. [1] As the package inserts (PIs) are the most available, accessible and most frequently used source of written medication information, by both patients and care givers. Based on the above, this study was conducted with the main objective of: Assessment of the Sudanese patients' knowledge, attitude and perception towards written medication information in package inserts.

MATERIALS AND METHODS

One thousand (n=1000) patients were randomly selected from the public and private health facilities, in Khartoum and Gezira states, Sudan. These two states were chosen as they are neighboring each other, and were convenient for both the researchers and the interviewers, aside from their population diversity, density and their population's relatively high educational levels. They were then addressed with a pre-structured questionnaire consisting of nineteen (19), open to answer questions written in simple lay Arabic (the native language), to assess their knowledge, attitude and perception about the medications' package inserts, which are the most available and easily accessible form of written medication information for patients, in developing countries. Each recruit of the prospective study patients' population was first approached by one of the five interviewers (students of the faculty of pharmacy, Gezira University, Wad Medani). The five interviewers were well trained and oriented to the task needs. They were informed to firstly pay the due warm greetings to the recruits, how to introduce themselves clearly, confidently, politely, and expose the recruit to the general objective of the study and inform him/her of its possible benefits for the whole community, and requested him/her to cooperate on absolute free decision basis. The recruits were informed that their identity would not be disclosed, and that the informed that their participation, by filing the questionnaire and handing it back, would be considered a form of free informed written consent. They were assured that filling the questionnaire would not take more than a maximum of twenty minutes. Each recruit was advised to patiently and thoroughly read the questionnaire and he/she could ask any questions that might help in understanding it, but would never be provided with any answer, frank or implied. To completely rule out any possible bias, the researchers refrained from taking any part in this phase of the study. The first four questions in the questionnaire were about the demographic characteristics of the studied group. Thirteen of the remaining questions were closed –ended, while only two were open-ended multiple-choice questions. They were all about the package insert as a source of written medication information to patients, its importance, readability, understandability and usefulness from the view point of the respondent patients. For those marginally illiterate participants, the reviewer extended help in reading the question and writing down their exact answer. The written answer was read twice to him/her to verify the exact nature of the answer after being verbally endorsed by the respondent. Result was expressed in frequencies and percentages. They were analyzed using SPSS version 13.

RESULTS

Descriptive analysis

The following results were obtained on the knowledge, attitude and perception of Sudanese patients on written medications information in package inserts. One thousand (n=1000) patients from Khartoum and Gezira states were targeted. The average response frequencies and percentages for all of the nineteen questions were 887 (88.7%), as some of them did not answer all the questions. Table 1, shows the demographic characteristics of the respondent patients.

Nine hundred and forty seven (94.7%), of the respondents were aware of the availability of the PIs within their medication outer container. Seven hundreds and one (70.1%) used to read the PIs regularly. The ability of the respondents to read PIs texts was significantly correlated to their age and education level, Table 3, 4. For three hundred and fifty three (35.3 %) of the respondent patients, the written medication displayed in the PIs was difficult to understand. Table 4, shows that the PIs texts' language, terminology and font size, represented real barriers for the respondents' understandability of medication information. Respondents asserted that physicians and pharmacists provided them with medication information in (40.8%) and (57.8%), respectively; and advised them to read the PIs, before using their medication, in only (10 %) of the encounters.

Inference statistics for the Sudanese respondents patients (n=1000**).** Tables 2, 3, 5-7, show the bi-variant analysis using Chi – Square Test where: - The respondents' age and educational level were significantly related to their ability and keenness to read the PIs. The pharmacist's provision of information about medications to the respondent's

patients was significantly related to their educational level. Respondents reading of PIs was significantly related to their practice of cross - treatment and acts of stopping treatment altogether or decreasing the dose of their prescribed medications (P 0.005, 0.000, 0.000, 0.028, and 0.034) respectively.

DISCUSSION

Discussion of the results of the studied (n = 1000) Sudanese patients, from Khartoum and Gezira states, Sudan. The core interaction indicators subject to discussion of our study of the respondents patients will be centered on their knowledge, attitude and perception, towards the medications information for patients in general and those displayed in the package inserts, in particular. Table 1, shows the results of the demographic characteristics of the respondent patients. Males were dominant (62.8%) among respondents. That males' dominance might be due to the fact that in Sudan, the dominant Islamic and oriental cultures, might be the cause, as females, were not usually easily approachable to foreigners, same to males. Other reasons, unknown to the researchers, could also be the causes.

The educational level showed that those respondents' patients having secondary school education and above were a majority (88.4 %), while those who were illiterates or just had basic school (8th grade) education were 98 (9.8%). This part of study results did not reflect the ideal distribution of the educational level in Sudan, but as usual when it comes to reading and comprehension of written materials, like written questionnaires, volunteering and willingness for participation, might mainly rest on educated individuals. This was one of the shortcomings of this study. Nine hundred forty seven of the respondent patients (94.7%) were aware of the presence and availability of PIs in their medications' small packs. This might be referred to the respondents' high educational level, where they might be asked to help other illiterate or marginally educated patients, in reading same and/or, reading their own medications' PIs.

Moreover, the exclusive majority of the registered and prescribed medications are in small packs, which must by law contain package inserts. Seven hundred and one (70.1%) of the respondents patients confirmed their keenness to read the package inserts, possibly because they recognized their importance as the most available and easily accessible source and reference for written medication information, as it is case in developing countries. This result also reflected a wide acceptance for the PIs reading by a wide respondents' audience. This high percentage of respondents' keenness to read the package inserts was higher than that reported in the findings of other researchers, [10] but lower than the results recorded by other researchers. [11]

The bi-variant analysis using Chi Square Test, Table 2,3, show that the correlation between patients ability to read the PIs' texts, by their age, from one side, and by their educational level, as well. Both correlations were significant, (p 0.005, 0.000, respectively). It was reported in one study [12] that, reading was not always correlated to understanding of medications instruction. From an ethical and legal point of view, it was considered imperative that the package inserts be easily understandable and provides all the necessary medication information. [13] In line with the above, only three hundred and fifty three (35.3%) of the respondents, stated that it was difficult for them to understand the medication information displayed in PIs. This result was matching to results recorded by other researchers. [14] Understanding written medication information is necessary to avoid medication errors. It also was reported that the language and technical terminology used in the package inserts, were among many factors that, might impair easy understanding of the package insert. [15]

Respondents related difficulties for understanding the PIs, to the language (18.2%), terminology (20.4%) and small texts' font size (10.3%), Table 4. As per the stipulations of the Sudanese regulatory authorities, [16] the PIs were intended for the prescribers and patients. Compared to patients, the prescribers, by their very professional competencies, might face no or very slight difficulty in understanding the language and technical terminology used in the PIs texts. The implication of the PIs' texts language as a barrier for patients' understanding was well documented in the literature. [15] Many authors advised that patients' own native language be used in written medication information materials. As language barriers may lead to major health adverse consequences. [17] Out of those patients who responded, 204 (20.4%) asserted that the technical terms used were the cause for that understandability difficulty. This matched the opinions of other authors. [12]

The Sudanese Pharmacy and Poison Act, [16] stipulated that, the package insert shall address the prescribers and patients. This would mean that it can be basically addressing the prescribers who, as medical professionals, are well versed in high technical medical terminology. Though they were

the ones going to use the prescribed medications, and also the ones paying for the cost of the package insert, which might be their only and most accessible source of written medication information, the patients' interest were given the second seat. [11] A small minority (10.3 %) of respondent patients considered the PI text font size as a barrier for understanding the medication information. This low reported rate of the font size barrier effect on PIs' reading and understanding might be referred to the dominant young (88.4%) respondent population (18–44 years), who might be less prone to suffer visual impairment. [18] Other researchers, [14] recommend a font size of 10-11 points, as optimal for package inserts legibility. These results were matching with the finding of several other authors. [19] The particulars of the medication information most important to the respondents patients mainly centered on: - How to use the medication, its dose(69.5%), side effects (64.1%), Indications (56.1%), contraindications (52.6 %),warnings (52.6%), drug – drug interactions and food – drug interactions (41.2 %) and use in pregnancy and other special groups of patients (37.8%). These results were in line with the findings of some German researchers. [20] As for the form of medication information most preferred by the respondent patients, respondents preferred to receive their needed medications information in a combination of both the verbal and written form (59.7%). The verbal form of medication information alone, was preferred by (18.3%) of the respondents, while (28.8%) preferred the written form. This result was matching to the findings and recommendations of other researchers. [16] It was shown in others' studies that the verbal message can easily be forgotten, [3] misunderstood, not understood, [5] or only a very small amount of it (14%) might be remembered, correctly. That calls for and necessitates the provision of written medication information side by side to the verbal one, to complement and reinforce and support the verbal information, but not to replace it. [6, 7]

The respondents' patients endorsed the importance of medications information acquisition in helping patients to optimally use their medications. A group of other researchers, [15] asserted that, lack or deficiency of information about medications might lead to inappropriate use of medications, and its possible unblessed consequences. The respondents asserted that physicians and pharmacists provided them with medication information in only (40.8%) and (57.8%) of encounters, respectively. Physician's provision of medications information to patients was mostly suboptimal to the needs of the patients**.** It was reported in one study that the mean dispensing time in two top Sudanese teaching public hospitals was 46.3 second/ encounter. [21] Inadequate and/or deficient patients' counseling is not only unjust to patients, but a frank failure of the pharmacists to meet their basic professional responsibilities. Other researchers from Botswana (South East Africa) reported that the mean dispensing and counseling time during the encounter of patients with pharmacists was a mere 25 seconds! [22] Respondent Pharmacists' provision of medication information to patients, proved to be significantly correlated to patients' age and educational level (p 0.000). Though other researchers recommended that patients should be advised and motivated, by their health providers, to read the package inserts before using their medications, [23] yet, only (10%) of the respondent patients asserted that their physicians and pharmacists used to advise them. This might be pointing to those physicians and pharmacists' apprehensions, that the patients might be intimidated of their medications side effects mentioned in the PIs when they read the PIs; as the manufacturers used to write them in a detailed and a highly defensive tone fashion, endeavoring to avoid any possible ensuing legal liabilities. Moreover, the opinions of other researchers was that physicians and pharmacists usually question the amount of side effects and safety information patients wanted, and thought that much medications information including side effects, might deter the patients from taking their medications. [10] According to other researchers, the provision of medications information to patients had never been linked to any apprehension of adverse effect! [1] Other reasons why physicians and pharmacists were not consistently advising patients to read the package insert, might be attributed to their possible apprehension that the patients, based on the information they find in the package insert, might advise others to use same medications for similar symptoms (cross - treatment).

Bi-variant analysis, Table 6, showed that the correlation between patients' reading of PIs and their practice of cross-treatment was significant (P 0.028). Same to the findings of other author researchers, [24] an appreciable minority (41.5%) of the respondent patients confirmed that they practice cross-treatment. [3] If the patients were exposed by their healthcare professionals to the risks of cross-treatment in a balanced, easily understandable, and an objective manner, its practice by patients might decrease substantially. Among the other negative impacts of reading the package inserts and its possible ensuing intimidation and anxiety from the risks of the medication portrayed, that it might lead patients to reduce their medications' dose or even downright

stop its use. Almost two fifth (39.4%) of the respondents patients, confessed that they sometimes decrease their medications' prescribed doses, or even stop taking them, altogether. The bi -variant analysis using Chi square test, Table 7, shows the correlation between patients' reading of PIs by their practice of reducing doses or stopping the use of their medications altogether, was significant (p value 0.034). Other researcher reported that, the verbal descriptors format of the probability of medications' side effects was associated with higher readers' estimations, than the numerical expression of side effects. [25 – 28] accordingly, medications' side effects in written materials, should be presented to readers numerically, (e.g. 0.01%, 1%, 10% etc.), rather than descriptively (rare, common etc) alone.

CONCLUSION

The medications' package inserts (PIs) represent vitally important source of written medication information for patient. Respondent patients were aware of PIs presence. PIs texts' language, technical terms and font size were cited by respondent patients as the main barriers for understanding of PIs. Healthcare providers shall advise and motivate patients to read and use PIs, before using their medications. To help patients deal more objectively with Information about medications' side effects, their frequencies of occurrence shall be expressed both numerically and descriptively.

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Table 1, the respondent patients' demographic characteristics.

Background characteristic.	**Frequency.**	**Valid Percent.**
Age		
18 – 29 year	687	68.7 %
30 – 44 year	197	19.7 %
45 – 60 year	95	9.8 %
60 >	14	1.4 %
Missing	7	0.7 %
Gender		
Male	628	62.8 %
Female	362	36.2 %
Missing	10	1 %
State		
Khartoum	682	68.2 %
Gezira	318	31.8 %
Educational level		
Illiterate	18	1.8 %
Basic	80	8.0 %
Secondary	387	38.7 %
University	460	46 %
Postgraduate	49	4.9 %
Missing	6	0.6 %

Table 2, the respondent patients' age by their ability to read PIs

Patients' age	Patients' ability to read PIs.		Total
	Yes	No	
14-29	457	186	643
30-44	151	40	191
45-60	77	12	89
60>	9	3	12
Total	694	241	935

Chi-Square Test

	Value	df	P_value
Pearson Chi-Square	12.703	3	0.005
N of Valid Cases	935		

The age of respondent patients, was significantly related to their ability to read the package inserts (p 0.005).

Table 3, the respondent patients' educational level by their ability to read the package inserts.

	Patients' ability to read PIs.		Total
	Yes	No	
Illiterate.	10	8	18
Patients' Educational level. Basic.	75	5	80
Secondary.	356	31	387
University.	452	8	460
Postgraduate.	49	0	49
Total.	942	52	994

Chi-Square Tests

	Value	df	P_value
Pearson Chi-Square	76.044	4	0.0000
N of Valid Cases	994		

The educational level of the participant patients was significantly correlated to their level of reading the package insert (p 0.000).

Table 4, Language, terminology and font size, were cited as real barriers for PIs texts understandability.

Barriers for understandability of written medication information in PIs.	Frequency.	Yes percentage	No percentage.	Missing frequency
The language.	182	18.2 %	16.9 %	649
The terminology.	204	20.4 %	14.6 %	650
The font size of the text.	103	10.3 %	24.4 %	653
Other (undisclosed) reasons.	57	5.7 %	29.3 %	650

The average response rate to this question was very low, compared to others. The package inserts' texts terminology (20.4%), and language (18%), was cited, by the respondents, as main barriers to understandability, more than the font size (10.37%).

Table 5, the pharmacist provision of medication information to patients by respondent patients' educational level.

	Pharmacist provision of medication information to patients.		**Total**
Patient's Education. Level.	Yes	No	
Illiterate	10	7	17
Basic	52	26	78
Secondary	245	136	381
University	247	210	457
Postgraduate	19	29	48
Total	573	408	981

Chi-Square Test

	Value	df	P_value
Pearson Chi-Square	18.222	4	0.0000
N of Valid Cases	981		

The provision of information about medications to the participant patients by pharmacists is significantly correlated to the participant patients educational level (p 0.000).

Table 6, Respondent patients' reading of the package insert by the act of cross - medication practice.

	Cross-treatment practice		**Total**
	Yes	No	
Reading PI			
Yes	169	180	349
No	138	206	344
Total	307	386	693

Chi-Square Tests

	Value	**df**	**P_value**
Pearson Chi-Square	4.846	1	0.028
N of Valid Cases	693		

There was a significant correlation between the respondents' practice of cross-treatment by their level of reading the package inserts (p 0.028).

Table 7, Respondents reading of the PIs by their practice of' decreasing their medications' doses or stopping their use, altogether

	Patients stopping medications use, or decreasing its dose.		**Total**
Patients' Level of reading PIs	Yes	No	
Yes	151	199	350
No	176	168	344
Total	327	367	694

Chi Square Test

	Value	df	P_value
Pearson Chi-Square	4.478	1	0.034
N of Valid Cases	694		

There was a significant correlation between the respondent patients reading of the package inserts by their act of stopping the use or decreasing dose of their medications (p 0.034)

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