

1 Knowledge, Attitude, Perception and Behaviour 2 of patients towards Drug Leaflet in Riyadh, 3 Saudi Arabia 4

5 ABSTRACT

6 **Background:** Patient-tested and -friendly information leaflets provide sufficient, accurate,
7 and pertinent information about prescribed and over-the-counter medications to health
8 consumers for their safety, enhanced satisfaction, improved outcomes and no medication
9 errors across the globe. However healthcare consumers' knowledge, attitude, behaviour and
10 perception concerning different items of drug leaflets differ across the board. **Objective:** This
11 study aimed to explore knowledge, attitude, behaviour and perception of patients towards
12 drug/patient information leaflets in Riyadh, capital city of Saudi Arabia. **Methods:** This
13 cross-sectional study used a self-designed reliable questionnaire for collecting relevant data
14 about drug leaflets from purposefully selected participants (n=319) attending ambulatory
15 clinics of a main hospital of King Fahad Medical City, Riyadh. **Results:** The majority of
16 patients were females (75%), 61% patients were between the ages of 20 to 30 years, and 58%
17 of the participants were educated to university level. About 61% to 97% of participants
18 agreed to knowledge, attitude and behaviour items, and only 26 % patients perceived that the
19 drug information provided by healthcare professionals suffices on its own without the drug
20 leaflets. About 62 % of the participants observed that the information in the drug leaflet is
21 more useful than the information given verbally by healthcare professionals. The majority of
22 patients (66% to 99%) expressed variably positive behaviour and favourable attitudes toward
23 drug leaflet information. The participants ranked 'indications' (31.4%) and 'how to use'
24 (26.7%) drugs as the two most important sections in drug leaflet. **Conclusion:** Drug leaflets
25 are important sources of drug information for patients globally and improve their knowledge
26 as well as positive effects on their attitude, perception and behaviour. Healthcare
27 professionals need to encourage health consumers to read the drug leaflets which need to be
28 patient-friendly and be written clearly in understandable lay terminology and native language.

29 **Keywords;** Drug leaflets, patient information leaflets, package inserts, knowledge, attitude,
30 perception, Saudi Arabia.

31 1. INTRODUCTION

32 Patient information leaflet (PIL) or drug leaflet (DL) are important sources of providing
33 guiding principles of safely using prescribed and over-the-counter drugs by patients around
34 the world [1,2,3]. In a randomized comparison study, Whatley and colleagues reported that
35 PILs often describe many important drug items on traditional leaflet but provide little
36 information about the likelihood of harm and benefit of a medication and suggested the use of
37 alternate leaflets with familiar icons and graphs and professionals need to discuss with
38 consumers about other sources of drug information [4]. The qualitative and quantitative
39 information in PIL enhance patients' knowledge and positive behaviours, in addition to what
40 they have gathered from consultants in clinical settings [5,6].PILs have many advantages
41 including patient outcomes, decision making about drug choice and no major negative
42 consequences but some disadvantages or harms such as anxiety or frightening reactions, non-
43 adherence, medication errors, multiple rehospitalization and needless investigations may be
44 attributed to tedious information, difficult-to-read PIL and not reading the PIL at all (50% of
45 patients), "nocebo effect", and misinformation [2, 5, 7-17]. To mitigate these harms, the
46 patient-tested and -friendly PIL formats supported by drug guidelines and "drug facts box"
47 need to have familiar icons and graphs along with clear simplified, evidence-based qualitative
48 and quantitative drug information written in lay terminology and native language [3, 18-24].
49 Furthermore Traynor and others criticized manufacturer-produced patient medication
50 information (PMI) or consumer medicine information (CMI) and suggested multiple
51 strategies including third party involvement in producing unbiased medication leaflets and
52 their availability online [24-27]. Overall, this brief review of international literature informs
53 that despite many researches in the evolution of package inserts, a clear understandable
54 standardized PMI is yet to be finalized for global recognition and acceptance.

55 **1.1 National Landscape**

56 A PubMed search of regional literature using keywords drug leaflets OR patient information
57 leaflets OR package inserts AND Saudi Arabia AND Gulf countries retrieved a dozen of
58 articles on PIL and in summary these studies have explored several different perspectives
59 including stakeholders' attitude and comprehension and what essential information to be
60 included in drug leaflets and their evaluation along with counseling practices and methods to
61 avoid of medication errors [28-34]. Interestingly, Alotaibi and colleagues developed a text
62 readable tool based on machine learning approach to check the readability of Arabic drug
63 leaflets [35]. In a related development, two health organizations developed important
64 guidelines for developing summaries of product characteristics, labelling information and

65 drug leaflets in Saudi Arabia and other Gulf countries [36,37]. Since August 2011, a patient
66 information leaflet (PIL) is now required to be submitted during the drug registration process
67 [36,37]. Overall, there is scanty literature on PIL in Arabian Gulf countries and, hence,
68 further research is needed in different domains of PILs. Therefore, we designed this
69 exploratory study to assess the knowledge, attitude, perception and behavior of patients
70 towards PIL. The patients' perspective in terms of patient-tested and –friendly is crucial in for
71 the development of PILs across the world. The relevance of this research is that it will
72 encourage local researchers to carry out further researches in PILs that help achieve patient
73 safety, improved knowledge, enhanced satisfaction, good outcome and no negative
74 consequences.

75 **1.2 Aim of the Study**

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

78 **2. METHODS**

79 **2.1 Study Design**

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

84 .

85 **2.2 Setting**

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

93 **2.3 Sample Selection**

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

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2.4 Questionnaire

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

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

133 were asked to rank the following six important items in the DL; caution, indications, how to
134 use, adverse effects, compositions and drug interactions. This ranking was based on their
135 perception in decreasing priority, i.e., from the most important to the least important.

136 **2.5 Inclusion and Exclusion Criteria**

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

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143 **2.6 Procedure**

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

156 **2.7 Data Management and Analysis**

157 Data were entered into the Statistical Package for Social Sciences (SPSS) software version.
158 21 (SPSS Inc., Chicago, IL, USA) for coding, cleaning the data, data management and
159 analysis. The entries were double checked and any discrepancies were corrected. The data
160 were subsequently analysed to facilitate a calculation of summary statistics of the sample
161 using a 95% confidence interval (CI).

162 **2.8 Ethical Approval**

163 The first author submitted the research protocol to the Ethics Committee (IRB) of the
164 Academic and Training Affairs of KFMC. The Ethical Committee approved the research
165 protocol and gave permission for conducting the study. The patients were fully informed in
166 non-technical language about the aims and objective of this research. Further clarifications

167 were made if they raised any query concerning this study. They were also informed that they
 168 can withdraw from the study without affecting their treatment and followup in the clinics.
 169 Individual participant gave consent prior to filling up the questionnaire. No financial
 170 incentives were given to the participants. Notably, this study presented no risk to the patients.
 171 **Ethically, it is more appropriate to take "written and signed consent" from each participant.**

172 **3. RESULTS**

173 **3.1 Demographic Characteristics**

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

179 **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		

180

181 **3.2 Patients’ Knowledge, Attitudes and Behaviour and DLs**

182 The majority of the participants (n=309, 97.2%) believed that the drug leaflet information
 183 should be read before the drug was used. In addition, 275 (86.8%) participants stated that the

184 drug leaflet could help to reduce medication errors. About 61% of the participants were
 185 satisfied with the information included in the drug leaflet. The language used in the drug
 186 leaflet was easy to read for 222 (71.2%) of the participants. A proportion of the participants
 187 (62%) expressed the view that information provided in drug leaflets is usually much more
 188 beneficial than verbal information given by healthcare professionals. In fact 193 participants
 189 (61.5%) did not believe that information provided by healthcare professionals would be
 190 sufficient without DL information (Table 2).

191 **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

192
 193 Table 3 presents the patients’ attitudes and behaviour towards the drug leaflet information.
 194 Most of the participants (68.1%) recorded having a positive feeling when they read the drug
 195 leaflet before using the drug. A total of 178 (56.3%) participants were not reassured that the
 196 drug leaflet had helped to reduce their concerns about the use of the medication. However,
 197 about 42% were ‘sometimes’ annoyed when they did not understand the information in the
 198 drug leaflet. About 75% of the participants ‘always’ read the drug leaflet before they used the
 199 drug; however,49% of the participants recorded that they did not read the drug leaflet more
 200 than once. Unexpectedly, 36% of the participants felt that healthcare professionals did not
 201 want them to read the drug leaflet. This was supported by 27.4% of the participants, who
 202 noted that healthcare professionals did not always advise them to read the drug leaflet. About
 203 60% of the participants stated that the drug leaflet always increased their level of
 204 understanding regarding the drug. Similarly, about 67% of the participants reported that the
 205 drug leaflet made them use the medication properly. A large proportion of the participants
 206 (74.6%) read the drug leaflet as soon as they received it; however, one-fourth of the
 207 participants ‘rarely’ kept the drug leaflet. Concerning item 12, the physicians and pharmacists

208 were the patients' first choice when it came to discussing the drug (53.8% and 44%,
 209 respectively).

210

211 **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

212

213 3.3 Patients' Rankings and DL

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

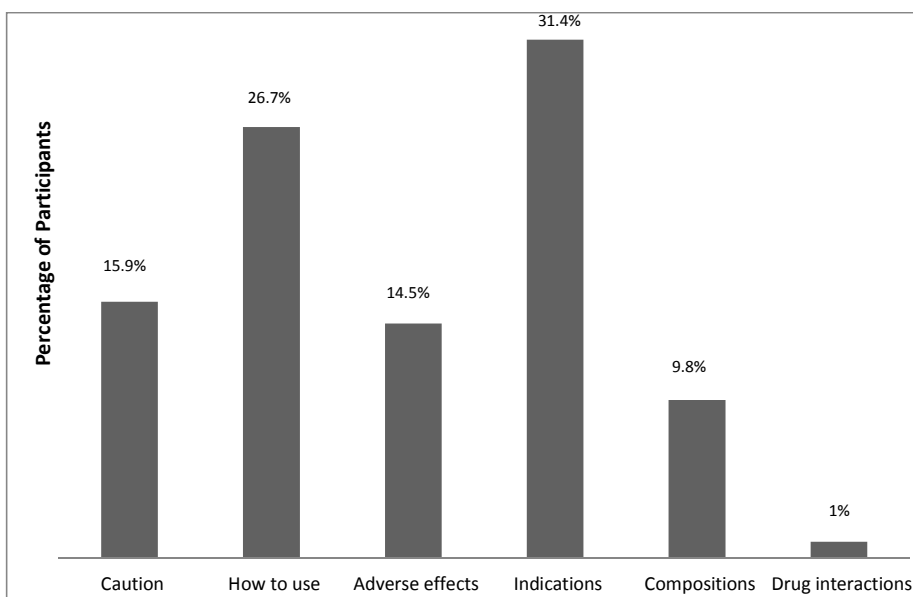


Figure 1 Patients' rankings of the drug leaflet components by perception

4. DISCUSSION

This study explored the sociodemographic features, knowledge, attitude, perception, and behavior 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.

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

239 important sections of great interest [28]. In most regional and international studies, the
240 participants suggested a DL/PIL to be concise with clarity, easy to read and comprehend,
241 reasonable indications, contraindications, drug interactions and side-effect profile with stated
242 precautions, harms and benefits of specific drug, evidence-based quantitative and qualitative
243 information with added icons, graphic presentation and 'drug facts box', and be written in lay
244 terminology and native language [4-6, 18-25, 28, 31, 34]. According to some researchers,
245 PIL/CMI also needs to be patient-tested and patient-friendly and available online/central
246 repository freely accessible to medication users, health providers and pharmacists [24-27].
247 We suggest that this PIL/PMI agenda should apply both to prescribed and over-the-counter
248 medications (generic and brand-name) across the board [3, 31].

249 In a comparative study of package inserts, Bawazir et al. (1991) reported that medications
250 marketed in Saudi Arabia had inadequate information compared with drugs available in USA
251 [29], and currently this scenario seems to be changed as shown in the present study.
252 However, there remains a substantial disagreement in information between the package
253 inserts (PIs) of generic and brand products marketed in Saudi Arabia [30]. As there is no
254 standardized PIL or patient medication information (PMI) accepted globally, the differences
255 in loaded information in all formats of PIL/DL will continue to persist, as also found by
256 Alaqeel [33]. According to our study, though the verbal information provided by the
257 physicians is useful (62% agreed) and sufficient (only 26% agreed vs. 61% disagreed), and,
258 therefore, counseling or instructions by physicians are not a substitute to PIL [31]. This is
259 also because of deficiencies found in drug dispensing and medication counselling at
260 community pharmacies and academic centers in Riyadh [31, 32]. Similarly, Hung and
261 colleagues suggested that the direct-to-consumers advertising is no substitute for well-written
262 relevant information leaflet format associated with decision-making by consumers and also
263 safe use of medications [24]. According to Wells and Metherell, there were different
264 problems of consumer medicine information (CMI) such as content, format and accessibility
265 modes and roundtable discussion among all stakeholders might solve these issues resulting in
266 a clear, readable, patient-friendly CMI with adequate medication information [27].

267 According to this study, the participants expressed some negative attitudes, perceptions and
268 behaviors; increased distress, displeased when information is not clear and unambiguous, and
269 misperception about healthcare providers' notion about reading or not reading the DLs.
270 However, PIL in fact might be anxiety provoking [15], loaded with unclear and deficient
271 information [27, 29] and not easy to read [17]. Are these attitudes really negative in nature? It

272 seems that the answer is no as suggested by relevant literature on DL/PIL [15, 17, 27, 29].
273 Overall, despite extensive studies carried out globally, there remain many problems with the
274 development of a standardized and universally accepted PIL.

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

283 **5. CONCLUSION**

284 Drug leaflets are important sources of drug information for patients and have positive effects
285 on their knowledge, attitude, perception and behaviours. Healthcare professionals need to
286 encourage healthcare consumers to read the drug leaflets which need to be patient-friendly
287 and be written clearly in understandable lay terminology and native language.

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