Introduction

• To improve clinical trial engagement, the public needs to understand relevant research details. One measure of the understanding of written informational material is readability.
• Readability scales assign a score to a written text identifying the grade level of education needed to comprehend it.
• Here we focus on one readability scale: the Simple Measure of Gobbledygook (SMOG).

Objective of the Study

• To evaluate associations between various study characteristics and ICF readability.

Hypotheses

• Readability of ICFs used in the U.S. is above the recommended reading grade level.
• Average readability score of consent forms with a key information section will be better (lower) than for those without a key information section.
• Average readability score of consent forms for studies that include pediatric participants will be better (lower) than ICFs for studies that only include adult participants.

Methods

• Developed a database of 359 ICFs from 317 studies conducted between July 1, 2018 and July 1, 2019 using information from ClinicalTrials.Gov.
• Formatted ICFs to include informative text only, then analyzed each ICF’s reading level using the online WebFX readability calculator.
• Not all readability data is entered: some ICFs are unavailable until 60 days after studies end.
• Conducted bivariate analyses using RStudio.

Results

• The violin plots below show the distribution of SMOG scores across different study characteristics.
  • The width of each entry corresponds to the number of ICFs with that readability score.
  • The red lines show 6th- and 8th-grade reading levels.
  • Internal to each violin plot entry is a box plot; outliers are shown as points.
  • Note: “All” in the age categories refers to studies including Child, Adult, and Older Adult participants.

<table>
<thead>
<tr>
<th>Category</th>
<th>#N</th>
<th>SMOG Median (25th, 75th percentile)</th>
<th>p-value (rank-sum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Forms with Key Information Sections</td>
<td>41</td>
<td>9.3 (8.9, 9.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Consent Forms without Key Information Sections</td>
<td>234</td>
<td>9.7 (8.6, 10.6)</td>
<td></td>
</tr>
<tr>
<td>Consent Forms with Key Information Sections</td>
<td>234</td>
<td>9.7 (8.6, 10.6)</td>
<td>0.015</td>
</tr>
<tr>
<td>Key Information Sections</td>
<td>39</td>
<td>8.9 (8.2, 9.7)</td>
<td></td>
</tr>
</tbody>
</table>

Discussion

• Recommended 6th-grade reading levels were not met.
• ICFs with key information sections are significantly less readable than those without.
• Key information sections may be more common in longer, more technical ICFs.
• ICFs from studies that include child participants are significantly more readable.
• These studies may orient ICF information towards a wider audience.

Questions

• Further research is needed to determine the relationships between clinical research designs, improved readability levels, and study recruitment/retention outcomes.
• Limitations of this study: Data was limited to English-language ICFs from U.S. studies and information available at ClinicalTrials.gov.

Conclusion

• Future efforts to improve accessibility of participant communication in clinical trials may shorten sentences and simplify language.
• All clinical studies would benefit from devoting more attention to readability of informational materials.

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