Journal of
Clinical Research Bioethics

Valentini et al., J Clin Res Bioeth 2013, 4:3
DOI: 10.4172/2155-9627.1000156

Research Article Open Access

Application of a Readability Score in Informed Consent forms for Clinical Studies

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Abstract

Study background: The Information Leaflet is the most important document for participants in clinical research to guarantee an ethical treatment.

Methods: We compared readability of several Italian ILs with articles from Italian newspapers and explored if the ILs modified by Ethics Committees were more understandable than the original versions. We studied basic and modified ILs, newspaper general articles and medicine articles, using GULPEASE index, percentage of unusual words, words/sentence ratio.

Results and conclusion: Basic ILs and general articles were not understandable for people with low education. Percentage of unusual words is the highest in the general articles (31.7%) and the lowest in the modified ILs (21.16%). The difference between basic ILs and general articles is statistically significant (p=0.0021). The readability score and the other tests could be useful tools for improving ILs. However, they have intrinsic limits. The consideration about the use of the GULPEASE score could be valid for similar tests for other languages.

Keywords: Informed consent; Clinical research; Readability; Readability score

Introduction

Ethical treatment of human subjects is fundamental to the conduct of research. Many principles and guidelines are in place today to protect involved subjects and assure that research is conducted in a way that prevents harm [1]. The Information Leaflet (IL) is the most important document for any potential participant in research. Ethically the informed consent should be based on a true understanding of the purpose of the research, ensuring that subjects know exactly what the study is about, what they are agreeing to do, the research procedures, any risks and benefits, any alternatives available, any financial implications, the right to confidentiality and privacy [2]. In many ways, informed consent serves as a patient's bill of rights [3]; right to be completely informed about the study, with understandable information, and to agree to participate willingly without coercion. This process should include 5 elements: voluntarism, capacity, disclosure, understanding, and decision. However, it involves the interaction of psychological and intellectual characteristics of an individual and depends on educational status, level of general knowledge, personal attitudes, which are affected by the society morals and customs [4].

A large literature supports the notion that the language used in ILs is not comprehensible to most people [5]. Subjects may not fully read IL because it is too long, they do not understand it, and are confused by medical and legal terms. Standardized methods for assessing the adequacy of informed consent to research are lacking. Unfortunately, heterogeneous methods of analysis and conceptual difficulties with the definition of informed consent hinder the interpretation and synthesis of the empiric literature on it. Indeed, despite efforts to develop a standardized assessment tool, there is no widely accepted method for defining or measuring the outcome of the informed consent process [6-8].

There are two methods actually mentioned in literature to test the readability of informed consent: questionnaire about the consent (QuIC) [6] and Flesch-Kincaid test for readability of sample text for English language [9] (and the corresponding tests for other languages: Fernandez Huerta for Spanish, Kandel & Moles for French, LIX for Swedish and Danish, GULPEASE test for Italian). The QuIC, originally applied to cancer clinical trials, objectively assessed some of the components of informed consent through interview questions to a sample of common people. It is a careful tool, but it is time consuming and not so easy to apply during the preparation of the documents needed for a clinical trial. Flesch-Kincaid test assigns a score on the basis of the minimal grade level (range 0 to 12) required to read and understand English test. This is an automated instrument of Microsoft Word and has been demonstrated to be reliable and valid [10]. It assesses readability on the basis of the average number of syllables per word and the average number of words per sentence [11]. The use of this scale has been used by several studies [12-15].

The GULPEASE index is a tool developed for the Italian texts; it evaluates the number of letter per word and the number of words per sentence and correlates them with the educational status of the reader [16]. Also this scale is an automated instrument of the Italian version of Microsoft Word and it could be a simple, inexpensive, generic measure to test the readability of information and consent form in Italian language. Our study has a double aim: first of all, we would compare the readability of several Italian ILs with articles taken from some Italian newspapers; then we would explore if the ILs modified by the Ethics Committees (ECs) were more understandable than the original versions.

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Received June 21, 2013; **Accepted** August 20, 2013; **Published** August 29, 2013

Citation: Valentini M, D'Alonzo D, Pirozzoli MC,Lucisano G, Nicolucci A (2013) Application of a Readability Score in Informed Consent forms for Clinical Studies. J Clin Res Bioeth 4: 156. doi:10.4172/2155-9627.1000156

Methods

We selected 13 ILs about randomized and observational studies, from industries and independent organizations, used in the studies conducted in / in collaboration with our laboratory during the last 2 years; five leaflets were about the data protection and privacy within these clinical studies and one of them was the one proposed by the Italian Data Protection Authority (IDPA) [17]. For all ILs but the ones proposed by the IDPA we also considered the versions modified by the ECs (Table 1).

As far as the newspapers articles, we chose the top five Italian headings (excluding sport newspapers), according to Audipress [18], an Italian society for surveys about newspapers reading. We selected the first article published in the web site of these newspapers on the 26th July, 2011; moreover we selected one of the articles published during the last 30 days in their medicine insert.

To evaluate the readability, we used: GULPEASE index, percentage of unusual words, and words per sentence ratio.

The GULPEASE formula is: Readability = [89+ (300*number of sentences-10*number of letters)]/number of words. The range is 0-100; the higher score corresponds to a higher readability. The score can be related to the educational level through specific scales, as shown in Figure 1 [16].

The percentage of unusual words is automatically calculated by the tool "Readability statistics" of Microsoft Office Word 2007 in Italian.

The ratio words/sentence is a simple tool to measure the text readability; in Italian language, a sentence is considered understandable when it is composed by about 25 words [19].

All endpoints were analyzed with a hierarchical linear model for repeated measurements to assess differences over study among the studied documents [20,21].

Results for the multivariate models were reported as estimated mean percentage along with 95% confidence intervals.

P-values < 0.05 were considered statistically significant. All analyses were performed using SAS Statistical Package Release 9.1 (SAS Institute, Cary, NC).

Type of information leaflet	Intervention	Related leaflets modified by ECs
RCT, independent	drug	19
RCT, independent	drug	2
RCT, independent	drug	2
RCT, from industry	drug	8
RCT, independent	medical device	6
RCT, independent	educational intervention	1
OS, independent	questionnaire	0
OS, from industry	drug	15
Privacy, from IDPA	NA	NA
Privacy, independent RCT	drug	3
Privacy, independent RCT	drug	2
Privacy, independent RCT	drug	1
Privacy, OS from industry	drug	2

EC: Ethics Committee
RCT: Randomized Clinical Trial
OS: Observational Study
IDPA: Italian Data Protection Authority
NA: Not Applicable

Table 1: Classification of information leaflets.

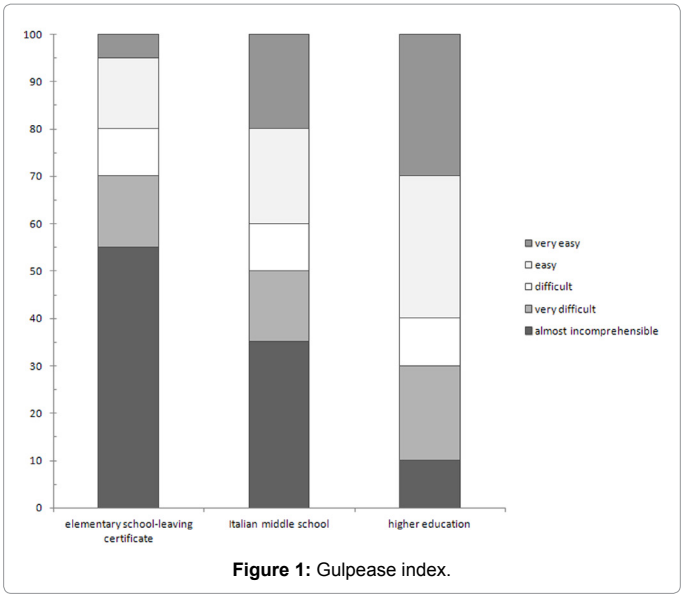

Figure 1: Gulpease index.

Ethic committees

In the case of multi-center clinical trials Italian law permits that every EC can modify the IL, in order to adapt it to the local situation. Therefore it is possible to have different ILs across the centers participating to the same multi-center clinical trial.

Results

We compared the readability of 13 basic ILs, 61 modified ILs, 5 newspaper general articles, and 5 newspaper medicine articles.

Gulpease

The results are summarized in Table 2 and Figure 2. The mean score of the basic ILs was 46.31, that is almost not understandable for people with elementary school-leaving certificate, very difficult to understand for people with first three years of a secondary school certificate, easy to understand for people with higher education. The modifications requested by ECs ameliorated the readability of ILs (mean=48.3), but the difference was not statistically significant and the relationship with the educational level did not change.

The newspaper medicine articles had a mean score of 47.8 and the newspaper general articles had a mean GULPEASE score of 53.33. The difference between the mean basic ILs score and the mean newspaper general articles score is at the limit of statistical significance (p=0.0553), but the relationship with the educational level did not change a lot: almost not understandable for people with elementary school-leaving certificate, difficult to understand for people with first three years of a secondary school certificate (Italian middle school), easy to understand for people with higher education.

Percentage of unusual words

The results are summarized in Table 3. This value is the highest in the general newspaper articles (31.7%) and the lowest in the modified ILs (21.16). The difference between the basic ILs and the general newspaper articles is statistically significant (p=0.0021). The differences between the basic ILs and the other documents are not statistically significant.

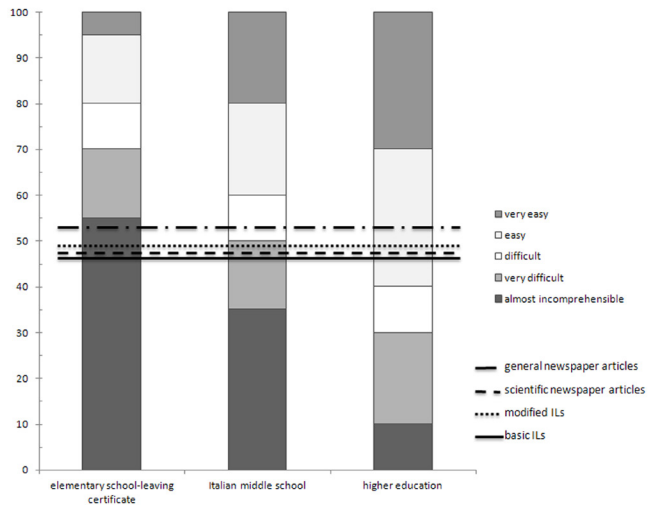

Figure 2: Gulpease value of information leaflets (ILs) and newspaper articles.

Word per sentence ratio

Table 4 shows the results relative to this end point. The medicine newspaper articles had the highest ratio (26.53) and the general newspaper articles had the lowest one (21.59). None difference was statistically significant.

Interpretation

Readability index formulas only work for a specific language. As our documents are all in Italian language we used the GULPEASE score. It differs from the Flesch-Kincaid score because it considers the number of letters instead of the number of syllables. This difference is due to the structure of the Italian language. However the consideration about the GULPEASE scores could be valid also for the Flesch-Kincaid score or for other similar tests for other languages.

The use of a readability score could supply a new tool to improve the information and consent forms drafting and consequently the comprehensibility by people involved in clinical studies.

The development of a simple, inexpensive, generic measure of informed consent readability would have several important benefits. First, it would permit comparison of ILs across different clinical trials, phases of research, diseases, and research populations. Second, it could be used to evaluate interventions designed to enhance the informed consent process. Finally, it could be used by institutional review boards as a practical tool to oversee the process and outcome of informed consent [22,23].

Our sample of ILs could be considered representative of the several types of information for patients; the analyzed documents came from independent research institute, industries and institutions.

In literature analysis of readability on ILs are present but works that analyze readability comparing newspaper articles and ILs are not known. This is important because the GULPEASE score obtained for the ILs should seem very low but practically comparing it with the score of a common article the result is quite similar.

Our results showed that, in terms of GULPEASE score, the basic ILs are understandable only by more educated people. The values of the 95% CI indicate that there is no variability among these documents. The requests of ECs did not modify the readability of the basic leaflets and also the newspaper scientific articles are difficult to understand.

These results suggest that maybe writing about scientific topics is difficult in itself. This could be confirmed by the GULPEASE score of the general newspaper article. However also in this case the readability is difficult for less educated people.

Word per sentence ratio reflects results shown by GULPEASE score. In fact this ratio is lower when the document is more readable. However the ratios of the studied documents are equal to or lower than 25, therefore they can be considered readable. Maybe our document contains short sentences, but the words are too long to be considered readable according the GULPEASE score.

Therefore by looking at the text properties of these documents it is possible to correlate how much "words per sentence" influence readability.

The readability score of a document does not depend by the number of unusual words used but it could be influenced by the way to write an article. Probably scientific articles necessitate a use of terms, words, sentences which produce papers less readable.

Percentage of unusual words is not considered in GULPEASE formula. It could add some information about readability. In our results this value is higher for the general newspaper articles and is lower for the ILs (basic and modified). This data is not in accordance with the results obtained by GULPEASE test. It could be the result of the effort to make the scientific matter more understandable by common people. This aspect is very important in writing ILs for patients to be involved in clinical studies.

The modifications requested by the ECs slightly ameliorated the readability (better GULPEASE score, fewer unusual words, shorter sentences), but no difference was not statistically significant. Moreover,

Type of document	Mean	95% CI	*p* value
Basic ILs	46.31	42.76-50.16	--
Modified ILs	48.3	46.59-50.07	0.348
Medicine newspaper articles	47.8	42.11-54.27	0.679
General newspaper articles	53.33	47.29-60.13	0.0553

CI: Confidence Intervals
IL: Information Leaflet

Table 2: Mean Gulpease score.

Type of document	Mean	95% CI	*p* value
Basic ILs	23.45	20.96-26.23	--
Modified ILs	21.16	20.04-22.35	0.1075
Medicine newspaper article	25.68	21.60-30.53	0.387
General newspaper article	31.7	27.13-37.04	0.0021

CI: Confidence Intervals
IL: Information Leaflet

Table 3: Percentage of unusual words.

Type of document	Mean	95% CI	*p* value
Basic ILs	24.24	21.71-27.07	--
Modified ILs	22.49	21.33-23.71	0.230
Medicine newspaper articles	26.53	22.38-31.45	0.383
General newspaper articles	21.59	17.87-26.07	0.298

CI: Confidence Intervals
IL: Information Leaflet

Table 4: Word per sentence ratio.

the readability correlated with the educational level did not change (Figure 2).

According to our results, the situation about ILs is worrying: these documents are difficult to understand for less educated people. When considering the most common chronic pathologies (diabetes, cardiovascular diseases, the most common neoplasms, ...), the mean age of patients is high, and high is the probability of patients with low education level. So the risk that a considerable number of patients participating in clinical trials on these pathologies could not understand what they are really doing is real and worrisome.

The European Directive on clinical trials states that the EC has to evaluate "the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent" [24]. However the Declaration of Helsinki does not request a written information leaflet; in fact, article 24 says that "each potential subject must be adequately informed of the aims, methods…, of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal… After ensuring that the potential subject has understood the information, the physician … must then seek the potential subject's freely-given informed consent, preferably in writing" [25].

Maybe for trials involving presumably low education level it could be useful to study also other modalities to inform the patients, in alternative to or accompanying the classic written IL.

From this point of view also the role of the ECs should be different. Our results showed that the readability of modified ILs was not significantly better than the readability of the basic versions. Maybe it could be more useful for the trials patients that the ECs review the modalities adopted by the investigators to obtain the informed consent instead of the formal respect of the rules about the ILs. This aim could be achieved moving the evaluation of the process of the informed consent from the EC meeting to the clinical trial setting. This is not the exact context to discuss this matter; this is only a suggestion to improve the evaluation of some of the procedures that should protect people involved in clinical trials.

Our work has some limits related to the intrinsic characteristics of the readability tests: readability does not equal understandability. Moreover, a readability score is not an exact science. For example, it does not consider test disposition that could be very important for the ILs; this is the case of the list of the side effects of a drug or the description of diseases complications.

Another item not considered by the readability score is the text content. Surely writing in a simple way about a clinical trial is more difficult than writing about more common matters. Our results show clearly this aspect.

The great limit of the readability scores (and also of the other parameters studied in our work) is that they evaluate only the syntax of a document, without evaluation of other important parameters: for example, they cannot distinguish whether the sequence of information is correct. So it is possible that a document with a high readability score is not understandable at all.

Moreover the readability score itself does not reflect the level of patient understanding, that depends on intrinsic factors (first language, culture, education level).

Undoubtedly tools like the QuIC could be the gold standard to assess whether a text is understandable.

Maybe the best way for preparing information sheet is the combination of the readability score (during the drafting) with a questionnaire about the document submitted to a sample of common people (before the final approval). However this procedure is difficult to apply because it requests too much money and human resources.

The readability score can be a useful tool for improving the readability of the information sheet. The use of the other statistic test analyzed in our work (percentage of unusual words, word per sentence ratio) could also contribute to ameliorate the text legibility. However, it is important to keep in mind the intrinsic limits of these methods.

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