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## Readability of information imprinted in patient information leaflets (PILs) in Saudi Arabia: The case of antihypertensive medications

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## ABSTRACT

**Background:** The Saudi Food and Drug Authority (SFDA) requires marketing authorization holders to submit a PIL in both Arabic and English language. However, the readability of imprinted and disseminated Patient information leaflets (PILs) was not assessed extensively in Saudi Arabia. This study aims to assess the readability of PIL of antihypertensive drugs in both Arabic and English languages.

**Method:** This study was a descriptive quantitative analysis conducted in Saudi Arabia in August 2021. PILs of all oral antihypertensive medications in Saudi Arabia were included in the study. The Arabic and English PILs were extracted from the Saudi Drugs Information System (SDI) and pharmaceutical companies' registration documents. The study used Flesch-Kincaid grade level to assess the readability of English and sentence length to assess the Arabic texts. Descriptive analyses were used to assess the readability scores and the mean differences.

**Results:** It was found that almost 88% of English PILs were above recommended readability level compared to 79% of Arabic PILs. About 89% of English PILs of generic and 86% of brand-name medications were above the readability cutoff point compared with 83% of Arabic PILs of generic and 68% of brand-name medications. The means of grade level for readability of PILs for the widely used antihypertensive medications including angiotensin II receptor blockers (ARBs), antiadrenergic, diuretics, Beta-blockers (BBs), calcium channel blockers (CCBs), and combination antihypertensive medications, and CCBs were higher than the recommended readability level ( $p < 0.05$ ). The highest mean grade level for readability among English PILs was for combinations of antihypertensive agents ( $9.35 \pm 1.38$ ,  $p < 0.01$ ) and among Arabic PILs was for ARBs ( $6.15 \pm 1.62$ ,  $p < 0.01$ ).

**Conclusions:** The majority of PILs of antihypertensive medications were above the recommended readability level that can be understood by the majority of the public, especially among generic medications and the most widely used antihypertensive medications. The study findings highlight the need of implementing guidelines to improve the readability of information imprinted in PILs and adopt new regulations requiring readability assessment for manufactures before submitting the PILs to the SFDA.

### 1. Introduction

Patient Information Leaflets (PILs) are an important source of medication information as it guides patients on the optimal way to consume, utilize, or handle medical products. The reading of medication leaflets can help improve and optimize the patients' decision-making and use of medication in managing their illness. PILs are provided with all medicines, they are generally underutilized by consumers.<sup>1</sup> The underutilization is potentially due to the low readability of PIL.<sup>1,2</sup> Previous studies have highlighted that majority of patients were found to be unable to make informed decisions from the information provided with medicines leaflet,

which might be attributable to the limited provision of information and low health literacy.<sup>2-4</sup>

Different health literacy levels of patients should be considered when communicating written health materials. Previous studies have attempted to assess the readability of written health materials.<sup>5-7</sup> Different readability formulas have been used to assess written health material. Most of these formulas are based on word length or syllable number.<sup>5,8</sup> One of the most used formulas to assess readability is the Flesch-Kincaid grade level (FKGL) formula.<sup>6,8</sup> The recommended level of reading difficulty for written health material is recommended to be up to eighth-grade level, which is the average reading level of an adult in the United States.<sup>5</sup> They found that

**Abbreviations:** PILs, Patient Information Leaflets; SFDA, Saudi Food and Drug Authority; FDA, Food and Drug Administration; EMA, European Medicine Agency; SDI, Drugs Information System; ACE, Angiotensin-converting enzyme; ARBs, Angiotensin II receptor blockers; BBs, Beta-blockers; CCBs, Calcium channel blocker; PAH, Pulmonary Arterial Hypertension; FKGL, Flesch-Kincaid grade level; FRE, Flesch Reading Ease; MENA, Middle East and North Africa.

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written health information provided to patients often exceeds the recommended level.<sup>5–8</sup> In a study conducted in Saudi Arabia, 17.3% of patients reported that PILs had long sentences, which they believe that they were very difficult to understand.<sup>9</sup> Assessing health materials is an important step to improving the reading levels of written materials to be inclusive of patients with limited literacy. Improving the readability of health materials will help improve patients' medication adherence and lead to better health outcomes.

The Saudi Food and Drug Authority (SFDA) requires marketing authorization holders to submit a PIL in both Arabic and English language.<sup>10</sup> PILs are packed in the original packaging of each approved medicinal product. Drug regulatory bodies set out recommendations on that should be considered during the preparation of PILs. The SFDA and other regulatory bodies including Food and Drug Administration (FDA) and European Medicine Agency (EMA) have published guidelines for patient leaflets and labeling information in order to better guide pharmaceutical companies on how to develop these materials.<sup>10–12</sup> Still, the current guidelines do not provide directions on what constitutes readable and comprehended language level by the general population. Moreover, the readability of imprinted and disseminated PILs was not assessed extensively before in Saudi Arabia.<sup>13</sup>

Therefore, there is a need to assess the quality and readability of information imprinted in PILs for the most prescribed drugs in Saudi Arabia. Evaluating the readability of PIL will help assess the need of issuing new guidance to pharmaceutical applicants to improve the readability and minimize the potential comprehension issues among general consumers.

The current study aims to assess the readability of both English and Arabic texts imprinted in patient information leaflets of all oral antihypertensive medications registered in Saudi Arabia. The study focused on antihypertensive medications due to the high prevalence of hypertension in Saudi Arabia.<sup>14</sup> The Saudi Health Interview Survey- a national health survey conducted in 2015 findings showed that hypertension (17.7% for males and 12.5% for females) was the most prevalent chronic disease that affects the Saudi population.<sup>15,16</sup> The national census surveillance found that about two million have hypertension in Saudi Arabia in 2018.<sup>15,16</sup>

The secondary objective of this study is to assess the differences in PILs readability between medications in terms of four main characteristics: type of medication, therapeutic class, country of the medication manufacture company, and country of medication marketing company.

## 2. Methods

### 2.1. Study design

This was a cross-sectional descriptive quantitative analysis study that aims to assess the readability of patient information leaflets of all available antihypertensive medications used in Saudi Arabia. The study was conducted in Saudi Arabia in August 2021. All oral antihypertensive medications registered and marketed for the treatment of hypertension in Saudi Arabia and listed in the SFDA databases, were included in the study. Medications excluded were those approved but not currently available (either suspended or withdrawn), not or registered at SFDA. The study dataset included only oral medications (both generics and brands) and one PIL for each medical product with different concentrations.

A total of 249 medications meet the study eligibility criteria. The PILs of antihypertensive medications were extracted from the Saudi Drugs Information System (SDI) and pharmaceutical companies' registration documents.

Ethical approval was exempted by the SFDA research ethics committee due to the study nature.

### 2.2. Data entry

All eligible antihypertensive medications with their registered characteristics were extracted from the SFDA system. The leaflet information of

each medication was extracted from the SDI and pharmaceutical companies' registration documents, entered into a data entry spreadsheet, cross-reviewed by two data collectors, and finally reviewed and validated by the study PI.<sup>17,18</sup> The data collector used the Flesch-Kincaid readability calculator to extract the needed data for English PILs including: Flesch-Kincaid Grade Level, Flesch Reading Ease Score, average words per sentence, average syllables per word, the number of sentences, and the number of words. For the Arabic PILs average words per sentence, the number of sentences, and the number of words were entered for each medication.

### 2.3. Variables and measurements

#### 2.3.1. Medications characteristics

Medication characteristics including type of medication, therapeutic class, country of the medication manufacture company, and country of marketing company were collected. Type of medication was classified as brand name (defined as a “drug marketed under a proprietary, trademark-protected name”) or generic name (defined as “medication created to be the same as an already marketed brand drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use”).<sup>19,20</sup> Therapeutic classes (based on similarity of mechanisms) of the antihypertensive drugs were categorized as Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), antiadrenergic, diuretics, Beta-blockers (BBs), calcium channel blockers (CCBs), antihypertensive for Pulmonary Arterial Hypertension (PAH), or antihypertensive combinations. The country of the medication manufacture company is defined as the country where the medication is manufactured. The country of marketing company of medication is defined as the country where the medication marketing company is located. Both country of the medication manufacture company and country of marketing company were classified as local, regional, and international; where local includes medications manufactured or marketed in Saudi Arabia, regional includes medications manufactured or marketed in regional Arabic speaking countries including Kuwait, United Arab Emirates Oman, Egypt, Jordan, Lebanon, Morocco, and medications manufactured or marketed internationally including all other countries including: Austria, Canada, Cyprus, Denmark, France, Germany, Greece, Hungary, Japan, India, Ireland, Italy, Mexico, Netherlands, Portugal, Poland, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States.

#### 2.3.2. English PILs readability

The study used both Flesch Reading Ease Score and Flesch-Kincaid grade level formulas to assess the readability of English text information provided in each PILs.<sup>21</sup> Flesch-Kincaid was used in this study as its one of the most validated formulas used to assess the readability of text in the health literature.<sup>2</sup> The Flesch Reading Ease Score and Flesch-Kincaid grade level formulas were:

*Flesch-Kincaid grade level (FKGL) formula*

$$0.39 \times (\text{words/sentences}) + 11.8 \times (\text{syllables/words}) - 15.59$$

*Flesch Reading Ease (FRE) Score*

$$206.835 - 1.015 \times (\text{Total Words/Total Sentences}) - 84.6 \times (\text{Total Syllables/Total Words})$$

Flesch-Kincaid reading ease (FRE) is based on a ranking scale of 0–100, and the higher the text score the easier to read it. Flesch-Kincaid Grade Level (FKGL) scores were interpreted based on a US school grade level as in [Appendix A Table 1](#). A higher grade level for readability indicates higher difficulty in reading the text by the general public. Scoring between 70 and 80 is equivalent to school grade seven, which is considered to be “fairly easy” for the average adult to read. The acceptable readability level is set to be less than 8th & 9th grade (level 4) for the FKGL; as 7th grade (level 3) is

**Table 1**  
Characteristics of PILs included in the analysis.

Characteristics	Levels	Medications with English PILs n (%)	Medications with Arabic PILs n (%)	Total without missing	Total with missing <sup>a</sup>
Type of medication	Generic	152 (70.70)	131 (68.59)	152 (70.70)	175 (70.2)
	Brand	63 (29.30)	60 (31.41)	63 (29.30)	74 (29.7)
Country of the manufacture company <sup>b</sup>	Local	77 (35.81)	97 (50.79)	77 (35.81)	86 (34.5)
	Regional	46 (21.40)	29 (15.18)	46 (21.40)	55 (22.1)
	International	92 (42.79)	65 (34.03)	92 (42.79)	108 (43.4)
Country of marketing company <sup>b</sup>	Local	106 (49.30)	70 (36.65)	106 (49.30)	117 (47)
	Regional	36 (16.74)	36 (18.85)	36 (16.74)	46 (18.5)
	International	73 (33.95)	85 (44.50)	73 (33.95)	86 (34.5)
Therapeutic class	ACE	15 (6.98)	14 (7.33)	15 (6.98)	21 (8.4)
	ARBs	44 (20.47)	39 (20.42)	44 (20.47)	46 (18.5)
	Antiadrenergic	5 (2.33)	5 (2.62)	5 (2.33)	7 (2.8)
	Diuretics	11 (5.12)	8 (4.19)	11 (5.12)	15 (6)
	Beta blockers	27 (12.56)	24 (12.57)	27 (12.56)	30 (12)
	Calcium channel blockers	26 (12.09)	25 (13.09)	26 (12.09)	32 (12.5)
	Antihypertensive for PAH	8 (3.7)	7 (3.7)	8 (3.7)	9 (3.5)
	Combinations	79 (36.74)	69 (36.13)	79 (36.74)	89 (35.7)
Total		215	191	215	249
Missing <sup>a</sup>		58	34	58	

<sup>a</sup> Missing data (PILs were not available) were not include it in the final analysis.

<sup>b</sup> Defining country categories:

- Local: Saudi Arabia
- Regional: all regional Arabic speaking countries
- International; all other countries

the recommended reading level that can be read by 80% of the general population.<sup>7,21</sup>

### 2.3.3. Arabic PILs readability

With the lack of a valid readability assessment tool for Arabic texts, the readability of Arabic PILs was assessed using the sentence length. Average sentence length is one of the text lexical features to extract the readability of the Arabic text.<sup>22,23</sup> Most validated readability tools including Flesch-Kincaid depends on sentence length as one of the main readability indicators.<sup>6,24</sup> Moreover, the recent guidance on presenting PILs published by the SFDA recommends the use of short sentences with few words and avoids the use of long sentences.<sup>25</sup> Therefore, this study used the sentence length, which is the average number of words per sentence to assess the Arabic text readability:

*Sentence length*

*Number of words/ number of sentences*

Higher sentence length indicated indicates more difficulty in reading the text by the general population.<sup>22,23,25</sup> From the study data, the sentence length formula generates scores between 3 and 14 words per sentence. The cutoff point was determined based on the median sentence length from the study data; which was five words per sentence.

### 2.4. Data analysis

Excel spreadsheet was used for data retrieval, entry, and cleaning. Characteristics of medications with English and Arabic PILs were described using frequency and percentages. The readability of English text was assessed using the FKGL calculator and Arabic text was assessed using sentence length. The mean, standard deviation, minimum, and maximum values were calculated for the main readability assessment items for Arabic and English PILs. Cross tabulation and Chi-square were used to assess proportional differences of PILs readability (based on the determined cutoff point (English: <8th & 9th grade (level 4), Arabic: <5 words per sentence)) by the characteristics of the medication. *t*-test and ANOVA were used, where appropriate, to examine the statistical differences by

the characteristics of the medications. The statistical significance was set at a *p*-value <0.05. The statistical package of STATA (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) was used for analysis.

## 3. Results

### 3.1. Characteristics of PILs included in the analysis

A total of 249 oral antihypertensive medications were registered and marketed in Saudi Arabia. Out of the 249 registered medications, 215 medications were included in the final analysis; as their PILs were available. The majority of medications were generic (*n* = 152, 71%). More than a third of medications (*n* = 92, 43%) were manufactured internationally and almost half of the medications were marketed by a local company (*n* = 106, 49%). A large percentage of antihypertensive agents were combined medication (*n* = 79, 37%). The most common therapeutic class was Angiotensin II receptor blockers (ARBs) (*n* = 44, 21%) followed by beta-blockers (BBs) (*n* = 27, 13%) and calcium channel blockers (CCBs) (*n* = 26, 12%). Slight proportional differences were observed in characteristics of medications with Arabic PILs and English PILs. Table 1 presents the characteristics of all medications, medications with English PILs, and medications with Arabic PILs (Table 1).

### 3.2. Readability assessment items

The mean number of sentences for English PILs and Arabic PILs were 262 (SD 104) and 441 (SD 181), respectively. The mean number of words per sentence for English PILs was 9.5 (SD 2.08, min 4.1, max 15.2) while for Arabic PILs was 5.5 (SD 1.31, min 2.45, max 13.88) (Table 2) (See Table 3).

The mean Flesch Reading Ease Score for English PILs was 50.6 (SD 9.2) and the mean Flesch-Kincaid grade level was 8.6 (SD 1.5). About 189 (87.91%) of English PILs were above recommended readability score (≥8th & 9th grade) compared to 150 (78.53%) of Arabic PILs were above the readability cutoff (≥5 words per sentence) (Table 2).

**Table 2**  
Means of readability assessment items for English PILs (n = 215).

Assessment items	Mean	SD	Min	Max
Average words per sentence (sentence length)	9.54	2.08	4.1	15.2
Average number of sentences	261.72	104.09	78	1066
Average number of words	2381.50	647.41	545	4348
Average syllables per word	1.74	0.12	1.5	2.6
Flesch reading ease score	50.62	9.21	9.6	69.6
Flesh-Kincaid grade level (FKGL)	8.58	1.52	5.5	14.7

**Table 3**  
Means of readability assessment items for Arabic PILs (n = 191).

Assessment items	Mean	SD	Min	Max
Average words per sentence (sentence length)	5.5	1.31	2.45	13.88
Average number of sentences	440.58	180.56	43	1379
Average number of words	2318.29	739.38	151	5394

### 3.3. Compression of readability of PILs based on the medication characteristics

About 89% of English PILs of generic and 86% of brand-name medications were above the readability cutoff point compared with 83% of Arabic PILs of generic and 68% of brand-name medications. Means of readability assessment items categorized by the medication type are presented in Table 4.

Almost 91% of medications manufactured locally, 83% regionally, and 88% internationally have English PILs that their readability level was above the recommended level. The majority of Arabic PILs were above the readability cutoff point, 81.43% among medications manufactured locally, 77.78% regionally, and 76.47% internationally. Almost 91% of medications marketed by a local company, 81% by regional company and 88% by international company have English PILs that their readability level is above the recommended level. The majority of Arabic PILs were above the readability cutoff point, 83.51% among medications marketed by a local company, 75.86% regional company, and 72.31% by international company. Means of readability assessment items categorized by the

**Table 4**  
PILs readability and medications characteristics.

Characteristics	English PILs (n = 215)			Arabic PILs (n = 191)						
	Below recommended readability score (<4) <sup>a</sup> n (%)	Above recommended readability score (≥4) <sup>a</sup> n (%)	p-value	Mean FKGL score (SD)	p-value	Below readability cutoff (<5) <sup>b</sup> n (%)	Above readability cutoff (≥5) <sup>b</sup> n (%)	p-value	Mean sentence length (SD)	p-value
Type of medication			0.53		0.85			0.02		
Generic	17 (11.18)	135 (88.82)		8.57 (1.55)		22 (16.79)	109 (83.21)		5.57 (1.36)	0.3
Brand	9 (14.29)	54 (85.71)		8.61 (1.44)		19 (31.67)	41 (68.33)		5.36 (1.19)	
Country of the manufacture company			0.39		0.195			0.75		
Local	7 (9.09)	70 (90.91)		8.55 (1.49)		13 (18.57)	57 (81.43)		5.62 (1.53)	0.01
Regional	8 (17.39)	38 (82.61)		8.45 (1.77)		8 (22.22)	28 (77.78)		5.50 (1.37)	
International	11 (11.96)	81 (88.04)		8.68 (1.41)		20 (23.53)	65 (76.47)		5.41 (1.08)	
Country of marketing company			0.28		0.77			0.21		0.01
Local	10 (9.43)	96 (90.67)		8.69 (1.53)		16 (16.49)	81 (83.51)		5.72 (1.45)	
Regional	7 (19.44)	29 (80.56)		8.18 (1.59)		7 (24.14)	22 (75.86)		5.38 (1.37)	
International	9 (12.33)	64 (87.67)		8.62 (1.44)		18 (27.69)	47 (72.31)		5.24 (1)	
Therapeutic class			<0.01		0.01			0.03		<0.01
ACE	7 (46.67)	8 (53.33)		7.6 (1.15)		4 (28.57)	10 (71.43)		4.96 (0.83)	
ARBs	11 (25)	33 (75)		8.18 (1.54)		0	39 (100)		6.15 (1.62)	
Antiadrenergic	1 (20)	4 (80)		7.42 (1.06)		2 (40)	3 (60)		5.79 (1.42)	
Diuretics	0 (0)	11 (100)		8.7 (1.34)		2 (25)	6 (75)		5.23 (1.14)	
Beta blockers	4 (14.81)	23 (85.19)		8.37 (1.82)		8 (33.33)	16 (66.67)		5.45 (1.35)	
Calcium channel blockers	1 (3.85)	25 (96.15)		8.2 (0.94)		7 (28)	18 (72)		5.03 (1.15)	
Antihypertensive for PAH	1 (12.5)	7 (87.50)		7.55 (0.65)		2 (28.57)	5 (71.43)		5.3 (1.27)	
Combinations	1 (1.27)	78 (98.73)		9.35 (1.38)		16 (23.19)	53 (76.81)		5.48 (1.15)	
Total	26 (12.09)	189 (87.91)		8.58 (1.52)		41 (21.47)	150 (78.53)		5.5 (1.31)	

<sup>a</sup> Level 4 = 8th & 9th grade based on the Flesh-Kincaid grade level; as level 3 (7th grade) is the recommended reading level that can be read by 80% of the general population.<sup>6</sup>

<sup>b</sup> Based on sentences length; assessed by the average number of words in a sentence; as 5 words per sentences was the median (cutoff point).

manufacturing country of the medication and the country of the marketing company are presented in Table 4.

The highest mean grade level for readability among English PILs was for combinations of antihypertensive agents ( $9.35 \pm 1.38$ ,  $p < 0.01$ ), and among Arabic PILs was for ARBs ( $6.15 \pm 1.62$ ,  $p < 0.01$ ). The means of grade level for readability of English PILs for Angiotensin II receptor blockers, beta-blockers, and calcium channel blockers were as followed (8.18, SD 1.54, 8.37, SD 1.82, 8.2, SD 0.94). Mean differences between therapeutic classes were found to be significant ( $p$ -value 0.01). Among the Arabic PILs, the means of sentence length for antihypertensive combinations, beta-blockers, and calcium channel blockers were as followed (5.48, SD 1.15, 5.45, SD 1.35, 5.03, SD 1.15). Mean differences between therapeutic classes were found to be significant ( $p$ -value <0.01). Further details can be found in Table 4.

## 4. Discussion

This study assessed the readability of patient information leaflets of all anti-hypertensive medications in Saudi Arabia. A total of 215 medication PILs met the inclusion criteria, 71% were for generic medications and 29% were brand anti-hypertensive medications. The majority of PILs were above the recommended readability level that can be understood by the majority of the public. It was found that almost 88% of English PILs were above recommended readability level and 79% of Arabic PILs were above the readability cutoff. The mean number of words per sentence for English PILs was 9.5 (SD 2.08) while for Arabic PILs was 5.5 (SD 1.31). The means of grade level for readability of PILs for widely used antihypertensive medications including ARBs, BBs, antihypertensive combinations, and CCBs were higher than the recommended readability level. Differences in PILs readability between medications were also noticed in terms of medication type, country of the medication manufacture company, and country of marketing company.

PILs are one of the main sources of information for medication consumers. Reading and understanding of information and instructions provided in the PILs by consumers are essential to ensure that medications are being used safely and appropriately. This study found that the majority of PILs of antihypertensive medications, 88% of English and 79% of Arabic, were above the recommended readability level i.e. need a higher level of education to be understood by the general public. These results were



aligned with other studies conducted regionally and globally. A study conducted to assess the readability of PILs of antidiabetic medications in Qatar found that only 2.2% of PILs had an acceptable readability level for the average adult to read.<sup>2</sup> Two studies conducted in the UK found that the mean readability of medications in the UK market was above the reading level of the general population.<sup>1,4</sup> The existing literature has assessed the readability of medications and found gaps between the readability score and target patients' readability level. Patient information leaflets have readability levels that are higher than recommended to be understood by the general population, which is a concerning issue in communicating medication information to patients.

One of the main readability indicators is sentence length. This study found that the mean number of words per sentence for English PILs was 9.5 (SD 2.08) while for Arabic PILs was 5.5 (SD 1.31), which is above the recommended syntax. It is recommended to use simple sentences with fewer words to improve the readability of the text in all languages.<sup>26</sup> The recently published SFDA guidance for presenting PILs and labeling recommends the use of simple sentences of few words and avoiding using long sentences<sup>25</sup>; as long sentences can be confusing to some readers, especially to those with poor reading skills or poor health literacy.<sup>27</sup> In Saudi Arabia, almost 50% of the Saudi population has a low health literacy level.<sup>28</sup> Moreover, 17.3% of patients reported that PILs had long sentences, which they believe that they were very difficult to understand.<sup>9</sup> Therefore, readability indicators of the texts have to consider all consumers' literacy when designing PILs to be understood and readable for the majority of the general population.

Variations in the PILs readability between medications were observed in terms of their type. The majority of PILs of generic medications have higher school levels for readability compared with brand medications. Among English PILs, 89% of generic and 86% of brand medications were above the recommended readability level, while for Arabic PILs 83% of generic and 68% of brand medications were above the readability cutoff. Differences in medication labeling between generic and branded medications were found in previous studies.<sup>29,30</sup> A recently published study conducted in Saudi Arabia to assess the quality of PILs found that 54% of PILs showed a low accuracy and compliance with the PILs guidelines.<sup>9</sup> This might indicate an opportunity for improvement to be considered by the manufacturers of the generic medications when designing the medications' written materials.

The readability of PILs of commonly used and prescribed antihypertensive medications including ARBs, BBs, antihypertensive combinations, and CCBs were found to be higher than recommended level to be read by the average adult. The highest mean grade level for readability among English PILs was for antihypertensive combinations (9.35, SD 1.38) and among Arabic, PILs was for ARBs (6.15, SD 1.62). The higher-grade level for readability of the PILs of medications was found to be an associated factor with misinterpretation of medication instructions and potential use errors.<sup>2,31,32</sup> A limited number of small-scale studies with methodological variations were conducted to investigate the readability level of leaflets of different medications.<sup>1,2,4</sup> The existing studies found gaps between the readability of PILs and grade level for readability by the average adults, which need to be addressed to avoid the impact of misinterpretation of medication instructions on patient safety.

Globalization of the pharmaceutical manufacturer has a potential impact on the quality of medications including the quality of patient information leaflets.<sup>33,34</sup> This study found variations of PILs readability based on the country of the medication manufacturing company and country of marketing company. The highest mean of grade level for readability of English PILs was for medication manufactured internationally (8.68) and marketed by a local company (8.69). While for Arabic PILs, the highest mean of sentence length was among medications manufactured locally (5.62) and marketed by a local company (5.72).

#### 4.1. Limitations

This study has several limitations. This study assessed the PILs of antihypertensive medications, so it is hard to generalize the results for other

medications' PILs. However, we have assessed the readability of all antihypertensive medications registered in Saudi Arabia to minimize the selection bias. Another limitation, we have assessed the readability based on the syntax ignoring other readability factors such as line spacing, font style, font size, text width, and pictorial aids. The third limitation is that this is a descriptive study, so temporal associations between readability and medication characteristics cannot be established. The fourth main limitation of this study is that, to our knowledge, we have not found any published validated readability tool that can be used to assess Arabic health materials. Therefore, the Arabic PILs' readability was assessed using the median sentence length rather than using a validated readability score. However, sentence length is one of the main readability indicators used in many validated readability tools in many languages.<sup>6,24,35</sup> Moreover, this is one of the first studies that attempt to assess the Arabic readability of PILs with limited evidence on the readability of PILs, specifically Arabic PILs in Saudi Arabia, the Middle East and North Africa (MENA) region, and globally.

## 5. Conclusion

Overall, the study found that there is a gap for improvement regarding the readability of patients' information leaflets. The majority of antihypertensive medications' PILs have a high-grade level for readability recommended for general population comprehension. Differences in readability levels were noticed based on the main characteristics of medications; the higher school level for readability was found among generic medications and most widely used antihypertensive medications including combinations of antihypertensive agents and ARBs.

There is a need to improve the Arabic and English PILs to make them readable at different literacy levels. The study findings highlight the need of implementing guidelines to improve the readability of information imprinted in PILs, for example by reducing the sentence length and jargon to simplify the syntax of these texts. Moreover, the study findings highlight the need to adopt new regulations requiring readability assessment for manufacturers before submitting the PILs to SFDA.

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## Disclaimer

Conclusions reached in this article are based on the personal scientific interpretations of the authors and does not necessarily represent the opinion of SFDA.

## Ethical approval

Ethical approval was exempted by the SFDA research ethics committee due to the study nature.

## Conflict of interests

The authors declare no conflict of interest.

## Authors' contributions

AA: study design, analysis and writing. SA and SM: data collection. RH: study supervision. All authors have made substantial contributions to editing the manuscript.

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## Appendix A

**Table 1**  
Flesch–Kincaid grade level score interpretations.

Score	School level	Notes
100.00–90.00	5th grade (level 1)	Very easy to read. Easily understood by an average 11-year-old student.
90.0–80.0	6th grade (level 2)	Easy to read. Conversational English for consumers.
80.0–70.0	7th grade (level 3)	Fairly easy to read.
70.0–60.0	8th & 9th grade (level 4)	Plain English. Easily understood by 13- to 15-year-old students.
60.0–50.0	10th to 12th grade (level 5)	Fairly difficult to read.
50.0–30.0	College (level 6)	Difficult to read.
30.0–10.0	College graduate (level 7)	Very difficult to read. Best understood by university graduates.
10.0–0.0	Professional (level 8)	Extremely difficult to read. Best understood by university graduates.

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