SPECIAL ARTICLE

Readability Standards for Informed-Consent Forms as Compared with Actual Readability

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ABSTRACT

BACKGROUND

Institutional review boards (IRBs) are charged with safeguarding potential research subjects with limited literacy but may have an inadvertent role in promulgating unreadable consent forms. We hypothesized that text provided by IRBs in informed-consent forms falls short of the IRBs' own readability standards and that readability is influenced by the level of research activity, local literacy rates, and federal oversight.

METHODS

To test these hypotheses, we conducted a cross-sectional study linking data from several public-use sources. A total of 114 Web sites of U.S. medical schools were surveyed for IRB readability standards and informed-consent-form templates. Actual readability was measured with the Flesch–Kincaid scale, which assigns a score on the basis of the minimal grade level required to read and understand English text (range, 0 to 12). Data on the level of research activity, local literacy rates, and federal oversight were obtained from organizational Web sites.

RESULTS

The average readability score for text provided by IRBs was 10.6 (95 percent confidence interval, 10.3 to 10.8) on the Flesch–Kincaid scale. Specific readability standards, found on 61 Web sites (54 percent), ranged from a 5th-grade reading level to a 10th-grade reading level. The mean Flesch–Kincaid scores for the readability of sample text provided by IRBs exceeded the stated standard by 2.8 grade levels (95 percent confidence interval, 2.4 to 3.2; $P<0.001$). Readability was not associated with either the level of research funding ($P=0.89$) or local rates of literacy ($P=0.92$). However, the 52 schools that had been made subject to oversight by the Office for Human Research Protections (46 percent) had lower Flesch–Kincaid scores than the other schools (10.2 vs. 10.9, $P=0.005$).

CONCLUSIONS

IRBs commonly provide text for informed-consent forms that falls short of their own readability standards. Federal oversight is associated with better readability.

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EDUCATIONAL MATERIALS FOR PATIENTS and informed-consent documents present highly complex information that must be understood by patients.[1-3] This complexity is a major barrier to comprehension for the approximately one quarter of American adults with low literacy skills.[4] A low level of literacy is independently associated with poor health outcomes and billions of dollars of additional annual health care expenditures.[5-9] When documents are incomprehensible, health care providers may risk liability.[10-12]

Obtaining informed consent for participation in medical research is particularly challenging because it requires a level of comprehension beyond that required for consent to usual care.[13] A large literature already supports the notion that the language used in informed-consent forms is not comprehensible to most Americans.[14] However, the origin of this problem is unclear.

Institutional review boards (IRBs) are charged with safeguarding potential subjects with limited literacy,[15,16] but they may have an inadvertent role in promulgating unreadable informed-consent forms. IRBs commonly present investigators with readability standards and informed-consent text, in the form of templates and sample forms. We surveyed U.S. medical schools to test the hypothesis that IRBs fail to meet their own standards for readability in the informed-consent text offered to investigators.

METHODS

DATA SOURCES

We obtained all data from publicly available Web sites, which were accessed between December 2001 and February 2002. A total of 123 U.S. medical-school Web sites were surveyed for specified readability standards and suggested text for informed-consent documents. Data were obtained from 114 of the Web sites (93 percent). We were unable to collect data from the other nine Web sites because information about the IRB was restricted to intranet access (six sites) or because the Web site contained no information about an IRB (three).

Data on the rank order of medical schools that received funding in 2001, obtained from the Web site of the National Institutes of Health,[17] were used as an indicator of research activity. Local literacy rates were obtained from the Web site of the National Institute for Literacy, which provides literacy rates by congressional district.[18] Data on federal oversight were obtained from the Web site of the Office for Human Research Protections, which lists medical schools that were made subject to oversight between July 2000 and February 2002.[19] Federal oversight is initiated to evaluate indications of noncompliance with federal policy.[20]

READABILITY STANDARDS

Each medical-school Web site was examined for information about readability standards. Descriptive standards (e.g., "in lay language") and specific grade-level standards (e.g., "at or below an 8th-grade reading level") were recorded.

SAMPLE TEXT

Web sites were examined for sample informed-consent text to be used for adults who have full decision-making capacity. Text intended for special populations (e.g., children) or special circumstances (e.g., genetic testing) was excluded from the analysis. Applicable templates and sample language were downloaded into Microsoft Word 2000 (Microsoft).

READABILITY SCORE

The readability of sample text was measured with the use of the Flesch–Kincaid readability scale (grade-level range, 0 to 12), which is automated in Microsoft Word and has been demonstrated to be reliable and valid.[21] The Flesch–Kincaid scale assesses readability on the basis of the average number of syllables per word and the average number of words per sentence.[22] The Flesch–Kincaid grade level that we assigned to a document was the average of three separate measurements conducted on the three largest uninterrupted blocks of text (Table 1).

An additional measure of readability was applied to a randomly selected 20 percent subsample of materials according to the method developed by Fry.[22] The Fry score, expressed as the number of years of education required for comprehension (range, 1 to 17 or more), is based on the average number of syllables per three 100-word blocks and the average number of sentences per three 100-word blocks.

STATISTICAL ANALYSIS

We used the Wilcoxon signed-rank test to compare readability scores with grade-level standards for readability. Analysis of variance was used to test the association of readability with quartile means for the level of research funding and local literacy rates. Readability scores for schools that had been subjected to federal oversight and those that had not

Table 1. Examples of Informed-Consent Text Provided by Institutional Review Boards at U.S. Medical Schools.*

Readability Level	Voluntary Participation	New Information about Risks	No Direct Benefits	Involuntary Removal
4th Grade†	"You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor's attitude toward you will not change."	"We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study."	"There is no benefit to you from being in the study. Your taking part may help patients in the future."‡	"You may be taken out of the study if: 1. Staying in the study would be harmful. 2. You need treatment not allowed in this study. 3. You fail to follow instructions. 4. You become pregnant. 5. The study is canceled."‡
6th Grade†	"Taking part in this study is your choice. If you decide not to take part, this will not harm your relations with your doctors or with the University."	"We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information."	"You may receive no direct benefit from being in this study. However, your taking part may help patients get better care in the future."	—§
8th Grade†	"Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled."	"We will tell you about new information that may affect your willingness to stay in this study."	"There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research."	"The study doctors have the right to end your participation in this study for any of the following reasons. It would be dangerous for you to continue. You do not follow study procedures as directed by the study doctors. The sponsor decides to end the study."
10th Grade†	"Your participation in this study is voluntary and you are free to withdraw at any time. Participation or withdrawal will not affect any rights to which you are entitled."	"We will tell you about new information that may affect your health, welfare, or willingness to stay in this study."	"There is no guarantee that you will receive direct benefit from your participation in this study."	"The study doctor, or the sponsor, may stop my participation in this study without my consent."
12th Grade¶	"Your participation in this study is strictly voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without prejudice to your future health care or other services to which you are otherwise entitled."	"You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate. If new information becomes known that will affect you or might change your decision to be in this study, you will be informed by the investigator."	"There may be no direct benefit to me, however, information from this study may benefit other patients with similar medical problems in the future."	"You may be terminated from this study without your consent if you have serious side effects, you fail to follow your doctor's instructions, your disease gets worse, or the sponsor closes the study. If this should happen, your doctor can discuss other available treatment options with you."
College¶	"You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University."	"During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained."	"The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study."	"Your participation in this research project may be terminated by your doctor without your consent if you are not benefiting from the treatment/procedure, or if the treatment/procedure is determined to be inappropriate to your case. You may also be terminated from participation at any time, at the study physician's discretion, for any reason he/she deems appropriate."

* All the examples are taken directly from medical-school Web sites unless otherwise noted.
† The readability level is based on the Flesch–Kincaid readability scale.
‡ The passage was modified to present key concepts at a 4th-grade reading level.
§ No passage was found at this reading level.
¶ The readability level is based on the Fry readability formula.

were compared with use of the Wilcoxon rank-sum test. All significance tests were two-tailed. Analyses were conducted with Stata software, version 8 (Stata).

RESULTS

READABILITY STANDARDS

Grade-level readability standards were specified at 61 of the 114 Web sites (54 percent). The standards ranged from a 5th-grade reading level to a 10th-grade level (mode, 8th grade). Forty-seven other Web sites (41 percent) contained descriptive guidelines such as "simple lay language," and six (5 percent) contained no guidelines for readability.

READABILITY OF SAMPLE TEXT

The mean Flesch–Kincaid grade level for sample text supplied by IRBs was 10.6 (95 percent confidence interval, 10.3 to 10.8). Among the 61 schools with specific grade-level standards, only 8 percent (95 percent confidence interval, 3 to 18 percent) met their own standards; the mean score for readability exceeded the stated standard by 2.8 grade levels (95 percent confidence interval, 2.4 to 3.2; P<0.001) (Fig. 1).

The magnitude of this disparity was amplified by application of the Fry formula. In a representative subsample of materials from 24 medical schools, the modal score for readability was 13 (range, 6 to 16), and the mean score was 13.0 (95 percent confidence interval, 12.2 to 13.9). The modal Flesch–Kincaid score for these materials was 10.9 (range, 5.8 to 12.0), and the mean score was 10.7 (95 percent confidence interval, 10.1 to 11.3).

Several schools presented sample text for informed-consent forms that did meet their own standards. For example, the text supplied by the State University of New York Downstate Medical School, which specifies a 6th-grade reading level as the standard for readability, had a Flesch–Kincaid score of 5.8 and a Fry score of 6. The University of Washington and the schools of the University of Minnesota met their goal of an 8th-grade reading level.

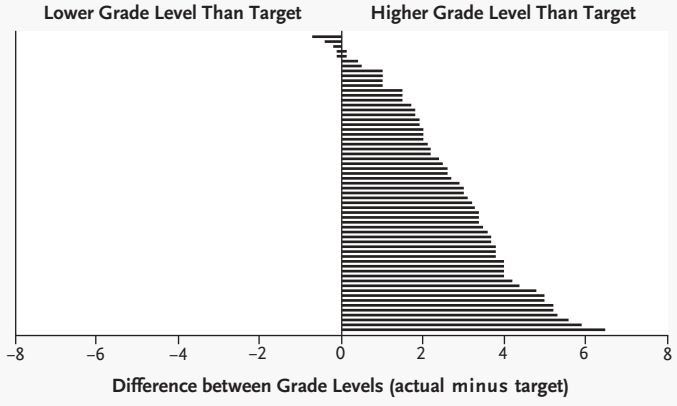

Figure 1. Difference between Actual Readability and Target Readability.
Each bar represents 1 of the 61 institutional review boards that indicated a specific grade-level target as a readability standard.

FACTORS THOUGHT TO INFLUENCE READABILITY

Neither the level of research funding received from the National Institutes of Health nor the local rate of literacy was associated with the readability of informed-consent text (P=0.89 and P=0.92, respectively). However, there was a small but significant association between federal oversight and readability. The grade-level score was lower for text provided by the 52 medical schools that had been subjected to federal oversight than for text presented by the other schools (10.2 vs. 10.9, P=0.005). This association was even stronger when the oversight predated the posting of the informed-consent text (readability score, 9.8 vs. 10.9; P<0.001).

DISCUSSION

Our findings suggest that the sample texts provided to investigators by IRBs of U.S. medical schools generally fail to meet the IRBs' own standards for readability. The readability of sample text does not appear to be influenced by the level of research activity or the local rate of literacy but does appear to be influenced by prior oversight by the Office for Human Research Protections. Previous reports have demonstrated the complexity of informed-consent forms[23-32] but have not examined the language promulgated by IRBs.

The strengths of this study that lend weight to our conclusions are its nearly complete coverage of IRBs at U.S. medical schools and the use of standardized instruments for data abstraction. Nonetheless, several limitations should be kept in mind. First, data were obtained exclusively from Web sites. Although it is likely that the materials presented on IRB Web sites accurately reflect local practices, additional materials were not examined. Second, our analysis was limited to templates and samples rather than actual consent forms. Investigators some-

times modify the language in templates to make the forms more readable. Third, we did not attempt to evaluate content. It is possible that variations in conceptual complexity influence readability as well. Fourth, the grade level of text is only one aspect of the suitability of informed-consent forms. Additional factors, such as the type font, layout, and length, also affect readability.[27,33-37]

We chose the Flesch–Kincaid scale for our main analysis primarily because of its convenience: of the dozens of readability scales, the Flesch–Kincaid system is the most widely available for computerized use, since it is embedded in Microsoft Word. Other advantages include its wide use in studies of readability, excellent repeatability, and high correlation with other established readability scales (r=0.87 to 0.90).[21] However, since the Flesch–Kincaid scoring method in Microsoft Word artificially truncates readability at the 12th-grade level, it underestimates the actual reading level required for complex text. Had we applied the more laborious Fry method in our main analyses, the disparities between readability standards and sample forms would have been even more striking. Furthermore, neither method accounts for the complexity introduced by short but unfamiliar medical terms. Both these limitations tend to result in underestimation of the actual reading level required for medical documents.

Almost half of American adults read at or below the 8th-grade level.[3] Illiteracy in the United States is mainly the result of insufficient education. The text of informed-consent documents can be written at a 4th-grade level, as Table 1 shows. Even though consent forms are never used in isolation, text written at a 4th-grade level would promote the autonomy of most candidates for participation in medical research. People who have poor literacy skills should not be excluded from such participation. Alternative methods for obtaining informed consent, such as multimedia systems, are also likely to be of substantial benefit.[38]

To achieve systemic change, IRBs need to improve the templates and sample text they offer to investigators. Although federal review appears to improve the readability of these materials, models are already available for interested medical schools. Institutions as diverse as the National Cancer Institute and the State University of New York Downstate Medical School have presented informed-consent templates and sample forms that are below an 8th-grade reading level.[39] Our study suggests that a 4th-grade to 6th-grade reading level may be a suitable target, since text at this level appears to convey key concepts simply and directly.

Important documents for patients must be written in clear, direct language. Plain language requires honesty and a good understanding of what to convey.[40] We believe that IRBs should lead by example.

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