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Dockets Management Branch
Food and Drug Administration
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To whom it may concern:

I strongly support FDA's plan for public disclosure of information on clinical trials involving gene therapy or xenotransplanation. However, I hope that such information is written in "plain English' so that the public will be able to read and understand it. If not in "plain English," but in typical drug company style (full of legal and medical jargon), the information will be virtually useless.

My concern is that if the information is provided by drug or biotech companies, the material submitted to FDA will be as unreadable as the "brief summary" that's often posted on drug company web sites posing as "consumer information." Plus, there's considerable research on the unreadability of clinical trials consent forms--which average patients may find very hard to understand. (See enclosed articles.)

Perhaps the FDA can provide specific guidelines to companies that will help them write "plain English" materials--since they don't seem to be able to do it on their own.

Yours truly,

Mark Hochhauser

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How readable is your writing?

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The Research Roundtable
Investigator and IRB Issues in a Monthly Newsletter
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Readability Expert, and IRB Member, Gives Perspective about $3.5 Million Tampa General, University of South Florida Settlement on Informed Consent

Mark Hochhauser, Ph.D., is a psychologist who researches, writes and consults on readability issues with Institutional Review Boards ("IRBs"), mutual fund companies, managed care organizations and law firms. Dr. Hochhauser is also an IRB member, and therefore is quite familiar with informed consents for research studies.

This newsletter sent Dr. Hochhauser the informed consent document that was at the center of the controversy in the $3.8 million settlement in Tampa (see September and October issues for a discussion of this case) and the full consent decree that brought an end to 'ten years of litigation on this matter. (Note: The informed consent and the court's consent decree now are available in their entirety on our website at www.ResearachRoundtable.com). Readability tests performed by Dr. Hochhauser indicated that the Tampa informed consent was written on a second-year-of-college reading level. In addition, Dr. Hochhauser indicated that the layout of the informed consent was "terrible," as there were no titles, headings or subheadings to organize the document, thus making it hard for the reader to integrate all the different pieces of information.

Upon reviewing the available case documents, Dr. Hochhauser noted the case seems to assume that an informed consent written at a high reading level will become much more understandable and comprehensible if it is re-written at a lower reading level. Dr. Hochhauser found several references in the literature on this issue that did not support this position. According to Dr. Hochhauser, "one study of consent forms rewritten from a grade 16 to a grade 7 reading level found virtually no difference in understanding." ***See Davis, T.C., Holcombe, R. F., et al. (1998) Informed Consent for Clinical Trials: a Comparative Study of Standard versus Simplified Forms. Journal of the National Cancer Institute. 90(9), 668-674.*** Another study found no difference in understanding between consent forms written at a grade 12 level versus a grade 8 level. ***See Cardinal, B.J. (2000) (Un)Informed Consent in Exercise and Sport Science Research? A Comparison of Forms Written for Two Reading Levels. Research Quarterly for Exercise and Sport. 71(3), 295-301.***

One journal article supporting the position that consent forms written at a lower grade level promoted better comprehension was found, however. See Young, ***D.R., Hooker, D.T. & Freeberg, F. E. (1990) Informed Consent Documents: Increasing Comprehension by Reducing Reading Level. IRB: A Review of Human Subjects Research, May-June 1990, I-5.*** Hochhauser summarized the article by noting:

Two versions of a consent form (6th grade, or low reading level, and grade 16 or. high reading level) were developed Researchers found higher comprehension scores for the low reading level consent form than for the high reading consent form. Comprehension increased with education, with participants who attended or graduated from college scoring higher at both reading levels than participants with a "high school or less" education level.

As a follow-up to his readability assessment of the informed consent in the Tampa General Hospital and University of South Florida case, we interviewed Dr. Hochhauser:

Q. Representatives of the University of South Florida criticized the notion of lowering the reading level of informed consents, stating that if the informed consent were "dumbed down" to the 6" or 7th grade reading level, it would be an insult to the reader. Is this true or false?

A. ***Some people will say true. I disagree and I really hate the term "dumbing down." I don't see that writing something in clear English that***

people can understand is "dumbing down. " I've never heard people complain that something was too easy to understand. If you look at the current best sellers, fiction or non-fiction. I believe you see that some of the best writers find ways to communicate in a very clear, unambiguous way.

Some years ago, I made a presentation to a religious group. I thought I'd give the audience something on readability that they would appreciate. So I ran the Ten Commandments through my readability software. Now the passage was short, as we all know, and you can quibble about what bible you should use, but the point was that it came out at a 4th grade reading level. This tells me that if you want the masses of people to understand things, you simplify it,

"Dumbing down" is a phrase that makes the hair on the back of my neck stand up. On the flip side of this example, can you imagine if the Ten Commandments were written by lawyers? It would read something like, "The party of the first part shall not engage, behave, or act in any way style, or custom that will cause the party of the second part to be terminated with extreme prejudice" (33 words) or "Thou shall not kill" (4 words). So "dumbing down" is a bad term in my opinion.

Q. You found two references in the literature where reducing the reading level of a document didn't improve its understandability., Many would say that's counter-intuitive, thinking that a simpler document is more likely to be better understood.

A. ***It does appear to be counter-intuitive. And I think the researchers were mystified because they expected it to be just the opposite. Certainly, I would like to see more research done on this subject. I wouldn't want to base a conclusion on two studies that were limited in terms of the subject population studied and consent forms used. One study used only a 300-word consent form. The hospital IRB that I'm on frequently sees consent forms between 1,000 and 3,000 words. in the really long consent forms, readability 'isn't the only problem - subjects may experience information overload. Too much information, even at a readable level, means that readers will still have a hard time understanding the consent form. So readable consent forms are necessary, but not sufficient. intuition and logic are fine, but at some point. researcher; have to validate their position with data.***

Q. If I represented a concerned IRB, and I was facing the question of producing readable and understandable informed consents, why wouldn't my IRB run every informed consent through the simple readability tests contained on word processing software, and mandate that the reading level be in the single digits (9th grade or less)? The IRB would know that there's not a perfect correlation between lower reading levels and document understandability, but at least it would have something in hand -- hard physical proof -- that its informed consent was of a medium reading level.

A. ***If you want to protect yourself and you need documentation, numbers are one way to do that. And based on the Tampa General/University of South Florida case, it sure looks like that was all that concerned the parties. So, sure, you can protect yourself by saying let's get the reading level of the document at least into single digits. I certainly understand that position. However, given the constraints of inadequate staffing and inadequate finding facing an average IRB today, I wonder who is going to do this measuring?***

Q. Wouldn't you measure readability of an informed consent, if you were consulting with an IRB on the issue of informed consents?

A. ***Sure, one of the things I would look at would be the reading level of the document. Let's keep in mind, however, that the target population of a research study may be college-educated subjects. The consent form has to take into consideration its target population, and that target population may not have the low reading level skills that seemed to be important in the Tampa case.***

There are other criteria for evaluating the understandability of documents, such as the layout and design issues, that should be considered. If the Tampa case results in IRBs simply manipulating consents to score in the single digit range of a reading level test, what concerns me is that, the industry won't feel compelled to go the extra step and say there are

other things in the informed consent document that we can improve.

I'm a great believer in the organization and the visual presentation of a document. I believe we should take advantage of 21st century technology. One example of this would be to make the consent look like a newsletter. Why does a consent document have to be just black type on white paper like it's been for so many years?

I'd also like to see an informed consent with a "Frequently Asked Questions" section. That's a technique that is common today in documents, and it can aid in understandability. In the future, I think we'll see the informed consent get more visual, whether it's on videotape, on a CD-ROM or on an internet site.

Q. If you re-wrote the informed consent for an IRB in order. to improve its readability and understandability, and the target population of the study contained a high percentage of low literacy people, would the reading level of your document be in the single digits (9th grade reading level or below)?

A. ***It probably should be, but with that population of low literacy subjects, my concern would be with the vocabulary that is used in the consent form. My concern is that there may be a lot of words, even short words, which these people don't understand Certainly, as a consultant, I could help re-write an improved informed consent. But what they really need to do is have people from the target community involved in drafting*** or ***evaluating the consentform.***

Q. What are the practical problems IRBs and investigators face in adjusting the reading levels of informed consents?

A. ***My concern is on a multi-center clinical trial study that's being conducted nationally or internationally by one of the big pharmaceutical companies. How much flexibility does the local investigator or IRB have in changing the informed consent form?***

Prior to the start of a clinical trial, an investigator and/or IRB usually negotiate with the study sponsor over a few standard clauses - clauses for women of child-bearing potential, for example. What happens when the investigator or IRB proposes 25 or 50 wording or phrasing changes to the informed consent to bring the readability of an informed consent from the 15th grade to the 9th grade reading level? Re-writing a consent form from a college to a junior high reading level can be a hard sell, and any big pharma company, worried about a long delay caused by such a process, certainly can take its study elsewhere -- to an institution that wouldn't request "readability changes. "

Q. What are the probable solutions to this whole issue of readability and understandability?

A. ***To get Big Pharma's attention, it would take a suit against them in one of their drug studies. If such a suit were successful, then they may decide that informed consents have to change.***

Another possible solution may come from government. In a lot of states, to sell life insurance or health insurance, the states say that the policy has to be written at a certain reading level. I think it's going to come down to something like that with consent forms. I'm not sure who is going to decide what the bar is going to be, however,

Q. You also discovered something interesting about the University of South Florida's current practice on informed consents.

The University of South Florida has an Office of Research Compliance. On its web site @tart at www. research. usf. edu/cs/d101. htm), they have an 'Adult Informed Consent Template. " I downloaded the form to analyze its reading level. As a template, there were a lot of incomplete sentences, so I eliminated them and only analyzed the complete sentences, many of which were for genetic testing/blood and tissue banking issues. Even so, I was able to get about I70 sentences out of it. It tested between a 12th an 13th grade reading level. On the Flesch Reading Ease Scale, it was on the border between "difficult" and '[fairly difficult." ⏭

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THE INFORMED CONSENT FORM: DOCUMENT DEVELOPMENT AND EVALUATION

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The informed consentprocess can be viewed as a sales presentation, with the consent form serving as the written advertisementfor the drug research So viewed, drug companies can use basic document design, layout and typography principles from advertising, as well as strategies from the "plain English" movement both to improve recruiting strategies and enhance participant understanding.

This article evaluated 12 consent forms for investigational drug studies submitted to a Minnesota hospital institutional review board. Consent form text characteristics were compared to recommendations from the National Cancer Institute. Computer analyses judged the consent forms as difficult to read at a grade 13 to 14 reading level; forms included too many uncommon words, too many words per sentence, and too few active voice sentences, giving a "poor" overall style rating. The 12 forms did not always meet good principles of document design in terms of typeface, paragraph justification, and words per line. ***Several strategies for*** testing the ***consent form and reader comprehension were suggested***

Key Words: Readability; Informed consent; Document design; Plain English

INTRODUCTION

IN SOME WAYS, clinical drug research is a service that research participants can choose to buy-or not buy. Some participants (consumers) may benefit from buying a product (a new drug); many researchers (salespeople) will be paid for each subject they recruit. As a result, some consent forms are beginning to include statements about researcher compensation so that prospective participants can assess the financial aspects of the research project, including possible financial conflicts of interest.

So viewed, the consent process can be thought of as a sales presentation, with the consent form being the written advertisement for the research. From that perspective, why should drug companies not use basic document design (1) and layout and typography principles (2,3) from advertising, as well as strategies from the "plain English" movement to improve both participant recruitment efforts as well as participant understanding of the research project? One review found 14% to 44% refusal rates (4) although the reasons for such refusals are not clear.

In October 1998, the National Cancer Institute (NCI) (5) published recommendations for developing informed consent documents for cancer clinical trials. Appendix 3 of that document is a checklist that can help ensure the development of easy-to-read consent forms. Unfortunately, the checklist is very brief, and does not include examples or explanations for any of the over 30 recommendations for text and graphic items.

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METHODS

The researcher is a member of the Institutional Review Committee (IRC) at North Memorial Medical Center, Robbinsdale, Minnesota. With permission from the IRC chair, the IRC secretary randomly selected 12 informed consent forms for investigational drugs studies submitted to the committee in 1999. The consent forms were scanned into a computer, optically read by Textbridge Pro 9.0, and analyzed by seven DOS-based software programs: Corporate Voice, FS Text, Key Grammar, Prose, Pro-Scribe, Reader, and WStyle. Each of these programs provides different statistical data that can help assess the "plain English" characteristics of the consent forms.

RESULTS AND DISCUSSION

NCI Recommendations (in italics) and Comments

"Words are familiar to the reader. Any scientific, medical, or legal words are defined clearly."

Unfortunately, the NCI does not define "familiar words" or give consent form writers any strategies to determine familiar and unfamiliar words in an informed consent form. Words that are commonly used by researchers may be completely unfamiliar to prospective participants. One way to more systematically approach this issue is to consider the frequency with which words appear in written documents. Table 1 categorizes the word frequency of some words from 12 investigational drug study consent forms reviewed by the North Memorial Medical Center Institutional Review Committee.

Word frequency was based on The Educator's Word Frequency Guide (6). This guide calculated word frequency based on 17 million words from 61000 samples of text from over 6000 written materials used in American schools and colleges. Most readers would probably be able to read and understand words with a frequency of 100 per million words or greater. The uncommon words (30 per million words or less), however, may present serious reading problems. If research participants do not read much, they probably will not encounter many of these uncommon words, so when they see them in the consent form, they will have a hard time reading and understanding them.

Word familiarity has been shown to be a major factor in a reader's ability to understand written materials. Since word frequency is a good estimate of word difficulty, words that do not appear in print very often are harder to read and understand than words that appear frequently (7). Too many uncommon words will make a consent form virtually incomprehensible to the "average" reader.

Waggoner (8,9) has identified many research-related words and phrases that people do not understand very well, including: efficacy, double-blind, washout period, protocol, randomly, Institutional Review Board, baseline visit, concurrent drugs, sponsor, and so forth. Prospective participants have a hard time understanding not only words, but basic clinical research concepts as well.

As shown in Table 2, the 12 consent forms used too many uncommon words, making both reading and comprehension more difficult for the prospective research participant. There are, however, translations of unfamiliar medical terminology into familiar medical terminology (10,11), such as those shown in Table 3.

"Sentences are short, simple, and direct."

Although the NCI does not define short, simple, and direct, the work of Rudolf Flesch (12) has been influential in establishing some basic guidelines. Flesch recommended that sentences average about 15 to 17 words for maximum readability. The 12 consent forms averaged 20 words per sentence, which is not too far from the recommended range.

Beyond calculating the number of words per sentence, some software programs (eg,. Corporate Voice) can categorize sentences as simple and normal; or wordy, pompous, and complicated. While that program suggests

TABLE 1
Word Frequency Analysis of 12 Informed Consent Forms

Word Frequency	Examples
10000/million words	a, and, are, as, for, in, is, it, of, on, one, that, the, to, with, you
3000/million	about, an, be, from, had, have, he, into, like, more, no, not, or, other, out, people, so, there, this, time, up, we, when, who, will, your
1000/million	after, also, any, because, even, every, first, food, help, how, however, important, know, made, make, may, me, might, most, much, must, my, new, only, part, see, should, such, take, used
300/million	able, become, care, done, given, group, information, known, let, low, need, number, possible, problems, questions, read, study, sure, understand, without
100/million words	available, blood, cells, chance, choose, continual, decision, determine, doctor, explain, follow, future, health, heart, hour, immediately, loss, months, occur, physical, purpose, receive, related, remain, research, results, safety, sign, similar, skin, test, visit
30/million words	additional, administration, appropriate, approximately, assigned, benefit, bone, cancer, circumstances, commonly, data, discuss, drawn, drug, examination, female, include, laboratory, legal, maximum, mild, needle, otherwise, pain, plus, potential, procedure, routine, severe, site, treatment
10/million	alternative, bleeding, calcium, commitment, compensation, consent, conventional, criteria, customary, disorder, effectiveness, evaluate, functional, governmental, infection, injury, liability, multiple, participate, physician, pregnant, prior, random, risks, specimens, symptoms, withdraw
3/million	aggregate, applicable, assess, capability, chronic, clinical, complications, comply, discomfort, dose, duration, elevated, extensively, incidence, likelihood, medication, monetary, orally, sponsor, theoretical
<1/million	adverse, bruising, catheter, centigrade, chemotherapy, confidentiality, definitive, dehydration, designee, diluted, disclosed, discontinuation, documented, exhibiting, generalized, hereby, hypersensitivity, identifiable, impairment, inconveniences, incur, inflammation, infusion, intermittently, investigational, jeopardize, localized, monitoring, percutaneous, placebo, protocol, regimen, unforeseen, unreimbursed

that 80% of sentences should be "simple" and "normal," only 67% of the consent form sentences met that standard. While no more than 20% of the sentences should be "wordy," "pompous," and "complicated," 33% were in those categories.

A related measure is the percentage of sentences that are written at a college-to-graduate school reading level. Although only five percent of sentences should be written at this level of complexity, 21% of the sentences were written at that level. Thus, the major [ex] problems with the consent forms are that the sentences were a bit too long, with too many long and unfamiliar words.

Sentence length is a major variable in almost all readability formulas. The Flesch Reading Ease for the consent forms was 49, putting them in the "difficult-to-fairly difficult" categories. Flesch rated scores of 31 to 50 as "difficult" and scores of 51 to 60 as "fairly difficult." The average score of 49 puts the consent forms on the edge of these two categories.

TABLE 2
Text Statistics of 12 Informed Consent Forms

Text Criteria	Average	Range
Flesch Reading Ease	49: Difficult/fairly difficult	45–57
Flesch Human Interest	46: Very Interesting	41–61
Word commonness	1816	1075–2943
<1450 = common words		
1450 = normal words		
>1450 = uncommon words		
Sentences written at grade 16–20		
(5% is best)	21%	4%-33%
Words per sentence (15-20 is best)	20	17-23
Words with 3 or more syllables	10%	7%-12%
Active voice sentences (60% is best)	38%	31%–48%
Percentage of simple and normal sentences (80% is best)	66%	55%–80%
Percentage of wordy, pompous, and complicated sentences (20% is best)	34%	20%–45%
Overall style score	37% (poor)	25%–57% (poor)-(satisfactory)
Reading Grade Level	13-14	11–15

"Verbs are in active voice (ie, the subject is the doer of the act)."

Writing in the active voice make sentences more readable as well as understandable. "You are being asked to take part in this research study" (passive voice) should be rewritten as "Will you take part in this research study?" (active voice). Overusing the passive voice makes the writing seem detached, formal, and legalistic. About 50% of the consent form sentences were written in the passive voice.

TABLE 3
Translations of Unfamiliar Medical Terminology into Familiar Medical Terminology

Uncommon Words	Common Words
abstain	avoid
assist	help
chronic	long-term
discontinue	stop
induce	cause
new indication	newuse
sensation	feeling
uncommonly	rarely

"Readability analysis is done to determine reading level (should be eighth grade or lower)."

Although word processing programs such as Microsoft Word and WordPerfect include methods for assessing document readability, that technique can be somewhat perilous for researchers unfamiliar with the strengths and weaknesses of software readability formulas (13,14). As a way of meeting a readability standard (such as an eighth grade reading level), some writers will "write to the formula," taking one long sentence and cutting it into two or three shorter sentences. Unfortunately, while the document may score at an eighth grade reading level, it may be hard to read and understand because of the choppy nature of the sentences. One stndy of consent forms rewritten from a grade 16 level to a grade 7 level found virtually no difference in understanding (15)! The researchers concluded that simplified consent materials can make the forms more appealing and easier to read-but may not improve reader comprehension.

The 12 consent forms scored from an eleventh grade to a second year college reading level, the average being between the first and second year of college-about five to six grade levels higher than the NCI recommendation.

"Avoid... Words containing more than three syllables."

Such long words can be hard to read and understand because they are long (hard to pronounce), and because they are often unfamiliar to most readers. Unfamiliar words, especially if they are not explained in the text, can slow down the reading process. If there are too many long words, the reader may just give up, perhaps refusing to participate in the study, or perhaps signing the consent form without really understanding the nature of the study.

Some Additional Factors

Although not identified by the NCI, there are two additional factors that make consent forms easier and more enjoyable to read. One is the use of personal pronouns (eg, Flesch Human Interest Score). Readers are more likely to be interested in a consent form that refers to "you" instead of "the subject" The 12 consent forms were all at a 'Very interesting" level.

Overall writing style combines basic text elements into a broader measure. The program WStyle calculates "overall writing style" based on:

1. Use of the active voice-35 points,
2. Word economy-25 points,
3. Readability-20 points, and
4. Word choice-20 points.

Only one of the 12 informed consent forms scored as high as "satisfactory-the other 11 were all written in a "weak" or "poor" writing style, with an overall average rating Of "poor."

DOCUMENT DESIGN ISSUES

"Style of print is easy to read."

Typeface is the type (or font) that the writer chooses for the informed consent form. While there are literally hundreds of type faces, the most important distinction is between serif and sans serif type.

Serif fonts are generally believed to be more readable (2), because they have both thick and thin strokes, and serifs, the small strokes at the end of a letter. The serifs do not get in the way of reading (3). On the other hand, sans serif strokes are usually of a single thickness, and do not have the small strokes at the end of a letter. Sans serif fonts are harder to read over many pages of single-spaced text. These fonts lack the small strokes on the ascending and descending letters (such as b, d, f, g, h, j, k, l, p, q, and t). so the eye cannot follow the text as easily. *For* example:

Serif: Before participating in this research study, it is important that you read and understand this statement which describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. Signing the consent form will indicate that you have been informed and that you give your consent.

Sans Serif: Before participating in this research study, it is important that you read and understand this statement which describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. Signing the consent form will indicate that you have been informed and that you give your consent.

Of the 12 informed consent forms evaluated, 10 were written in a serif typeface, and 2 in a sans serif typeface.

"Left margins are justified. Right margins are ragged."

Justification means that both margins are straight. Even so, there are two types of justified text. Ragged right justification means that the right margin is uneven. There are two kinds of even right justification: one where the spaces between the words are even @referred) and one where the spaces between the words are uneven (not recommended). When spaces between the words are not even, the overall design leads to "riv-

ers," or open white spaces that flow down the page (1). Although some typographers recommend ragged right justification, while others recommend even right justification, research does not show that readers have a preference for either one.

Text that is justified both left and right looks like a block, especially if the paragraph is fairly long. This kind of justification is typical of formal documents, manuals, and medical information, and while it may offer a pleasing appearance, readers often find it inaccessible because of its formal structure.

Of the 12 consent forms, eight were ragged right justified and four were even right justified.

"Upper and lower case letters are used."

Capitalization should be used sparingly. Readers find it hard to read too much text that is in all caps. While consent form writers may use all caps to highlight a particularly important area, typographers recommend using lowercase type and bold or italics rather than all caps. When text is in all caps, there is no text above the line (ascenders) or below the line (descenders)—all the text is the same height, making it difficult for the eye to recognize letters. Furthermore, all caps have a rectangular form, and must be read letter-by-letter, instead of word by word (3):

ALL CAPS: I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, HAVE HAD MY QUESTIONS ANSWERED, AND I VOLUNTARILY CONSENT TO PARTICIPATION IN THIS RESEARCH STUDY. I UNDERSTAND THAT I MAY WITHDRAW FROM THIS STUDY AT ANY TIME WITHOUT INTERFERING WITH MY MEDICAL CARE. A COPY OF THIS CONSENT FORM HAS BEEN GIVEN TO ME OR TO MY FAMILY/LEGAL GUARDIAN.

Lowercase: I have read and understand the above information, have had my questions answered, and I voluntarily consent to participation in this research study. I understand that I may withdraw from this study at any time without interfering with my medical care. A copy of this consent form has been given to me or to my family/legal guardian.

Of the 12 consent forms, all used a mix of upper and lower *and* throughout the consent form, although eight capitalized the major headings (INTRODUCTION, PURPOSE OF THE STUDY, etc.), while four used lowercase.

"Line length is limited to 30–50 characters and spaces."

A readable document should have about 8 to 12 words (40 to 70 characters) per line (1). Condensed text produces too many words per line, expanded text too few—both make reading more difficult. Words per line and size of text are particularly important for older readers, whose eyes may have a hard time reading small typefaces and too many words per line.

Readers get tired when there are more than 70 characters per line. In addition, readers may have a hard time finding the next line, and may reread the same line over again, losing their place in the text (1). The 12 consent forms averaged 15.6 words per line, with a range of 14 to 18 words per line, suggesting the need for larger typefaces and wider margins.

"Headers are simple and close to text."

Leading refers to the amount of vertical space between lines of text (1). Too little spacing creates very dense text. The 12 consent forms averaged 5.6 lines per vertical inch, ranging from four lines per inch (double-spaced text) to 8 lines per inch (single-spaced text.)

Too much spacing makes it hard to associate headings and subheadings with the appropriate text. If a subheading is four spaces below a previous paragraph, and four spaces above an upcoming paragraph, the subheading just seems to float in the white space. The reader may not be able to readily associate it with the right paragraph. Of the 12 consent forms, five were spaced appropriately, but seven had too many spaces between the heading and the text.

PLAIN ENGLISH

Writing in "plain English" has been suggested as a good way to improve corporate and government communications with the public. Although the "plain English movement" has been popular for many *decades* in the United Kingdom, Canada, and Australia, it seems to not have taken hold in the United States, even though there has been some emphasis on plain English in law (17) as well as in business (18). In June 1998, President Clinton signed a "Presidential Memorandum on Plain Language," which directed government agencies to use plain language in all new documents by October 1, 1998, and to rewrite older documents in plain language by January 1, 2002.

A Medline search of "informed consent" and "plain English" turned up only one citation, Blenkinsop's 1997 chapter (16) which bemoans the lack of plain English consent forms in the United Kingdom. While many *of* the NCI recommendations are essentially plain English recommendations, the phrase "plain English" does not show up anywhere in the NCI document, including the references.

Although the consent process has been designed to protect the rights of human subjects who voluntarily choose to participate or not to participate in a research study, the consent process has also been designed to legally and financially protect the company sponsoring the research. As a result, consent form language (especially when dealing with "compensation") is often full of "legalese." Rewriting consent forms into "plain English" should help potential research subjects make more informed decisions about whether to participate in research or not. If they cannot easily read or understand a consent form, they may rely almost exclusively on the recommendation *of* the researcher—who may not always be looking out for the subject's best interest.

TESTING CONSENT FORMS AND TESTING READERS

Testing the Consent Form

There are several methods for testing the consent form itself, including:

1. **Readability Formulas** (which often are part of a word processing program). If properly used, these formulas can give a rough estimate of the grade level at which the consent form is written. But equally important is an understanding of the literacy skills of the target population who will be expected to read the consent form,
2. **The Readability and Processability Formula** (19). This is a series of 20 questions that can be used to assess consent forms, and
3. ^ **Suitability Assessment of Materials** (20). This 22-item questionnaire that assesses content, literacy demands, graphics, layout and typography, learning stimulation/motivation, and cultural appropriateness.

While these three methods can give researchers some insights into the strengths and weaknesses of their consent form, these methods cannot assess reader comprehension.

Testing the Reader

There is no substitute for direct testing of readers, although this process certainly takes more time and money than testing of the consent form itself. Reader testing can be done via:

1. **Informed Consent Interviews.** Searight and Miller (21) used an 11-item interview, asking questions such as "What can you tell me about the study that you were involved in?" This study found fairly good understanding of the consent process, but the results may be unique to the sample studied (14 white, 41 year-old participants averaging 14.4 years of education). These participants, however, did not clearly understand the difference between personal medical care and research,
2. **The Deaconness Informed Consent Comprehension Test (DICCT).** This test (22) includes 14 open-ended questions such as "What is the purpose of this study?" "What are the possible risks of

TABLE 4
Consent Form Layout, Design, and Testing issues

	Strength	Weakness
Text factors:		
Typeface:	Serif	Sans Serif
Type size:	Legible	Illegible
Type case:	Lowercase	UPPERCASE/ALL CAPS
Word selection:	Simple, everyday words	Uncommon, technical words
Sentences:	Short, simple, direct active voice	Long, complex, passive voice
Headings/Subheadings:		
Heading:	Lowercase	UPPERCASE/ALL CAPITALS
Punctuation:	No period	Ends with a period.
Spacing:	Close to next line	Floats between paragraphs
Formatting:		
Justification:	-Justified lines	Ragged lines (sometimes OK)
Characters/line:	40–70 (8–12 words)	QO or >70 (43 or >12 words)
Spacing:	Equal space between words	Uneven spacing between words (rivers)
Leading:	Space between lines (leading)	no space between lines (no leading)
Readability/Usability:		
Grade level:	6th–9th grade	High School-to-Graduate School
Document testing:	Readability formulas, Readability and Processability Formula, Suitability Assessment of Materials	No Testing
Reader testing:	Interviews, DICCT, cloze	No reader testing

discomforts associated with the study?" and so forth. Such open-ended questions are crucial, since research shows that most researchers ask potential subjects closed-ended questions such as "Do you understand?" or "Do you have any questions?' (23) where the participants answer only "yes" or "no," and

3. Cloze Testing. The Cloze procedure (20,24) is based on the Gestalt psychological principle of closure, and involves deleting every fifth word in a consent form and asking the research participant to fill-in-the-blanks. A reasonable Cloze estimate requires about 50 to 100 blanks (and at least 25 respondents), so Cloze testing of a consent form requires about 250 to *500* words, meaning that only a small part of the consent form could undergo Cloze testing. Having participants "cloze" an entire consent form would probably be too hard for most people. The Cloze is scored simply on the percentage of correct responses: 60% to 100% correct means that the materials are suitable; 40% to 59% means that the material can be used with supplemental information; less than 40% correct means that the materials are unsuitable and should be revised.

CONCLUSION

The essence of this article is expressed in Table 4, which summarizes consent form strengths and weaknesses in a 15-item checklist form. Consent form writers can use this table as a way to evaluate their consent forms in terms of text factors, headings and subheadings, formatting, and readability/usability strategies.

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". . .in language understandable to the subject (?)"

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Office for Protection from Research Risks
Food and Drug Administration
National Human Subjects Protections Workshop
Rush-Presbyterian-St. Luke's Medical Center

Hyatt Regency Chicago
June 8-9, 2000

Abstract

According to FDA regulations, informed consent forms should be written in language that is understandable to the subject. However, much research shows that consent forms are often unreadable to the average subject, an issue that is even more important with cognitively impaired research subjects.

Cognitive impairment may be due to biological factors such as AIDS dementia, Alzheimer's Disease and other dementias, brain tumors, cerebrovascular accidents (strokes), Korsakoff's syndrome, or traumatic brain injury--as well as psychological stress. Thus, a consent process that works reasonably well with cognitively unimpaired subjects may not work very well at all with cognitively impaired subjects.

Potential subjects who are cognitively impaired and/or under emotional stress may not be able to 'process information very well, and will probably have a hard time understanding the fairly abstract informed consent process.' Instead of relying almost exclusively on reading and listening--two very abstract ways of communicating complicated information--this presentation will suggest several concrete strategies that may increase the amount of information that cognitively impaired subjects can understand.

Some causes of cognitive impairment

- AIDS dementia
- Alzheimer's Disease/other dementias
- Brain tumors
- Korsakoff's Syndrome
- Strokes
- Traumatic Brain Injury

Cognitive impairment and catastrophic illness

"Many individuals develop a temporary state of cognitive and emotional impairment after being diagnosed with catastrophic illness. Thus, when crucial decisions about medical treatment are required, they are unable to assimilate information; or worse, the legal need to be informed can rival a psychological desire to not be informed."

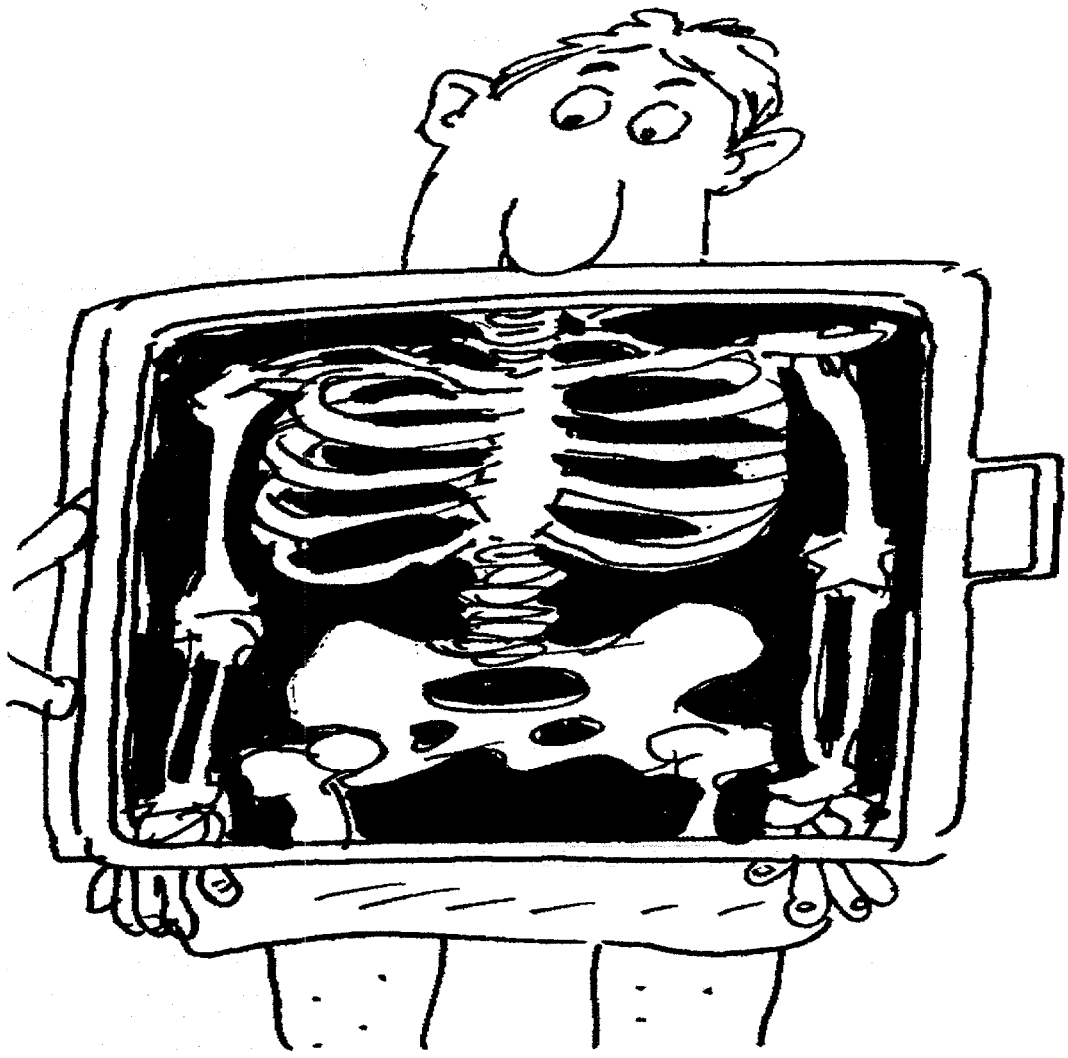
Carnerie, F (1987)

Emotions and cognitive impairment insick patients

Physically Sick

Emotionally Depressed

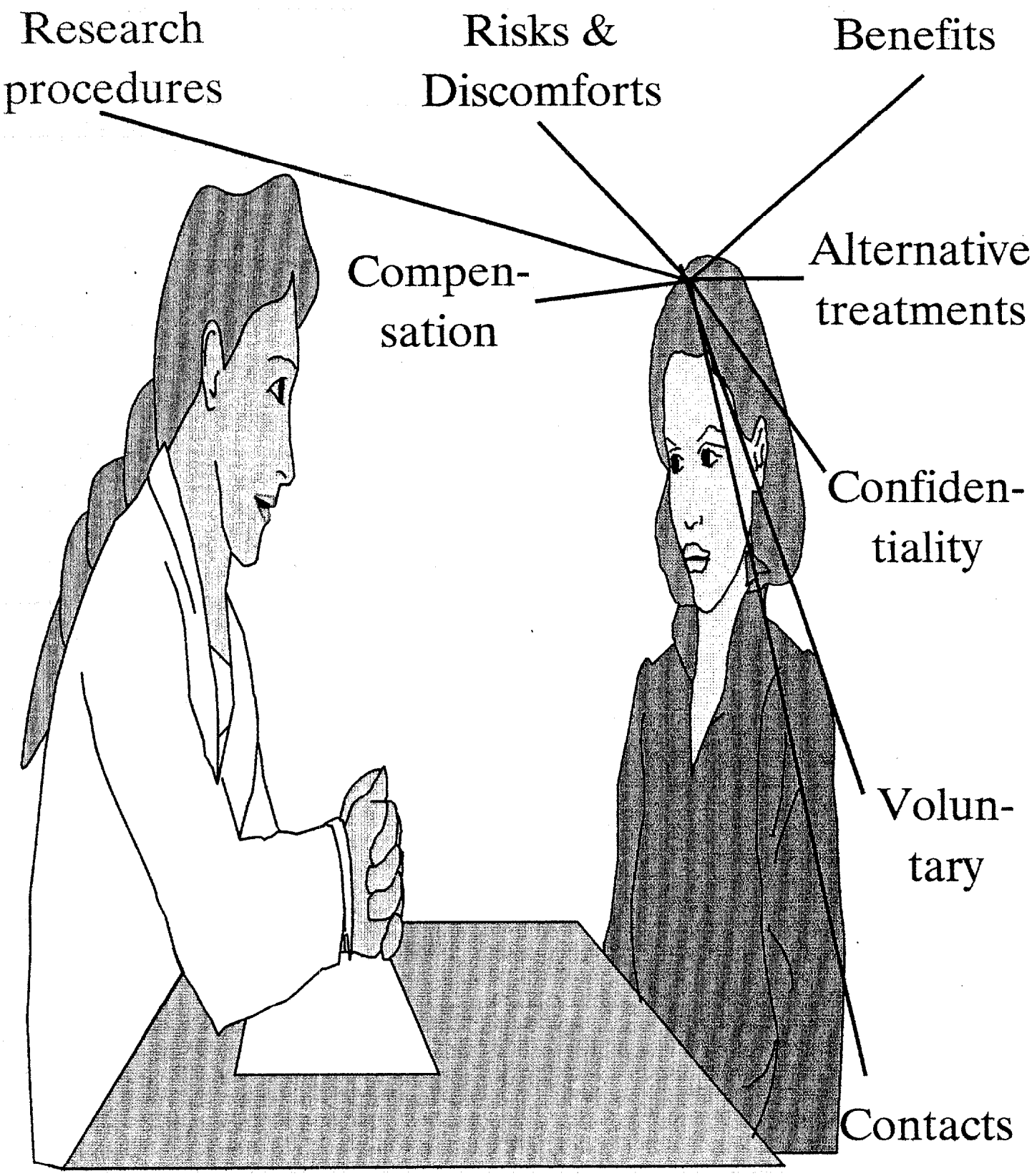
Psychologically Stressed

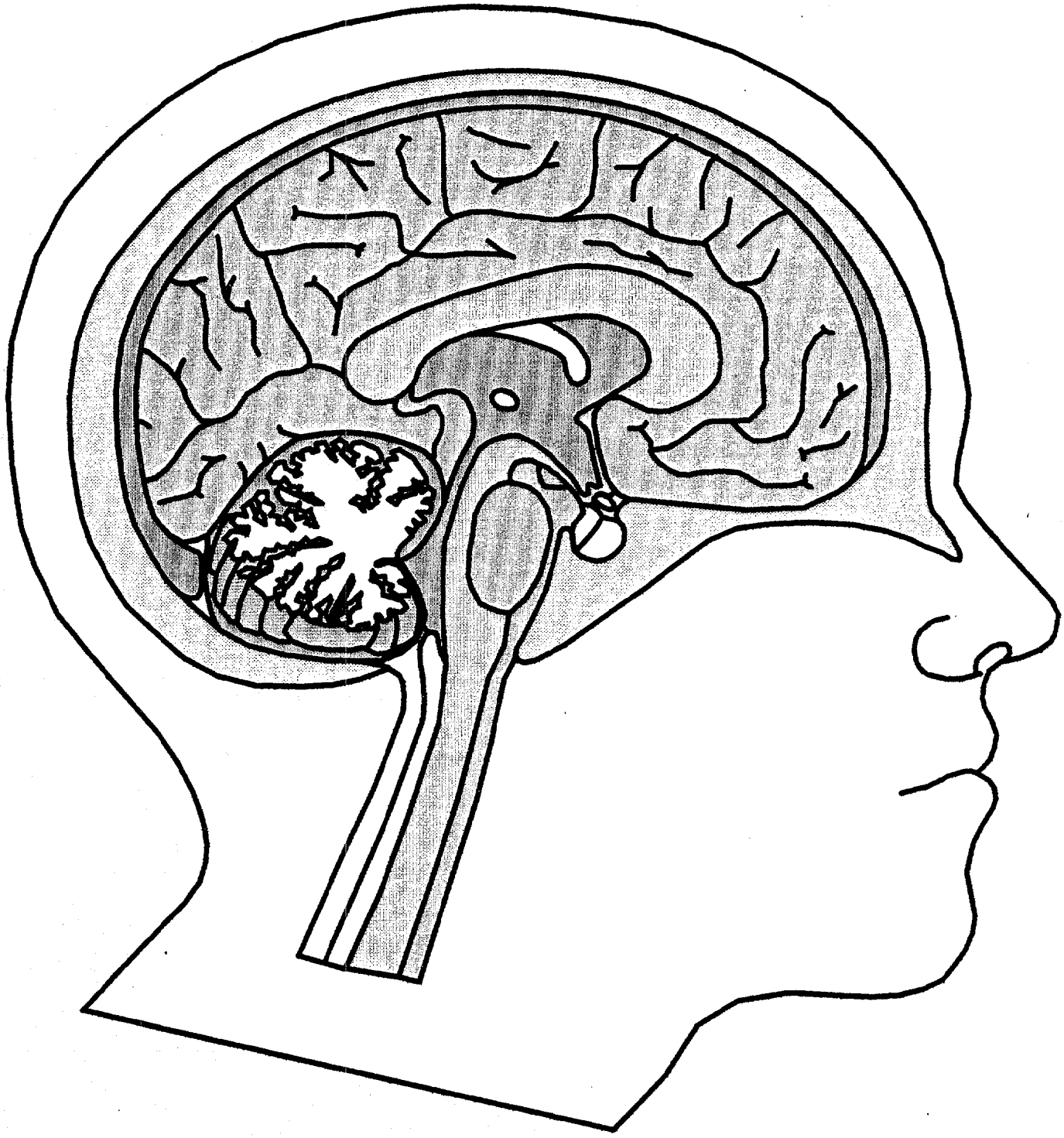


Cognitively Helpless

Fear of Unknown

Cognitive complexity and informed consent





The real decision maker

Levels of Cognitive Complexity

(Impact of cognitive impairment?)

Level #1: Unilateral Descriptions

Subjects simplify-the situation by focusing on one idea or argument; do not identify alternatives or bring in new information, meaning, or perspectives. Subjects make good/bad and either/or assertions, appeal to authority or simple rules, and simply paraphrase, restate, or repeat information.

Level 2: Simplistic Alternatives

Subjects identify simple and obvious conflicts, but do not pursue or analyze the conflicts. They develop positions by dismissing or ignoring one alternative, while supporting the other with assertions and simple explanations--they don't make deep assessments of the situations.

Level 3: Emergent Complexity

Subjects identify more than one possible explanation or perspective, establish and preserve complexity. They introduce new elements, and support their positions through comparisons and simple causal statements.

Level 4: Broad Interpretations

Subjects use broad ideas to help define and interpret the situation, and manipulate ideas within the perspective they've established. They have a clearly recognizable explanatory theme, and can integrate ideas into '"subassemblies'?--each of which supports a component of the explanation.

Level 5: Integrated Analysis

Subjects restructure or reconceptualize the situation so they can approach the problem from a new point of view. They contract a network of cause-and-effect relationships, and can integrate and extrapolate ideas. Subjects arrive at new interpretations by analogy, application of principles, generalizations, and world knowledge. They construct an organizing framework, sketch connections, and predict consequences.

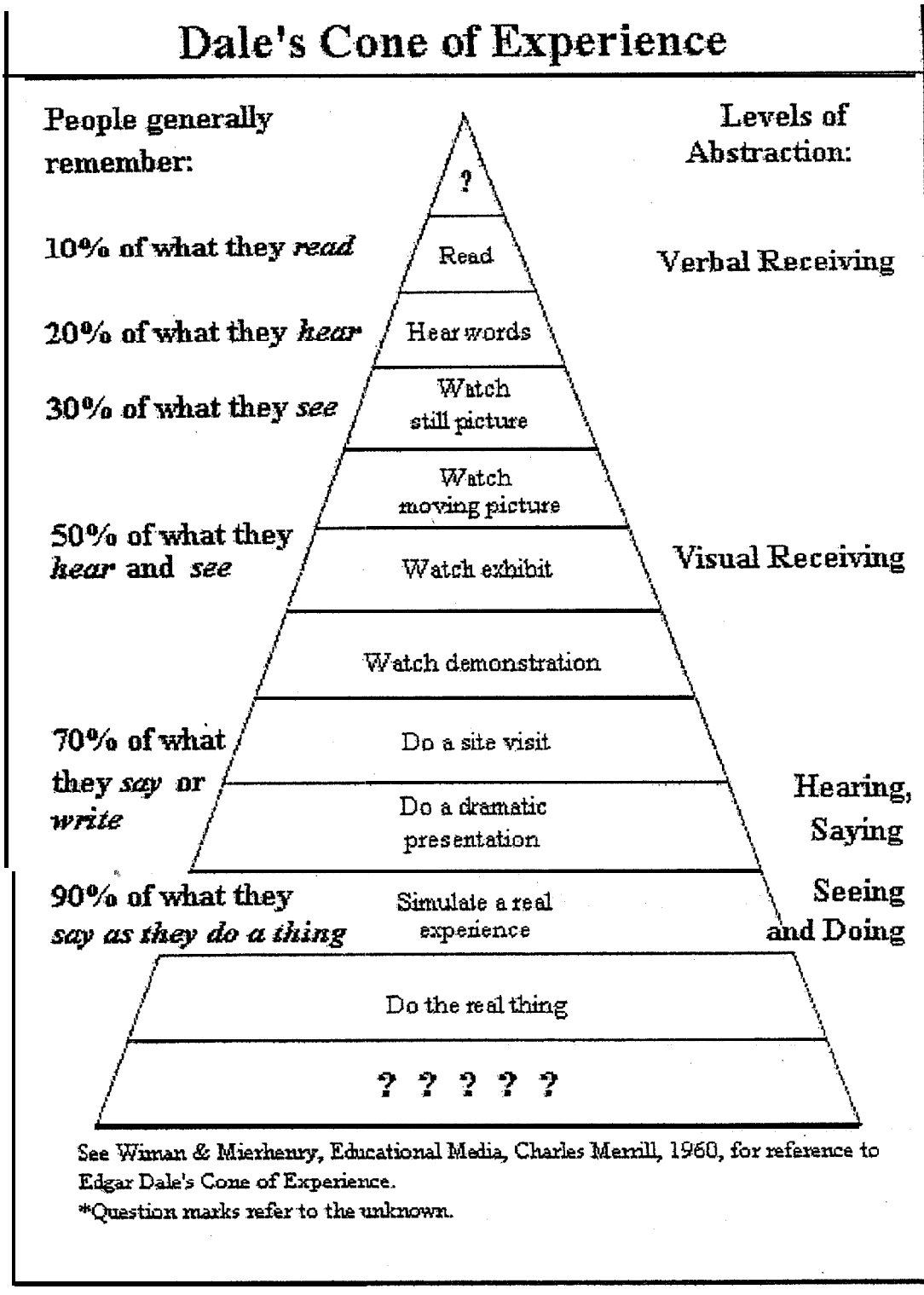
Adapted from McDaniel and Lawrence, 1990

Thinking skills needed to understand a consent form
(based on Benjamin Bloom's "Taxonomy of Educational Objectives")

Six skills that go from concrete (knowledge) to abstract (evaluation)

Skill:	Definition:	Consent Form Component
1. Knowledge	Recalling specific information (listing, describing, collecting)	Contacts if subject has questions; Confidentiality--who has access?
2. Comprehension	Lowest level of understanding: using information without relating it to other material or seeing its implications (summarizing, interpreting, estimating)	Compensation for medical costs of research-related injuries Alternative procedures
3. Application	Using abstractions in specific situations (calculating, examining, discovering)	Voluntary nature of the study; No penalty or loss of benefits
4. Analysis	Breaking down information into components (ordering, classifying, selecting)	Risks and benefits
5. Synthesis	Combining elements to make a whole (formulating, integrating, preparing)	Understanding research (purpose, duration, procedure)
6. Evaluating	Judging the value of material based on criteria (deciding, concluding, ranking)	Deciding to participate or not

Dale's Cone of Experience



See Wiman & Mierhenry, Educational Media, Charles Merrill, 1960, for reference to Edgar Dale's Cone of Experience.

*Question marks refer to the unknown.

Consent Strategy	% Remembered
Verbal Receiving:	
Read Consent form	**10%**
Listen to researcher	**20%**
Visual Receiving:	
Look at pictures, photos, charts	30%
Watch videotape or CD of' study	50%
Virtual reality experience	**50%**

Consent strategy	% Remembered
Hearing, Saying, Seeing, Doing:	
Do a site visit of all research settings	70%
Present research project to others	70%
Go through a simulation of the research project	90%
Go through the real research project	90%

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Some Overlooked Aspects of Consent Form Readability

by Mark Hochhauser

Can subjects read and understand their research consent forms? Most research on the readability of informed consent forms has relied on a "grade level" estimate of the form's writing, and an implied comparison to the reading level of American adults. Based on the 1990 census, about 7 percent of the population (19 million) has a graduate degree, 13 percent (34 million) has a bachelor's degree, 25 percent (65 million) has some college education, 30 percent (79 million) has a high school diploma, and 25 percent (65 million) has less than a high school diploma.

These statistics may be particularly seductive, since it's easy to take the educational level attained by segments of the population and compare it to the reading level of the consent form. In fact, the software program Correct Grammar 2.0 does exactly that, providing not only a grade level estimate, but also the percentage the adult population that can "understand" the document. However, research on reading ability shows that people often read three or four grades lower than their highest educational achievement, so that someone with a high school diploma may be reading at an eighth or ninth grade reading level. There is no one-to-one correspondence between reading ability and educational attainment.

A more appropriate measure might be data from the 1993 National Adult Literacy Survey,[1] which studied a cross-section of 14,000 adults. The "average" American with a high school diploma was able to interpret instructions from an appliance warranty, identify and enter background information on a social security card application, and calculate total costs of a purchase from an order form. The "average" college graduate could read a lengthy article to identify two behaviors that meet a stated condition, use a bus schedule to choose the right bus, and calculate miles per gallon based on a mileage chart. About 7 percent of the population reported needing help understanding written materials.

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Calculating Readability

Original readability formulas were done "by hand." When the programs were translated from hand calculations to software calculations, it was up to the programmer to make the conversion. Unfortunately, while a person may have little trouble breaking a word into syllables, it may be quite a bit more difficult to write a program that will break words down into syllables, especially when writers use words that aren't in the computer's memory.

It's not surprising that different programs may use slightly different ways of counting words, syllables, and even sentences. Even the same formula may give different results when used by different programs. For example, Mailloux et al.[2] found in their comparison of four software programs (Corporate Voice, Grammtix (sic) IV, MS Word and RightWriter) that each gave a somewhat different estimate—scores for the Flesch-Kincaid ranged from 5.6 to 7.2.

The authors noted that readability formulas used in the software were provided for three of the four programs, and although the formulas were identical, the grade results were different. They concluded that "This finding is difficult to explain because if the formula [sic] were truly identical, no discrepancy should be found."[2] What they don't explain is that even if the formulas were identical, the programmers still had to give the program a way of identifying and counting words and syllables and sentences. For example, is 1997 counted as one word or four words? As Klare notes,[3] syllables can be estimated by several different methods, including the number of vowels per word, the number of consonants per word, or the number of letters per word.

Most readability programs calculate the number of sentences by counting periods. Consider the sentence "Research shows that 1.2 percent of patients are likely to suffer from angina (i.e., chest pain)." There are four periods, which will calculate as four sentences (one sentence of 4 words, one of 10 words, one of 1 word and one of 2 words), instead of one sentence of 15 words. Readability researchers must be careful to remove periods that do not come at the end of a sentence.

If a sentence is separated by a colon or semi-colon, some software programs will count it as one sentence, some as two sentences. That clearly means that the user must be careful to set the options for each software program. Unless each program is calculating readability using the same rules, it's not surprising that results will differ. In a document with only a few hundred words, such differences can be substantial. Table 1 shows how six readability software programs calculate the number of sentences, syllables, words per sentence, and Flesch Reading Ease when using only the default (standard) software setting.

Although the Flesch Reading Ease Score estimated by these software programs varies from 37 to 45, the g-point range of scores falls into Flesch's "Difficult" category.

Readability Formulas

Researchers often use readability formulas as if they are interchangeable, not always realizing that different formulas calculate readability in different ways, and may be more appropriate more for one kind of writing than for another. Although there are dozens of readability formulas, a few ac-

count for most of the research. A good summary of the different formulas can be found in the reference manual for Prose.[4]

The Dale-Chall formula was published in 1948. It uses a list of about 3,000 words that were known by 80 percent of fourth grade students-in 1948. Each word in the document is compared to the list. The formula uses two variables: the percentage of unfamiliar words and average sentence length. Although it's a good general purpose readability formula, it may score 'high" on technical materials that include many words not on the 1948 list, but which may be familiar to the audience.

The Flesch-Kincaid Formula determines readability based on average sentence length and the average number of syllables per word. It's best used with technical manuals, and some federal government agencies require materials to meet a specific grade level based on this formula.

The Flesch Reading Ease Score is based on the number of syllables per 100 words and the average sentence length for a passage of 100 words. The reading ease scores range from 0 to 100. It seems to be a good general purpose readability formula, but may be most accurate for secondary school materials.

The Fog Index is based on average sentence length and number of polysyllabic words. It tends to score "high."

The Fry Graph plots the average number of syllables per 100 words on the x-axis and the average number of sentences per 100 words on the y-axis. Most software programs convert this from a graph to a grade level estimate. It's best suited for testing primary grade reading materials, and tends to score "high."

The SMOG Index (Statistical Measure of Gobbledygook) looks only at the number of polysyllabic words per 30 sentences. It also scores 'high."

The original readability formulas were done by hand calculations, usually involving a 100-word sample. Conversion to computer programs meant that an entire document could be analyzed, not just a small sample of the document. (Some might argue that since the original formulas were based on 100-words samples, application of the formula to an entire document is a violation of the basic statistical assumptions.) Thus, some readability research on consent forms is based on a 100-word sample,[5] on three 100-word samples,[6] or on the entire document.[7] For a 2,000 word consent form, these analyses represent 5 percent, 15 percent, or 100 percent of the text, respectively.

Table 1: Readability software comparisons for one consent form

Software	Number of sentences	Number of syllables	Words/ sentence	Flesch Reading Ease
Program #1	35	1,313	21	45
Program #2	35	1,289	21	44
Program #3	30	1,286	25	38
Program #4	31	1,201	22	36
Program #5	30	1,290	23	43
Program #6	30	1,296	25	37
Range:	30-35	1,201-1,313	21-25	37-45
Average:	31.9	1,279	22.9	40.5

Grade level estimates:

	Flesch-Kincaid	FOG Index
Program #1	13.7	16.4
Program #2	12.1	15.5
Program #3	15.5	NA
Program #4	13.9	15.9
Program #5	14.3	16.4
Program #6	14.4	18.0
Range:	12.1-15.5	15.4-18.0
Average:	14.0	16.2

Notes: The Flesch-Kincaid, based on the average sentence length and the average number of syllables per word, tends to score "low." The FOG Index, based on average sentence length and number of words with 3 or more syllables, tends to score "high."

Weaknesses and Strengths of Readability Formulas

Despite the widespread use of readability formulas to assess consent form readability, examination of the references in these studies shows that researchers are unfamiliar with the strengths and weaknesses of readability formulas.[8,9]

Weakness 1: Readability formulas are not equivalent, since estimated grade levels vary depending on the formula. *Response:* Why should all formulas agree? Since they measure different text elements, it's the user's responsibility to choose the right formula.

Weakness 2: Readability formulas do not consider text organization, since sentences can be rewritten with words in random order and the readability score will be the same. *Response:* Software programs (style checkers, grammar checkers) can provide a more detailed analysis of the text than just a grade level readability estimate, and can identify such problems. Text analysis can be much more sophisticated than just a grade level estimate. Too often, researchers seem unfamiliar with the intricacies of their grammar checking software.[10-12]

Weakness 3: 'Writing to the formula" may have no impact on the reader's ability to understand the material. *Response: No* writer should rely on one readability formula exclusively; writing to the formula may or may not affect understanding. Some studies have found that lower reading levels alone improve comprehension,[13-15] other studies have-found that-

illustrations and narrative text can aid comprehension, especially among poor readers.[16] Other factors (layout and design, use of headings and subheadings, bullet, points, font style and size) will affect readability as well. No researcher should rely on a single formula to improve consent forms.

Weakness 4: Readability formulas don't consider background knowledge of the reader, motivation, cultural experiences, etc. *Response:* There is no way to consider all factors that affect all readers. If readability formulas were thrown out, what would replace them?

Strength 1: Readability formulas are better than nothing. While they should not be used as an end in themselves, they can provide useful information. Many criticisms are based on the exclusive reliance on a single "grade level" estimate, not a more detailed text analysis, And many criticisms are based on readability analyses that had to be done "by hand," before software was available.

Strength 2: If used properly, readability formulas can provide valuable information. As computer programs become *more* sophisticated, more detailed text analysis may be possible. For example, the Educational Testing Service is developing a computerized method for scoring student essays.

Strength 3: Software programs are reliable, which allows different pieces of writing to be compared using the same criteria. Imagine the results if 10 IRBs each reviewed a consent form—would there be 10 different readability assessments? A readability program offers some consistency that cannot be achieved any other way, Besides, for some criteria, a software-based evaluation is faster and cheaper than an evaluation by researchers or subjects.

Readability Software for the PC

Many software programs will assess readability. Grammar checker programs (either as part of a word-processing program or a stand-alone program) may also give readability estimates. There are some Windows-based programs, but most were written for DOS in the late 1980s.

Windows programs include Correct Grammar 2.0 (1992), Grammatik 6.0 (1994), Key Grammar Checker (1990), RightWriter 6.0 (1992), and Readability Calculations (1996). There are even more DOS-based programs. However, since some are available as "shareware" through online services, you may need an "unarchiving/unzipping" program to install the program. DOS programs include Breeze (1995) Chall (1990), Critic 2.3 (1995), FS Text Version 2.1 (1991), Pro-Scribe (Professional Scribe) Version 4.8 (1992), PROSE: The readability analyst, (1988), Readability Analysis: Teacher Resource, Readability Estimator (1985), Readability Plus 2.0 (1989), Corporate Voice (1990), Readutil 1.1 (1990), WC Text Analysis 1.4 (1994) and WStyle: Writing Style Analyzer (1992).

What Does "Grade Level" Really Mean?

Most readability software programs report their findings in terms of a "grade level." However, readability formulas were originally developed to help schools decide whether textbooks were appropriate for students at a particular grade level. For students in sixth grade, a textbook written at a twelfth grade level would probably be inappropriate.

Researchers have taken this concept of grade level and used it inappropriately. While it may be appropriate in a K-12 setting to assess the grade level of textbooks for students who are learning how to read, that strategy may be less appropriate for adults who have already learned how to read. It's common for researchers to conclude that people must have 15 years of education (a college degree) to read a consent form that's been estimated to be at a grade 15 reading level. That's wrong.

First, a grade-16 reading level is just another way of stating that the material is complex and may be hard to read. Flesch's seven reading ease categories (very easy, easy, fairly easy, standard, fairly difficult, difficult, and very difficult) would be a better way of expressing the complexity of the material.

Second, grade level estimates provide a level of precision that may not be justified. Based on a readability estimate, researchers may conclude that a subject "needs 3.0 years of college to understand the consent form." But what does "3.0 years of college" mean? Does it mean that someone with 3.0 years of college will have total understanding of the *consent* **form,** but someone with 2.0 years of college will have no understanding of the form? Such estimates may be relevant for elementary school books, where there may be big differences between students at the beginning of second grade and at the end of second grade. But such precise estimates have less relevance for adults.

Third, having 15 years of education does not guarantee that a person can read and understand a grade-15 consent form. Consent forms tend to be written from a biomedical perspective; would someone with a college degree in history have the same comprehension skills as someone with a college degree in biology? Depending on grammar, syntax, and layout, a consent form may be comprehensible or incomprehensible-regardless of its estimated grade level. Without testing the consent form on people, researchers cannot legitimately conclude that the form is understandable or not based only on a grade level estimate.

Readability and Informed Consent

In terms of informed consent, Young[17] found that 33 percent of respondents reading a consent form at a grade-15 level found it to be somewhat easy or very easy, while 64 percent of respondents reading the same consent form at a 6th grade level rated it as easy or very easy. Not surprisingly, respondents who graduated from college had better comprehension than those who attended college (but did not graduate) or those with a high school education or less.

Getting a document from a higher readability level to a lower level is difficult. A study of consent forms that had been revised's found that none improved by more than a single grade (the average was one-tenth of a grade), and readability scores for some consent forms actually got worse after being revised!

Grammar checking programs may not affect readability, since grammatical recommendations may not have much effect on sentence length, number of words per sentence, or other sentence characteristics that are used to calculate readability. An original consent form may be written poorly at a grade-14 reading level, and after being run through a grammar checking program and modified, it may simply become a well-written grade-14 consent form.

While readability estimates can be helpful, they can also be harmful. It's easy to "write to the formula." Just take long sentences with long words and turn them into shorter sentences with smaller words. But making a consent form more readable (according to the software) does not necessarily make it more understandable (according to the research subject).

Consent "Concepts"

A consent form is more than a series of words strung together to form sentences. For example, one basic element of informed consent requires that a subject be told that the study involves research. Although "research" is a small word, it may be conceptually beyond the grasp of someone who has never participated in a research project, or read about research studies in a book or magazine or newspaper article, or watched news reports about research. How would the average subject define "research"?

At a deeper level, understanding of a consent form may be based on the cognitive development achieved by the subject. During adolescence, there are psychological shifts in thinking, from simple to complex, from concrete to abstract, from immediate to future. Many adolescents will progress to a more mature level of adult thinking-some will not. Consequently, some adults may have thinking styles more similar to an adolescent than to an adult.

Although the consent process requires that subjects be given a description of "foreseeable risks," not all subjects will be able to think very far into the future. One explanation for adolescent risk-taking behavior is that adolescents are not yet able to imagine the consequences of their behavior. In the same way, some adults may have a hard time imagining the consequences of their research participation. Although FDA requires that information in the consent form be presented in a language that is understandable to the subject, the ability of a subject to understand the consent language is not the same as the ability to understand the consent concepts.

In a study of the consent process as viewed by children, adolescents and young adults (ages 7-20), researchers found that study subjects knew most about consent elements that addressed concrete information and less about consent elements that addressed abstract information.[19] Sixty to 90 percent of the subjects correctly knew the role of the participant, benefit to self, voluntary participation, duration of research and freedom to ask questions; 40-45 percent knew freedom to withdraw and alternative treatments; and fewer than 25 percent knew the purpose of research, knowing 50 percent or fewer risks, knowing 50 percent or more procedures, freedom to withdraw, benefit to others, and knowledge of research participation.

Researchers often conclude that a subject needs 14 years of education to read a consent form written at a grade-14 reading level. Such conclusions have not been scientifically validated, however. If a consent form is written at a grade-14 level, researchers should give it to people who have 14 years of education (college sophomores/juniors) and determine whether they can understand the form. Is a consent form at a 12th grade level more understandable than one at a 14th grade level? The same consent form at different levels of readability, should be tested to identify optimal reading levels. Grade level estimates of complex writing are often taken far too literally by researchers who have only a superficial understanding of the readability concept.

Document design and layout are at least as important, perhaps more important than readability estimates. One study[20] found that reducing the readability of a consent form based on software recommendations was not as useful as restructuring the document using a different layout. Instead of just using text to describe drug side effects and the schedule of clinic visits, they replaced the. text with tables and boxes, and used italics, bold, and larger type.

However, their research methodology did not include some important information. The researchers used Correct Grammar (version/date not listed), and stated only that they edited each consent form based on software suggestions. However, the authors did not specify the style rules they used to evaluate the forms. For example, the 1992 version (Correct Grammar 2.0 for Windows, Wordstar Inc., Novato, California) has ten style guides (academic, advertising, basics, business, custom, fiction, informal, legal, reviewer, and technical), and over 40 settings for spelling and punctuation, sentence structure, usage and style, etc. Different settings produce different recommendations.

Conclusion: The Need for User Testing

A careful reading of the readability literature has lead some to suggest that readability formulas are counterproductive. Redish and Selzer[21] argue that (1) readability formulas have been applied inappropriately with no research basis; (2) the formulas are not good predictors of how understandable a document will be for adult readers; (3) short sentences don't always make the document easier to understand; (4) using the same equations to assess any text for any reader for any purpose does not fit

with an understanding of information processing; and (5) readability formulas do not consider many features critical to understanding documents.

Because formulas focus the writer's attention on statistical aspects of words and sentences, they, draw attention away from important sources of reader's problems. However, some of these problems are the fault of the researcher, not the formula.

Redish and Selzer rightly conclude that the ultimate measure of readability is the reader's ability to read and understand written material. For them, usability testing is more important than readability testing. Along that line, Waggoner et al.[22,23] have studied people's ability to actually define (in their own language) common terms found in consent forms. Even small words (such as sponsor, investigator, malaise, serum, renal, prorated, etc.) were not known by many of the subjects. This approach of asking people about their understanding-instead of relying only on a readability analysis-is an important part of researching the consent process. Perhaps the new NIH initiative that will fund projects on informed consent research will help the field identify those factors that contribute to "informed" consent.

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Informed Consent and Patient' s Rights Documents: A Right, a Rite, or a Rewrite?

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Both research participants and patients are presumably offered protection from harm through the processes of informed consent and patient's rights. However, both documents are often written at unacceptably high "college" reading levels, making them incomprehensible to the "average" reader who may be reading at a junior-high reading level. Readability researchers are often unfamiliar with important details of readability software, leading to consistent underestimates of document readability. Most informed consent and patient's rights documents are written in a one-size-tits-all style and fail to take into account important differences based on cognitive development. Several strategies are described to improve the quality and effectiveness of these materials.

Key words: informed consent, patient's rights, readability, cognitive development

Informed consent may be required in a variety of settings using a variety of standards. Researchers studying drugs and devices must follow consent guidelines from the Food and Drug Administration (1995). Clinical and counseling psychologists have requirements based on state law (Handelsman, Martinez, & Geisendorfer, 1995). University-based researchers must comply with consent requirements mandated by their Institutional Review Board (IRB), and researchers may have to comply with research ethics required by professional organizations such as the American Psychological Association (1982).

Health care organizations have accreditation standards from the Joint Commission for the Accreditation of Health Organizations, requiring them to establish procedures to determine if patients can understand informed consent

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procedures. In health care facilities informed ':onsenɪ is an issue not only for specific clinical end research activities buɪ may be a part of "patient's rights." So viewed, this article addresses readability ənd comprehension issues for boɪb informed eonsenɪ and patient's rights.

HOW READABLE ARE CONSENT FORMS?

There is no shortage ϑε research showing that both research and clinical informed ɛonsenɪ forms are usually written at a level ɪϑϑ high for the "average" reader. Using readability formulas such əs the Flesch–Kincaid, Flesch Reading Ease, Fog, oɾ Fry, virtually all researchers have concluded that consent forms are too complicated if they score *əboɥɒ* an eighth-grade reading level.

For example, angiography ':onsenɪ forms were at a 2nd-year college level (Briguglio, Cardella, Fox, Hopper, & TenHave, 1995). Clinical radiology forms were ə$ ə 3rd-year college level, and radiology research ':onsenɪ forms were at Grade12 (Hopper, TenHave, & Hartzel, 1995). A review of consent forms from an IRB ɛϑund a 3rd-year college reading level (Hammerschmidt & Keane, 1992); consent forms from ə Veterans' Administration Medical Center were 1st-year college (LoVerde, Prochazka, & Byyny, 1989). Cancer clinical trial consent forms from studies at the National Cancer Institute were 2nd-year college (Meade & Howser, 1992). Consent forms from two university IRBs were at ə 12th-grade reading level (Goldstein, Frasier, & Curris, 1996). A review of consent forms submitted ɪϑ three IRBs ɛϑund an average 2nd-year college reading level (White, Jones, Felton, & Pool, 1996), and a review ϑɛ 108 consent forms from an IRB ɛϑund a 3rd- $o 4th-year college reading level, depending on the readability formula usɐd (Ogloff & Otto, ɪ991).

Thus, although average Americans have 12.5 years of education—but probably read 3 oɾ 4 grades below that—most ':onsenɪ forms are written at a college reading level. From the standpoint ϑε grade level comparisons, ɭbɐ average informed consenɪ form may bɐ 5 oɾ ß grades higher than the reading level of the average patient.

Going beyond basic readability statistics, Philipson, Doyle, and Gabram (1995) usɐd a 20-point Readability ənd Processability Form ɪϑ evaluate 76 consent forms. They ɛϑund problems not only with readability (96% of the forms were at too high ə reading level) but also with comprehension strategies that were nɐɐdɐd ɪϑ understand the ':onsenɪ forms.

"Do You Understand?"

Unfortunately, prospective participants with literacy problems are not likely to admit ɪϑ researchers that they cannot read ɭbɐ ':onsenɪ form. One sɪudʞ (Parikh, Parker, & Nurss, 1996) found that low-literacy patients were likely to be male, have less than a high school education, ənd bɐ oɥɐɾ the age ϑε 60. Only two thirds of the participants admitted having trouble reading and understanding what ɭbɐʞ read. Many admitted shame ənd bəd nɐɥɐɾ told their spouses oɾ children ϑε their reading difficulties; some nɐɥɐɾ told anyone. If given ə eonsenɪ form ənd asked, "Do pou understand," they would probably say "Yes," oɾ make excuses such əs "ɪ left my glasses at home" oɾ "I'll read this later," oɾ perhaps sign the eonsenɪ form without reading it.

Of course, a consent form is only part of the eonsenɪ process. A signed consent form is noɪ the same əs informed consent. Just because ɭbɐ ':onsenɪ form itself has problems with readability does not mean that ʎɑʞ consent issues were not discussed with participants by the investigators who were seeking eonsenɪ, Unfortunately, although there bəs bɐɐn considerable research on the readability of the consent form, there has bɐɐn far less research on the consent process itself.

In their study of the informed eonsenɪ process, Titus ənd Keane (1996) concluded that əbouɪ one third ϑε the researchers they studied gave no indication that they ʎɑuW how to talk əbouɪ research to prospective participants! Over 80% of ɭbɐ researchers usɐd closed-ended questions such əs "Do you understand?" and "Do you bəɥɐ any questions?"—questions that will produce relatively simple "yes" oɾ "no" responses. The other 20% of researchers usɐd more open-ended strategies, asking questions such əs "... would you please explain ɪϑ me what you think we ¡uɐ going to ask you ɪϑ do?" oɾ "Describe in your own words the purpose ϑε ɭbɐ study" (p. 62).

Closed-ended questions turn the informed consent process into more of ə dɭɐ (i.e., ə customary practice) than a part of a broader ':onsenɪ process. Without ə full discussion of eonsenɪ issues with the prospective research participant oɾ patient, informed consent is little more than ə procedure designed ɪϑ get a signature on a piece oɾ pəpɐɾ* A signature on a eonsenɪ form is no guarantee that the person who signed ɭbɐ form doɐs in fact understand what she oɾ he signed; one study ϑε hospitalized patients (LaVelle-Jones, Byrne, & Rice, 1993) found that 69% of patients admitted ɪϑ not reading the consent form before signing it.

Testing Research Participants and Patients

Testing ':onsenɪ forms for readability is necessary buɪ not sufficient, because ə grade level estimate alone does not really show whether the reader is capable of reading and understanding the consent form. At best, ':onsenɪ form readability is only a proxy measure ɛoɾ assessing ɭbɐ complexity ϑε written information. A more direct strategy is ɪϑ assess reading ¿ɹnd comprehension skills directly, bʞ administering either ə generic reading test oɾ ə ɭɐsɪ specifically developed ɛoɾ health care materials.

Such tests include the Wide Range Achievement Test-Revised (Estey, Musseau, & Keehn, 1991), the Test of Functional Health Literacy in Adults (Parker, Baker, Williams, & Nurss, 1995), the Medical Terminology Achievement Reading Test (Hanson-Divers, 1997), and the Rapid Estimate of Adult Literacy in Medicine (Murphy, Davis, &Long, 1993). Although all of these instruments have tested generic patient reading and comprehension skills for basic health information, none has been applied to patient's rights or informed consent materials. Indeed, it may be that researchers should develop a specific test for patient's rights or informed consent that uses common language found in patient's rights and consent form documents, rather than just the more medically oriented terms used in these existing instruments.

Another way to test patient comprehension is the Cloze *procedure* (Doak, Doak, & Root, 1996), which is based on the Gestalt principle of closure. The Cloze procedure involves deleting every nth word (usually the fifth or seventh) in a document. Reader comprehension is tested by having them fill in the blanks.

A reasonable Cloze estimate requires about 50 to 100 blanks, so a document needs between 250 and 700 words. More than that and the task becomes too much for the reader. The Cloze is scored simply on the percentage of correct responses by the reader: 60% to 100% means that the materials are suitable; 40% to 59% means that the material can be used with supplemental information, and less than 40% means that the materials are unsuitable. To illustrate the Cloze procedure, I include a 480-word excerpt from a 2,000-word "'Model Consent for Use of Tissue Samples for Human Genome Project Cell Lines" from the U.S. Department of Energy and the National Center for Human Genome Research.

Consent for Use of [Tissue] Samples to make a cell line and a DNA Library for the Human Genome Project

This research is part of the Human Genome Project, the principal goal of which is to map and sequence all of the genes contained in human DNA. You are being asked to provide samples of [tissue] to create a "cell line" and a "library" of DNA to be used in research as part of the Human Genome Project. This form describes the research that will be done and what providing samples would mean, so that you can decide whether or not you want to donate samples. The choice is completely up to you.

What we will do with your [tissue] samples, what they will be used for, and who will use them. We will divide your sample into two parts. We will take cells from one part of your sample and treat them so that they become a permanent "cell line," which means that they can be grown in the laboratory whenever they are needed. Creating a cell line will allow us to have a source of your DNA to use for research in the future, without having to come back to you to ask for another [tissue] sample.

You will not be given any information about your own DNA. There are four reasons why we will not tell you anything about *your* own DNA. First, we believe that a person has the right to keep his/her DNA sequence information private. Therefore, apart from the signed informed consent document, we will not retain any records that link your identity to the DNA sequence information. Second, if we were to *give you* specific information about your DNA, and you were then asked by someone (such as an insurer of employer) to provide that any information, you would likely be required to, whether or not you wanted to at that time. It is possible that such information could then be used to deny you insurance or employment, even in the absence of a known disease. Third, at present, the health implications of specific DNA sequences often are unclear; therefore, in most circumstances it would be very difficult to provide you with any specific information about what your DNA sequence might mean for you or your relatives. Finally, the purpose of this project is to develop new knowledge about the genetic makeup of human beings, not to provide clinical information to you.

You will not receive economic gain from commercial products. It is likely that some of the research that would be done using your DNA will lead to the development of commercial products. However, your DNA would represent only a very small contribution to the development of a successful product. Even though the law in this area is not completely clear, you should not expect to get any part of these profits.

Figure 1 illustrates the Cloze procedure for the excerpt based on blanking out every 5th word, giving 86 blanks to be completed. If that was too difficult for the reader, the Cloze could be redone, using every 7th word, or even every 10th word. Different Cloze frequencies can be used to test virtually every word in the document; one version could test every 5th word, one version could test every 6th word, every 7th, every 8th, every 9th. The Cloze test can include a mixed-up pool of words from which the reader can choose.

Some patients and research participants may be more at risk for reading problems than others. For example, a study of drug users (Johnson, Fisher, & Davis, 1996) found an average reading level of about sixth to eighth grade, and a study of patients in substance abuse treatment centers (Davis, Jackson, & George, 1993) found client reading levels 4 to 5 years below the level needed to read and understand standard treatment materials. Over half of the public patients and about one third of the private patients had reading skills below ninth grade. In a very different setting, the average reading level of a Medicaid population was about sixth grade (Weiss, Blanchard, &McGee, 1994). Given the diversity likely to be found among prospective research participants and patients, it may be necessary to develop more than one version of a consent form.

Consent for Use of [Tissue] Samples to make a cell line and a DNA Library for the Human Genome Project

This research is part of the Human Genome Project, the principal goal of which is to map and sequence all of the genes contained in human DNA. You are being asked (1)_____ provide samples of [tissue] (2)_____ create a "cell line" (3)_____ a "library" of DNA (4)_____ be used in research (5)_____ part of the Human (6)_____ Project. This form describes (7)_____ research that will be (8)_____ and what providing samples (9)_____ mean, so that you (10)_____ decide whether or not (11)_____ want to donate samples. (12)_____ choice is completely up (13)_____ you.

What we will (14)_____ with your [tissue] samples, (15)_____ they will be used (16)_____, and who will use (17)_____. We will divide your (18)_____ into two parts. We will (19)_____ cells from one part (20)_____ your sample and treat (21)_____ so that they become (22)_____ permanent "cell line," which (23)_____ that they can be (24)_____ in the laboratory whenever (25)_____ are needed. Creating a (26)_____ line will allow us (27)_____ have a source of (28)_____ DNA to use for (29)_____ in the future, without (30)_____ to come back to (31)_____ to ask for another (32)_____ sample.

You will (33)_____ be given any information (34)_____ your own DNA. There (35)_____ four reasons why we (36)_____ not tell you anything (37)_____ your own DNA. First, (38)_____ believe that a person (39)_____ the right to keep (40)_____ DNA sequence information private. Therefore, (41)_____ from the signed informed (42)_____ document, we will not (43)_____ any records that link (44)_____ identity to the DNA (45)_____ information. Second, if we were (46)_____ give you specific information (47)_____ your DNA, and you (48)_____ then asked by someone ((49)_____ as an insurer of (50)_____) to provide that any (51)_____, you would likely be (52)_____ to, whether or not (53)_____ wanted to at that (54)_____ is possible that such (55)_____ could then be used (56)_____ deny you insurance or (57)_____, even in the absence (58)_____ a known disease. Third, at (59)_____, the health implications of (60)_____ DNA sequences often are (61)_____; therefore, in most circumstances (62)_____ would be very difficult (63)_____ provide you with any (64)_____ information about what your (65)_____ sequence might mean for (66)_____ or your relatives. Finally, (67)_____ purpose of this project (68)_____ to develop new knowledge (69)_____ the genetic makeup of (70)_____ beings, not to provide (71)_____ information to you.

(72)_____ will not receive economic (73)_____ from commercial products. It (74)_____ likely that some of (75)_____ research that would be (76)_____ using your DNA will (77)_____ to the development of (78)_____ products. However, your DNA (79)_____ represent only a very (80)_____ contribution to the development (81)_____ a successful product. Even (82)_____ the law in this (83)_____ is not completely clear, (84)_____ should not expect to (85)_____ any part of these (86)_____

FIGURE 1 Cloze testing of excerpts from the model consent form for use of tissue samples for Human Genome Project Cell Lines (U.S. Department of Energy).

Active Versus Passive Consent

Because active consent involves getting a signed consent form from research participants and their parents or guardians, some researchers (e.g., Ellickson & Hawes-Dawson, 1989; Severson & Biglan, 1989) have argued for the use of passive consent in low-risk studies of children and adolescents that usually involve surveys of alcohol and other drug use. In passive consent, a child's parents respond only if they want to refuse consent. Not responding is considered approval for their child to participate in the proposed research. In this case, passive consent is presumed consent.

However, consent form readability has been overlooked in the debate over active versus passive consent. None of the published articles on consent form readability has addressed the readability of active consent forms versus passive consent forms. What happens if the participant cannot understand the passive consent form? Ellickson and Hawes-Dawson (1989) reported that 87% of the passive consent parents who were contacted said that they had received and understood the consent materials. Unfortunately, there was no independent verification of parental understanding, and given the general findings on consent form readability, this figure seems rather high.

In a comparison of active versus passive consent, Dent, Galaif, and Sussman (1993) found important differences between the active and passive consent groups. Perhaps most important for this analysis, the passive consent group had a greater percentage of Blacks, Hispanics, and other ethnicities and had parents who were less educated than the active consent group. Less education probably equates with lower reading level. If so, consent form readability for ethnic minorities with less education may be a critical factor in their ability to understand the consent form and respond appropriately. Unfortunately, the authors did not provide any information about the readability of the consent form used in their research. If a parent passively consents, is it because the parent believes that the research is of minimal risk or because the parent could not understand the consent form?

MODELS OF ANALYSIS

Grade Level Is Not Enough

Most readability researchers rely only on grade level estimates of consent forms. Although there is much research on the readability of informed consent forms, no research has yet been published on patient's rights, of which informed consent may be only one component. Yet grade level is only one feature of the writing and may obscure even more important elements of the form. Table 1 depicts a summarized

TABLE 1
Readability of "Patient's Bill of Rights" (n = 7)

	Average Text Statistics[a]	*Range Of Scores*[b]
Word commonness < 1450 = common words 1450 = normal words > 1450 = uncommon words	1,241	931–5, 623
Big words (more than 2 syllables; less than 10% is best)	23%	20%–25%
Sentences written at grade 16-20 (5% is best)	27%	13%–47%
Words per sentence (15-20 is best)	19	11-22
Active voice sentences (60% is best)	52%	33%-83%
Percentage of simple and normal sentences (80% is best)	69%	48%–93%
Percentage of wordy, pompous, and complicated sentences (20% is best)	31%	7%–56%
Overall style score	45% (weak)	33% (weak)–68% (good)
Reading level		
Grade level	14	12.2-15.5
Percentage of adults at that level	25%–30%	50%–20%

[a]Reading ease was difficult, and human interest was very interesting. [b]Reading ease was "difficult" for all, and human interest was dull to dramatic.

readability analysis of Patient's Bill of Rights, based on a sample of seven forms downloaded from the World Wide Web.

This summary includes 11 criteria based on the output of many DOS software programs (e.g., Corporate Voice, FS Text, PC Style, Prose, Pro-Scribe, Reader, Readability Calculations, Readability Plus, WStyle). Although a grade level estimate is illuminating, there are other text analysis components that are equally important, especially as they impact on how easy and how interesting the text is to read, including the use of personal pronouns, the number of common words and hard words, the percentage of active voice sentences, the percentage of simple sentences versus complex sentences, and so forth.

Readability formulas and file cleaning. Readability researchers are often vague about the procedures used to calculate readability. Most will identify the formula used, sometimes the software used, and the size of the text sample to be analyzed. However, there is more to it than that. Some readability formulas recommended taking three 100-word samples from a document. That procedure was fine when readability had to be calculated by hand. However, word processing programs often come with readability formulas built into the grammar checker, so it is much easier to assess readability by software than by hand. However, although it

may be fairly easy for a researcher to calculate words per sentence and number of syllables per word, it is much harder to write a computer program to do that.

In their comparison of four software readability programs, Mailloux, Johnson, and Fisher (1995) were unable to explain why different software programs using the same readability formulas provided different grade results. The authors noted that "This finding is difficult to explain because if the formula were truly identical no discrepancy should be found" (p. 224).

Hochhauser (1997) found that in analyzing the same file, six software programs gave slightly different estimates for the Flesch-Kincaid grade level, ranging from Grade 12.1 to Grade 15.5-a difference of 3.4 grades! Such differences were probably the result of different programmers writing different algorithms to count words, sentences, and syllables for each of the six programs. Klare (1974-1975) noted that computerized readability programs are not based on a direct syllable count (which would probably involve putting every word in the English language into the software with its corresponding syllable count) but on methods for estimating syllables based on the vowels-word, consonants-word, or letters-word algorithm. Although six programs may use the same readability formula, they may each use a different method for calculating the number of syllables in a word or the number of words in a sentence-hence different grade level estimates from different programs.

Readability software may count a sentence every time that it encounters a period (or a semicolon or colon). Thus, researchers who use readability software should be careful to clean the files of extraneous periods that might be found in abbreviations; otherwise, the software might count U.S.A. as three l-word sentences, which would throw off the readability estimate. This might not be much of a problem (perhaps half a grade level) if the entire document is assessed, but it might be more of a problem if only three 100-word samples were evaluated. For example, using a sample of 250 words from a consent form, one software program calculated 23 sentences with periods in abbreviations but only 13 sentences when the periods in abbreviations were removed, leading to an estimated grade level (Flesch-Kincaid) of about Grade 7.3 for the former and Grade 10.9 for the latter-a difference of about 3.5 grades! For the entire document (without extra periods), the software calculated a readability level of Grade 9.7.

Writers may argue over whether a sentence with a semicolon is one sentence or two sentences, but researchers should know whether their readability software counts it as one or two. Because none of the research on consent form readability has addressed these issues, it is probably fair to assume that researchers have kept periods in abbreviations, colons, and semicolons in the text that they have analyzed. Based on such observations, many readability statistics on consent form readability may be inaccurate, depending on the formula reported, the software used, and the cleanliness of the file. If so, this means that the published readability

estimates are probably a bit lower than they should be and that consent forms would probably score even higher if re-analyzed.

Word Difficulty

There are several ways to approach the consent form readability. One way is to rely on readability formulas to calculate the grade reading level of the consent form. This is the approach taken by virtually all researchers, and it provides a relatively easy way of calculating the grade level of the consent form so that it can be compared to the self-reported reading level of the research participant or patient.

Taken by itself, this approach has several limitations. First, it leads many researchers to believe that a consent form written at a 3rd-year college level means that it takes 3 years of college to understand the consent form. Actually, a consent form written at a 3rd-year college reading level means only that the form is written in a complicated style and will be very difficult for the average reader. It does not mean that 3 years of college are needed to read and understand the form.

College students can major in subjects from A(rt history) to Z(oology). Aside from the common vocabulary that students may encounter in introductory undergraduate courses, each major has its own specialized language, jargon, and style of thinking. By the time a graduate, students in different majors may have very different vocabularies. Thus, 3 years of college does not guarantee that every student can understand a biomedical consent form written at a 3rd-year college reading level. One limitation of readability formulas is that they do not take into account the actual words that are used in the consent forms.

Chall and Dale (1995) noted that although over 100 factors have been identified that may contribute to reading difficulty, the 2 most consistent factors are word difficulty and sentence length. In their early work, Dale and Chall developed a readability formula based on words that were known to 80% of fourth graders in the early 1940s. (The New Dale–Chall Readability Formula has updated their list of common words to the late 1970s and is now available with a software program, although it calculates readability based only on several 100-word samples rather than on an entire text.)

Word frequency corpora calculate the frequency of words in the English language. In general, small words are the most common words (and the easiest to understand), and long words are the most uncommon words (and the hardest to understand). Thus, word frequency is an important component of comprehension. Materials written at an overall ninth-grade reading level may still be fairly incomprehensible, depending on the commonness of words in the form.

Word frequency: Patient's Bill of Rights. In addition to requiring informed consent for research, many hospitals have developed a Patient's Bill of Rights that identified rights that patients can expect to have both in terms of patient

care and research participation. Although there has been considerable research done on the readability of consent forms, no studies could be found that looked at the readability of patient's rights documents, even though they may be considered part of the research agreement between the health care organization and the patient or research participant.

One way to estimate word difficulty is to consider word frequency. Breland (1996) concluded that word frequency is a reasonable approximation of word difficulty. Words that do not appear very often in print are usually harder to read and understand than words that appear frequently. Since 1920, several word corpora have been developed to take into account the frequency with which words appear in written text. This usually involves taking samples from thousands of publications and counting the frequency of words within those samples. Breland's work shows that word frequencies for the four corpora that he analyzed were highly correlated with word difficulty.

Table 2 categorizes the commonness of words used in the seven Patient's Bill of Rights documents analyzed in Table 1. Commonness was based on *The Educator's Word Frequency Guide* (Zeno, Ivens, Millard, & Duvvuri, 1995), which calculated word frequency based on 17 million words from about 61,000 samples of text from over 6,000 written materials used in American schools and colleges. Most readers would probably be able to read and understand words with a frequency of 100 per million words or greater. However, the uncommon words (30 per million words or less) may present serious reading problems. If readers do not read much, they probably will not come across many of these uncommon words, so when they see them in the document, they will probably have a very hard time reading and understanding them.

Beyond the relatively straightforward concepts of word commonness and sentence length is the more complicated issue of reading comprehension. Readability formulas take into account only text measures; they do not consider what is going on in the mind of the reader. For example, Chall, Bissex, Conard, and Harris-Sharples (1996) proposed methods for the qualitative assessment of text difficulty that are applicable to understanding the consent process, because research and treatment can be done across all ages. Table 3 shows what the reader needs to bring to the text to read science materials with understanding. This information can be helpful in working backwards from a complicated consent form or bill of rights, because it identifies the comprehension skills available for people at different educational levels.

COGNITIVE-DEVELOPMENTAL ISSUES

Based on their level of cognitive development, different people will have different ways of understanding both their rights and consent forms. Not surprising, most of

TABLE 2
Word Frequency Analysis of "Patient's Bill of Rights" ($n = 7$)

Word Frequency	*Examples*
10, 000/million words	a, and, are, as, for, in, is, it, of, on, the, that, they, do, with, you
3, 000/million words	about, all, an, at, be, by, can, has, have, if, or, their, this, your, we, what, when, which, who
1, 000/million words	any, after, also, know, may, must, only, right, such, where
300/million words	care, during, give, information, need, others, possible, questions, understand, upon, within, without
100/million words	complete, condition, doctor, expect, health, hospital, medical, necessary, program, provide, required, research, unless
30/million words	advance, appropriate, concerning, existence, explanation, patients, payment, procedure, reasonable, respect, responsible, sufficient, transfer, treatment
10/million words	access, alternatives, assistance, authorized, consent, consequences, continuing, designated, dignity, entitled, framework, informed, participate, personnel, physician, prior, privacy, probability, reasonable, refuse, regarding, request, specified, substantial, voluntary
3/million words	advisable, behalf, compliance, confidential, considerate, consultation, continuity, delegate, diagnosis, endeavor, ethical, experimentation, facility, imminent, inquire, medication, mortality, pertinent, priority, safeguard, transferring, understandable
< 1/million words	adherence, appropriateness, augmented, clinical, discreetly, endorses, detrimental, facilitated, hygiene, incapacitation, insofar, jeopardize, medically, overriding, pertaining, prognosis, pursuant, terminate, undue

this work has been done with children and adolescents, because they have been the subject of most research on cognitive development. Although consent forms may be rewritten to a lower grade level for those projects that require consent (or assent) by adolescents and children, most researchers have not considered how the consent forms should be rewritten to take into account different cognitive-development perspectives. Research protocols targeting patients 18 to 80 years old are not uncommon, yet researchers often do not take into account the different text processing strategies of the elderly (e.g., Meyer, Marsiske, & Willis, 1993).

Broome and Stieglitz (1992) noted how important it is to distinguish between chronological age and developmental stage and to recognize that the consent process will have to be different for children in the preoperational stage (ages 2–6), concrete operational stage (ages 7–12), and the formal operations stage (ages 13 and beyond). However, level of cognitive development does not account for all of the differences in perspective. Dorn, Sussman, and Fletcher (1995) found that among 7- to 20-year-olds, knowledge of research participation was related more to psychological factors of control and trait anxiety than to developmental factors. Clearly, basic principles of child development are likely to influence the consent and assent process with children and adolescents (Koocher & Demaso, 1990).

TABLE 3
What the Reader Needs to Bring to the Text to Read Science Materials With Understanding

Reading Levels	*1, 2, 3*	*4*	*5–6*	*7–8*	*9–10*	*11–12*	*13–15 (College)*	*16+ (Graduate)*
Knowledge of vocabulary	Mainly familiar words.	Some technical terms related to our technological society.		Wider use of technical terms with more exact and specified meanings.		Highly technical ud specified science terms. Use of words related to theoretical and abstract thinking.		Uncommon vocabulary, theoretical and abstract.
Familiarity with sentence structure	Short sentences uid structure.	Somewhat longer and complex sentences and phrases.		Longer, more complex sentences with more embedded phrases.				Long, highly complex sentences with highly embedded phrases.
Subject-related and cultural knowledge	Can draw upon everyday experiences.	Draws both upon everyday experiences and information learned from books.		Requires knowledge gained from observations, demonstrations, experiments, and from books.				High extent of prior scientific knowledge. Knowledge of hypothesis testing. Knowledge of science principles.
Technical knowledge	None, except that gained from everyday experiences in a technological society.	Some technical vocabulary and explanations.		Knowledge and use of more specified ud exact scientific terms.		Highly specified uid more exact technical ud scientific knowledge.		
Density or ideas	Ability to deal with a few, often repeated ideas.	Ability to deal with increasing number and density of ideas.				Ability to deal with many, often highly embedded ideas.		Ability to deal with highly embedded ideas, often inferred.
Level of reasoning	Concrete, easily demonstrated, observed.			Begins to require abstract and theoretical thought.		Ability to apply abstract and theoretical ideas.		Highly abstract and theoretical.

Note. From *Qualitative Assessment of Text Difficulty* (p. 64), by J. S. Chall, G. L. Bissex, S. S. Connard, and S. Harris-Sharples, 1996, Cambridge, MA: Brookline Books. Copyright 1996 by Brookline Books. Reprinted with permission.

Greene, Rubin, and Hale (1996) focused on adolescent egocentrism (the imaginary audience and personal fable) as important factors in developing health promotion messages. Although not directly addressing adolescent informed consent or patient's rights issues, they have addressed adolescent risk taking, which is certainly one component of informed consent. An adolescent's perception of research risk will probably have as much to do with adolescent cognitive development (e.g., egocentrism) as it will with the risks that are explained in the consent process. Generic adolescent risk-taking may be related to the adolescent's willingness to take risks in research projects, although the evidence for that observation is mostly indirect.

A study of cognitive complexity and risk taking (Orr & Ingersoll, 1995) found that adolescents who were at lower levels of cognitive complexity and who began puberty earlier than their peers were more likely to engage in risky behaviors, whereas those adolescents who had higher levels of cognitive complexity and who began puberty later than their peers were less likely to engage in risky behavior. How would these two groups respond to research risks? Might the former group of adolescents be more likely to assent to risky research, whereas the latter group would be less likely? Obviously not all adolescents are the same in terms of maturation, so perhaps consent procedures should take into account the maturation level of the adolescent research participant. On the other hand, other research (Dorn et al., 1995) suggests that control and trait anxiety were more closely related to understanding of research participation than age or cognitive development. Such inconsistencies may be due, at least in part, to different methods of measuring adolescent cognitive development.

A study of hospitalized patients 7 to 20 years old (Susman, Dorn, & Fletcher, 1992) found that although participants were most knowledgeable about consent elements that assessed concrete information (benefit to self, duration of research, freedom to ask questions, role of participation, and voluntary participation), they were less knowledgeable about consent elements that assessed abstract information (purpose of research, benefits to others, alternative treatments, freedom to withdraw, identifying procedures and risks, and knowledge of research participation). Although they found no differences in knowledge due to age, they did find that adolescents and young adults were no better than children in their understanding of abstract concepts.

A study of the knowledge of risks, benefits, and voluntariness in children (Abramovitch, Freedman, & Henry, 1995) found that although children 7 to 12 years old could describe the purpose of research studies, they did not understand possible benefits and risks of participating. However, the researchers did not consider the level of cognitive development attained by these children. Most were probably in the concrete preoperational stage, suggesting that they would have a hard time understanding relatively abstract concepts of benefits and risks and might find it almost impossible to really think about risks and benefits because those are events that occur in the future. Because most 7- to 12-year-olds are oriented to the present, thinking into the future may require cognitive skills that they have not yet attained.

Researchers and clinicians must keep in mind that children are not adults and that making a consent form understandable by writing it at a lower grade level does not guarantee that concrete-thinking children will understand the abstract concepts of informed consent or patient's rights. Most researchers have taken the basic elements of informed consent at face value—that is, they simply include all of the required elements of informed consent in their consent form. However, from a cognitive-developmental perspective, the basic elements of informed consent are not equal because they require different levels of cognitive development to be understood thoroughly.

METHODS TO IMPROVE READABILITY

The Personalized Consent Form

Because consent forms are written by researchers who have learned to write in the third person, consent forms are often written in a style that is more appropriate for a professional journal than for the communication of important information. In a study using the Colorado State Grievance Board's Model Disclosure form, Wagner, Davis, and Handelsman (1998) found that a more personalized form increased ratings of therapist attractiveness and of both the relevance and satisfaction of the forms, as well as client recall. They made the impersonal form more personal by such changes as "Disclosure Form" to "Your Disclosure Form" and "Rights and Information" to "Your Rights, and Important Information for You."

The same problem is apparent with patient's rights materials, which are probably written with much input from lawyers who have learned to communicate using a legalistic style of writing. Although a patient's rights document may protect the health care organization because it identifies what a patient or prospective research participant may expect in the way of treatment, an overly legalistic description will only confuse the reader who is not skilled in the interpretation of legal writing. The patient will not understand his or her rights at all.

The use of personalized writing is not new. Although many readability researchers rely on Rudolph Flesch's Reading Ease score as a way of assessing readability, almost no one seems familiar with Flesch's Human Interest Score, which is based on the use of personal pronouns. Readers are much more likely to be interested in reading materials that are directed to them personally instead of referring to them impersonally.

Aliteracy. *Aliteracy* refers to people who can read but won't. Not much research has been done on the subject (e.g., Thimmesch, 1984), and most of what has been done views the problem within the context of students who do not want to read rather than of adults who do not want to read. Thus, aliteracy has been viewed primarily as a problem for students and teachers in elementary school through high school.

However, aliterate adolescents grow up to be aliterate adults and may decide not to read consent forms or their rights-especially if those documents are written in a dense scientific and legalistic style. Perhaps a more personalized writing style and the use of plain English standards would at least make the materials more attractive and more likely to be read. Consent form authors should keep this question in mind: "Why should the reader want to read this?'

Rewriting the document. If the major problem with informed consent forms and patient's rights documents is that sentences are too long and the words are too uncommon, then cutting one long sentence into two short sentences and replacing long words with shorter words should make the form more readable. Unfortunately, research does not support that kind of easy fix. Although researchers can improve consent forms by improving the form's readability, using rewriting principles and being aware of the reader's comprehension levels can both improve the document as well (Meade & Howser, 1992). Thus, Chall and Dale (1995) noted that the largest gains in comprehension come not from reducing sentence length and replacing words but *from* more qualitative changes, such as the organizational structure of the document, its personal appeal to the reader, and so forth.

Unfortunately, it seems that consent forms are not often rewritten very well. Hammerschmidt and Keane (1992) studied consent form revisions and found that none had improved by more than a single grade. Readability scores for some forms were actually worse after being revised! In a comparison of two versions of a consent form-a high reading level version (Grade 16) and a low reading level version (Grade 6)-Young, Hooker and Freeberg (1990) found that participant's comprehension was significantly affected by reading level. Participants in the Grade 6 version answered 14 of 21 questions correctly, whereas participants in the Grade 16 version correctly answered 13.4 of 21 questions. Key questions showed larger differences; regarding the overall purpose of the test, 77% in the 6th-grade version answered correctly versus 44% in the Grade 16 version.

Peterson, Clancy, Champion, and McLarty (1992) found that following the recommendations of grammar checking software (Correct Grammar) reduced the over-reading-grade level of consent forms by less than one grade. They concluded the most improvement in consent forms will come from using graphics and simple declarative summary statements as headings for each paragraph.

Given that there are so many different kinds of research (e.g., biomedical, psychological, educational) and so many kinds of research participants (e.g., stage of cognitive development, ethnicity), it is impossible to come up with a single set of recommendations that will be appropriate for all settings. Nevertheless, there are a few research-based suggestions (Silva & Sorrell, 1988). Consent form comprehension will be affected by both terms of information (amount of information, clarity of information, type of information, and difficulty of information) and method of presentation (personnel who present the consent form, amount of time to read the consent, format of the form). A 12-page single-spaced consent form with all text written at a college graduate grading level using technical jargon that has to be read immediately will probably not be as comprehensible as a 6-page double-spaced consent form with a chart or bullet points written at a 7th-grade reading level using common words that can be read overnight.

There are emerging standards for patient materials. The National Work Group on Literacy and Health (1998) noted that over 40 million Americans have only rudimentary literacy skills. Communication with these patients should be written at about a fifth-grade reading level (or even lower) and supplemented by nonwritten communications, such as videotapes and computer-based multimedia programs.

In their assessment of the informed consent process, Appelbaum, Lidz, and Meisel(l987) suggested a two-part consent form, the first part being the standard written disclosure to patients and the second part being a simple questionnaire designed to test the patient's comprehension. However, a "simple" questionnaire (e.g., multiple choice, fill in the blanks, Cloze, etc.) may not be so simple to design, implement, and evaluate in a research or clinical setting, although it might provide useful research data.

CONCLUDING REMARKS

It is seductive to think that problems with consent forms and patient's rights materials can be eliminated if only Grade 16 reading level documents are rewritten to a Grade 8 reading level. Although such revisions might help some participants read and understand the document, they do not address participant cognition and the ability of prospective research participants to really understand some of the abstract issues addressed in understanding patient's rights and informed consent. Perhaps this problem could be addressed by a broader assessment of the consent process itself, as well as by involving prospective participants and patients in the consent writing process.

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Writing, Reading, and Understanding
Research Consent Forms

Mark Hochhauser

Can the "average" American understand a research consent form? This is an important question, because the U.S. Food and Drug Administration (FDA) requires that "the information that is given to the subject or representative shall be in language understandable to the subject or the representative," and that "technical and medical terminology should be avoided or must be explained . . ."[1]

More important, does signing a consent form indicate that the subjects truly understand their rights and responsibilities? Despite efforts to improve the readability of consent forms, many subjects do not really understand what is going on in the clinical trials they participate in. Because the quality of informed consent has implications not only for the success of individual trials but for the public image of medical research, it is worth taking a holistic approach to improving subjects' understanding. In such an approach, the consent form is only the starting point in a dialogue between the patient and the investigator.

Producing readable consent forms is only the beginning. Ensuring that subjects understand their role in a study requires two-way communication between subjects and investigators.

The "average" American

Who is an average subject, and what can that average subject read and comprehend? There are several ways to answer that question. One way is to consider the educational attainment of the adult population (Table 1). Since only 20% of adults have been educated at the bachelor's level or above, it's not surprising that many people may have trouble reading and understanding consent forms, which are often written at a college or graduate school reading level.

Reading and understanding are not the same, and it's possible for someone to be able to read written material (accurately pronouncing the words) without being able to understand the words. This issue was addressed in the National Adult Literacy Survey, a study of 14,000 Americans' ability to understand prose, documents, and quantitative information.[2] Table 2 summarizes the results of the survey.

Adults with the most years of schooling were 40 to 54 years of age. Those 65 and older had the fewest years. In terms of ethnicity, Asian/Pacific Islanders had the most years of schooling, Hispanic groups the least. Overall, about 7% of the population reports not being able to read English very well.

However, reading ability does not correspond well to years of schooling. Many studies have shown that average adults read three or four grades below their highest level of schooling. Thus, consent forms should be written at about an eighth-grade reading level, instead of a college or graduate school reading level. Eight grades make a big difference in reading ease.

Readability of informed consent forms

Given the literacy skills of American adults, it's not surprising that many will have a hard time reading and understanding consent forms. Their comprehension will be limited even more if the consent form itself is incomplete or unreadable. One study found that the average grade level of forms was 12.2, with about only 10% at the appropriate sixth to eighth grade level.[3] Almost one-third of the forms were left unrevised by the applicant prior to IRB approval, and fewer than 2% were revised more than once. Revisions did not improve readability scores!

Another study found an average grade level of 13.4, with 22% of the passages at a postgraduate reading level.[4] A third study found an average grade level of 15.[5] Most had to be rewritten, but none improved by more than one grade level, and scores for some revisions got worse! Rewriting a consent form to be six grades lower is not easy.

Assessing readability. Most readability research has relied on standard readability measures, such as the Flesch Reading Ease Score, Fry Graph, Gunning Fog Index, Smog Index, and similar measures. These readability estimates involve calculating the number of words in a sentence, the length of words, and the number of multisyllable words. Estimates can be done either "by hand" or by computer software, such as the grammar checking programs that come with some word processing programs or specialized readability programs.

Running a document through a grammar checking program may not affect its readability, because gram-

TABLE 1 Educational attainment of U.S. adults[a]

Educational attainment	Percentage (number) of adult population
8th grade or less	10.4% (27.3 million)
some high school (no diploma)	14.4% (37.8 million)
High school diploma	30.0% (78.8 million)
Some college (no degree)	18.7% (49.1 million)
Associate degree	6.2% (16.3 million)
Bachelor's degree	13.1% (34.4 million)
Graduate degree	7.2% (18.9 million)

[a]1990 census

TABLE 2 Average years of schooling

Age	Years
16-18	10.8
19-24	12.5
25-39	12.9
40-54	13.1
55-64	11.8
65 and older	10.7
Ethnicity	**Years**
White	12.8
Black	11.6
Asian/ Pacific Islander	13.0
American Indian/ Alaskan Native	11.7
Hispanic groups	10.2

matical recommendations may have little effect on sentence length, number of words per sentence, or other sentence characteristics that are used to calculate readability. A consent form may be written poorly at a 14th grade reading level, and after being run through a grammar checking program and modified, it may simply become a well-written 14th grade consent form.

Although readability estimates can be helpful, they can also be harmful. It's easy to "write to the formula." Just take long sentences with long words and turn them into shorter sentences with smaller words. But making a consent form more readable (according to the software) does not necessarily make it more understandable (according to the research subject).

Researchers often conclude thata subject needs 14 years of education to read a consent form written at a Grade 14 reading level. But such conclusions have not been scientifically validated. If a consent form is written at a Grade 14 level, researchers should give it to peoplewho have 14 years of education(college sophomores or juniors) and determine whether they can understand the form. Too often, gradelevel estimates of complex writing are taken far too literally by researcherswho have only a superficial understanding of the readability concept.

Document design and layout are at least as importantas readability estimates—perhaps more important. One study found that reducing the readability level of a consent form based on software recommendations was not as useful as restructuring the document by using a different layout.[6] Instead of just using text to describe drug side effects and the schedule of clinic visits, they replaced the text with tables and boxes, wid used italics, bold, wid larger type.

Their research methodology did not, however, include some important information. The researchers used Correct Grammar (version and date not listed), and stated only that they edited each consent form based on software suggestions. However, the authors did not specify the style rules they used to evaluate the forms. For example, the 1992 version (Correct Grammar 2.0 for Windows, Wordstar Inc., Novato, CA) has 10 style guides (academic, advertising, basics, business, custom, fiction, informal, legal, reviewer, and technical), and over 40 settings for spelling and punctuation, sentence structure, usage and style, and other factors. Different settings produce different recommendations.

TABLE 3 Understanding of consent form words[a]

% understanding	Original words/phrases	Suggested words/phrases
Study 1[9]		
90%	Waive your rights	Give up your rights
82%	Topical product	Product applied to the skin
75%	Placebo	?
49%	Renal	Kidney
41%	Protocol	Study or study plan
38%	Efficacy	Effectiveness
22%	Randomly	By chance; by flip of a coin
17%	Double-blind	Neither subject nor researcher knows...
15%	Washout period	Explain in detail to subject
<10%	Took a culture	Took a sample
<1%	Vehicle preparation	Drug in the lotion
Study 2[10]		
95%	Fracture	N/A
56%	Sponsor	Company that makes the test drug
49%	Analgesic	Pain medication/pain reliever
41%	Baseline visit	First period
35%	Investigator	Study doctor
16%	Serum	Blood
7%	Concomitant drugs	Concurrent drugs

[a]Percentage of respondents who understand consent form words and phrases and alternative terms suggested as more understandable.

The FDA states that

> To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative) . . . Even when all the subjects speak English, the IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted. The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple words that the typical subject can read and understand.[1]

Although the FDA requires that technical and scientific terms be adequately explained, researchers may interpret "adequate" in very different ways. One interpretation is to consider the ability of the patient to understand common words and phrases found in consent forms. Research with the general public found that many people had a hard time understanding words and concepts that are commonly found in research consent forms (Table 3).[7,8] Only 12% knew what an institutional review board was. Most thought it was a medical records review committee that decided whether a person should be institutionalized. Those with a college education understood more than those with a high school education or less.

Basic elements of informed consent

The FDA lists eight basic elements of informed consent.[1]

- A statement that the study involves research, an explanation of the research purposes and expected duration of the subject's participation, a description of procedures to be followed, and identification of experimental procedures.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent to be used when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subjects involved in the study.

Omissions in consent forms

The FDA has identified the minimum elements of a consent form (see box). To help researchers, the FDA describes in some detail the rationale behind each of the elements of informed consent.[1] Nevertheless, consent forms are often incomplete in some elements. Common problems identified by the FDA include failure to

- include all the required elements
- explain technical/scientific language
- state the experimental nature of the research
- state all the purposes of research
- completely describe the procedures
- describe treatment alternatives
- describe confidentiality strategies
- describe payment
- provide contacts if questions arise
- include the "additional elements" when appropriate
- contain specific information (use of "boiler-plate"forms).

A study of 82 informed consent forms found 18 (22%) to be very incomplete, lacking nine or more federal requirements, with the average consentform lacking about five.[9] If important information is omitted from the consentform, it probably won't be communicated to the patient.

The consent process

Of course, it can be argued that focusing on readability overemphasizes the written aspect of the consent process. "Informed consent is more thanjust a signature on a form, it is a process of information exchange that includes recruitment materials, written materials, verbal instructions, question/answer sessions, and measures of subjectunderstanding."[1]

Research on the "consenting process" found that about one-third of researchers studied gave no indication that they knew how to speak to subjects about their research.[10] About half the researchers focused on a description of the study's purpose or its procedures, but only infrequently did they talk about benefits, risks, alternatives, costs, confidentiality, nonparticipation, or withdrawal. If basic elements of consent were not included in the consent form, and if they were not part of the researcher's discussion with the patient, it is clear that whatever consent was obtained was not very "informed."

Investigators didn't give subjects much time to ask questions or to think about the project. About 80% of the researchers used closed-ended questions, such as "Do you understand?" and "Do you have any questions?" Such questions are likely to elicit simple "Yes" or "No" responses. Open-ended questions—such as those beginning "what," "when," or "please describe"—are likely to elicit more detailed responses.

In theory, the consentform should be only one part of the overall consent process. In practice, the consentform seems to be the major part of the consent process, which makes its readability and completeness even more important.

There are several ways to enhance the overall consent process. One is to become more aware of problems that have been identified in consentforms (duration of participation, research purpose, experimental procedures, discomforts and risks, benefits, and alternative treatment,for example) and the solutions that have been presentedfor those problems.[11]

Another way is to stop relying on a text-based consentform. The AMC Cancer Center in Denver has been experimenting with a strategy that included an expert advisory panel (including literacy experts, data managers, health educators, and medical professionals), pretesting of consent forms with patients,and giving patients the opportunity to "circle any words [on the consent form]you would like explained."[12]

Writing better consent forms

"Readability formulas are concerned with judging the difficulty levels of writing . . writeability is concerned with writing, rewriting, or editing to get those materials to the desired readability level."[13] Edward Fry suggests that writeability can be improved by considering:

- Vocabulary. use more common (high frequency) words. Large words may be used as a way of sounding pretentious, or self-important. Don't use words that they reader doesn't know.
- Sentences. Keep sentences short, but not always. Sometimes, longer sentences communicate better. Active sentences are better than passive sentences.
- Paragraphs. Paragraphs should be short. Use this, if needed.
- Cohesion. How well does a paragraph "hang together"? Paragraphs should be about a single thought.
- Personal words. Take personal credit or blame. This targets the sentence to the reader.
- Imageability. Use concrete words that can be visualized. Use pictures, diagrams, maps, and graphs, etc.
- Referents. Make sure the reader understands what "it," "they," or "theirs" refers to.
- Motivation and subject matter. Fry's Readability Principle—is that high motivation overcomes writing that is hard to comprehend. Know your audience. With a lower readability level, readers are more likely to keep reading.

Here is some writing advice from C.A. McKnight, an editor of the *Charlotte Observer:*

- Use short, simple words (less than 165 syllables per 100 words).
- Use more one-syllable words and familiar words. (There are only 6,000 different words in the Bible.)
- Use personal words; use concrete words; use short sentences; use shorter, simpler paragraphs.
- Write to one person; work with one basic idea; write affirmatively.

Of particular note is the center's use of graphic displays of information, using boxes and weekly calendars to visually portray the schedule for chemotherapy administration. Most consent forms could have been produced on a typewriter—they are page after page of text, occasionally broken up by words that are in bold or italic type. They don't take advantage of software that can produce such aids as charts, tables, graphs, and decision trees.

A subject's ability to read and understand a consent form is not just a function of the form's statistical readability, but the ways in which the form can be used both to present information to the patient and to collect information from the patient. This exchange of information is the essence of true informed consent.

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Can Patients Understand Your Consent Form: The Ethics of Communication

Mark Hochauser, Ph.D.

Recent articles in the *Minnesota Psychologist* (Albert, 1 997; Schuchman, 1997) focused on important issues of informed consent in psychotherapy. Missing from these discussions was any recognition of the roles played by patient reading skills and psychologist writing skills in the consent process.

Patient Literacy

The average American has 12.5 years of education, but probably reads at an eighth- or ninth-grade reading level. Table 1 shows the educational attainment of U.S. adults.

Table 1: Educational attainment of U.S. adults (1990 Census)

Educational Attainment	Percent (Number) of Adult Population
8th grade or less	10.4% (27.3 million)
Some high school (no diploma)	14.4% (37.8 million)
High school diploma	30.0% (78.8 million)
Some college (no degree)	18.7% (49.1 million)
Associate degree	6.2% (16.3 million)
Bachelor's degree	13.1% (34.4 million)
Graduate degree	7.2% (18.9 million)

Of course, literacy ability varies on a state-by-state basis (Bureau of the Census, 1993). In Kentucky, for example, 19% of the population has less than a ninth-grade education, 65% has graduated from high school, and 14% has a college degree. In Minnesota, 9% of the population have less than a ninth-grade education, 83% have graduated from high school, and 22% have college degrees.

"Average" Literacy skills

But such general statistics don't give a very detailed picture of true reading ability. Categorization of people as "literate" or "illiterate" does accurately portray the continuum of reading ability. So, the 1993 National Adult Literacy Survey (Kirsch, Jungeblut, Jenkins, Kolstad, 1993) investigated the literacy ability of Americans in terms of prose literacy (skills needed to understand and use information from texts), document literacy (skills needed to find and use information in applications, forms, schedules) and quantitative literacy (arithmetic skills).

On a scale from 0-500, the "average" high school graduate had a prose score of 270 (able to interpret instructions from an appliance warranty), a document score of 264 (able to identify and enter background information on an application for a social security care), and a quantitative score of 270 (able to calculate total purchase costs from an order form). The "average" college graduate had a prose score of 322 (able to read a lengthy article to identify two behaviors that meet a stated condition), a document score of 314 (able to use a bus schedule to determine an appropriate bus for a given set of conditions), and a quantitative score of 322 (able to calculate miles per gallon given on a mileage record chart).

About 7% of the population reports that they can't read English very well; 10% reports not being able to write English very well; 9% gets help from family or friends to help them with printed information; 12% gets help with filling out forms, and 5% gets help with basic arithmetic.

Readability Issues

Health care information must be readable. Over the years, many readability formulas have been developed (Flesch-Kincaid, Fry, Fog, Smog, etc.) which give a grade level estimate for written materials. A piece of writing at a grade 15 reading level suggests that the reader needs three years of college to read and understand the material. But not really. Grade 15 writing means the material is complex—too many long sentences (30 words or more), too many big words (more than two syllables), too many unfamiliar words. Grade levels only estimate the complexity of the writing.

Readability is affected by type size (small type is hard to read, especially for older readers), TOO MANY CAPITAL LETTERS (WHICH SLOW DOWN THE READING PROCESS), number of words in a line of text (40 characters and spaces are best, 60-70 are the maximum), and document layout and design (use of white space, headings and subheadings), and font styles (normal, bold, italics, underlined). Most of these issues are addressed in basic texts on technical writing.

Informed Consent and the Law

Although the federal government specifies that research consent forms should be written in a "language that is understandable to the subject" (ZO CFR 50.20), most research on informed consent finds that the forms are written at far too high a reading level (college or graduate school) for the "average" patient/subject. Clinical consent forms fare no better than research consent forms. While most of the research has focused on biomedical consent forms, one study (Handelsman, Kemper, *et al.*; 1986) focused on consent forms used by psychologists in private practice. About 30% of the respondents reported using written consent forms—because they preferred oral agreements. An analysis of those consent forms found that they primarily addressed fees, with little information on treatment risks or alternative treatments. The average readability of the consent forms was in the "difficult" range—equal to an academically oriented magazine.

Much has changed in clinical psychology in the past 10 years, so it is possible that more clinical psychologists are using written consent forms, and that the forms are written at a more readable level. But I doubt it. In a study of poor and minority patients at two urban public hospital (Williams, Parker, *et al.;* 1 995) researchers found that 60% could not understand a standard informed consent document. About one-third of the English speaking patients and over 60% of the Spanish-speaking patients had inadequate or marginal functional health literacy.

Virtually every readability analysis done on consent forms (either research or clinical) concludes that the forms are written at a level that most adults will have a hard time reading and understanding, and recommends that the forms be written at a sixth- to

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eighth-grade reading level—if they are to truly be "informed" consent forms. Otherwise, the forms that patients sign represent "misinformed" consent at best, and "uninformed" consent at worst.

Why would clinical patients sign a consent form that they don't really understand? Some may sign because they have complete trust in the clinician—who will do them no harm. Some may sign because they believe they cannot refuse to sign. Some may sign just because it's another form that they're given. Some may sign because they don't want to ask questions of a clinician who's too busy to talk with them. Or, some might sign because they know that they won't be able to understand the clinician's answers to their questions. Verbal information can be as complicated as written information. Of course, written consent is only one part of the consent process, so it's possible that the consent discussion is more understandable to the patient than the consent form.

Ultimately, these problems in communication between health care providers and patients may require greater legal input. From a legal perspective, Brandes (1996) has summarized cases related to literacy, health, and the law. With respect to consent, she concluded that:

> ...the law as it stands suggests that a health provider could be held responsible if an injured patient who signed a consent form can substantiate that s/he is not literate and had not been verbally informed about the procedure involved. Some recent cases as well as case law from other areas of the law point in the direction of liability." (p. 28)

Why would clinical patients sign a consent form that they don't really understand? Some may sign because they have complete trust in the clinician—whowilldothemno#P∂JIM ●

Treatment vs. Research

Almost in passing, Albert (1997) reports R. Christopher Barden as saying "Legally speaking, 'treatment' modalities that are not supported by empirical research tend to be viewed as experimental procedures." This is an issue that has long confronted biomedical ethicists, who note that serious ethical problems can arise when physicians are both healers and researchers (Annas, 1996). Roles (and responsibilities) can be blurred both for the researcher/clinician and subject/patient, creating the potential for serious harm.

Basic Elements of Research Informed Consent

If a treatment really is more an experimental procedure than an accepted clinical protocol, basic elements of research informed consent must be part of the consent process. Otherwise, the patient is not given the chance to make an informed decision about her/his willingness to participate in an "experiment." In the future, there will probably be more emphasis on this issue from third-party payers, who may be unwilling to pay for "experimental" therapies, and who may require that their members be given detailed informed consent with respect to mental health services.

As a model, the FDA (1995) lists eight basic elements of informed consent, including:

1) A statement that the study involves research, an explanation of the research purposes and expected duration of the subject's participation, a description of procedures to be followed, and identification of experimental procedures.

2) A description of any reasonably foreseeable risks or discomforts to the subject.

3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5) A statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent (to be used when appropriate) include:

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3) Any additional costs to the subject that may result from participation in the research.

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5) A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided to the subject.

6) The approximate number of subjects involved in the study.

To help researchers, the FDA (1995) describes in some detail the rationale behind each of the elements of informed consent. Nevertheless, consent forms are often incomplete in some elements. Common problems identified by FDA include failure to include all the required elements, failure to explain technical/scientific language, failure to state the experimental nature of the research, failure to state all the purposes of research, failure to completely describe the procedures, failure to describe treatment alternatives, failure to describe confidentiality strategies, failure to describe payment, failure to give contacts if questions arise, failure to include the "additional elements" when appropriate, and failure to contain specific information (use of "boiler-plate" forms). A study of 82 informed consent forms (Goldstein, Frasier, Curtis,

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et al; 1996) found 18 (22%) to be very incomplete, lacking nine or more federal requirements—with the average consent form lacking about five.

Understanding APA Ethical Rules and Procedures

What can a patient do who has ethical problems with a therapist? One strategy is for the patient to contact the American Psychological Association for a copy of the APA Ethics Rules and Procedures. About a year ago, the American Psychological Association revised the APA Ethics Rules and Procedures (DeAngelis, 1996). One goal was to make the Rules more accessible to the public, by making the Rules more user-friendly, using language that is understandable to the public at large, taking out the "legalese." However, the evidence does not support APA's claims of improvement. My readability analysis of the 1996 APA Rules and Procedures found them to be written at a difficult (scientific) level, dull, very hard for the average reader. Grade level estimates placed it at about a fourth-year graduate school reading level (about grade 20)—equal to the educational level of less than 7% of adults. For a patient whose native language is not English, this document would be useless. As shown in Table 2, overall statistics for the "improved" 1996 version were almost identical to the original 1992 Rules and Procedures!

While these statistics do not address informed consent directly, they do focus both on the broad context of ethical issues in clinical practice, and the ability of clients to understand their ethical rights within the treatment setting. Such readability analyses lead to more questions than answers.

What are the ethical implications of giving patients consent forms that they cannot read or understand? As a discipline, is clinical psychology minimizing the number of patient complaints because the patients can't understand the complaint process? Just how accurate are annual ethical reports that are based on patient complaints? Would an independent patient audit give a more accurate picture? Do psychologists have an ethical responsibility to communicate in ways that the patient can understand?

Editor's Note: *Mark Hochhauser, Ph.D., is a psychologist in Golden Valley.*

Table 2: Readability of 1992 & 1996 APA Ethics "Rules and Procedures"

Criterion:	1992 Version	1996 (Improved) Version	
Reading Ease	Difficult (Scientific)	Difficult (Scientific)	
Human Interest	Dull (Scientific)	Dull (Scientific)	
Positivity	Affirmative/optimistic	Affirmative/mostly positive	
Overall Evaluation	Very hard to read	Very hard to read	
Readability Level:	About grade 19	About grade 20	
Equals education of:	<7% of adults	<7% of adults	
Sentence Characteristics:			**(Recommended)**
# of words per sentence	36.8	36.4	15-20
# syllables per word	1.72	1.75	1.4
% complex words	15%	15%	<10%
% active voice sentences	22%	22%	60%
overall style score	20% (poor)	19% (poor)	80%
% sentences grade 16+	47%	50%	10%-15%

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How To

Healthcare Teaches

MARK HOCHHAUSER

Writing for Staff, Employees, Patients, and Family Members

Know Your Audience

To whom are you communicating—staff, employees, patients, or family members? Each audience may require different communication strategies depending on its level of education, reading skills, reading comprehension, and understanding of healthcare terminology.

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Words common to healthcare providers may be completely unfamiliar to patients and their families, so you cannot assume that everyone has your level of vocabulary. Ask yourself if you are writing based on the words that you know and understand—or based on the words that your audience knows and understands.

One method to assess your audience is to consider adult educational attainment (1990 U.S. Census): About 25 percent of Americans have less than a high school diploma, 30 percent are high school graduates, 25 percent have some college or an associate degree, 13 percent have a bachelor's degree, and 7 percent have a graduate degree. Although that national summary of educational attainment may give an overall picture, there is considerable state-to-state variation, so writing styles may have to be tailored further for your specific target audience.

Educational attainment is only one estimate of reading ability. Readability researchers often determine the complexity of written materials by first calculating their reading level using formulas such as the Flesch, Flesch-Kincaid, FOG, or SMOG. These formulas were originally developed to be done by hand, but all have been converted to software so that entire documents can be evaluated. Some of the formulas can be found in grammar checking sections of word processing programs. Many readability programs were developed to evaluate schoolbooks to make sure that the reading level required by the textbook was right for the reading level achieved by the students.[1] By comparing the result

to national educational attainment statistics, you can judge that particular materials are too complex for a certain percentage of the general population. For example, a brochure written at a graduate school reading level is only understandable to 7 percent of the population.

A few studies have made assessments of the actual reading ability of a specific target audience. Jubelirer, Linton, and Magnetti (1994) tested oncology clinic patients for their reading vocabulary and reading comprehension. Interestingly, they found that although the patients averaged 12.5 years of education, their reading vocabulary was at grade 11.3, and their reading comprehension at grade 10.5—two grades lower than their actual educational achievement. A study of parents in a pediatric setting (Davis et al. 1994) found that although the parents averaged approximately 11.5 years of education, their actual reading skills were at the seventh or eighth grade level—about four grades lower.

Such findings suggest that self-reported education levels will probably overstate patients' actual reading ability by two to four grades and that materials should be written to match readers' actual reading ability—not their highest level of education.

Internally, staff and employees probably show similar discrepancies. Materials for broad distribution in-house could be based on human resources department data on employee educational attainment, minus two to four grades. While healthcare professionals with advanced degrees might be expected to read and understand almost anything, it's nevertheless true that overcomplicated writing may require too much time and effort to be effectively read and understood.

Readability Formulas

Flesch: The Flesch Reading Ease Score was developed by Rudolf Flesch in the late 1940s and is one of the most widely used formulas. It is based on the number of syllables per 100 words and the average sentence length for a passage of 100 words. Scores range from 0 to 100, with a score of 0 meaning *very difficult* and a score of 100 *very easy*. Many states require insurance policies to have a reading ease score above 40.

Flesch-Kincaid: The Flesch-Kincaid is a modified version of the Flesch Reading Ease Score. Instead of a reading ease score, it can be used to produce a grade-level score. The results are based on the average sentence length and the average number of syllables per word.

FOG: The FOG Index is one of the easier formulas to use. It is based on average sentence length and the number of words with three or more syllables.

SMOG: The SMOG is a "Statistical Measure of Gobbledygook." This formula is based on the number of polysyllabic words per 30 sentences.

Complicated Words	Common Words
additional	more
administer	give
approximately	about
complications	problems
consequences	results
discomfort	minor pain
discontinue	stop
equivalent	equal
following	after
for purposes of	because
immediately	at once
in the event of	if
initiate	start
medications	drugs
otherwise	besides
periodically	once in a while
prior to	before
the reason for	because
waive	give up

The Literacy Continuum

People are not just literate or illiterate but have varying degrees of reading ability, and research shows that good readers and poor readers use very different reading strategies (Doak, Doak, and Root 1996). For example, whereas good readers interpret the meaning of what they read, poor readers often take instructions literally, without interpreting them differently for new situations, following instructions to the letter even when it may not be appropriate. Good readers read automatically; poor readers read sentences one word at a time, forgetting earlier words and missing the meaning of sentences, a problem made worse by sentences with too many words (over 25) to be held in working memory. These problems can be minimized by using concrete examples that show the reader how to use the information, by writing sentences with fewer words, and by organizing sentences more coherently.

Good readers get help with unusual words, using a dictionary or asking someone for the meaning. Good readers are persistent, but poor readers often skip over unusual words and tire easily. Skipping over too many words or stopping before all words have been read is almost guaranteed to confuse the poor reader. Finally, whereas good readers

Educational Attainment of U.S. Adults

Educational attainment	Millions of Americans	State range	
		Worst	Best
Eighth grade or less	27.3 (10.4%)	Kentucky 19%	Utah 3%
Some high school (no diploma)	37.8 (14.4%)	Mississippi 20%	Alaska 8%
High school diploma	78.8 (30%)	District of Columbia 21%	Pennsylvania 39%
Some college (no degree)	49.1 (18.7%)	West Virginia 13%	Utah 30%
Associate degree	16.3 (6.2%)	District of Columbia 3%	North Dakota 10%
Bachelor's degree	34.4 (13.1%)	West Virginia 7.5%	Colorado 18%
Graduate degree	18.9 (7.2%)	Arkansas, North Dakota 4%	District of Columbia 17%

Source: 1990 U.S. Census.

understand the context of the writing, poor readers miss the context, cannot make inferences about what they have just read, and are often unable to connect what they read to their own lives.

These problems can be minimized by using more common words, by defining uncommon words, and by giving concrete examples that will help readers connect the information to their lives. This last point requires that writers understand not only health information but also reader characteristics (age, gender, ethnicity, community) that will help shape the content of the writing.

Know Your Vocabulary

Healthcare is full of jargon, complicated words, and abstract concepts that many people outside of healthcare find hard to understand. That suggests that healthcare-related terms frequently need to be translated into "plain English" by replacing complicated words with more common ones. Of course, context, as well as meaning, is integral to word choice. Steinert (1977) has an informed consent glossary of technical medical terms that can be very helpful in translating medical terms to lay language.[2]

Dumbing Down versus Confusing Up

Some will argue that writing in plain English is "dumbing down" the language. But there are good reasons to write health information in plain English: Health information may involve life and death decisions, and patients who don't understand complicated healthcare information could get sicker, or even die.

Too often patients may be labeled noncompliant because they did not follow written directions. It is easier to blame the reader than to blame the writer, but either way, efforts to assign blame do no good. On the other hand, some compliance problems can be averted if patients are involved in the planning, writing, and evaluation of an organization's written materials.

For example, in October 1995, the Minnesota Health Data Institute distributed one million copies of "You and Your Health Plan," a report on a statewide survey of 18,000 Minnesota consumers' opinions about their health plans. The report was very technical; a computer program that assesses readability placed it at a second or third year college level, indicating that it would be "difficult" or "very hard" for the average reader to understand. In addition, readers of the report were asked to keep six issues in mind when comparing plans: (1) response rate, (2) plan comparison, (3) numbers and symbols, (d) sample size, (5) benefits and coverage, and (6) margin of error. No guidelines were offered as to how to mentally juggle these six issues while trying to make a decision. Given the writing style of the survey, and its 14 pages of bargraphs, would average Minnesotans be able to use the report to make an informed choice about their healthcare plan?

After a million copies of the report were distributed, the Minnesota Health Data Institute evaluated consumer reaction to it. It turned out, unsurprisingly, that although most people had seen or read the report, fewer than half found it helpful, describing it as cumbersome, complex, and detailed (Hibbard and Jewett 1997). At least some of these problems could have been averted if the materials had been written in collaboration with members of the public who were expected to read, understand, and act on the information in the report.

How to Evaluate Written Materials

There are several strategies for evaluating written materials. The best way is to pretest them on a small group of people from your target audience, perhaps using a focus group format. Give group participants your written materials and a highlighter to identify those sections that they have a hard time understanding. Talk with them in detail about what they understand, what they don't understand, and what can be done to improve the materials. If you simply ask, "Do you understand this information?" such a closed-ended question is almost guaranteed to elicit a "yes" response.

Another strategy is to use readability formulas (or software) to estimate the complexity of the writing. Word processing programs often contain with a grammar checker that gives a grade level estimate using standard readability formulas. Before relying too heavily on readability formulas, however, writers should have a deeper understanding of the strengths and weaknesses of such formulas (Hochhauser 1997). A third way is to test the health literacy of patients using instruments such as the REALM (Rapid Estimate of Adult Literacy in Medicine), a two to three minute assessment of a patient's ability to read common medical words and lay terms for body parts and illnesses (Murphy et al. 1993).

On a less-formal level, ask family members (teenagers, parents, grandparents) to read and critique the information. But train them and provide some objective criteria to evaluate the information, such as the SAM (Suitability Assessment of Materials) developed by Doak, Doak, and Root (1996). The SAM involves scoring 22 items by six factors (content, literacy demand, graphics, layout and typography, learning stimulation and motivation, cultural appropriateness) and can be very helpful in evaluating a single document or in comparing different documents. All of these evaluation strategies come with some costs—materials, computer software, training time, and the risk of finding out that materials are not as well done as originally thought. However, evaluating written materials is the only way to ensure that they are appropriate for the intended readers and that the writing does not create more problems than it solves.

This article is written at about a fourth-year college reading level.

NOTES

1. The software program "Readability Calculations," which has 7–9 readability programs, is available for about $50 from: Micro Power & Light Co., 8814 Sanshire Avenue, Dallas, TX 75231; 214/553-0105.

2. The informed consent glossary by Steinert can be obtained from Bruce W. Steinert, Ph.D., Department of Urology, William Beaumont Hospital, 3601 West Thirteen Mile Road, Royal Oak, MI 48073–6769.

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Eight Tips For Writing More Effectively

BY MARK HOCHHAUSER, PHD

A communications expert offers advice on improving memberpubliwgons

ε an the members of your health plan read and understand your organization's written materials? Before you answer that question, see bow you respond tothese eight questions.

1 oes your writing have a goal?

What do you want your writing to ccomplish? Do you expect patients to ast become more knowledgeable on a topic, or do you expect your materials to cause patients to change their attitudes or health behavior?

Changing knowledge is fairly easy; changing attitudes and behaviors is much more complicated. A single brochure or booklet is not likely to change the way peoplebehave. Review the health behavior literature to make sure that your goal is consistent with what's known about behavior change. If you do have a goal eor your writing, try to find a way e0 evaluate how well your goal is met. The continuing assessment 0e your written materials can be a part of an overall continuous quality improvement strategy.

"We first make sure we write about issues crucial to our members," says Lori Campbell Tighe, publications manager at Harvard Pilgrim Health Care, a Brookline, Mass.-based health plan. "To gather story ideas we seek counsel from our internal network 0e contacts who deal directly with member issues. Member Services, which handles all member questions, serves as an excellent resource. Our primary member publication has a clinical review board, a group 0e three key doctors who monitor the pulse of our members' health concerns."

2 Are your materials readable?

Written materials must be readable. Over the years, many readability formulas have been developed, including the Automated Readability Index, Coleman-Liau Formula, Farr-Jenkins-Paterson Formula, Flesch Reading Ease Score, Flesch-Kincaid Formula, Fry Graph, Gunning Fog Index, and the Smog Index. Using somewhat different methods, each formula gives a grade level estimate eor written materials. For example, something written at a grade 15 reading level suggests that the reader needs three years 0e college to read and understand the material.

Although writers often rely on this grade level estimate, readability formulas are nor that precise, since they're really trying to assess the complexity 0e the writing. Some health materials are written at a graduate school reading level—grade 17 wd above. This doesn't mean that you need a graduate degree to read it (even a PhD doesn't help eor soinc brochures), only that the material is very complex—too many long sentences (30 words or more) and too many long words (more than two syllables).

Although most 0e these formulas can be done "by hand," they are *@so* available in some word processing programs, in stand-alone programs, or in freeware or shareware on some online services, such as CompuServe or America Online. DOS-based programs include Corporate Voice, Critic, FS Text, Prose, Pro-Scribe, Readability Plus, and Writing Style Analyzer, while Windows-based programs include Correct Grammar, Grammatik 6.0, Key Grammar Checker, and Right-Writer 6.0. Because 0e rapid changes in the software field, some of these programs may be difficult or impossible to find.

3 Is your writing legible?

Sometimes, information is written in a typeface that is just e00 small to be read easily. This is a problem particularly eor older readers who have more problems with their eyesight than younger patients. Reading ease may be affected by:

- Using too many capital letters, as a way 0e emphasizing certain information. RESEARCH SHOWS THAT CAPITALS SLOW DOWN THE READING PROCESS. THEY HAVE NO ASCENDERS (LETTERS THAT ε0 ABOVE THE LINE) OR DESCENDERS (LETTERS THAT ε 0 BELOW THE LINE) TO HELP YOU RECOGNIZE WORDS. THEY TEND TO BE READ LETTER-BY-LETTER AND SHOULD NOT BE USED FOR CONTINUOUS TEXT.

- Squeezing too many words into a line of text. The best line length seems to be about 40 characters and spaces, with a maximum of 60-70. People with middle-aged (or older) eyes may have a hard time reading very small print.
- Using sanserif type. Sanserif type faces don't have the small picks that extend from the edges of each character. These type faces are harder to read. Serif type faces, which do have the small picks at the edges of each character, are easier to read.

What is the reading level of your members?

The "average" American has about 12.5 years of education, but probably reads at a 9th or 10th grade reading level—or less. Do you know the "literacy demographics" of your members? If not, there are several ways that you can at least estimate their reading level. Your marketing department probably has information on the educational level of your members; talk to them about a breakdown by education—keeping in mind that many people read lower than their highest grade level.

Or, get literacy information from your state department of education. Statistics vary considerably from state to state. For example, only 7.5 percent of the West Virginia population has a bachelor's degree, compared to 18 percent of the Colorado population. If you write for a national health plan, review the 1993 National Adult Literacy Survey (NALS) done by the U.S. Department of Education. Know your readers before you start to write.

5 Do you write to impress or inform?

Health care has its own jargon—words, phrases, and concepts that are easily understood by others in the field, but almost incomprehensible to the average reader. Sometimes, it's hard to separate your ego from your writing, which is why some writers have such a hard time with criticism. They see the criticism as not just a reflection of their writing style, but of themselves. If you use a lot of jargon, very few people will be able to criticize your writing. Your writing may be impressive, but it won't be clear. If your goal is to communicate and inform the patient, write at a simpler level. Reading researcher Edward Fry offers these tips for "writeability":

- Use more common words. Don't use words that the reader doesn't know.
- Keep sentences short, but not always. Sometimes longer sentences are better, but active sentences are almost always better than passive sentences.
- Keep paragraphs short, and use lists if they will help.
- Be organized. Use the Statement-Example Restatement (SER) sequence. Use subheadings. Use signal words to indicate a sequence (first, second, third); a reverse idea (however, but); or uncertainty (maybe, if).
- Use concrete words that create an image. Use pictures, diagrams, or graphs.
- Use short, simple words—fewer than 165 syllables per 100 words.
- Use more one-syllable words and familiar words. (There are only 6,000 different words in the Bible.)

Instead of writing	consider...
Administer	Give
Approximately	About
Discontinue	Stop
Equivalent	Equal
For purposes of	Because
Initiate	Start
Innovative	New
In the event of	If
Terminate	End
Utilizing	Use
Waive	Give up

6 Do you blame the patient or blame the author?

Sometimes, patients don't behave the way that health care providers think they should behave. These patients may be described as problem patients or non-compliant patients because they're not "following instructions." Or maybe they just can't read and understand the instructions. While personal responsibility is a key part of health care, writers must be aware of how their writing may contribute to the problem.

Unhealthy behaviors may *be* linked to three informational problems. First, the information (written at a college reading level) may not be readable by the patient (reading at a junior high reading level). Second, even if it is readable, the information may be conceptually too complicated to understand. If they can't understand it, they can't act on it. Third, even if the information is both readable and understandable, it may not fit with the patient's cultural belief system. While the American health care system emphasizes personal control over health, many cultures are much more fatalistic, believing that health is due more to God's will than to their own behaviors. In our increasingly multicultural society, a one-size-fits all approach to written information will not work for everyone, and may do harm to some.

7 What are the ethical implications of your writing?

Some health information, such as an informed consent form, provides patients with information regarding the risks associated with specific medical procedures so that they can decide whether to participate or not. Some consent forms contain both medical and legal jargon, often producing a document that may be difficult for the patient or the patient's family to understand.

Even if a patient has signed such a consent form, ethicists have argued over whether the consent was truly "informed" or "uninformed." Just because a patient signs a consent form does not necessarily mean that the patient understands the consent form. Thus it is important to buttress consent forms with personal contact by health plan staff to answer questions and to assist the patient in making a decision about the treatment or procedure.

Know Your Audience

In terms of educational attainment of adults, the 1990 U.S. Census found:

Educational attainment	Number of Americans
8th grade or less	27.3 million (10.4%)
Some high school (no diploma)	37.8 million (14.4%)
High school diploma	78.8 million (30%)
Some college (no degree)	49.1 million (18.7%)
Associate degree	16.3 million (6.2%)
Bachelor's degree	34.4 million (13.1%)
Graduate degree	18.9 million (7.2%)

8 Do you test your materials?

To make sure it is communicating clearly, Harvard Pilgrim Health Care does member surveys polling its success rate in communicating key information, readability, and interest. It then uses that information to fine-tune its publications, says Tighe.

The best way to ensure that your materials are readable is to test them with a representative sample of members who will be expected to read the materials. If you're doing a brochure on mammograms, bring in a small group of women who have had mammograms to help you write the brochure. Or, write the brochure first, and then test it in a focus group setting. You will be astonished at what you find.

PacifiCare, for example, tests its materials. "We ask members and non-members about the balance of text to graphics, the length of the publication, which articles they read in-depth, which they skim, and which they don't read," says Marge Grey, director of publications for the Cypress, Calif.-based health plan. "We then *use* that information to make changes to content and/or design."

Reading researcher Jane Chall notes that for good readers, reading level may not be a problem, since they can read and understand complex writing. But reading level may be a major problem for poor readers, who may have reading strategies that make it hard for them to read and understand unfamiliar material. They may skip over words they don't know, or throw the booklet away, or conclude that they're "dumb" because they don't understand. Long words may interrupt their train of thought, slowing down the automatic processing of words that is essential for reading. Health care writers often think of readers as a single audience, rather than a group made up of excellent readers, average readers, poor readers, and illiterate readers.

Even so, many writers find testing to be too threatening, *too* time consuming, or too expensive, and will continue to write materials that are appropriate for other health care providers, but inappropriate for the patient. If you don't have the time or money to do it right the first time, where will you get the time and money to do it right the second time—or third time? ■

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