



Knowledge, Attitude, Perception and Behaviour of Patients towards Drug Leaflet in Riyadh, Saudi Arabia

O. A. Alkhamees¹, N. A. Qureshi^{2*}, M. A. Al Fadhel³ and S. M. Alsanad^{1,2}

¹College of Medicine, Imam Muhammad Ibn Saud Islamic University (IMSIU), Riyadh, Saudi Arabia.

²National Center for Complementary and Alternative Medicine, Riyadh, Saudi Arabia.

³King Fahad Medical City, Ministry of Health, Riyadh, Saudi Arabia.

Authors' contributions

This work was carried out in collaboration between all authors. Authors OAA, MAAF, SMA, and NAQ designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors NAQ and SMA, MAAF and OAA managed the analyses of the study. Authors NAQ, SMA and MAAF managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Background: Patient-tested and -friendly information leaflets provide sufficient, accurate, and pertinent information about prescribed and over-the-counter medications to health consumers for their safety, enhanced satisfaction, improved outcomes and no medication errors across the globe. However healthcare consumers' knowledge, attitude, behaviour and perception concerning different items of drug leaflets differ across the board.

Objective: This study aimed to explore knowledge, attitude, behaviour and perception of patients towards drug/patient information leaflets in Riyadh, capital city of Saudi Arabia.

Methods: This cross-sectional study used a self-designed reliable questionnaire for collecting

*Corresponding author: E-mail: n.qureshi@nccam.gov.sa, qureshinaseem@live.com;

relevant data about drug leaflets from purposefully selected participants (n=319) attending ambulatory clinics of a main hospital of King Fahad Medical City, Riyadh.

Results: The majority of patients were females (75%), 61% patients were between the ages of 20 to 30 years, and 58% of the participants were educated to university level. About 61% to 97% of participants agreed to knowledge, attitude and behaviour items, and only 26% patients perceived that the drug information provided by healthcare professionals suffices on its own without the drug leaflets. About 62 % of the participants observed that the information in the drug leaflet is more useful than the information given verbally by healthcare professionals. The majority of patients (66% to 99%) expressed variably positive behaviour and favourable attitudes toward drug leaflet information. The participants ranked 'indications' (31.4%) and 'how to use' (26.7%) drugs as the two most important sections in drug leaflet.

Conclusion: Drug leaflets are important sources of drug information for patients globally and improve their knowledge as well as positive effects on their attitude, perception and behaviour. Healthcare professionals need to encourage health consumers to read the drug leaflets which need to be patient-friendly and be written clearly in understandable lay terminology and native language.

Keywords: Drug leaflets; patient information leaflets; package inserts; knowledge; attitude; perception; Saudi Arabia.

1. INTRODUCTION

Patient information leaflet (PIL) or drug leaflet (DL) are important sources of providing guiding principles of safely using prescribed and over-the-counter drugs by patients around the world [1,2,3]. In a randomized comparison study, Whatley and colleagues reported that PILs often describe many important drug items on traditional leaflet but provide little information about the likelihood of harm and benefit of a medication and suggested the use of alternate leaflets with familiar icons and graphs and professionals need to discuss with consumers about other sources of drug information [4]. The qualitative and quantitative information in PIL enhance patients' knowledge and positive behaviours, in addition to what they have gathered from consultants in clinical settings [5,6]. PILs have many advantages including patient outcomes, decision making about drug choice and no major negative consequences but some disadvantages or harms such as anxiety or frightening reactions, non-adherence, medication errors, multiple rehospitalization and needless investigations may be attributed to tedious information, difficult-to-read PIL and not reading the PIL at all (50% of patients), "nocebo effect", and misinformation [2,5,7-17]. To mitigate these harms, the patient-tested and -friendly PIL formats supported by drug guidelines and "drug facts box" need to have familiar icons and graphs along with clear simplified, evidence-based qualitative and quantitative drug information written in lay terminology and native language [3,18-24]. Furthermore Traynor and others criticized manufacturer-produced patient medication information (PMI) or consumer

medicine information (CMI) and suggested multiple strategies including third party involvement in producing unbiased medication leaflets and their availability online [24-27]. Overall, this brief review of international literature informs that despite many researches in the evolution of package inserts, a clear understandable standardized PMI is yet to be finalized for global recognition and acceptance.

1.1 National Landscape

A PubMed search of regional literature using keywords drug leaflets OR patient information leaflets OR package inserts AND Saudi Arabia AND Gulf countries retrieved a dozen of articles on PIL and in summary these studies have explored several different perspectives including stakeholders' attitude and comprehension and what essential information to be included in drug leaflets and their evaluation along with counseling practices and methods to avoid of medication errors [28-34]. Interestingly, Alotaibi and colleagues developed a text readable tool based on machine learning approach to check the readability of Arabic drug leaflets [35]. In a related development, two health organizations developed important guidelines for developing summaries of product characteristics, labelling information and drug leaflets in Saudi Arabia and other Gulf countries [36,37]. Since August 2011, a patient information leaflet (PIL) is now required to be submitted during the drug registration process [36,37]. Overall, there is scanty literature on PIL in Arabian Gulf countries and, hence, further research is needed in different domains of PILs. Therefore, we designed this exploratory study to assess the knowledge, attitude, perception and

behaviour of patients towards PIL. The patients' perspective in terms of patient-tested and – friendly is crucial for the development of PILs across the world. The relevance of this research is that it will encourage local researchers to carry out further researches in PILs that help achieve patient safety, improved knowledge, enhanced satisfaction, good outcome and no negative consequences.

1.2 Aim of the Study

This study explored the patient perspectives in terms of knowledge, attitude, perception and behavior towards DL/PIL in Riyadh, Saudi Arabia.

2. METHODS

2.1 Study Design

This was a cross-sectional, semi-analytical tertiary hospital-based survey of purposefully selected sample of patients (n=319) visiting outpatient clinics at main hospital of King Fahad Medical City (KFMC), Riyadh, KSA.

2.2 Setting

This study was conducted at King Fahad Medical City, during the year 2012. The KFMC was established in year 2004. This KFMC was selected because the researchers had easy access to patient population visiting ambulatory specialties clinics and, hence, ease of data collection from outpatients. The main hospital is a specialized center that provides medical specialties, surgical, critical care and dental services. It also contributes to the health education and teaching at the local level besides enhancing treatment of diseases through medical research and specialized medical training programs.

2.3 Sample Selection

The approximate number of patients consulting various clinics in main hospital of KFMC is about 430/month and the sample was drawn from these patients with a variety of diseases. The purposeful sample selection technique was used in this study. According to some researchers, caregivers need to be included in studies concerning PIL or drug leaflets.

2.4 Questionnaire

A pre-designed, structured questionnaire with closed-ended questions was used for the

purpose of this study, which was developed in Arabic language after a literature review of the topic of research in a similar setting to tap the participants' outcomes, i.e., knowledge, attitude, perceptions and behaviors about DL/PIL in Riyadh city. Five academics from public health department and pharmacy services participated in developing this questionnaire. The questionnaire was translated into English and then back into Arabic by two bilingual experts and one neutral expert to check its accuracy, with modifications applicable to the community of Saudi Arabia. The questionnaire - Arabic and English versions – was finally reviewed by the same five academics to ensure the relevance and feasibility of the questionnaire items. All the experts reached 98% agreement on all questions that were included in this questionnaire. This one-page questionnaire was pilot tested on a sample of 25 patients for assessing the logistics, suitability, and clarity of the data collection along with administration time. The patients suggested minor changes in Arabic version, and the modifications were made with the agreement of all the five experts with regard to any question included in this questionnaire. The questions were further revised for the sake of clear coding system and the data entry. Consequently the questionnaire was made easy to be completed by individual patients and to ensure that the necessary completion time was not more than 15 to 20 minutes. The administration time was the only burden on the participants. Finally, all the experts reached consensus regarding this questionnaire, its English and Arabic versions. This developmental process and four major sections based on final bilingual experts' consensus may reflect acceptable psychometric properties especially reliability. English language version was necessary because many participants requested it.

Finally, this self-administered questionnaire comprised of four main components: (1) The participants' sociodemographic information; (2) six items relating to patients' knowledge/comprehension of the drug leaflet based on three response choices (3-point Likert scale) for each question (agree, disagree, don't know); (3) 12 items regarding patients' behaviour and attitudes towards the drug leaflet, with four response choices (4-point Likert scale) for each question (always, sometimes, rarely, never); and (4) an exploration of patients' perceptions about the importance of each section in the DL. In addition, patients were asked to rank the following six important items in the DL; caution,

indications, how to use, adverse effects, compositions and drug interactions. This ranking was based on their perception in decreasing priority, i.e., from the most important to the least important.

2.5 Inclusion and Exclusion Criteria

The inclusion criteria were age 17 years and above who were able to give informed consent to participate in the study, and Saudi nationals who can understand at least Arabic language. The exclusion criteria were expatriates, age below 17 and those with intellectual disability, and those who cannot read or write Arabic.

2.6 Procedure

The study was conducted at main hospital KFMC located in Riyadh during the period from March through May 2012. The participants were informed to answer all the questions by two trained pharmacy technicians who distributed the questionnaire to those who agreed to participate in this survey. The pharmacy technicians approached outpatients when they were waiting for filling prescriptions in the pharmacy waiting area. The pharmacy technicians clarified queries raised by any participant concerning questionnaire items. Patients were not coerced in any way to take part in the study, and completion of the self-administered questionnaire was entirely voluntary. If patients agreed to participate in the study, they were asked to completely fill out the questionnaire and return it to the pharmacy. The act of filling out the questionnaire and returning it to the pharmacy was considered consent to participate in the study.

2.7 Data Management and Analysis

Data were entered into the Statistical Package for Social Sciences (SPSS) software version. 21 (SPSS Inc., Chicago, IL, USA) for coding, cleaning the data, data management and analysis. The entries were double checked and any discrepancies were corrected. The data were subsequently analysed to facilitate a calculation of summary statistics of the sample using a 95% confidence interval (CI).

2.8 Ethical Approval

The first author submitted the research protocol to the Ethics Committee (IRB) of the Academic and Training Affairs of KFMC. The Ethical Committee approved the research protocol and

gave permission for conducting the study. The patients were fully informed in non-technical language about the aims and objective of this research. Further clarifications were made if they raised any query concerning this study. They were also informed that they can withdraw from the study without affecting their treatment and followup in the clinics. Individual participant gave consent prior to filling up the questionnaire. No financial incentives were given to the participants. Notably, this study presented no risk to the patients. Ethically, it is more appropriate to take "written and signed consent" from each participant.

3. RESULTS

3.1 Demographic Characteristics

A total of 323 questionnaires were returned to the pharmacy at main hospital in KFMC. Of these, 319 (98.8%, 95% CI: 96.9-99.5) were usable questionnaires while 4 (1.2%) were returned partially blank. The majority of the participants were female (n=238, 75.1%). Most of the respondents were between 20 and 30 years of age (n=179, 60.9%). Majority of the participants (n=181, 58.2%) were educated to university level (Table 1).

Table 1. Participants' Sociodemographic characteristics (N=319)

Characteristics	N (%)	95% CI
Gender		
Male	79 (24.9)	20.5, 29.9
Female	238 (75.1)	70.0, 79.5
Total*	317	-
Age		
Under 20	6 (2)	0.9, 4.3
20-30	179 (60.9)	55.2, 66.2
31-40	73 (24.8)	20.2, 30.1
41-50	22 (7.5)	4.9, 11.1
51-60	10 (3.4)	1.9, 6.2
61-70	3 (1)	0.4, 2.9
Over 70	1 (0.3)	.06, 1.9
Total*	294	-
Education		
Primary	10 (3.2)	1.7,5.8
Secondary	21 (6.8)	4.5,10.1
High School	82 (26.4)	21.8,31.5
University	181 (58.2)	52.7,63.6
Postgraduate	17 (5.5)	3.4, 8.6
Total*	311	-

*some information missing and % derived from the total number of each variable

3.2 Patients' Knowledge, Attitudes and Behaviour and DLs

The majority of the participants (n=309, 97.2%) believed that the drug leaflet information should be read before the drug was used. In addition, 275 (86.8%) participants stated that the drug leaflet could help to reduce medication errors. About 61% of the participants were satisfied with the information included in the drug leaflet. The language used in the drug leaflet was easy to read for 222 (71.2%) of the participants. A proportion of the participants (62%) expressed the view that information provided in drug leaflets is usually much more beneficial than verbal information given by healthcare professionals. In fact 193 participants (61.5%) did not believe that information provided by healthcare professionals would be sufficient without DL information (Table 2).

Table 3 presents the patients' attitudes and behaviour towards the drug leaflet information. Most of the participants (68.1%) recorded having a positive feeling when they read the drug leaflet before using the drug. A total of 178 (56.3%) participants were not reassured that the drug leaflet had helped to reduce their concerns about the use of the medication. However, about 42% were 'sometimes' annoyed when they did not understand the information in the drug leaflet. About 75% of the participants 'always' read the drug leaflet before they used the drug; however, 49% of the participants recorded that they did not read the drug leaflet more than once. Unexpectedly, 36% of the participants felt that healthcare professionals did not want them to read the drug leaflet. This was supported by 27.4% of the participants, who noted that healthcare professionals did not always advise

them to read the drug leaflet. About 60% of the participants stated that the drug leaflet always increased their level of understanding regarding the drug. Similarly, about 67% of the participants reported that the drug leaflet made them use the medication properly. A large proportion of the participants (74.6%) read the drug leaflet as soon as they received it; however, one-fourth of the participants 'rarely' kept the drug leaflet. Concerning item 12, the physicians and pharmacists were the patients' first choice when it came to discussing the drug (53.8% and 44%, respectively).

3.3 Patients' Rankings and DL

Most of the participants perceived 'indications' (31.4%) and 'how to use' (26.7%) as the two most important sections in the drug leaflet, which were then followed by the 'caution'(15.9%), 'adverse effects' (14.5%), the 'composition' (9.8%) and lastly the 'drug interactions'(1%) (Fig. 1).

4. DISCUSSION

This study explored the sociodemographic features, knowledge, attitude, perception, and behaviour of outpatients towards drug leaflets in Riyadh city. Majority of the participants were young adult females with university level education. This demographic trend may make some sense; besides taking care of household chores, females are now holding jobs and pursuing higher education, and all that may invite considerable stress and, hence, increase both in diseases and consultations. This pattern may also be attributed to study methods including research settings.

Table 2. Patients' knowledge, attitudes and perceptions towards the DL

Items	Agree N (%)	Disagree N (%)	Don't know N (%)	Total
1.It is necessary to read the drug leaflet	309 (97.2)	6 (1.9)	3 (0.9)	318
2.Reading the drug leaflet can contribute to a reduction in medication errors	275 (86.8)	23 (7.3)	19 (5.9)	317
3.The information included in the drug leaflet is considered adequate	192 (60.6)	72 (22.7)	53 (16.7)	317
4.The language used in the drug leaflet is clear and easy to read	222 (71.2)	74 (23.7)	16 (5.1)	312
5.The information in the drug leaflet is more useful than the information given verbally by healthcare professionals	195 (61.8)	95 (30.0)	26 (8.2)	316
6.The information provided by healthcare professionals suffices on its own without the drug leaflet information	81 (25.8)	193 (61.5)	40 (12.7)	314

Table 3. Patients' attitudes and behaviour regarding the drug leaflet

Item	Always N (%)	Sometimes N (%)	Rarely N (%)	Never N (%)	Total
1.I feel good when I am provided with the drug leaflet	216 (68.1)	88 (27.8)	7 (2.2)	6 (1.9)	317
2.The drug leaflet increases my concerns about the use of medication	44 (13.9)	178 (56.3)	49 (15.5)	45 (14.3)	316
3.I feel upset when I do not understand the information included in the drug leaflet	113 (35.9)	132 (42.0)	49 (15.7)	20 (6.4)	314
4.I feel that healthcare professionals do not want me to read the drug leaflet	30 (9.8)	110 (36.1)	80 (26.2)	85 (27.9)	305
5.Healthcare professionals advise me to read the drug leaflet	52 (16.6)	86 (27.4)	69 (21.9)	107 (34.1)	314
6.The drug leaflet increased my understanding of the drug	187 (58.9)	99 (31.2)	24 (7.6)	7 (2.3)	317
7.Once I have the drug leaflet, I read it	238 (74.6)	60 (18.8)	18 (5.7)	3 (0.9)	319
8.Once I have the drug leaflet, I keep it	98 (30.9)	97 (30.6)	75 (23.7)	47 (14.8)	317
9.After reading the drug leaflet, the way I use the drug improves	211 (66.8)	81 (25.6)	16 (5.1)	8 (2.5)	316
10.I usually read the drug leaflet more than once	85 (26.8)	161 (50.8)	54 (17.0)	17 (5.4)	317
11.I usually read the drug leaflet before using the medication	218 (68.6)	77 (24.2)	18 (5.6)	5 (1.6)	318

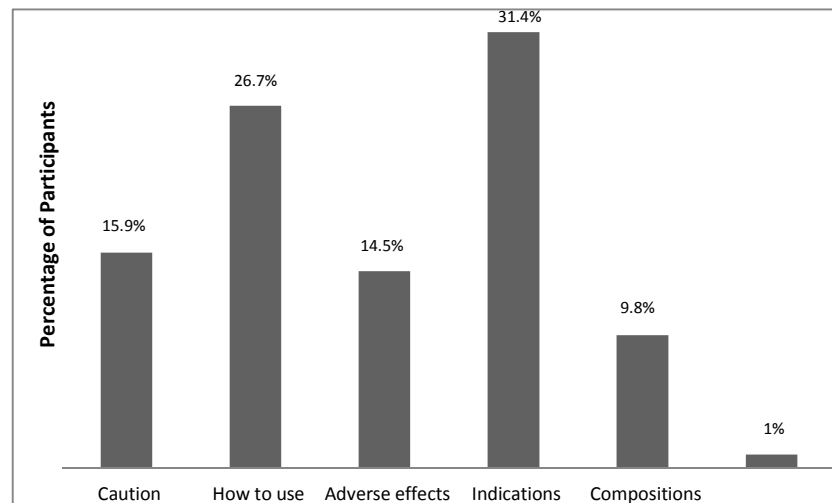


Fig.1. Patients' rankings of the drug leaflet components by perception

According to this study, there were multiple motivational behaviours to always read the DLs (75%); reduction in medication errors, clear, usefulness and adequacy of information, proper use of medication, knowledge and comprehension improvement, improve outcomes, confidence building and its indispensability. In a study, Bawazir et al (2003) reported various purposes of reading patient inserts (88%) including to know more about drugs, adherence, decision making to take the medication, and to understand information complementary to instructions (and counselling) of the clinicians and clinical pharmacist [28]. In the present study, the patients' prioritized "indications" and "how to use" the medications given in the ranking list; the respondents considered "indications" and "adverse drug effects" as the most important sections of great interest [28]. In most regional and international studies, the participants suggested a DL/PIL to be concise with clarity, easy to read and comprehend, reasonable indications, contraindications, drug interactions and side-effect profile with stated precautions, harms and benefits of specific drug, evidence-based quantitative and qualitative information with added icons, graphic presentation and 'drug facts box', and be written in lay terminology and native language [4-6,18-25,28,31,34]. According to some researchers, PIL/CMI also needs to be patient-tested and patient-friendly and available online/central repository freely accessible to medication users, health providers and pharmacists [24-27]. We suggest that this PIL/PMI agenda should apply both to prescribed and over-the-counter medications (generic and brand-name) across the board [3,31].

In a comparative study of package inserts, Bawazir et al. (1991) reported that medications marketed in Saudi Arabia had inadequate information compared with drugs available in USA [29] and currently this scenario seems to be changed as shown in the present study. However, there remains a substantial disagreement in information between the package inserts (PIs) of generic and brand products marketed in Saudi Arabia [30]. As there is no standardized PIL or patient medication information (PMI) accepted globally, the differences in loaded information in all formats of PIL/DL will continue to persist, as also found by Alaqeel [33]. According to our study, though the verbal information provided by the physicians is useful (62% agreed) and sufficient (only 26%

agreed vs. 61% disagreed), and, therefore, counseling or instructions by physicians are not a substitute to PIL [31]. This is also because of deficiencies found in drug dispensing and medication counseling at community pharmacies and academic centers in Riyadh [31,32]. Similarly, Hung and colleagues suggested that the direct-to-consumers advertising is no substitute for well-written relevant information leaflet format associated with decision-making by consumers and also safe use of medications [24]. According to Wells and Metherell, there were different problems of consumer medicine information (CMI) such as content, format and accessibility modes and roundtable discussion among all stakeholders might solve these issues resulting in a clear, readable, patient-friendly CMI with adequate medication information [27].

According to this study, the participants expressed some negative attitudes, perceptions and behaviors; increased distress, displeased when information is not clear and unambiguous, and misperception about healthcare providers' notion about reading or not reading the DLs. However, PIL in fact might be anxiety provoking [15], loaded with unclear and deficient information [27,29] and not easy to read [17]. Are these attitudes really negative in nature? It seems that the answer is no as suggested by relevant literature on DL/PIL [15,17,27,29]. Overall, despite extensive studies carried out globally, there remain many problems with the development of a standardized and universally accepted PIL.

This study has some limitations. This is a cross-sectional study and does not provide any cause-effect associations between sociodemographic variables and participants' responses on the questionnaire. This study is conducted in tertiary care hospital in Riyadh and, hence, findings cannot be generalized to other regions or general/specialist hospitals of Saudi Arabia. However, the strength of this study is that PIL tends to improve knowledge of participants as well as positive effects on their attitude and behaviors, and written information was not linked to any negative consequences. Further studies with improved methods and design of clearly understandable PIL/DL are needed in future.

5. CONCLUSION

Drug leaflets are important sources of drug information for patients and have positive

effects on their knowledge, attitude, perception and behaviours. Healthcare professionals need to encourage healthcare consumers to read the drug leaflets which need to be patient-friendly and be written clearly in understandable lay terminology and native language.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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