

## Difficult Words in Informed Consent Forms

By Norman M. Goldfarb

U.S. federal regulations, ICH guidelines, and good ethics require informed consent forms that potential subjects can understand.<sup>1,16</sup> Understanding requires that the forms be readable. "Readability" measures the ease with which a reader can absorb, understand and retain the contents of a document. It also contributes to reading speed and persistence in memory. Unfortunately, the readability of most informed consent forms (ICFs) is problematic, especially given literacy levels in the U.S.<sup>2</sup> In addition, national literacy surveys use newspapers, magazines and other popular reading materials to measure general reading skill. Thus, they do not measure literacy in specialized areas such as healthcare.

Studies of ICF comprehension generally show disturbingly low levels of comprehension.<sup>14,15,22</sup> They also demonstrate little or no correlation between the readability of the document and comprehension.<sup>3</sup> This counterintuitive result may be explained by the sample populations (too literate, uncontrolled prior knowledge), lack of motivation (not real-world), and inadequate measures taken to produce the "readable" test document. Further, in most informed consent readability studies, researchers do not use validated measures of comprehension.<sup>17,18</sup>

Most authors find it difficult to write effective documents for people unlike themselves. ICF authors have relatively high literacy, experience with informed consent forms, and relevant technical knowledge. They may have no personal interaction with potential study subjects who have none of these attributes. Authors may not appreciate that their ability to read well does not translate directly into the ability to write well. For these reasons, it is difficult for them to perceive how difficult their writing may be for their target audience. Objective measures of readability can help authors calibrate their writing.

### Readability

Numerous elements contribute to document readability. The major contributors, in order of importance, are: content (subject matter), style (e.g., vocabulary, complexity of the sentences, and voice), design (e.g., font and page layout), and organization.<sup>3,4,19,23</sup> If the content is inherently difficult, readability relies on the other factors, especially vocabulary and sentence complexity.<sup>5,6,7</sup>

Readability formulas have been used to measure the readability of ICFs since the 1970s.<sup>22</sup> The most widely used formulas today are the Flesch Reading Ease and Flesch-Kincaid formulas in Microsoft Word's Readability Statistics. These measures count average words per sentence and average syllables per word. The Flesch Reading Ease formula scores text on a scale of 1 to 100, with 1 being very difficult (above 16<sup>th</sup> grade) and 100 being very easy (5<sup>th</sup>-grade level). The Flesch-Kincaid formula conveniently scores readability by grade level. Words-per-sentence measures sentence complexity. Syllables-per-word measures vocabulary difficulty. These formulas ignore organization and design, which are relatively simple to accomplish but seldom employed in informed consent forms.<sup>8,27</sup>

The formulas are much more reliable when testing an existing text than when using them to create or modify a text. Some research shows little or no correlation between improvements in the formula scores and improvements in comprehension.<sup>24</sup> "Writing to the formula" – blindly substituting short words for long ones and chopping long sentences into short ones – generally does not improve comprehension.<sup>23</sup> However, good writing does help.<sup>28,29</sup> To

substantially improve comprehension, all the factors of readability should be addressed.<sup>9,10,26</sup>

## Word Rarity

The number of letters or syllables in a word is a good, but imperfect, measure of its difficulty. Another measure of a word's difficulty is its rarity in day-to-day usage; people tend to be unfamiliar with words that are seldom encountered.<sup>26</sup> "Rigors" and "stent," for example, are very short words that are unfamiliar to the general public, and thus difficult. The most readable texts minimize both the length and word rarity of words.

The American National Corpus consists of over 22 million words of American English, primarily from written sources.<sup>11</sup> The database is used for education, linguistic and lexicographic research, and technology development. The British National Corpus is a similar database of 100 million words of spoken and written British English.<sup>12</sup> These and numerous other databases are available through the Linguistic Data Consortium.<sup>13</sup> With these data, we can identify words that the general public rarely sees.

Table 1 shows the statistical characteristics of word rarity in a random sample of 41 ICFs. The table also shows statistics on the prevalence of long words (12 or more characters), another measure of vocabulary difficulty.

**Table 1. Informed Consent Form Word Difficulty**

<b>Word Frequency (per Million)</b>	<b>Mean</b>	<b>Median</b>	<b>Std Dev</b>	<b>Min</b>	<b>Max</b>	<b>Typical</b>
Not Found	0.6%	0.4%	0.6%	0.0%	2.3%	14
Extremely Rare (<=1/m)	1.2%	1.2%	0.6%	0.3%	2.8%	44
Very Rare (<=5/m)	2.5%	2.6%	1.0%	0.5%	5.1%	96
Moderately Rare (<=10/m)	1.8%	1.8%	0.5%	1.0%	3.1%	65
Somewhat Rare (<=25/m)	5.4%	5.2%	0.8%	4.2%	7.4%	191
Somewhat Common (<=50/m)	5.0%	4.9%	0.9%	3.3%	7.4%	178
Moderately Common (<=100/m)	7.9%	7.9%	0.8%	6.6%	9.8%	288
Very Common (<=500/m)	20.1%	20.0%	1.7%	16.7%	23.0%	732
Extremely Common (>500/m)	55.6%	55.8%	3.9%	43.8%	65.1%	2,042
Long words (>=12 characters)	2.4%	2.4%	0.6%	1.2%	3.6%	89

The median number of words in the sample documents is 3,663 (mean=4,142, std dev=2,465). Thus, the typical informed consent form is likely to include 14 words (including multiple uses) that are usually not found in a sample of 1 million words, 44 words that are usually found only once or less, etc.

The problematic words are primarily those with frequencies of 10 or less per million: moderately rare, very rare, extremely rare, and not found. A typical informed consent form will include 219 (6.0%) of these words (including multiple uses). (The document will also include 89 (2.4%) different long words, which may overlap with the rare words.) Some of these words will be proper nouns; authors should review the others for potential substitution, clarification or elimination. The most readable of the sample documents includes 2.3% rare words (less than 40% of the median), while the least readable includes 12.2% (more than double the median).

Not all rare words are difficult. For example, the word "two" is moderately rare (5.7/million) and the word "three" is very rare (2.7/million) because numerals are often used instead of

these words. Thus, judgment is required in determining which words are likely to be difficult for readers.

Table 2 shows examples of words in each category that appear in the sample informed consent forms. The table also shows substitutions and clarifications that may be useful, depending on the context.

**Table 2. Difficult Words in Informed Consent Forms**

<b>Category</b>	<b>Word</b>	<b>Substitution or Clarification</b>
Not Found	asthenia	weakness
	autoinjector	syringe you use yourself
	co-insurance	second insurance policy
	curettage	scraping away of tissue
	dehiscence	bursting out
	endoscope	lighted tube used to look inside the body
	fibrillate	uncontrolled fast beat
	genotoxicity	can damage genes
	sub-investigator	doctor in the study; researcher in the study
Extremely Rare	tardive	late
	anonymized	without names
	anticoagulant	drug used to stop blood from clotting
	dyskinesia	jerky movements
	dyspepsia	upset stomach after eating
	hematocrit	amount of red blood cells in the blood
	hypoglycemia	not enough sugar in the blood
	perforation	hole; tear
	recuperation	getting better
Very Rare	transdermal	through the skin
	well-tolerated	without serious side effects
	abdomen	belly
	anaphylaxis	sudden and very serious allergic reaction
	concurrent	at the same time
	discontinue	stop
	enroll	join
	hemorrhage	fast loss of a lot of blood
	intramuscular	in the muscle
Moderately Rare	revoke	take back; cancel
	subcutaneous	under the skin
	thrombosis	blood clotting in a blood vessel
	administered	given
	adolescent	teenager
	anticipate	expect
	blinded	kept secret
	compensate	pay
	fatigue	tiredness
fibrillation	fast uncontrolled heartbeat	
formulation	recipe	
intravenous	into a blood vessel	
specimen	sample	

Many difficult words, especially medical terms, do not have synonyms that employ common words. Nevertheless, such terms require explanation. Table 3 shows examples of such words:

**Table 3. Difficult Words without Easy Synonyms**

<b>Word</b>	<b>Definition</b>
anesthetic	drug used to prevent pain by numbing part of your body or putting you to sleep
antibody	particle that sticks to germs and foreign matter to protect the body from infection
double-blind	when neither you nor the researcher knows what treatment you are getting
enzyme	a protein produced by the body for performing processes of life
inflammation	response of tissues to irritation or injury: redness, heat, swelling and pain
open-label	when the drug or device is known to the subject and the investigator
pathology	the study of the changes in the body and body tissue caused by disease
platelet	material that causes blood to clot
X-ray	invisible radiation used to take pictures of the inside of the body

Table 4 shows examples of acronyms that appear in the sample informed consent forms. It cannot be assumed that a study subject will know the meaning of even a common acronym such as "TSP." It is therefore common to define acronyms when they are first used in a document; doing so makes documents easy to read (ETR).

**Table 4. Acronyms**

<b>Acronym</b>	<b>Phrase</b>
CBC	Complete Blood Count
CRC	Clinical Research Coordinator
DVT	Deep Vein Thrombosis
ICF	Informed Consent Form
IRB	Institutional Review Board
IVRS	Interactive Voice Recognition System
QD	Quiaque Die (everyday)
TSP	Teaspoon

Some difficult words have potential replacements that do not carry exactly the same meaning, but depending on the context, may be suitable. Examples of such words and their possible replacements include: confidentiality (privacy), investigational (study), investigator (doctor), pharmaceutical (drug), and requirements (rules).

Replacing or eliminating difficult words may not always be desirable. The primary purpose of informed consent is to help potential subjects make informed enrollment decisions. A secondary purpose is to help them participate in an informed manner. Including some technical terms (e.g., "HIPAA") in the ICF – with explanations – may thus be appropriate.

A glossary of difficult words used in informed consent forms, with substitutions and clarifications, is available at <http://www.firstclinical.com/icfglossary>. A tool for analyzing and

improving the readability of informed consent forms is available at <http://www.firstclinical.com/words>.

## Conclusion

Given the complexity of most ICFs, a good informed consent discussion is essential.<sup>20,21,30</sup> ICF understandability is a matter of degree, so every little bit of readability helps. Reducing the difficulty of words contributes to readability. A simpler vocabulary is also useful in informed consent discussions.

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### **Author**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).