Analyzing readability of medicines information material in Slovenia

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Abstract

Objective: Readability has been claimed to be an important factor for understanding texts describing health symptoms and medications. Such texts may be a factor which indirectly affects the health of the population. Despite the expertise of physicians, the readability of information sources may be important for acquiring essential treatment information. The aim of this study was to measure the readability level of medicines promotion material in Slovenia.

Methods: The Flesch readability formula was modified to comply with Slovene texts. On the basis of determining the Slovene readability algorithm, the readability ease related to the readability grade level of different Slovene texts was established. In order to estimate an adjustment of the texts to the recommended readability grade level of the targeted population, readability values of English texts were set. One sample t-test and standard deviations from the arithmetic mean values were used as statistical tests.

Results: The results of the research showed low readability scores of the Slovene texts. Difficult readability values were seen in different types of examined texts: in patient information leaflets, in the summaries of product characteristics, in promotional materials, while describing over-the-counter medications and in the materials for creating disease awareness. Especially low readability values were found within the texts belonging to promotional materials intended for the physicians. None of researched items, not even for the general public, were close to primary school grade readability levels and therefore could not be described as easily readable.

Conclusion: This study provides an understanding of the level of readability of selected Slovene medicines information material. It was concluded that health-related texts were not compliant with general public or with healthcare professional needs.

Keywords: Ease of readability, Flesch readability formula, readability algorithm, promotional drug texts, Slovenia

Introduction

Establishing readability or the readability grade level has been widely used in many countries. An appropriate level of readability is important in health and drugs texts, since understanding them may influence treatment decisions and potentially, patient outcomes. An inappropriate ease of readability has been globally recognized and in some developed countries the solutions have been suggested. The present study has aimed at contributing to the present knowledge and at exposing an established problem. Namely, English text studies related to the medications have often been published³⁴, however Slovene texts have just started to be analyzed.

Alongside many pharmaceutical companies, one generic drug producer has been present on the Slovenian market for some time; another pharmaceutical producer of generic drugs was also active, but was taken over by a larger international producer. The cost of the majority of prescription drugs is covered by health insurance schemes, when treatments comply with necessary prescription procedures and the patients have been paying their premiums regularly. The Slovenian pharmaceutical market has become increasingly competitive. Drug registration procedures have been largely facilitated by common European Union procedures, and some new drugs registered according to national and other procedures. Areas of responsibility of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia encompass protection of public health through regulation and supervision of medicinal products and medical devices, blood, tissues and cell cultures and related activities in the private and public sectors. Neither hospital drugs or over-the-counter (OTC) drugs usage have yet been systematically monitored. Rough estimates for total market value exceed 400 million Euros in Slovenia. Closer supervision of drug sales and related activities is supported by legislative provisions but promotional activities have not been sufficiently controlled. The advertising arbitration board has interceded in certain cases of allegedly inappropriate advertising for OTC drugs.
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Advertising, as a specific part of the promotion through mass media, has been regulated in Slovenia. According to the Drug and Medical Devices Advertising Rules, OTC medicines advertising is permitted in Slovenia, but prescription drug advertising to the general public has not been allowed.

As part of routine practice, in Slovenia, it is expected that the necessary instructions regarding prescription medications is provided by physicians and pharmacists. Patients should also be advised to carefully read Patient Information Leaflets (PILs). The authors have previously reported that analyzed PILs were too complex to be an appropriate source of information for consumers, hence emphasized that there was a need to improve communication. In Slovenia, prescription medications are dispensed following the advice of different healthcare professionals. On the other hand, when purchasing an OTC medicine, the pharmacy is the sole supplier of advice and proper written information on OTC medications such as PIL is warranted. The Summaries of Product Characteristics (SmPCs) have complied with professional public needs and official requirements.

Inadequate readability is related to a low level of literacy. Literacy has been increasingly recognized as a critical factor, affecting communication between the patient and the physician and therefore impacting on treatment outcomes. Williams et al. have shown a frequently low health literacy level, especially in elderly persons. An appropriate literacy of the general public has been identified as: knowing an alphabet, an ability of fast and easy reading, a vocabulary and understanding, defined as deriving a meaning from a text, as described in the health literacy study. Rudd et al. found that increasing professional and a public health literacy awareness is important. In their study, education of medicine students and of the physicians and an improved communication ability between the patients and the physicians were emphasized. In PISA study, good reading skills have been related to an improved innovativeness.

According to Schutten and McFarland, readability has been referred to an ease with which a text can be read and understood. If an individual reading skill is significantly below that of the readability level of the document, then it is reasonable to assume that the individual is not able to fully understand the text. Readability formulas are tools that have often been used for determining the readability of text; as the ease of understand text by the average reader can be estimated. Usability of a readability formula has been described to enable easy understanding of the documentation. The patient health education can also be improved on the basis of readability formulas. The readability ease formula by Flesch and the Flesch-Kincaid readability grade level formula have often been used very often.

Pelcher et al. noted that many patients seem to retrieve information from searches on the Wikipedia. The average readability grade level of websites which included 50 most common prescribed medications in the USA amounted 15.4, therefore well above the high school grade level. Within the English algorithm the material posted on these websites can be described as difficult to read. Pelcher et al. concluded that these articles were not aiming at educating patients. An adjusted readability ease of health and medication promotional texts was recognized as an important factor for the comprehensibility of a dose regime. Improving the readability and understanding the texts can facilitate the communication between the physicians and the patients and also patient understanding. Creating easily understandable health information is particularly important for the persons with reading or comprehension difficulties. The readability within the 4th and the 6th grade level range can lead to the required level of comprehension. This range coincided with a readability ease description of ‘very easy’.

Appropriate readability does not always translate into ease of comprehension. Even the texts with a low readability grade can be difficult to understand, when organization, layout and design have not been considered. Pelcher et al. found that simplification has not always equated to better readability. Therefore simplification of the wording alone has not been sufficient for increasing the comprehension; keeping the cohesion of a text has also been essential.

This study was designed by assuming that there is a problem with regards to inappropriate readability in Slovenia. The readability formulas were used to measure the readability ease. The present research has been set out to explore the following hypotheses.

H1: Health-related texts are not adjusted to the targeted public.

According to the present knowledge, readability levels in English texts are not compliant with those advised, and a similar situation is assumed for Slovene texts.

H2: Medication risks are less readable than the benefits of the promoted medicines.

Benefits are assumed to be better and the risks less accentuated, due to the tendency of pharmaceutical companies to promote demand and play down the importance of perceived risks.

H3: Readability values of patient information leaflets, creating disease awareness materials and OTC promoting materials, all belonging to the group for the general public, are predicted to be higher than readability values of the materials, intended for the scientific public, encompassing summaries of product characteristics and the materials for promoting to physicians.

The texts for health professionals should be easily readable to facilitate transferring the message to the patients and in-order to be less time-consuming for the health professional. The ease of readability was assumed to differ according to the type of analyzed material. Final readability standards can be determined after testing established readability values. We find establishing readability levels important, since poor readability of medication texts is predicted to be related to potentially improper behaviour, coincided with unexpected treatment results and adverse events. However, this can only be confirmed by further research results. Hence, the aim of this study was to measure the readability level of medicines information material in Slovenia.
Methodology

Slovene readability values were determined in accordance with the Flesch method. An algorithm was validated by applying it to two daily newspapers. The sample and statistical methods are described in this section.

Readability formulas and algorithms

Readability formulas have been used to determine a readability ease and a readability grade level for the average reader in order that level of understanding of the text could be estimated.

The Flesch formula involves the following calculation:\textsuperscript{18}

\[ \text{Readability ease} = \frac{206.835}{1 + \frac{0.39 \times \text{Average sentence length}}{1 + \frac{11.8 \times \text{Average number of syllables per word}}{\text{Number of words/Number of sentences}}} - 15.59} \]

The Flesch and Kincaid established a year of education, complying with understanding a text:\textsuperscript{18}

\[ \text{Readability grade level} = \frac{50 - 60}{\text{Easy}} + \frac{40 - 49}{\text{Standard}} + \frac{< 39}{\text{Difficult}} \]

A Slovene readability algorithm was identified and served as a standard. It was introduced due to a difference in both language syntaxes and in scholarly systems. Text samples were collected from the textbooks for the first, the third, the fifth, the seventh and ninth graders. Further samples were extracted from the textbooks for the first, the third graders of the high school and the university, respectively. The sample from the literature for the university graduates was also taken\textsuperscript{20}. The values were obtained by the established Flesch formula. A regression analysis was then performed to acquire new values within the Slovene algorithm (Table 1) and a new formula was derived:

\[ \text{Readability ease} = \frac{206.835}{1 + \frac{0.306 \times \text{Number of words/Number of sentences}}{1 + \frac{83.585 \times \text{Number of syllables/Number of words}}{\text{Number of words/Number of sentences}}} - 15.59} \]

The readability ease of two newspapers was determined to validate the Slovene readability algorithm. Finance has been termed as a financial daily newspaper with economic analyses. Everyday news have been encompassed in daily newspaper Slovenske novice.

Sample: text for analysis

A sample of examined materials was based on the larger sample with 1,474 materials and 10,396 products for the treatment or for the care, as it is described below. This original sample included materials describing OTC medicines, publications, materials with nutritional supplements, materials with cosmetic products, materials packaged with medical devices, materials for creating disease awareness, educational materials, materials with social marketing messages, materials not complying with advertising for the general public and other materials.

In Table 2 please see corresponding shares of material groups, used for a part of the present study, within an original sample.
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With t-test was small (p ≤ 0.01), this is evidence that the mean is different from the hypothesis value. When the p-value is not small (p > 0.01), the null hypothesis is not rejected. As test values, the readability ease of 45 was used at Slovene texts and 90 at English texts, as readability values relate to the recommended 4th to 6th grade level, corresponding to a very easy to an easy level. These values were used for the materials directed at the general public16, as well as for the materials directed at health professionals13, since low grade levels were advised also for the medical documentation. The deviations from arithmetic means were determined by the quotient between mean differences and test values. The calculations were made for Slovene and English texts.

Results

The results are presented according to the material type. The values have been presented textually and in the tables within four sub-sections. Statistical estimations have been included.

Readability of Patient Information Leaflets and Summaries of Product Characteristics

The results show (Table 3) that the Patient Information Leaflet (PIL) has greater readability than the Summary of Product Characteristics (SmPC), regardless of the language used. The readability of the Slovene PIL (10) as well as of the SmPC (-11) is described as difficult. Slovene texts were compared to the English ones. The English PIL, with a readability ease score of 34, was identified as difficult to read. The test of the English SmPC was marked as very confusing (-5). The content of SmPCs in both languages were highly comparable. A statistical t-test (p = 0.01) showed a non-significant difference between the Slovene PIL and the test value (45) and a non-significant difference related to the corresponding test values. Larger deviations of readability values from the arithmetic means were established for Slovene texts in comparison with English texts. This was the case for PILs (0.79 vs. 0.63 in absolute values), as well in the case of SmPCs (1.25 vs. 1.06).

Readability of promotional materials for osteoporosis treating drugs, intended for the professional public

Slovene and English texts were selected relating to osteoporosis treatments containing a combination of two active substances from a group of bisphosphonates in a combination. After analyzing these texts, grade levels which exceeded the graduates grade level, were established. The values appeared to be very low (Table 3). Even lower readability values were found in Slovene (-47), described as difficult, compared with English texts (-33) described as very confusing. A non-significant difference (t-test, p = 0.01) was attributed to English promotional materials for physicians, with the deviation 1.37 from the arithmetic mean.

Materials comprised of texts on medication products were identified. The texts were collected from a representative sample of Slovene pharmacies, as part of a previous study 21, 22. Material relating to OTC medicines and some disease awareness samples were obtained through systematically visiting the pharmacies, and every different material reviewed in all selected pharmacies. Twenty six Slovene pharmacies were visited, 19 public and 7 private ones. Three therapeutic OTC drug groups; for treating viral infection, allergies and osteoporosis were identified. The discussed osteoporosis treatment medication has contained a combination of two active substances from the bisphosphonates in combination group. There has been a rationale for selecting the materials from these therapeutic groups. The medications from the three groups mentioned were widely dispensed at Slovene pharmacies.

Thirty OTC drug promotional materials were collected, spread equally across the therapeutic groups. Six leaflets (materials) from the creating disease awareness group, related to three therapeutic groups in both languages, were evaluated. Other materials were collected in one sample each, in both languages in comparable texts. At sampling, the third paragraphs of every second page were analysed. As per Flesch’s criteria, each part of the text that was analysed had to include at least 100 words, or an addition of words to finish a particular sentence14. A part of the sample was derived from specific websites, mainly official websites of the manufacturers of targeted medicines. English versions were analyzed when the texts were comparable.

Statistical analysis

The intention was to compare the readability values and to estimate statistical significance, related to the test value. Statistical significance, determined by the one sample t–test was used, with a 99% confidence interval. A two-tailed statistical significance was attributed when the p-value was lower or equal to 0.01. T-test was performed when enough values were available to enable the calculations to be undertaken. The null hypothesis claimed that the population mean was equal to the specified value. For testing the null hypothesis, arithmetic means were compared to test values. When the p-value associated

Table 2. An original sample, as a source for the materials for analysis

<table>
<thead>
<tr>
<th>Original sample – materials</th>
<th>% of the materials in the sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials describing OTC medication</td>
<td>22.0 %</td>
</tr>
<tr>
<td>Publications (also containing OTC medication descriptions)</td>
<td>4.3 %</td>
</tr>
<tr>
<td>Materials for creating disease awareness</td>
<td>2.6 %</td>
</tr>
<tr>
<td>Other groups of medication and health-related materials</td>
<td>71.1 %</td>
</tr>
</tbody>
</table>
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Table 3. Readability values of comparable Slovene/English PIL, SmPC and creating disease awareness texts, respectively.

<table>
<thead>
<tr>
<th>Material</th>
<th>Slovene texts</th>
<th>English texts</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Readability</td>
<td></td>
<td>Intermediate values</td>
<td>t-test</td>
<td>Readability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ease (Mean) value; standard deviation</td>
<td></td>
<td></td>
<td></td>
<td>ease (Mean) value; standard deviation</td>
<td></td>
</tr>
<tr>
<td>Patient Information Leaflet</td>
<td>Difficult 10; d = 0.79</td>
<td>Difficult 34; d = 0.63</td>
<td>t = 2.463 p = 0.133 NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>Difficult -11; d = 1.25</td>
<td>Very confusing -3; d = 1.37</td>
<td>t = 5.155 p = 0.007 NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials for physicians</td>
<td>Difficult -47</td>
<td>Very confusing -33; d = 1.37</td>
<td>t = 4.731 p = 0.133 NS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral diseases awareness material</td>
<td>Difficult 19</td>
<td>Difficult 34</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergy awareness material</td>
<td>Difficult 23</td>
<td>Very confusing 24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis awareness material</td>
<td>Difficult 5</td>
<td>Very confusing 11</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Readability of texts for creating a disease awareness

Slovene disease awareness texts as related to all three therapeutic groups, were compliant with a description ‘difficult’ within the Slovene algorithm. Slovene texts were also compared with English disease creating awareness texts, due to a content similarity. English texts for creating awareness of viral diseases reached the readability ease value 34 and, were described as difficult. With a readability score of 24 and of 11, a description ‘very confusing’ was assigned to creating allergies awareness and osteoporosis awareness texts respectively (Table 3).

Readability of texts for promoting OTC medications

The statements regarding the benefits and possible risks of treatment with specific OTC medications were extracted from text segments. Readability values for all texts were rated as difficult (Table 4). The texts, related to possible risks of taking these medications, were less readable than the text with a description of the benefits, regardless of the chosen therapeutic group. Readability ease values of the benefits related to treatment of viral diseases and allergy treatment were 4 and 0 respectively. The readability ease of the text describing medicines risks for the treatment of viral diseases reached -19 and, a similar value (-17) was reported for allergy related medicines. Especially low readability values were attributed to OTC medicines for osteoporosis with the benefit readability score of -3 and risks of -40. In Table 4, average and intermediate values are stated. t-test; confidence interval = 99%, p = 0.01.

A statistically significant difference in readability, relating to test values, was observed at the benefits and risks (p ≤ 0.01) of texts relating to OTC medicines for treating viral diseases. A non-significant difference was seen for the benefits related to OTC medicines for osteoporosis treatment (p = 0.033). Comparison of the deviations of readability values demonstrated a larger deviation for medicines for treating viral infections (1.43). Comparatively lower deviations were noted for the benefits of treating osteoporosis (1.07) and viral infection (0.92).

Discussion

The Slovene algorithm reveals decreasing values of the readability ease as grade levels are higher. This study has shown inappropriate readability grade levels of texts, confirming results from previous studies. This study shows that the readability of the Slovene PIL was difficult. Within the corresponding algorithm, the English PIL was also described as difficult to read. A statistical difference concerning corresponding test values, defined above as the values we are aiming at, was not found, regardless of the language. It can be concluded from this study that an advancement should be made in both language materials.
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In comparable studies, a high readability grade level and letter size slightly below the recommended within a PIL for inhaled corticosteroids products have been reported5. Exceeding a recommended readability grade level, calculated by a Flesch-Kincaid formula, was also evident in PILs for selected eye medications 1. Inappropriate readability grade levels have also been associated with texts about warfarin4. When researching hospital PILs, an average readability ease 60 was determined by the Flesch method, with a Flesch-Kincaid grade of 7.8. This study found that the Slovene SmPC was rated as difficult to read and the English SmPC as very confusing to read. The difference between the stated readability values and the test values was substantial and statistically significant. Although a high educational level of experts should enable comprehension, easier readability should facilitate the experts’ work.

The results of this study, related to PILs and SmPCs, has also shown larger standard deviations in readability values when Slovene texts were compared with English. These findings, along with discrepancies between this study and previous published results3, 4, 5 suggest that lack of use of readability formulas with Slovene medicines information material may have lead to lesser concern and lower uniformity of text readability.

Promotional materials for physicians written in Slovene and English largely exceeds university graduates grade level. However, in English the promotional material for professionals, statistical significance was not achieved. Since similar results derived from the SmPC analysis, it can be concluded that more attention should be dedicated to adjusting the texts based on the needs of health professionals.

High readability grade levels of the materials which relate to creating disease awareness were observed in our study. Slovene materials regarding disease awareness were described as difficult to read, in accordance with the Slovene algorithm. Viral diseases awareness materials in English were described as difficult to read and the materials related to the other two therapeutic groups were described as very confusing to read. This study supports the notion that all targeted texts should be adjusted to appropriate readability levels. Materials for educating on HIV infections intended for the patients have also been reported to have excessive readability grade levels7, 8.

Awareness materials related to viral infections and for allergies (derived from internet sources) had slightly higher readability ease values (19 and 23) than osteoporosis awareness materials (5), which were obtained from a pharmacy. The results of the materials for creating disease awareness in Slovene and in English are comparable, however this suggests there is a need to ensure optimal readability of all forms of text analysed in this study.

Irrespective of the therapeutic groups, readability ease values of benefits and risks, related to OTC drug texts were described as difficult. The readability of risks is rated as more difficult than the readability of benefits within the analyzed promotional texts. A statistically significant difference in viral infection therapeutic group and a non-significant difference concerning the benefits of the osteoporosis therapeutic drug group was demonstrated. These results have confirmed our previously defined set of hypotheses.

This imbalance in readability between the benefits and risks in medicines promotional materials show that it did not meet the standards. According to the recommendations of the Food and Drug Administration (FDA), the usage of appropriate language and content should help to present risk information more clearly23. The results of this study suggest that the text relating to benefits of OTC medications is presented more clearly than the risks, with standard deviations taken into account. Besides the possibility that neither Slovene text was appropriately

| Table 4. Readability values of risks and benefits of OTC medication texts |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Material                        | Description     | Readability ease | Intermediate values | t-test            | Description     | Readability ease | Intermediate values | t-test            |
| OTC drugs for treating viral diseases | Difficult       | 4 ; d = 0.92     | 5, 17, 37, -2, -18, 3, 13, 9, 1, -8, 12, -26 | t= 8.686          | Difficult       | -19 ; d = 1.43  | -15, -1, -48, -13 | t= 6.381          |
|                                  |                 |                |                  | p= 0.000 S       |                 |                |                  | p= 0.008 S       |
| OTC drugs for treating the allergies | Difficult       | 0               |                  |                 | Difficult       | -17             |                  |                  |
| OTC drugs for the osteoporosis treatment | Difficult       | -3 ; d = 1.07   | -8, 14, -16      | t= 5.389          | Difficult       | -40             |                  |                  |
|                                  |                 |                |                  | p= 0.033 NS      |                 |                |                  |                  |

prepared to ensure ease of readability, the benefits may have been deliberately presented more clearly than the risks. This may have been undertaken to enhance the apparent advantages of the promoted medicine. Hence, a policy is needed to authorize competent institutions to test readability levels as a part of standard practice.

Research limitations and future research
To make the findings of this study more generalizable, a wider range of therapeutic groups could be analyzed. There is also a requirement to focus on exploring readability of materials for professionals, where less work has been undertaken. Likewise, also the benefits and the risks in OTC texts, including those from other therapeutic groups, are advised to be further studied. It is imperative that after testing factual grade levels and a decision-makers consensus, standards should be set for Slovene text. Besides printed materials, television OTC adverts could be subject of further research.

Conclusion
This study provides an understanding of the level of readability of selected Slovene medicines information texts. It was concluded that health-related texts were not compliant with general public or with healthcare professional needs. Since none of the studied Slovene texts for the general public complied with the primary school grade level of readability, the texts should be adjusted to appropriate levels. Due to their public health purpose, public-health organizations are expected to initiate the efforts to increase the readability of the texts with the medicines information.

Authors contribution
Both authors contributed to the paper’s design and to the research implementation, analysis and interpretation of the results.

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Conflict of interest
We declare that we have no conflict of interest.

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