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Evaluation of health literacy and the readability of information leaflets

ABSTRACT

The proper use of information leaflets for medications depends, among other factors, on its readability and on users' literacy, i.e. the ability to clearly identify letters, words and sentences and the ability to understand and use that information. The study purpose was to investigate the possible relationship between a measure of functional health literacy and the readability of a leaflet for a non-steroidal anti-inflammatory medicine, the later assessed by the appropriate European guideline. In a sample of 53 urban participants, recruited in 2010 from a pharmacy in Lisboa (Portugal) and with varying literacy, statistical analysis found no relationship between the level of literacy and the various parameters to assess the quality and readability of an information leaflet.

DESCRIPTORS: Package Inserts for the Patient, Medicine Package Inserts, Health Literacy, SAHLSA-50, Readability, Consumer Health Information.

INTRODUCTION

The basic skills of reading, writing and numeracy are especially important in the context of health, in which the participation of the patient in the planning and implementation of the treatment is critical for its success.⁶ According to the Institute of Medicine (IOM), health literacy is the "degree of individual capacity to obtain, process, and understand basic health information and services, needed to make appropriate health decisions".⁶ A limited health literacy is the biggest obstacle for efficient understanding of information about the disease and the treatment.⁷

In 2006, Lee et al³ developed an instrument of rapid administration (3-6 minutes) to assess functional health literacy of the Latino population in the United States, the Short Assessment of Health Literacy for Spanish-Speaking Adults (SAHLSA). SAHLSA comprises a list of 50 medical terms that the individual must read and identify; a performance of less than 37 correct answers indicates an inadequate level of health literacy.³

Most of the information provided to the patient, both verbal and written, is usually presented in a complex way.⁴ In the United States, the National Work Group on Literacy and Health recommended health materials to be written at a 5th grade readability level, but recognized that this level is still too difficult for about 25% of the North American population.⁴

One of the most important written materials that users receive about the use of drugs is the respective package leaflet (PL).² All medicinal products placed on the Community market in the European Union are required to be accompanied by labeling and package leaflet, which must provide a set of comprehensible information enabling the use of the medicinal product safely and appropriately, complementing the information provided by health professionals. Although it

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has not yet been possible to demonstrate that the PLs lead to an improvement in attitudes and behaviors of patients, their inclusion seems to increase knowledge.⁵ In fact, Directive 2001/83/EC^a requires, among other requisites, the PL be written and designed to be clear, legible and understandable in the official language or languages of the Member States, in which the product will be marketed. The European Medicines Agency issued a directive in 2009 providing indications of readability, i.e., on how to present the content of labelling and the PL.¹ These indications include questions regarding the satisfaction with the graphic print, easy reading and understanding of the text, especially the presentation of technical terms. Questions should be placed unambiguously and correctly assessing potential difficulties of patients.

The objective of this exploratory study was to identify a possible relationship between the European Guideline on the readability of the labelling and package leaflet of medicinal products for human use and the level of health literacy assessed by SALHSA-50.

METHODS

Given the exploratory nature of this observational and cross-sectional study, a convenience sample was used. These patients were selected among the population who used a community pharmacy in an urban area, as long as they were older than 18 years and did not present difficulties in reading and writing the Portuguese language.

In Portugal, the community pharmacy is the place where all outpatients get their medications, including those not subjected to medical prescription, health products and cosmetics. They are private enterprises from which customers generally receive a reimbursement or subsidy in the price of prescription drugs given by the Portuguese Government.

All customers who requested diclofenac 12,5mg for their own use, in tablets or soft capsules, marketed as Voltaren 12,5®, in a pharmacy located in the region of Lisbon in October 2010 were invited to participate in the study, after information consent and voluntary acceptance.⁸ Among all customers who required the product in question during the study period, only two refused to participate, due to lack of time. This anti-inflammatory was chosen because it is a drug of widespread consumption, for frequent symptoms (it is an analgesic, anti-inflammatory and antipyretic agent), its administration is done orally with well known contraindications, interactions and side effects. Among the most important precautions stand out allergy or hypersensitivity to non-steroidal anti-inflammatory drugs (breathing difficulties, skin rash,

oedema) or when there are gastrointestinal problems (stomach ulcer or bleeding). The patient should not take Voltaren if he is taking other anti-inflammatory drugs, such as aspirin at low doses. Moreover, in September 2008, it went from prescription-only-medicine to over-the-counter medication in Portugal.

The selected participants were directed to the pharmacy's private service room for a short interview. A translated SAHLSA-50 was administered,³ which aimed to assess participants' literacy, as well as a questionnaire proposed by the European directive, in which satisfaction was assessed by means of a Likert scale with 16 parameters of readability (1 – completely dissatisfied/bad to 5 – totally satisfied/good, and 3 – neutral/no opinion).¹ According to the directive, the test must include at least 20 potential users, excluding health professionals and including preferably seniors and people with limited comprehension. There was no intention of statistical significance per representation. Parameters or ordinal variables, assessed with the Likert scale were as follows:

- Font size
- Font
- Presentation of the section titles
- Print color
- Icons (dashes) used to display lists
- Language simplicity
- Size of phrases
- Size of paragraphs
- Way adverse effects are organized
- Simplicity of medical terms
- Way of giving instructions to the patient
- Use of abbreviations
- Repetition of brand name
- Paper thickness
- Paper color
- Paper brightness

Participants were divided into three educational groups: (1) basic education (from first to sixth grade), (2) secondary (from 7th to 12th grade) and (3) higher (frequency or completion of a degree or equivalent). They were also categorized into active (1) or inactive

^a Parlamento Europeu; Conselho da União Europeia. Directiva 2004/27/CE. Altera a Directiva 2001/83/CE que estabelece um código comunitário relativo aos medicamentos para uso humano [cited 2012 Jul 14]. Available from: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_pt.pdf

workers (0), the latter including students, unemployed or retired.

The statistical analysis was performed with SPSS v17, with a significance level of $p < 0.05$. As a measure of central tendency the median and the mean were used, and as dispersion, the standard deviation (sd). Nonparametric tests were used for comparing results between subpopulations (Mann-Whitney U and Kruskal Wallis' chi-square), given the little dimension and the distribution of the sample population. In some results, the SAHLSA-50 is presented in a binary form, with value of 0 for participants with inadequate literacy (lower than the cutoff, 37) and 1 when adequate. Data were collected anonymously and confidentially, and the study was approved by the Research Ethics Committee of the Faculty of Pharmacy within Universidade de Lisboa.

RESULTS

In total, 53 users participated in the study, 31 (58.5%) being female. Median age was 51 years (minimum 18 and maximum 81 years). Around 40% of participants reported higher education. As for employment status, 35.8% belonged to the "inactive" group.

Approximately 80% of the sample (42 participants) had adequate health literacy (SAHLSA-50 score > 37). All 11 users with inadequate level of literacy were female. Women had a median of 43, statistically lower to men ($U = 222.0, p = 0.002$). There were no statistical associations between the values of SAHLSA-50 and the age groups, but between the education levels ($K-W X^2 = 9.6, p = 0.008$), especially between basic and higher education. The median value of SALHSA-50 for the inactive was also significantly lower than that for the active ($U = 179.0; p = 0.07$).

The Figure illustrates the mean satisfaction values obtained for each readability parameter under study. The total mean value was 3.48 (sd 0.69).

The majority of parameters showed a mean value above the neutral position and close to satisfactory. Parameters that had means significantly lower compared to the majority were font size, simplicity of use of medical terms and abbreviations.

No differences were found for mean values of each parameter according to sex, but for the parameters related to paper quality (color, brightness and thickness) between

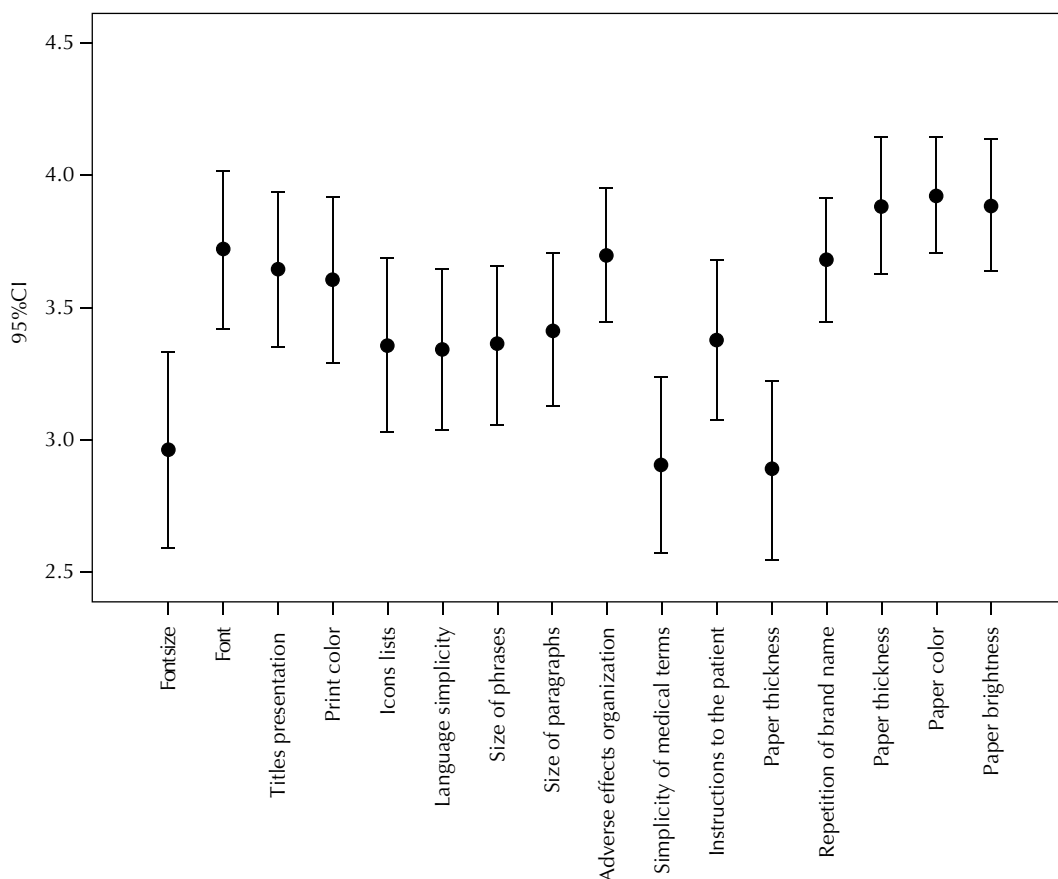


Figure. Distribution of readability results for the information leaflet, Lisbon, Portugal, 2010.

the three age groups, with less favorable opinions in the younger group. Regarding education, it was significant differences in the appreciation of the font type (between people of secondary and higher education, $p = 0.044$), with listings in bullet points, and in the color of the text (between basic and secondary education, respectively $p = 0.030$ and $p = 0.13$). There were no differences in satisfaction on any parameter between participants with inadequate and adequate literacy.

DISCUSSION

In this study, the total number of participants was above the number recommended by European guidelines of legibility ($n = 20$),¹ followed by a recommendation regarding the heterogeneity among potential users of the PL of the drug in analysis.

As expected, the health literacy test results are according to the education level of the participants (less education, lower literacy), as well as the status in relation to work (inactive, lower literacy). We may conclude that this sample, even without any sample power and statistical representation, seems not to suffer from significant bias regarding major cultural, social, and demographic variables.

Although presenting limitations in results extrapolation, this study suggests that not all the parameters proposed by the readability guideline will have the same relative importance. For instance, font size, lexical diversity and abbreviations can be critical points in reading, comprehension and use of the text. However, an interesting fact was that it was not possible to verify any differences or significant associations between health literacy and the different parameters of readability of the PL, in particular for those related to language. Therefore, it is questionable whether the readability test proposed by the guideline has adequate sensitivity and specificity to variations in literacy of potential users of the drug. Because there is no relationship between literacy and satisfaction with the

parameters of readability, one can assume that the method proposed by the guideline is independent of the level of schooling and education. Although this situation seems favorable in the construction of any PL, it is also clear that these parameters do not assess comprehension of the text, they only measure acceptance by the user. The independence between literacy and readability obtained in this study does not guarantee that in case of lower education and/or health literacy there is a comprehension and appropriate use of information written in the PL. The present study corroborates the disparities between the results of the tests of readability of the written materials and the results of health literacy of potential users of those leaflets.⁹

Although almost all of the recent studies are focused on the description of information gaps on the PL or in its low impact on changing the behavior of its users,² there seems to be no effective substitute for these pieces of written information, mandatory for drugs marketed in Europe. Thus, it would be appropriate to develop procedures for assessing readability that controlled the effect of variations in health literacy simultaneously, also performing an assessment of the acquisition of the knowledge acquired by reading the PL. After all, if the PL is still a key piece for the proper use of medications,^{2,9} legal guidelines should be improved to better meet the purpose of a safe and effective use of the therapeutic arsenal.

The main limitations of the study relate to the selection of participants and the small sample size, which limit its external validity. Thus, there was no control of bias associated with refusal to participate in the study, given that there was no intention of statistical significance. Additionally, there may have been problems in using a translated SALHSA-50. To ensure the best use of this instrument in the Portuguese population, it would be important to study potential changes, such as an increased number of terms, their modification or changes in the value of the cutoff point, in order to ensure its validity in this population.

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