

Prescription painkillers and controlled substances: an appraisal of drug information provided by six US pharmacies

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Background: Health literacy impacts health outcomes. Health literacy is a measure of a person's competence to find, access, contextualize, and understand the information needed to make health decisions. Low levels of health literacy have been associated with poor health status. Health literacy can be enhanced by improving the readability of health literature. Misuse and abuse of prescription medicines and controlled substances is rising. It could be argued that improving the readability of the drug-information documents associated with these medicines could serve to alleviate this situation in a small, albeit incremental, manner. This paper provides a readability assessment of 71 such documents.

Methods: The readability of drug-information documents associated with 12 commonly mis-used and abused painkiller medicines and controlled substances published by the top six US pharmacies was assessed. The Flesch-Kincaid Grade Level, Flesch Reading Ease, and Simple Measure of Gobbledygook (SMOG) indices were used to assess the readability of these drug-information documents. One-way analysis of variance (ANOVA) was used to compare the readability of the documents.

Results: The average Flesch-Kincaid Grade Level index score was found to be 11.16. The average Flesch Reading Ease index score was found to be 45.94. The average SMOG index score was found to be 13.60. Pharmacies C and E had the best average readability scores, whereas pharmacies A and B had the worst average readability scores.

Conclusion: Access, contents, and formatting of the documents were qualitatively analyzed to make recommendations to improve readability. Pharmacies C and E were used as benchmarks to identify the seven best practices. Good drug-information documents should have: (1) clear purpose, (2) limited scope, (3) summary/brief review, (4) well-placed graphics, (5) informative illustrations, (6) clean layout and lucid formatting relevant to the media, and (7) focus on the intended users.

Keywords: painkillers, analgesics, sedatives, stimulants, antispasmodics, readability, drug-information documents, Flesch-Kincaid Grade Level, Flesch Reading Ease, SMOG

Introduction

Health literacy can be described as an individual's capacity to access, process, and understand basic health information and obtain services needed to make sound health-related choices.¹ One in every three patients in the United States has basic or below-basic health literacy.² A person with low health literacy could have problems with tasks such as filling out forms, finding providers, and understanding the specifics of medication.³ Low health literacy could in turn lead to ineffectiveness in health care delivery. Naidu⁴ showed that low health literacy is related to low health status. Lauder et al⁵ and Osborn et al⁶ found that low health literacy had a strong relationship with poor health outcomes. Badarudeen and Sabharwal⁷ presented the importance and relevance of health

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literacy as the single best predictor of an individual's health. Williams et al⁸ explicated the improvement in health literacy that could be achieved by making patient education materials published for public consumption more readable. However, the National Assessment of Adult Literacy⁹ identified a large section of the society that lacked proficiency in prosodic, documentary, and qualitative interpretive skills. Furthermore, Davis et al¹⁰ identified the average reading ability in the United States as being at the eighth-grade level. This study assessed the readability of drug-information documents associated with painkiller medicines and controlled substances published by top US pharmacies, thereby highlighting the need to improve patient health literacy.

Readability health care literature for the general public

Hendrickson et al¹¹ found that many pediatric oral health pamphlets or brochures were not well suited for their target patient population. They assessed their readability in terms of the Flesch-Kincaid Grade Level, Flesch Reading Ease, and Simple Measure of Gobbledygook (SMOG) indices. Nicoll and Harrison¹² compared the readability of health-related documents with English national newspapers. They, too, found that these documents were not at a desirable readability level. Oates and Oates¹³ highlighted the need to focus on the target audience in crafting health-related documents by using the Flesch-Kincaid Grade Level and Flesch Reading Ease indices. Murphy et al¹⁴ and Wong¹⁵ emphasized the need to assess the readability of health literature to maximize their effectiveness. Amini et al¹⁶ and Grossman et al,¹⁷ in their respective studies, concluded that dental care and oncology-related documents they assessed were above the recommended sixth-grade level. Clauson et al¹⁸ also found that documents associated with dietary supplements were higher than the desired sixth-grade reading level. Collins et al¹⁹ and Osborne and Hochhauser²⁰ found that documents related to the US Health Information Portability and Accountability Act regulations and advance directives were at an eighth-grade readability level or higher. All these studies, thus, indicated that health care-related materials were not as readable as desired. Furthermore, it can be inferred that a large number of health-related materials do not cater to the reading and literacy skills of their target audience.

The following sections present a brief overview of the misuse and abuse of prescription painkiller medicines and controlled substances, the study's research questions, and its

data-collection methodology. The section on data analysis presents both its methodology and results. The discussion describes the drug-information documents published by the pharmacies included in the study. The conclusion section presents the lessons learned from this study and provides recommendations for future research.

Prescription painkiller medicines and controlled substances

Prescription painkiller medicine and controlled substance abuse and misuse can prove deadly. In the context of this study, misuse is defined as usage of a drug by a person other than the one who originally got the prescription. Abuse is defined as usage of a drug in a manner or for a purpose other than that originally prescribed. In 2008, over 36,000 people died from overdosing, primarily on prescription drugs.²¹ In other words, 100 people in the USA died from drug overdoses every day that year.²¹ This trend has been growing at an alarming rate. In fact, drug overdose death rates in the USA have more than tripled since 1990.²² Furthermore, the abuse and misuse of prescription painkillers and controlled substances was responsible for nearly 1.2 million emergency room visits, an increase of 98.4% since 2004.²¹ In 2010 more than 12 million people reported using prescription painkillers without a prescription, and for reasons not related to their health conditions.²³ It was reported that the largest group (~55%) among these users obtained painkiller medicines from a relative or a friend.²³ The second largest group (~18%) obtained prescriptions for the painkiller medicines directly from their health care providers.²³ It can be argued that health literacy has a role to play in improving this situation. The drug information that accompanies the painkiller medicines and controlled substances can be used to inform and educate potential abusers.

Drug information included in this study

The CDC²⁴ listed the 12 prescription painkiller medicines and controlled substances that are most commonly misused and abused: Adderall®, Adderall XR®, Ativan®, Concerta®, Duragesic®, Fentora®, OxyContin®, Percocet®, Ritalin®, Valium®, Vicodin®, and Xanax®. Hence, these drugs were made the focus of this study. The six pharmacies selected for this study accounted for an estimated 67% of US prescription revenue in 2011.²⁵ In other words, these six pharmacies could be termed the top six in terms of their revenue. It can be argued that drug-information documents published

by these pharmacies would most commonly accompany the 12 prescription painkiller medicines and controlled substances. Thus, it is pertinent to assess the readability of these documents.

Research questions

The readability of prescription drug-information documents published by the leading US pharmacies has not been adequately assessed. In order to address this gap, this research study tried to answer the following research questions:

1. What are the average Flesch-Kincaid Grade Level, Flesch Reading Ease, and SMOG index scores of the drug-information documents associated with 12 selected painkiller medicines and controlled substances published by the top six US pharmacies?
2. Do the Flesch-Kincaid Grade Level, Flesch Reading Ease, and SMOG index scores of the drug-information documents associated with 12 selected painkiller medicines and controlled substances vary between the top six US pharmacies?

Data collection

The drug-information documents associated with each of the 12 selected painkiller medicines and controlled substances can be found on the websites of the six pharmacies. It must be noted that the anonymity of the six pharmacies included in this study has been maintained by replacing their names with the letters A, B, C, D, E, and F. Of these six pharmacies, three were chain drugstores, two were supermarkets with drugstores, and one was a mail-order drugstore. Information for each drug can be looked up by searching for the name of drug in the drug-information section of the pharmacies' websites. This information is made available to the general public free of charge, with no login or password required. The drug information was searched on January 03, 2013. No information about Concerta® was found on Pharmacy C's website. Information about other drugs was found for each of the six pharmacies. Hence, a total of 71 documents were processed. The texts of these documents were then processed using Readability Studio™ software (version 2012.0.1) by Oleander Software (Dayton, OH, USA), to calculate the Flesch-Kincaid Grade Level, Flesch Reading Ease, and SMOG index scores in accordance with the recommendations from National Institutes of Health at the US Department of Health and Human Services.²⁶ No changes were made to the contents/text of the documents. However, implausible sentence fragments were realigned

by removing extra line breaks and/or white space before calculation of the readability scores.

Data analysis

Data analysis involved performing a descriptive analysis of readability scores to answer research question 1. One-way analysis of variance (ANOVA) was employed to address research question 2.

Flesch-Kincaid Grade Level and Flesch Reading Ease indices

The Flesch-Kincaid Grade Level and Flesch Reading Ease indices are most commonly used to assess readability.²⁷ The Flesch-Kincaid Grade Level index rates text in terms of US school grade levels. The Flesch Reading Ease index rates text on a 100-point scale. A higher Flesch Reading Ease score signifies that the document assessed is easier to understand. The Flesch-Kincaid Grade Level score²⁸ is given by

$$(0.39 \times \alpha) + (11.80 \times \beta) - 15.59, \quad (1)$$

and the Flesch Reading Ease score²⁸ is given by

$$206.835 - (1.015 \times \alpha) - (84.60 \times \beta). \quad (2)$$

In these formulae, α denotes the number of words divided by the number of sentences, and β denotes the number of syllables divided by the number of words. The results of the descriptive analyses associated with these indices are presented in Table 1. The mean Flesch-Kincaid Grade Level

Table 1 Descriptive analysis of the readability scores of 71 drug-information documents associated with 12 selected painkiller medicines and controlled substances published by the top six US pharmacies

	Flesch-Kincaid Grade Level index	Flesch Reading Ease index	SMOG index
Count	71	71	71
Average	11.16	45.94	13.60
Standard deviation	1.69	7.81	1.18
Coeff of variation	0.15	0.17	0.09
Minimum	7.80	34.00	11.30
Maximum	15.30	65.00	16.30
Range	7.50	31.00	5.00
Std skewness	-0.45	1.63	0.71
Std kurtosis	-0.72	-0.91	-0.84

Abbreviations: SMOG, Simple Measure of Gobbledygook; coeff, coefficient; std, standard.

score for the 71 documents assessed was 11.16 (standard deviation 1.69, range 7.50). The Flesch Reading Ease score for the 71 documents was 45.94 (standard deviation 7.81, range 31.00).

SMOG

The SMOG index approximates the number of years of education needed to fully understand a document.²⁹ It is widely used, particularly for checking health care-related documents. The SMOG grade level index score is given by

$$1.043\sqrt{p_s \times \left(\frac{30}{s}\right)} + 3.1291, \quad (3)$$

where p_s is number of polysyllables (words with three or more syllables) in a sample of 30 sentences and s is the total number of sentences.³⁰ The results of the descriptive analysis associated with SMOG indices are presented in Table 1. It was found that the mean SMOG index score for the 71 documents assessed was 13.60 (standard deviation 1.18, range 5.00).

The standardized skewness and standardized kurtosis values calculated for the 71 documents were either less than or equal to +2, or were more than or equal to -2. This finding provided evidence that the data were normally distributed. The normal distribution of the data was also confirmed by the probability plots shown in Figure 1. One-way ANOVA could therefore be applied to the data.

One-way ANOVA

The one-way ANOVA technique helps determine the impact of a single categorical independent factor on a dependent variable. The technique tests whether or not there are significant differences between the means and variances of the dependent variable at the different levels of the categorical independent factor. For this research study, pharmacies were represented by different levels of the independent categorical variable. The readability scores formed the dependent variables. It was found that for the Flesch-Kincaid Grade Level index, the F-ratio was 46.97, with a P -value of <0.01 . For the Flesch Reading

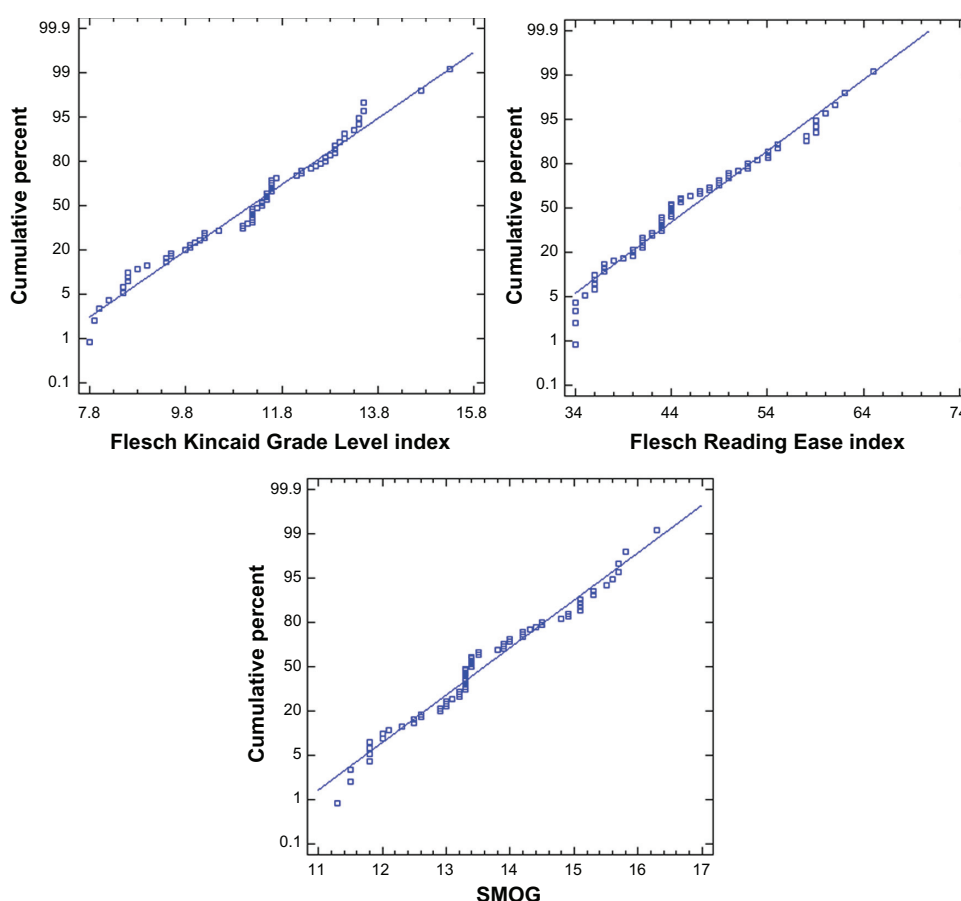


Figure 1 Normal probability plots of the readability scores of 71 drug-information documents associated with 12 selected painkiller medicines and controlled substances published by the top six US pharmacies.

Abbreviation: SMOG, Simple Measure of Gobbledygook.

Ease index, the F-ratio was 31.81, with a *P*-value of <0.01 . For the SMOG index, the F-ratio was 43.01, with a *P*-value of <0.01 . Thus, it can be concluded that there was a statistically significant difference between the mean of the readability scores of the six pharmacies at the 95.0% confidence level. In order to further explore the difference in the readability scores, multiple-range tests were performed using Fisher's least significant difference procedure at the 95.0% confidence level. The results are shown in Table 2. An asterisk placed next to a pair of pharmacies indicates that the pair shows statistically significant difference at the 95.0% confidence level. The differences in the readability score levels for all six pharmacies are shown in Figure 2.

The results of the one-way ANOVA showed that pharmacies C and E had significantly better scores, compared to the other pharmacies. Further, pharmacies A and B had the poorest readability scores among the pharmacies included in this study. For pharmacy C, the mean Flesch-Kincaid index score was 9.19, the mean Flesch Reading Ease index score was 55.50, and the mean SMOG index score was 12.40. For pharmacy E, the mean Flesch-Kincaid score was 9.23, mean Flesch Reading Ease score was 54.08, and the mean SMOG score was 12.49. For pharmacy A, the mean Flesch-Kincaid score was 12.97, the mean Flesch Reading Ease score was 42.5, and the mean SMOG score was 15.15. For pharmacy B, the mean Flesch-Kincaid score was 12.60, the mean Flesch

Reading Ease score was 37.90, and the mean SMOG score was 14.70. For pharmacy D, the mean Flesch-Kincaid score was 11.56, the mean Flesch Reading Ease score was 42.41, and the mean SMOG score was 13.43. For pharmacy F, the mean Flesch-Kincaid score was 11.53, the mean Flesch Reading Ease score was 42.58, and the mean SMOG score was 13.50.

Discussion

This section describes the drug-information documents published by the six pharmacies included in this study.

Since none of the documents contained adequate information about the possible additive effects of the drugs, it would be pertinent to the goal of improving such documents to add information addressing the additive and narcotic effects of the drugs in the drug-information documents.

Pharmacy A

Documents from this pharmacy included generic and brand names of a specific drug, along with the drug class, available strengths, and chemical ingredients. The document included a photograph of the drug, the available forms, and the name of the manufacturer. Information about proper use, and what to do if a dose was missed, was included in the documents. Other sections included information about interactions with common substances and other drugs. Information about side effects and proper storage was provided. A section of the documents addressed use before, during, and after pregnancy. The documents also included information about preexisting conditions a health care provider should know about before prescribing the medication.

Pharmacy B

Documents from this pharmacy contained sections dealing with considerations before using a specific drug, common and proper use of the drug, specific cautionary information, possible side effects, what to do in case of overdose, and where to find additional information. A photograph, chemical ingredients, and manufacturer information was also provided.

Pharmacy C

Documents from this pharmacy started by listing chemical ingredients and other descriptions of a specific drug, including the conditions it could treat. Other sections addressed what should be disclosed to the health care provider before taking the drug, how to properly use the drug, what to do were a

Table 2 Multiple-range test for one-way analysis of variance (ANOVA)

Between pharmacies	Significant difference between Flesch-Kincaid Grade Level index scores	Significant difference between Flesch Reading Ease index scores	Significant difference between SMOG index scores
A-B		*	
A-C	*	*	*
A-D	*		*
A-E	*	*	*
A-F	*		*
B-C	*	*	*
B-D	*	*	*
B-E	*	*	*
B-F	*	*	*
C-D	*	*	*
C-E			
C-F	*	*	*
D-E	*	*	*
D-F			
E-F	*	*	*

Note: *Statistically significant difference ($P = 0.05$) at the 95.0% confidence level, between the pair of pharmacies.

Abbreviation: SMOG, Simple Measure of Gobbledygook.

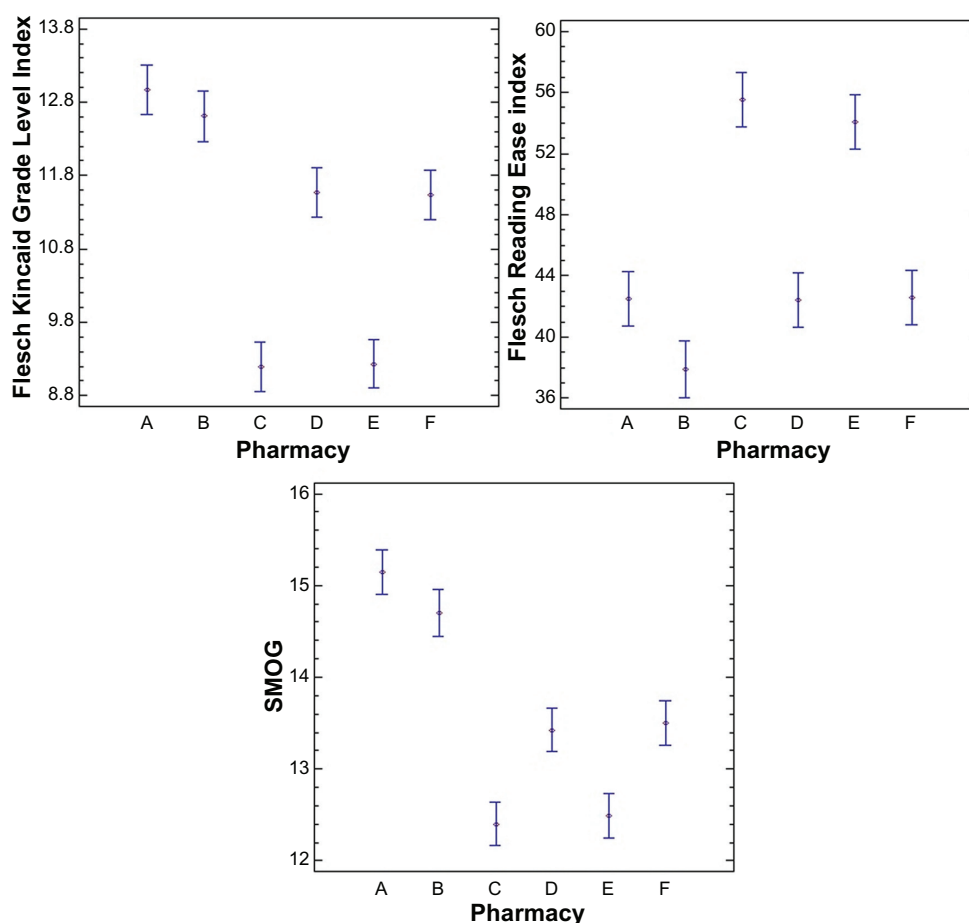


Figure 2 Readability score levels for the six US pharmacies.

dose missed, what the drug interacted with, what the possible side effects could be, how to monitor effects the drug had on the body, and where to store the drug.

Pharmacy D

Documents from this pharmacy included the following sections: side effects, precautions, drug interactions, overdose, missed dose, and storage. Other parts of the documents provided information about common brand names and proper usage.

Pharmacy E

Documents from this pharmacy started by providing a description of the specific drug. This was followed by information about prerequisite disclosures that should be made to the health care provider. The documents also contained information about how to properly use the drug, what to do were a dose missed, and what the drug interacted with. Information about possible side effects was included in the documents. Furthermore, a section of the documents also addressed proper and legal possession the drugs.

Pharmacy F

Documents from this pharmacy had the following sections: drug description, common and proper use, warnings and precautions, side effects, overdose, missed dose, drug interactions, and storage.

Conclusion

The mean ratings of the Flesch-Kincaid Grade Level index and the SMOG index indicated that the documents assessed were readable by people with an eleventh-grade educational level or higher. The mean ratings of the Flesch Reading Ease index showed that the documents accessed were difficult to read. These findings are consistent with findings of the other studies described earlier in this paper. Wilson,³¹ Kasabwala et al,³² and Wilson³³ held that the average American read at an eighth- or ninth-grade level. Furthermore, Badarudeen and Sabharwal⁷ reported that several health care organizations had recommended that the readability of patient education materials be no higher than the sixth- to eighth- grade level. Hence, it could be concluded that the readability of the documents assessed was not

adequate, and needed to be improved. It must also be noted that the standard deviation for all three indices was relatively low. This could be attributed to the consistency with which the documents were drafted. Furthermore, the pharmacies included in this study had outsourced the creation of their drug-information documents to specialized third parties.

The topics covered by the documents were very similar. However, pharmacies C and E provided the most-readable information. It seemed that the information contained in their documents had a logical flow. Furthermore, it was easier to search for the information on these pharmacies' websites. Other features of the documents from pharmacies C and E included the following: printer friendly versions, all information included on a single webpage, and recent or frequent updates. Supplementary to improving the overall readability, best practices were identified based on qualitative review of the drug-information documents included in this study. Good drug-information documents should have: (1) a clear purpose, (2) limited scope, (3) a summary/brief review, (4) well-placed graphics, (5) informative illustrations, (6) clean layout and lucid formatting relevant to the medium, and (7) a focus on the intended users. Additional guidelines to improve the quality of the health literature have been provided by National Institutes of Health,²⁶ Doak et al,³⁴ Reinhard et al,³⁵ and McKinney and Kurtz-Rossi.³⁶ Gill et al³⁷ provided an incremental improvement-process cycle and a list of dos and don'ts to improve the readability of medical literature geared towards the general public. Well written, effectively formatted, and easily found documents are easier to read and understand. It can be argued that by providing good quality, readable information to patients, the misuse and abuse of prescription painkillers and controlled substances could be curtailed, albeit to varying extents. Future experimental studies could help verify this hypothesis. Future studies could also verify the results of this study by assessing the readability of painkiller or controlled substances drug-information documents from other organizations and agencies. If poor readability is found to be widespread, concerted efforts need to be made in order to make these documents more usable, which in turn could improve public health literacy.

Disclosure

The author reports no conflicts of interest in this work.

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