Readability and Comprehensibility of Patient Information Leaflets for Antidiabetic Medications in Qatar

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Abstract

Background: The readability and comprehensibility of the patient information leaflets (PILs) provided with antidiabetic medications are of questionable standards; this issue negatively affects adherence to drug therapy, especially in patients with limited literacy skills. **Objective:** To evaluate the readability and comprehensibility of PILs supplied with medications used for the treatment of type 2 diabetes mellitus in Qatar. **Methods:** All PILs of the antidiabetic medications in Qatar were evaluated using the Flesch Reading Ease (FRE) score for readability. The Flesch-Kincaid Grade Level, Gunning-Fog Index, and SMOG Grading were used to estimate the comprehensibility of PILs in terms of school grade levels. **Results:** A total of 45 PILs were evaluated: 32 (71.1%) PILs of brand-name products and 13 (28.9%) for generics. Nine (20%) of the PILs were in English only; 8 (17.8%) were in English, Arabic, and French; and 28 (62.2%) were in English and Arabic. The mean FRE score was 37.71 (± 15.85), and the most readable PIL had FRE score of 62. The mean scores for the comprehensibility evaluations were 10.96 (± 2.67), 15.02 (± 2.52), and 11.41 (± 1.6) for the Flesch-Kincaid Grade Level, Gunning-Fog Index, and SMOG Grading, respectively. The most commonly used antidiabetic medication was metformin with 1372.9 (± 552.9) as PILs' mean number of words. **Conclusion:** Only 2.2% of PILs had acceptable readability scores. All PILs could be comprehended by at least an 11th grade student, which exceeds the recommended grade level for health-related materials. Approximately 20% of these PILs were in English only and were not readable by most patients.

Keywords

quality assurance, drug information, diabetes, antihyperglycemics, health care policy

Introduction

The Institute of Medicine Report defined health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”¹ Health literacy is fundamental to patient engagement, medication-taking behaviors, patient empowerment, decision making about treatments, and actions on health information.² Therefore, limited health literacy is considered an issue that deserves careful attention and extra vigilance from the health care community, community leaders, and global policymakers. The reported prevalence of limited health literacy is from 7% to 47% in developed countries, and it is assumed that limited health literacy is much higher in developing countries.^{3–6} In this information- and communication technology-dominant era, patients are expected to access appropriate medication information as part of their provided health care. In addition to the verbal and/or pictorial information that is

provided to patients when they receive medications to ensure safe and effective use and to enhance adherence to the instructions, patient information leaflets (PILs) are an indispensable tool to support the patient's ability to recall and retain the information. A PIL is a leaflet containing specific information about medical conditions or indications, drug doses, adverse effects, and other details; it is packaged with the medicine and provides product information for the user.⁷ PILs should contain useful, reader-friendly, high-quality information about the medications.

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Furthermore, PILs are primarily intended to give patients autonomy in making choices and to empower them in making informed decisions regarding their medicines and health care. An ethically sound, scientifically grounded, and psychologically effective leaflet accurately conveys both the benefits and risks of the treatment and optimizes the patient's expectations.⁸ PILs accompany medicines, and the information they contain is produced by the manufacturer and regulated by law. Therefore, they are both readily available and are (ideally) authoritative. To help achieve optimal therapeutic outcomes, the medicinal information must be high quality, and its readability and comprehensibility must meet the required criteria or standards. The readability and presentation of a PIL can affect its use, in addition to other factors related to the patient and surrounding environment, such as health literacy, health beliefs, and the experience and timing of the provision.^{9,10} Readability is the extent to which each sentence reads naturally, while comprehensibility is the extent to which the text as a whole is easy to understand.¹¹

PILs should be evaluated in advance, since low-quality information may lead to increased patient anxiety and appointment nonattendance, cancellation, or postponement. Commonly, the readability grades of medicinal information exceed the recommended standards; resolving this problem will require an effort from regulatory authorities and manufacturers to modify the format and increase its comprehensibility.¹² Patients are interested in understanding the benefit of their medicines, but they may lack the ability to comprehend the accompanying numerical information.¹³ Unfortunately, PILs are often of poor quality and are hard for patients to comprehend.¹⁴ This is especially a concern for patients with limited literacy skills. Patients want more medication information from a range of sources, and they value the PIL in addition to information they receive from their health care providers.¹⁵

Arabic is the official language of Qatar, but English and various Asian languages are commonly spoken in commercial activities and daily life, given the multicultural nature of Qatar. A study conducted by Sukkari et al on an evaluation of PILs in Saudi Arabia reported inadequacies and shortcomings in the quality of the information that they contained. The investigators reported that the Arabic leaflets failed to meet the definition of useful, scientifically accurate information and that they contained 30% or less of the required information.¹⁶ Qatar is a Middle Eastern country with a population of approximately 2 million people, predominantly expatriates. A considerable number of these expatriates have a low literacy level and may not understand Arabic or English, presenting a significant challenge to health care professionals.¹⁷ Therefore, drug regulatory authorities should regulate the languages of the PILs that accompany registered drug products in Qatar, taking into consideration the most commonly spoken languages, such as Malayalam, Hindi, Tamil, Urdu, Nepali, and Tagalog, in addition to the country's official

language of Arabic. In the Middle East, there is no documented evidence that PILs are being developed to consider the cultural, behavioral, and psychological perspectives of the people from diverse cultures who reside in these countries. Important and mandatory elements of the PILs, such as readability, comprehensibility, communicative focus, and user-testing, are not well established for the populations in this region.

There is a high prevalence of diabetes in the adult Qatari population (16.7%), and the trend is predicted to continue; by 2030, the number of people in Qatar with diabetes is expected to increase by 130%.¹⁸ Furthermore, poor numeracy skills are common among patients with diabetes, and poor numeracy is significantly associated with poorer glycemic control and limited self-management behaviors in these patients.¹⁹ In addition to the high prevalence of limited health literacy, there is a large variability in clinicians' assessments of patients' ability to recall and comprehend new concepts.²⁰

One of the strategies to improve medication adherence is providing useful written information in a "patient language" that clearly explains how the patient can correctly manage his/her medications. This information includes details on how to administer the medication, the exact time that the medicine should be taken and why, how long to take the medicine, steps to recognize and manage common adverse effects, and special precautions.²¹ Information about the prescribed medication is one aspect that influences medication adherence in type 2 diabetes mellitus patients.¹⁴ The readability and presentation of written drug information can affect its use, in addition to other factors related to the patient and surrounding environment, such as health literacy and health beliefs, and the experience and timing of provision.^{9,10} To achieve optimal therapeutic outcomes, medication information must be of high quality, and its readability and comprehensibility must meet the required criteria or standards. Therefore, this study aimed to evaluate the readability and comprehensibility of PILs for both oral and parenteral antidiabetes medications in Qatar.

Methods

Study Setting

The PILs of all antidiabetic medications that are available for the treatment of diabetes mellitus in Qatar (Table 1) were obtained from the government tertiary hospitals of Hamad Medical Corporation, primary health centers, and private community pharmacies.

Selection of Patient Information Leaflets for Evaluation

A total of 83 PILs that were supplied with antidiabetic medications were collected from the previously stated institutions. Duplicate PILs (ie, the same PILs collected by

Table 1. Characteristics, Readability, and Comprehensibility of Patient Information Leaflets for Antidiabetic Medications in Qatar.

Product Identification	Product and Strength	Language	Number of Words	Flesch Reading Ease score ^a	Flesch-Kincaid Grade Level ^b	Gunning-Fog Index ^c	SMOG Grading ^d
P1 (brand)	Repaglinide (0.5/1/2) mg/tablet	English	3637	28.1	10.2	15.9	11.5
P2 (generic)	Metformin HCL (500/850/1000) mg/tablet	Arabic + English	507	29.4	10.6	13.7	11.3
P3 (generic)	Glibenclamide (5/2.5) mg/tablet	Arabic + English	351	37.2	9.3	12	9.5
P4 (generic)	Gliclazide 80 mg/tablet	Arabic + English	256	24	11.1	14.4	11.4
P5 (brand)	Vildagliptin 50 mg/tablet	Arabic + English	3472	36.4	9.5	15.9	11.8
P6 (brand)	Gliclazide MR 60 mg/tablet	Arabic + English	2544	52.3	7.5	12.1	9.6
P7 (brand)	Glimepiride (1/2/3/4) mg/tablet	Arabic + English	2798	50.9	9.9	17	13.2
P8 (brand)	Metformin HCL XR 500 mg/tablet	Arabic + English + French	1768	38.8	9.2	20.2	14.7
P9 (brand)	Metformin HCL XR 750 mg/tablet	Arabic + English + French	1766	38.4	9.3	20.1	14.7
P10 (brand)	Sitagliptin (25/50/100) mg/tablet	Arabic + English	1429	55.7	8.6	10.4	8.9
P11 (brand)	Acarbose 50 mg/tablet	Arabic + English	2133	44.5	11.1	14	11.2
P12 (brand)	Acarbose 100 mg/tablet	Arabic + English	2159	42.5	11.3	13.9	11.1
P13 (generic)	Metformin HCL (500/850) mg/tablet	English	577	24.8	13.1	14.9	11.1
P14 (generic)	Gliclazide 80 mg/tablet	English	741	20.4	14	16.3	11.3
P15 (generic)	Glimepiride (1/2/3/4/5/6) mg/tablet	English	1394	17.4	14.5	16	11.7
P16 (generic)	Glimepiride (1/2/3/4/5/6) mg/tablet	English	1920	18	14.4	16.7	12.6
P17 (generic)	Metformin HCL 500 mg/tablet	Arabic + English + French	1375	23.9	13.9	14.3	11.1
P18 (generic)	Glibenclamide 5 mg/tablet	Arabic + English	508	14.6	15.1	13.8	9.8
P19 (generic)	Metformin HCL (500/850) mg/tablet	Arabic + English	2123	17.6	14.9	17.4	12.8
P20 (brand)	Sitagliptin and Simvastatin (100-10/100-20/100-40) mg/tablet	Arabic + English	2070	54.4	8.9	12.2	9.8
P21 (generic)	Gliclazide 80 mg/tablet	Arabic + English	1600	16.2	14.2	16.4	11.7
P22 (generic)	Glimepiride (1/2/3/4) mg/tablet	Arabic + English	2230	20.2	14.8	15.3	11.1
P23 (generic)	Metformin HCL (500/850) mg/tablet	Arabic + English	804	40.8	9	15	11.4
P24 (brand)	Metformin HCL 500 mg/tablet	Arabic + English + French	1648	36.4	9.3	20.1	14.6
P25 (brand)	Metformin HCL 850 mg/tablet	Arabic + English + French	1650	41.1	9.1	20.1	14.6
P26 (brand)	Metformin HCL 1000 mg/tablet	Arabic + English + French	1511	37.8	9.4	15.3	11.2
P27 (brand)	Metformin HCL and Glibenclamide (500-2.5/500-5) mg/tablet	Arabic + English + French	2102	31.1	10.7	14.6	11.4
P28 (brand)	Sitagliptin and Metformin HCL (50-500/50-1000) mg/tablet	Arabic+ English	2056	58.2	8.2	9.6	8.4
P29 (brand)	Insulin Glargine 100 units/mL solution for injection in a vial	Arabic+ English	3727	52	9.8	14.7	11.4
P30 (brand)	Insulin Glargine 100 units/mL solution for injection in a prefilled pen	English	5011	57.3	8.8	14.8	11.5
P31 (brand)	Insulin regular 100 IU/mL suspension for injection in vial	Arabic+ English	2164	61.7	7.5	12	8.8

(continued)

Table 1. (continued)

Product Identification	Product and Strength	Language	Number of Words	Flesch Reading Ease score ^a	Flesch-Kincaid Grade Level ^b	Gunning-Fog Index ^c	SMOG Grading ^d
P32 (brand)	Insulin Aspart 100 U/ml solution for injection in prefilled pen	Arabic+ English	3379	59.4	8.3	13.2	10.1
P33 (brand)	Insulin Aspart 100 U/mL suspension for injection in prefilled pen	Arabic+ English	3600	60.4	8	13	10.3
P34 (brand)	Insulin Lispro solution and Insulin Lispro Protamine suspension (25% to 75%/50% to 50%)	English	2616	25.4	13.9	16.3	12.3
P35 (brand)	<ul style="list-style-type: none"> 300 IU of Isophane Insulin suspension 300 IU of biphasic Isophane Insulin-30% Soluble Insulin/70% Isophane Insulin suspension 300 IU Soluble Insulin solution 	English	2665	30.4	12	16.7	12.6
P36 (brand)	Insulin regular 100 IU/mL solution for injection in vial	Arabic+ English	2069	62	7.2	11.2	9
P37 (brand)	Liraglutide 6 mg/mL solution for injection in prefilled pen	English	6605	25	14.1	16.9	12.5
P38 (brand)	Insulin regular 100 IU/mL suspension for injection in vial	Arabic+ English	2163	60.5	7.8	11.8	9
P39 (brand)	Insulin Detemir 100 U/mL solution for injection in prefilled pen	Arabic+ English	3299	60.8	7.9	13.5	10.6
P40 (brand)	Pioglitazone (15/30/45) mg/tablet	Arabic+ English	3245	16	15.7	17	12.5
P41 (brand)	Glibenclamide 5 mg/tablet	Arabic+ English+ French	924	38	11	14.5	11.8
P42 (brand)	Insulin Aspart 100 U/mL solution for injection in vial	Arabic+ English	2771	56.5	8.7	13.1	10.1
P43 (brand)	Glimepiride and Metformin (2-500) mg/tablet	Arabic+ English	2830	47.1	10.8	14.5	11.1
P44 (brand)	Vildagliptin and Metformin HCL (50-500/50-850/50-1000) mg/tablet	Arabic+ English	8220	21.2	14.1	17.4	13.2
P45 (brand)	Glipizide 5 mg/tablet	Arabic+ English	805	12.2	16.4	17.8	13.3
Mean (± SD)			2,293.82 (±1533.83)	37.71 (±15.85)	10.96 (±2.67)	15.02 (±2.52)	11.41 (±1.60)

^aFRE Score: 0 to 30: Very difficult; 30 to 50: Difficult; 50 to 60: Fairly difficult; 60 to 70: Standard; 70 to 80: Fairly easy; 80 to 90: Easy; 90 to 100: Very easy (Flesch²⁵).^bFlesch-Kincaid Grade Level: Rates text on a US school grade level. For example, a score of 8.0 means that an eighth grader can understand the document. For most documents, aim for a score of approximately 7.0 to 8.0 (Boulos⁴¹).^cGunning-Fog Index: The index estimates the years of formal education needed to understand the text on a first reading. A Fog Index of 12 requires the reading level of a US high school senior. The ideal score of a Gunning-Fog Index is 7 or 8. Anything above 12 is too hard for most people to read (Gunning²⁵).^dSMOG Grade: SMOG grade is the reading grade that a person must have reached if he is to fully understand the assessed text (McLaughlin²⁸).

different investigators) were verified and then removed such that only one version of each PIL was retained. This process resulted in a total of 45 PILs that were eligible for evaluation. All the PILs were approved for marketing and use in the state of Qatar by the Pharmacy and Drug Control under the Ministry of Public Health. However, PILs of any products that were approved but not currently available in the country were excluded from the study.

Readability and Comprehensibility Assessment

The most commonly used readability and comprehensibility formulas reported in the health care literature are the Flesch-Kincaid (57.42%), Flesch Reading Ease (FRE; 44.52%), SMOG (25.81%), Fry (11.61%), Gunning-Fog Index (10.32%), and Dale-Chall (2.58%) formulas.²² The Flesch-Kincaid and FRE formulas generally estimated lower reading grade levels than the Dale-Chall, Gunning-Fog Index, and SMOG formulas. However, the results of the FRE formula are reported as broad ranges above the eighth grade reading level (ie, some high school or high school to some college). Estimated reading grade levels using the Dale-Chall, Gunning-Fog Index, and SMOG formulas were generally similar, and they were higher than those from the Flesch-Kincaid and FRE formulas.²²⁻²⁴ Refer to the footnote in Table 1 for score interpretations for the various formulas.

The Flesch-Kincaid Grade Level formula is based on the number of words per sentence (sentence length) and the number of syllables per word (word length). The formula is calculated as follows: $(0.39 \times \text{number of words/number of sentences}) + (11.8 \times \text{number of syllables/number of words}) - 15.59$. The SMOG Grading score is calculated by adding the numerical value 3 to the square root of the polysyllable word count of 30 sample sentences. The mathematical formula for calculating Gunning-Fog Index is multiplying the sum of the average sentence length and the percentage of complex words by 0.4.

Evaluation of Readability of Patient Information Leaflets for Antidiabetic Medications

Our descriptive analysis involved a readability evaluation of the English PILs or English text of multilingual PILs for all antidiabetic medications using the FRE score.²⁵ We used FRE for the evaluation of readability because it has an excellent track record within the health care literature with evidence of its validity and reliability.^{23,25} The formula for the FRE score is $206.835 - (1.015 \times \text{ASL}) - (84.6 \times \text{ASW})$, where ASL is the average sentence length (the number of words divided by the number of sentences) and ASW is the average number of syllables per word (the number of syllables divided by the number of words). This evaluation process was performed by 2 pharmacy experts and a consensus was achieved using the Delphi technique. We

adapted the Delphi technique as a method of building consensus between the 2 experts with 75% as the predefined acceptable level of agreement, as suggested by Keeney et al.²⁶

Evaluation of Comprehensibility of Patient Information Leaflets for Antidiabetic Medications

The comprehensibility of the PILs supplied with antidiabetic medications was evaluated with the most commonly used tools, including Flesch-Kincaid Grade Level,²⁷ SMOG Grading,²⁸ and Gunning-Fog Index.²⁹ The reliability and validity of these tools have been previously described in many studies that focused on their use in health-related areas.^{23,30} It is recommended to use more than one tool for the purpose of improving the reliability of the results.³¹ Similar to the readability assessment, we used the Delphi technique for evaluation of PIL comprehensibility.

Ethical Approval

Ethical approval was not mandatory for this study and hence it was not sought.

Statistical Analyses

Statistical analyses were performed using the IBM Statistical Package for Social Sciences (SPSS) program for Windows, Version 21 (IBM Corp, Armonk, NY). Descriptive statistics were mainly used for data analyses, and the results are presented as the mean, standard deviation, frequencies, and percentages.

Results

Characteristics of Patient Information Leaflets for Antidiabetic Medications in Qatar

A total of 45 PILs that accompanied 83 different product strengths and formulations were evaluated in this study. There were 32 (71.1%) PILs for brand-name products and 13 (28.9%) for generic products.

Nine (20%) of the PILs were available in English only; 8 (17.8%) were available in English, Arabic, and French; and 28 (62.2%) were presented in English and Arabic. The mean number of words contained in a PIL was 2293.82 ± 1533.83 (the minimum was 256 words for P4 [generic] and the maximum was 8220 words for P44 [brand]). The details are shown in Table 1.

Readability of Patient Information Leaflets for Antidiabetic Medications in Qatar

The readability scores of the PILs using the FRE formula are shown in Table 1. The mean FRE score was $37.71 \pm$

Table 2. Comparison of Readability and Comprehensibility Scores and Number of Words.

Parameter	Flesch Reading Ease Score	Flesch-Kincaid Grade Level	Gunning-Fog Index	SMOG Grading	Number of Words
Mean $\pm$ SD	37.71 $\pm$ 15.85	10.96 $\pm$ 2.67	15.02 $\pm$ 2.52	11.41 $\pm$ 1.6	2293.82 $\pm$ 1533.83
Minimum	12.2	7.2	9.6	8.4	256
Maximum	62	16.4	20.2	14.7	8220

Table 3. Comparison of Patient Information Leaflet of Generic and Brand Metformin.

Parameter	Mean $\pm$ SD		Minimum		Maximum	
	Generic (n = 5)	Brand (n = 5)	Generic (n = 5)	Brand (n = 5)	Generic (n = 5)	Brand (n = 5)
Number of words	1077.2 $\pm$ 676.82	1668.6 $\pm$ 106.04	507	1511	2123	1768
Flesch Reading Ease score	27.3 $\pm$ 8.64	38.5 $\pm$ 1.71	23.9	37.8	40.8	41.1
Flesch-Kincaid Grade Level	12.3 $\pm$ 2.44	9.26 $\pm$ 0.11	9	9.1	14.9	9.3
Gunning-Fog Index	15.06 $\pm$ 1.41	19.16 $\pm$ 2.16	13.7	15.3	17.4	20.2
SMOG grading	11.54 $\pm$ 0.72	13.96 $\pm$ 1.54	11.1	11.2	12.4	14.7

15.85. The readability scores ranged from 12.2 for brand P45 (Glipizide 5 mg tablets) to 62 for brand P36 (insulin human vial). This result indicates that P36 had the highest readability index among the available PILs. In general, the brand-name products tended to have higher FRE scores than the generic products (average FRE score: 43.51 for brands vs 23.42 for generics). The range of FRE scores for brand-name products was 12.2 to 62 versus 14.6 to 55.7 for generic products.

Comprehensibility of Patient Information Leaflets for Antidiabetic Medications in Qatar

The comprehensibility of the evaluated PILs using the Flesch-Kincaid Grade Level, Gunning-Fog Index, and SMOG Grading are shown in Table 1. The mean Flesch-Kincaid Grade Level score, Gunning-Fog Index, and SMOG Grading Index were 10.96 $\pm$ 2.67, 15.02 $\pm$ 2.52, and 11.41 $\pm$ 1.6, respectively. The outcome of the evaluation was fairly consistent; it implied that the evaluated PILs can be comprehended by individuals who completed at least the 11th grade, which exceeds the recommended reading level. The recommended comprehensibility for patient education materials is the fifth to sixth grade level.^{31,32}

For instance, brand P8 (Metformin HCl XR 500 mg tablet) received the maximum score in our evaluations in both the Gunning-Fog Index (score, 20.2) and the SMOG Grading Index (score, 14.7). These PILs are too difficult for most people to comprehend and can only be understood by university graduates. Consistently, brand P28 (Sitagliptin/Metformin hydrochloride tablet) had the minimum score based on our evaluations with both the Gunning-Fog Index (score, 9.6) and SMOG Index (score, 8.4); however, this score is still above the recommended level.

Table 2 provides a summary of the mean, minimum, and maximum readability and the comprehensibility scores of all products, as determined by various scales.

Evaluation of the Most Commonly Used Antidiabetic Medications

The PILs of the most commonly used antidiabetic medication (ie, metformin; n = 10, 50% brand-name products and 50% generics with different strengths and dosage forms) were selected to evaluate their number of words, readability and comprehensibility scores. This simple evaluation (Table 3) indicates huge variations, in terms of readability, comprehensibility, and layout, for the same molecule (ie, brand vs generic).

Discussion

The languages of the evaluated PILs for antidiabetic medications were largely available in bilingual (English and Arabic) and multilingual (English, Arabic and French) versions. Raynor et al reported that leaflet quality varied among countries, reflecting their regulatory context. Australian leaflets performed well across all quality criteria, while US leaflets had significant shortcomings with the omission of vital information for the safe and effective use of the medications.^{12,33} In another study, New Zealand leaflets demonstrated the highest compliance rate with standard criteria, while those from the United Kingdom exhibited the lowest compliance rate.^{12,33} For many leaflets, comprehensibility, readability, and other parameters did not meet the standard requirements.^{34,35} Poor readability and comprehensibility can affect the patient's understanding and, consequently, their medication adherence.^{36,37} Most available patient

information was not provided at an appropriate reading level to help patients understand diabetes, despite a need to involve patients in treatment decisions.³⁸

Literature that evaluates the readability and comprehensibility of antidiabetic medications is scarce. Some studies evaluating the quality of PILs have been conducted.^{39,40} However, most of these studies evaluated the layout, availability of illustrations, diagrams or pictograms, information relevant to the safe and appropriate use of medications, and so on. In the current study, the overall mean readability score of the PILs using the FRE formula (37.71 ± 15.85) was far below the standard criterion, and only one (2.2%) of the 45 evaluated PILs achieved an acceptable FRE score (in the range from 60 to 70). In a UK study that examined consumer information on diabetes mellitus, the maximum FRE score was 73,⁴¹ while the maximum FRE score in our studied leaflets was 62. Brand-name products tended to have higher FRE scores than their generic counterparts. In Croatia, diabetes-related information showed a mean FRE score of 41.7, indicating that 86% of these evaluated materials were too difficult for adult patients to read.⁴² The information provided to patients required literacy skills above the recommended level. In the United Kingdom, the information provided was complicated and not easily understood by patients; only 20% of adults with limited literacy could make use of this information.^{43,44}

The evaluated PILs can be comprehended by patients who completed the 11th grade and above, according to results from the Flesch-Kincaid Grade Level, Gunning-Fog Index, and SMOG Index. These results vary from the recommended grade level. An evaluation of diabetic education materials in Washington showed readability at the 10th grade level.⁴⁵ Although some PILs are easily read by well-educated adults, comprehension may be difficult for a significant portion of the adult population.⁴⁶ In the current study, the most comprehensible leaflet scored at a Flesch-Kincaid Grade Level of 7.2, while in a UK study, the most comprehensible leaflet received a 6.⁴¹ In Australia, written medicinal information scored an 8, as measured by the Flesch-Kincaid Grade Level. This score is considered fairly easy, enabling a patient-specific, tailored medicinal information approach.⁴⁷ Excellent readability and a high acceptance of patient education materials were observed in Jordan, where the materials were prepared based on cultural and social expectations and written at a 6th grade reading level.⁴⁸ An in-house diabetic informational material at the 6th grade level was better comprehended by patients than 9th and 11th grade materials, as documented by a study in Australia.⁴⁹ We used more than one formula for finding the school grade level required to comprehend the leaflets, including the SMOG Grading formula, which demonstrates consistent results, uses recent validation criteria, and is simple to use and hence is considered the most suitable formula for health care research.²²

There is a huge variation in the number of words in the PILs for the most commonly used antidiabetic medication (ie, metformin); this nonconformity indicates an obvious gap in PIL development, even for a specific drug with multiple generics. The usability and understandability of the PILs, as well as the patient's ability to recall the information, can be improved by employing a patient-centered approach and by reducing the number of words.⁵⁰⁻⁵² Policymakers and pharmaceutical manufacturers should consider the cultural and language requirements of patients when designing patient information materials. The development of appropriate patient information is a unique opportunity for practicing pharmacists to ensure the availability of tailored medicinal information to patients and to be a part of continuous quality management in their care setting.

The limitations of this study include the evaluation of only the English versions of the PILs (rather than any other available languages) and the use of US-based comprehensibility scores for some formulas. However, the US-based scoring systems might not be applicable to the diverse population in Qatar because of the availability of varied educational systems and affiliations. Therefore, future studies should seek to develop a different scoring system as well as analyze the PILs in other languages for their readability and comprehensibility.

Conclusion

Only 2.2% of the evaluated PILs had an acceptable FRE readability score of 60 to 70. All the evaluated PILs could be comprehended by an 11th grade student, which exceeds the recommended grade level for health-related materials. Approximately 20% of these PILs were available only in English, and hence they were not readable by most of the patients in Qatar, especially those with limited literacy skills. Based on this study, we recommend that regulatory authorities and policymakers set a range of acceptable scores for readability, comprehensibility, and the number of words based on a brand-name product so that the patient receives a uniform PIL that ensures the safety, efficacy, and quality of the medication.

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