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Readability of Informed Consent Forms: Analysis and Recommendations for Development of Consent Forms for Use with Early and Beginning Readers (Poster)

Abstract: This poster presents a pilot study that analyzed a small corpus of informed consent forms used in research with children, adolescents, and adult early readers using Coh-Metrix, a readability measurement tool. Recommendations for increasing readability of consent forms in order to improve the informed consent process are also provided.

Résumé: Cet affiche présente une étude pilote. La recherche s'agit d'une analyse d'une collection modeste des formulaires de consentement éclairé qui ont été utilisé avec des enfants, des adolescents et des adultes qui ont un faible niveau d'alphabétisation. L'analyse était realisée avec Coh-Metrix, un instrument qui mesure la lisibilté des documents. Aussi inclues étaient des recommandations pour augmenter la lisibilité des formulaires de consentement afin d'améliorer le processus d'écrire des formulaires de consentement éclairé.

1. Introduction

Obtaining informed consent from research participants is an integral aspect of conducting ethical research. Traditionally, researchers obtain informed consent by providing participants with forms outlining the details of the research study, clarifying any benefits or potential risks of participation, the voluntary nature of participation, and providing contact information for both the researcher and their institutional review board (IRB). IRBs often provide standardized templates of these forms that meet these criteria. However, researchers working with vulnerable populations, such as adult early readers or children, should consider the informed consent process more carefully than the rote distribution of forms based on these templates. Many factors potentially influence how well such documents truly inform potential research participants, including participants' age (Fargas-Malet, McSherry, Larkin, & Robinson, 2010), physical and mental health (Wiles, Heath, Crow, & Charles, 2005), and literacy levels (Sudore, Landefeld, Williams, Barnes, Lindquist, & Schillinger, 2006). Additionally, as Fargas-Malet et al. (2010) note, "the ability to give informed consent depends on the quality of the explanation" (pp. 176-177). One factor influencing the quality of information provided within consent forms is readability.

This pilot study applied important findings in recent readability research to the analysis of a small corpus of informed consent forms used with participants for whom reading may present a challenge. A discussion of the findings and limitations will follow the section on methods and tools used in the analysis.

2. Readability Analysis

Readability is a quality that reflects how easy texts are to read for a particular individual (DuBay, 2004). Key findings from readability research confirm: (a) the increased benefits of easier-to-read texts for individuals with lower topic knowledge and low motivation; (b) that readability increases the likelihood of someone reading further, and (c) that easy-to-read text increases reading speed and retention (DuBay, 2004). What is less clear, however, is just what characteristics qualify a text as "easy-to-read." The standard and most used method of assessing the readability of text remains a surface analysis of word length, syllable count, and sentence length correlated with school grade level. It is important to note that literacy levels of individuals are also correlated with their level of education or school grade level. Research also confirms that reading encompasses deep comprehension processes such as inference-making (Graesser, Millis, & Zwaan, 1997).

A limitation of the classic readability formulas with considerable implications for the present analysis is the assumption embedded in these formulas that longer text is necessarily more difficult to read. Expository texts, such as informational documents that explain unfamiliar concepts or situations, are by necessity long. Their length, however, is due to added explanations and definitions that are meant to aid readers with comprehension.

Furthermore, vocabulary knowledge and school leveling alone are inadequate measurements of people's reading ability and, as such, are insufficient indicators of text readability (Benjamin, 2012; Duke & Carlisle, 2011; Feng, Elhadad, & Huenerfauth, 2009). This is especially the case within the context of the informed consent process for participants who are either children or adult early readers. Because of greater life experience, for instance, an adult early reader might experience less difficulty reading and understanding a consent form written at a 5th grade reading level than might a child who reads at that same level. The opposite scenario is also likely. This would mean a child with a 7th grade reading level might be better able to understand certain discourse structures, such as lists or phrase structures, than might an adult who tests at a 7th grade reading level.

Research on reading comprehension has looked beyond vocabulary knowledge. According to studies based on the construction integration model (Kintsch, 1998), readers use features of text and prior domain knowledge to make meaning of what they read, and features that make text more cohesive aid in the inference-making process involved in reading comprehension (Best, Rowe, Ozuru, & McNamara, 2005). Cohesive texts incorporate a set of cues that allow the reader to form a coherent mental model of what he or she is reading (McNamara, Graesser, McCarthy, & Cai, 2014, p. 19-20). When texts have low cohesion, individuals are forced to make more inferences in order to create a coherent mental model of the information presented in the text (McNamara et al., 2014). A reasonable hypothesis, therefore, is that individuals who have less experience reading certain texts (such as adult early readers) might experience difficulty forming a mental model of texts (comprehending) that are not cohesive.

3. Analysis of Informed Consent Documents

Since cues that make text cohesive are present in high-cohesion texts and are missing from low-cohesion texts, they can be automatically identified and analyzed with corpus

linguistic and natural language processing methods. For this study, a preliminary analysis of a machine-readable corpus of consent forms was performed. This small corpus is a convenience sample of consent forms used in the authors' previous research studies. It includes one assent form designed for children, one assent form designed for use with adolescent participants, two consent forms designed for use with parents of children recruited as research participants, and one consent form designed for adult early readers. A readability measurement tool called Coh-Metrix[i] was used to identify a number of linguistic features of these documents including syntax, semantic overlap, and discourse structure, and to compute a number of indices referring to the documents' overall readability, cohesion, and simplicity. The tool also calculates reading grade level using the Flesch-Kincaid Grade Level formula. Traditional readability measures, such as word length and sentence length, were compared with more recently derived measures, such as cohesion, narrativity, and syntactic simplicity.

Documents in the corpus ranged in length from 9-18 paragraphs and had between 349-824 total words. The average number of sentences per document was 35, and sentences tended to be an average of 18 words long. Preliminary analysis shows most of these documents have a high level of syntactic simplicity. This means, the sentences in the documents are relatively short and use simple, more familiar syntactic structures, and are therefore easier to comprehend. It is important to note, however, that the children's assent form scored the lowest for this measure. The forms designed for children and adolescents also scored highest in the narrativity measure, which indicates the language used in these documents resembles everyday, conversational language. The forms for children and adolescents scored a 7th grade reading level measured by Flesch-Kincaid Grade Level, while the documents created for adults scored at a 12th grade reading level (including the document designed for adult early readers). That said, the documents that scored highest on overall readability were those designed for children and adolescents. The forms designed for children, adolescents, and adult early readers scored the highest on referential cohesion. This measure indicates that words and concepts overlap across sentences and paragraphs in the documents, which can aid readers in making inferences and connections as they read.

4. Discussion

Based on this preliminary empirical analysis, the following recommendations can enhance the readability of consent forms designed for participants whose vulnerability to participate in research relates in part to their reading comprehension. To provide these participants with consent forms that are informative and easy to understand, forms should use simple sentence structures, include meaningful words instead of abstract concepts or jargon, preserve semantic overlap across sentences, and include explanatory text. Contrary to the Federal Plain Language guidelines (PLAIN, 2011), longer documents that include repetition, definitions and explanations are better for readers who are unfamiliar with the topic or contents presented in text.

A limitation of this study is that it has not yet been validated with vulnerable research participants for comprehension and readability or to assess their familiarity with certain concepts like "assent," "consent," and "research study." Future work will explore the readability of consent forms from the perspective of research participants. To ensure that participants fully understand what signing the document means for their participation in the study, researchers might include a brief, informal Q&A before asking for a signature.

For example, researchers might ask, “What can I explain or clarify before you make your decision to participate or not in this study?”.

Another important limitation is the size of the corpus used in the analysis. To further validate these early findings, the authors plan to expand the corpus of consent forms by asking other researchers who work with these vulnerable populations to deposit copies of the forms they use in their studies for analysis. Future work in this area will not only expand the corpus of consent forms analyzed, but it will also include evaluations of consent forms with different readability scores by a group of children and adult early readers.

5. Conclusion

Despite the relatively high reading grade level, the forms analyzed in this study included simple sentence structure, explanations of terms and concepts, and were cohesive; all features that can aid inexperienced readers understand new or unfamiliar topics. Researchers working with vulnerable populations such as children, adolescents, and adult early readers should pay special attention to these and other features influencing the readability of consent forms, while keeping in mind that formal consent documents are just one important component of the informed consent process.

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[i] available at http://cohmetrix.com/