

Objectives

- To increase awareness regarding effective communication of clinical trial summaries and how it relates to patient participation and compliance in clinical trials
- To suggest the application of readability formulas to assure public understanding of disseminated reports

Introduction

Public disclosure of clinical trial summaries by the research community is steadily increasing in frequency as transparency policies take effect around the globe¹; however, these study reports are still not often fully understood by patients and the public.

Current efforts to translate clinical trial summaries from technical to common language are effective when the target audience is members of the scientific or medical community.

Communicating the same information to patients still poses a challenge since governing bodies enacting transparency policies have not fully explored the comprehension of clinical trial data by the public. The average grade level reading ability for general public in the United States is 8th grade.²

Current efforts in the United States to publish clinical trial summaries for public dissemination includes the following:

- US National Library of Medicine (clinicaltrials.gov) is a web-based interface that publishes clinical studies and their results for everyone from patients to researchers.³
- The Center for Information and Study on Clinical Research (CISCRP) is a non-profit organization that focuses on education about clinical trials and works to improve patient communication.⁴

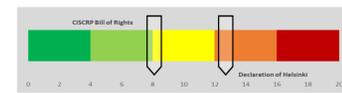
Methods

To establish a baseline understanding of the output of the available readability algorithms, the readability of The Declaration of Helsinki and The CISCRP Participant Bill of Rights were analyzed using an online tool (<https://readable.io/>) which analyzes text with 5 different established algorithms.⁵

Flesch-Kincaid Grade Level

- Rates text on a U.S. school grade level. For most documents, aim for a score of approximately 7.0 to 8.0.

$$0.39 \left(\frac{\text{total words}}{\text{total sentences}} \right) + 11.8 \left(\frac{\text{total syllables}}{\text{total words}} \right) - 15.59$$



Gunning Fox Index

- An interpretation is that the text can be understood by someone who left full-time education at a later age than the index.

$$0.4 \left[\left(\frac{\text{total words}}{\text{total sentences}} \right) + 100 \left(\frac{\text{complex words}}{\text{total words}} \right) \right]$$



Coleman-Liau Index

- Estimates the years of formal education the reader requires to understand the text on the first reading.

$$4.71 \left(\frac{\text{total characters}}{\text{total words}} \right) + 0.5 \left(\frac{\text{total words}}{\text{total sentences}} \right) - 12.43$$



SMOG Index

- Estimates the years of education needed to understand a piece of writing. Simple Measure Of Gobbledygook

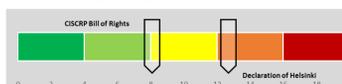
$$3 + \frac{\sqrt{\text{words with 3 or more syllables} \times 30}}{\text{total sentences}}$$



Automated Readability

- Approximate representation of the US grade level needed to comprehend the text.

$$4.71 \left(\frac{\text{total characters}}{\text{total words}} \right) + 0.5 \left(\frac{\text{total words}}{\text{total sentences}} \right) - 12.43$$



To assess readability of clinical trial summaries, four clinical trials were selected based on their availability on the CISCRP website. The trial summaries were retrieved from the clinicaltrial.gov database as well as from CISCRP. The 5 scoring algorithms were applied to each version of the clinical trials with <https://readable.io>.

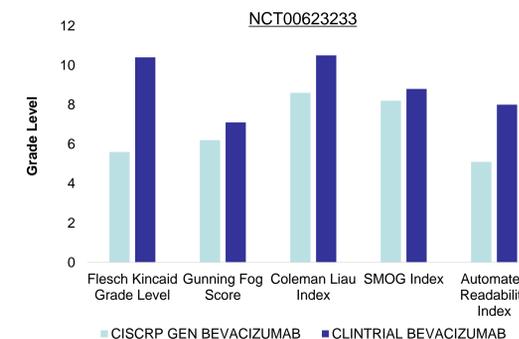
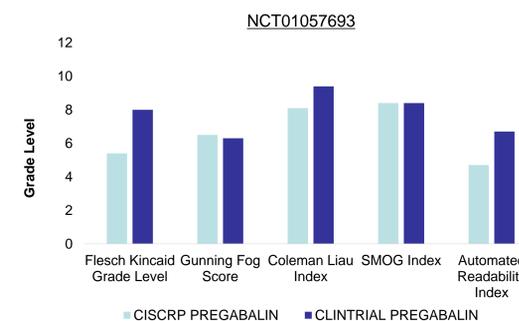
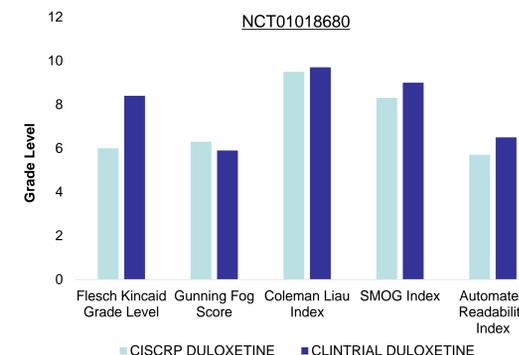
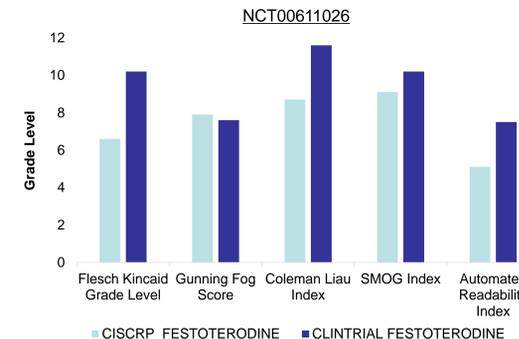
NCT00611026
fesoterodine in overactive bladder

NCT00623233
gemcitabine plus bevacizumab in breast cancer

NCT01018680
duloxetine versus placebo in osteoarthritis

NCT01057693
pregabalin for diabetic peripheral neuropathy

Results



Conclusions

Clinical trial summaries published by the clinicaltrials.gov are more difficult to read for the general population when compared to the same trials published by CISCRP. Regular application of readability formulas as a part of the writing process ensures appropriate comprehension levels for public dissemination.

Grade level 16

Silicone, when injected into areas with many blood vessels such as the buttocks, can travel to other parts of the body and block blood vessels in the lungs, heart, or brain. This can result in permanent damage to those tissues and lead to stroke or death. Surgery to remove large-scale injectable silicone may present additional risks and serious complications, and may not entirely rid the body of the silicone. Multiple medical and surgical interventions are sometimes needed to treat symptoms years after initial injection; even then, patients may continue to experience ongoing pain, infection, and scarring and permanent disfigurement requiring ongoing treatment.

Grade level 11

When silicone enters your body, it can spread and move around. This effect may make it difficult to remove if there are any serious side effects. Silicone, injected into your buttocks can travel to your lungs, heart or your brain causing damage leading to stroke or death. Many surgeries are often necessary to remove silicone from your body. After the silicone removal surgeries, you still may experience pain, scarring and permanent deformities.

Patient comprehension may increase participation and study compliance as the patients are armed with the knowledge of how their involvement helps.

References

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Disclosure

Author of this presentation has the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

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