

Readability of Invasive Procedure Consent Forms

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Abstract

Background: Informed consent is a pillar of ethical medicine which requires patients to fully comprehend relevant issues including the risks, benefits, and alternatives of an intervention. Given the average reading skill of US adults is at the 8th grade level, the American Medical Association (AMA) and the National Institutes of Health (NIH) recommend patient information materials should not exceed a 6th grade reading level. We hypothesized that text provided in invasive procedure consent forms would exceed recommended readability guidelines for medical information.

Materials and methods: To test this hypothesis, we gathered procedure consent forms from all surgical inpatient hospitals in the state of Rhode Island. For each consent form, readability analysis was measured with the following measures: Flesch Reading Ease Formula, Flesch–Kincaid Grade Level, Fog Scale, SMOG Index, Coleman–Liau Index, Automated Readability Index, and Linsear Write Formula. These readability scores were used to calculate a composite Text Readability Consensus Grade Level.

Results: Invasive procedure consent forms were found to be written at an average of 15th grade level (i.e., third year of college), which is significantly higher than the average US adult reading level of 8th grade ($p < 0.0001$) and the AMA/NIH recommended readability guidelines for patient materials of 6th grade ($p < 0.0001$).

Conclusion: Invasive procedure consent forms have readability levels which makes comprehension difficult or impossible for many patients. Efforts to improve the readability of procedural consent forms should improve patient understanding regarding their healthcare decisions. *Clin Trans Sci* 2015; Volume 8: 830–833

Keywords: consent form, comprehension, readability, informed consent, health literacy

Introduction

Informed consent is a pillar of ethical medical practice. Informed consent is achieved when patients fully understand the procedure they are considering. Ideally, informed consent is achieved through patient–physician conversation regarding the risks and benefits of all available interventions, resulting in voluntary permission to proceed with the procedure. Legally, intervention without informed consent may be grounds for negligence, malpractice, or battery and assault.¹ Ethically, the patient's understanding of the proposed procedure is paramount for them to make an informed decision.

The consent form was developed to document the informed consent conversation and to ensure that all necessary information is conveyed. The process of informed consent is particularly relevant as surgeons and other procedure-based physicians are burdened with increasing malpractice insurance costs and liability threats.² Improved understanding of the informed consent process is critical.

The level of patient comprehension during the informed consent process is frequently overestimated.³ In a prospective evaluation of patient comprehension of informed consent, Crepeau et al. found that surgical patient comprehension and recall immediately following a thorough discussion of the consent form was unexpectedly low.⁴ Previous investigations have examined the readability of consent forms use in research protocols as a contributing factor to poor comprehension.^{5–7} These research protocol consent forms are substantially different from consent forms used in daily clinical practice, and to our knowledge, no study has evaluated the readability of invasive procedure consent forms used in daily practice.

Because the average US adult reads at an 8th grade level,^{8,9} the National Institutes of Health (NIH) and the American Medical Association (AMA) recommend the readability of patient

materials be ≤6th grade reading level.^{20–24} Patient materials have been repeatedly shown to be too complex.^{9,15–24}

In this study, we evaluate the readability of invasive procedure consent forms used in daily clinical practice. We hypothesized that text provided in consent forms would exceed the AMA/NIH-recommended readability guidelines for medical information (i.e., reading level >6th grade).

Methods and Materials

Invasive procedure consent forms from each hospital type (private, public, government, community, and academic) were sampled by gathering consent forms from all hospitals in the state of Rhode Island that perform procedures. For each consent form, readability was analyzed using eight well-validated tests.

Consent forms

There are 17 hospitals in the state of Rhode Island, 14 of which perform invasive procedures. Due to several hospitals from the same hospital system sharing consent forms, there are 11 unique invasive procedure consent forms used statewide. All 11 (100%) of these consent forms were obtained between May and August, 2014.

Text from the consent forms was copied in plain text format into individual Microsoft Office Word 2010 documents (Microsoft Corporation, Redmond, WA, USA). As recommended by Flesch and others, all decimals, numbers, paragraph breaks, bullets, abbreviations, semicolons, colons, and dashes within a sentence were removed in order to avoid underestimating the readability level.^{25,26}

Readability analysis

Readability analysis was performed using well-validated scales that have been commonly used to evaluate healthcare-related

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Assessment scale	Formula	Output
Flesch Reading Ease Formula	$= 206.835 - (1.015 \times ASL) - (84.6 \times ASW)$	Score form 0–100 <ul style="list-style-type: none"> • 90–100 = 5th grade reading level • 60–70 = 8th and 9th grade reading level • 0–30 = college graduate reading level
Flesch–Kincaid Grade Level	$= (0.39 \times ASL) + (11.8 \times ASW) - 15.59$	Average student of the grade can read the text.
Fog Scale	$= 0.4 (ASL + PHW)$	<ul style="list-style-type: none"> • 5 = readable • 10 = hard • 20 = very difficult
SMOG Index	$= 1.043 \times \sqrt{C \times (30/S)} + 3.1291$	Average student of the grade can read the text
Coleman–Liau Index	$= 0.0588L - 0.00296S - 15.8$	Average student of the grade can read the text
Automated Readability Index	$= 4.71 (\text{characters/words}) + 0.5 (\text{words/sentences}) - 21.43$	Average student of the grade can read the text
Linsear Write Formula	$= (R + 3C)/S$ Then: <ul style="list-style-type: none"> • If >20, divide by 2 • If ≤20, subtract 2, and then divide by 2 	Average student of the grade can read the text

ASL = average sentence length (i.e., the number of words divided by the number of sentences [S]); ASW = average number of syllables per word (i.e., the number of syllables divided by the number of words); PHW = percentage of hard words (i.e., the number of 3+ syllable words [C] divided by the number or words in the sample passage); R = the number of words ≤2 syllables; L = the average number of letters per 100 words; average student of the grade can read the text = US school grade level (e.g., 7.4 = 7th grade).

Table 1. Assessment scales used for consent form readability.^{59–61}

materials.^{15–20,22–24,27–35} Readability scores were measured using the following tests: Flesch Reading Ease Formula, Flesch–Kincaid Grade Level, Fog Scale, SMOG Index, Coleman–Liau Index, Automated Readability Index, Linsear Write Formula, including the composite Text Readability Consensus Calculator (Table 1). The readability software utilized is publically available at <http://www.readabilityformulas.com/freereadability-formula-tests.php>.

Each of the readability measures is based on the English language and US grade levels, and uses different criteria to compute the readability (e.g., length of sentence, number of characters, number of syllables, number of words, or combinations thereof). The Readability Consensus formula combines the output of these measures and computes a composite grade level score across all seven methods.

Statistical analysis

Unpaired *t*-tests were utilized to compare the mean Text Readability Consensus Grade Level of consent forms with the readability level recommended by the AMA and NIH (6th grade), as well as with the average American adult reading level (8th grade). GraphPad Software (GraphPad Software, Inc., La Jolla, CA, USA) was used for statistical analysis. The $p < 0.05$ was used to establish statistical significance.

Results

All 11 consent forms were obtained and assessed (100%). The average grade level readability of invasive procedure consents forms was 15.0 (SD = 3.6) (Table 2). None (0/11) of the consent forms had a readability score below the 6th grade level. The readability of the consent forms exceeded this level by an average of 9.0 grade levels (95% CI, 6.7–11.3; $p < 0.0001$). None (0/11) of the consent forms had a readability score ≤8th grade level. The readability of the articles exceeded this level by an average of 7.0 grade levels (95% CI, 4.7–9.3; $p < 0.0001$) (Figure 1). Hospital names and affiliations have been de-identified for the sake of privacy.

Discussion

This investigation revealed that the readability level of invasive procedure consent forms exceeds the average patient's comprehension level by seven grade levels. The average consent form was significantly more difficult to read than both the NIH/AMA readability recommendations and the average reading level of adults in the United States. In 2003, Paasche-Orlow et al. found that the readability level of research-related consent forms from across the country to be 10.6.⁵ Our findings suggest today's clinically-used invasive procedure consent forms may be of even greater complexity.

Patient understanding of health information is at the core of informed consent validity. Consent forms may thus fail to effectively inform a substantial portion of the patient population because they cannot properly understand the content. Additionally, the sizeable patient population that does not read English fluently is likely to comprehend even less. Without comprehension, completely informed consent cannot be realized. One might argue that a comprehensive verbal discussion of the proposed procedure is sufficient for informed consent which, in fact, may be true. However, the record should reflect what actually occurs during patient care including informed consent. If a patient is asked to sign a document that they cannot comprehend due to their reading skill level, have they actually completed the process of true informed consent? Inadequacy of informed consent has the potential for significant legal and ethical consequences.

Furthermore, poor understanding may negatively impact health literacy, which is an important factor in health outcomes and costs. Health literacy is the “capacity to obtain, interpret, and understand basic health information and services and the competence to use such information and services to enhance health” —is therefore central to informed consent.³⁶ Nearly 50% of adults “experience considerable difficulty in performing tasks that required them to integrate or synthesize information from

Hospitals with unique consent forms	Health system	FRE	FKGL	Fog	SMOG	CLI	ARI	LW	Consensus
1	Private hospital system 1	41.1	11.8	14.9	11.4	13	11.8	12.5	12
2	Private hospital system 2	27.8	15.2	18	13.9	13	14.7	17.5	15
3	Private hospital system 2	46.5	10.4	14.5	10.6	13	10.2	10.6	11
4	Independent	32.1	14.1	18	13.1	14	14.6	15.8	14
5	Independent	30.1	15.5	18.7	13.7	14	16.9	18.6	16
6	Independent	2.7	22.6	20.7	18.8	15	24.7	30.4	22
7	Independent	28.3	15.1	18.4	13.9	14	15.6	17.5	15
8	Independent	14	20.7	22.6	18	14	22.7	28.8	21
9	State owned	30.5	14.2	17.1	13.3	15	15.4	15.9	15
10	Federally owned	35	12.9	14.8	12	14	12.9	13.4	13
11	Federally owned	41.3	11.4	14.5	11	13	11	11.4	11
Average ± SD	–	29.9 ± 12.5	14.9 ± 3.8	17.5 ± 2.7	13.6 ± 2.6	13.8 ± 0.8	15.5 ± 4.6	17.5 ± 6.5	15.0 ± 3.6

Table 2. Readability levels calculated by Flesch Reading Ease Formula (FRE), Flesch–Kincaid Grade Level (FKGL), Fog Scale (Fog), SMOG Index (SMOG), Coleman–Liau Index (CLI), Automated Readability Index (ARI), Linsear Write Formula (LW), and Text Readability Consensus Grade Level (Consensus).

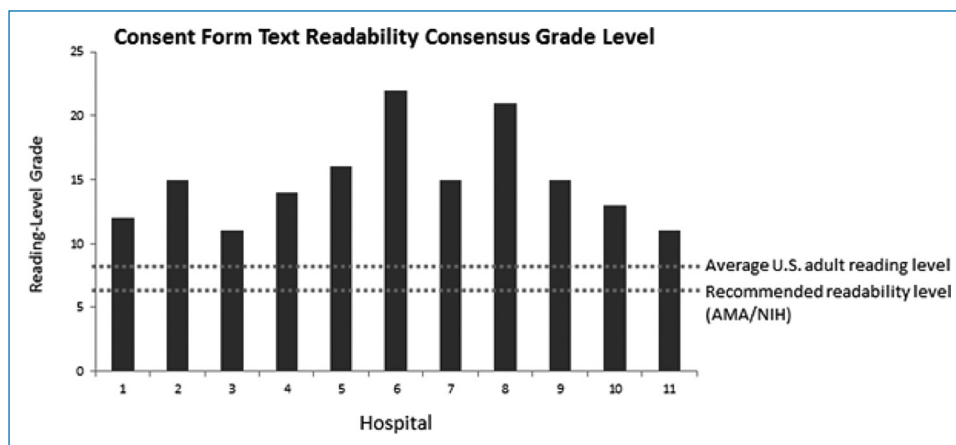


Figure 1. Consent form text readability consensus grade level.

complex or lengthy texts.³⁷ Although the average US adult reads at an 8th grade level,^{8,9} approximately one-fifth of these adults are unable to comprehend 4th grade-level text.⁹ Most importantly, health literacy predicts health-related quality of life,^{38–40} worse overall health,^{41–46} along with complication and hospitalization rates.^{42,47,48} Lower health literacy is associated with substantial additional annual healthcare costs.^{49–57} This study highlights an important gap between relevant and understandable healthcare information and patient comprehension.

This study has several possible limitations. We assumed those reading the consent forms possess comparable reading skills to the general population, which may or may not be the case. Additionally, nonhospital clinical settings’ consent forms were not sampled. Furthermore, the 11 consent forms analyzed may not represent similar content to forms from the entire country, although they do represent private, public, and government

hospitals including community health centers and large trauma centers. Many patients treated at these hospitals speak English as a second language, and consent forms are available in many additional languages as well. The present study does not address this issue, which in some regions may be significant. It is likely that the English reading level in areas with large immigrant populations may in fact be far lower than the national average. Foreign-language consent forms may represent a level of sophistication exceeding the population they target. This was not addressed in the current study. Finally,

the consent form is only one aspect of informed consent, and obtaining appropriate informed consent is a process requiring verbal communication rather than just the completion of a form, and no assessment of verbal consent processes was completed.

Screening and testing of the readability of invasive procedure consent forms is an important initiative to ensure health literacy. Certain consent form revision strategies may be of particular benefit. For example, shorter sentences, simpler terms, and pictures can improve readability.^{14,15} Innovative approaches, such as video informed consent, aimed at improving patient comprehension show promise.⁵⁸ Enhancing patient understanding and health literacy through modifying readability of consent forms has the potential to improve patient outcomes.

Conflict of Interest

None of the authors have directly pertinent conflicts of interest.

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