# Informed Consent Readability: Subject Understanding of 15 Common Consent Form Phrases

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To conduct research ethically, informed consent must be obtained from each subject or a representative. This consent is documented when the patient signs an informed consent form. According to law, the requisite information for consent is to be presented in "language understandable to the subject or the representative." If consent forms are written in language that subjects do not fully understand, there is no guarantee that they know all the information they need to know to make a well-educated decision regarding their involvement in a clinical research study. Many studies have attempted to evaluate whether consent forms comply to this criteria. Study designs commonly use standardized readability scoring [l-11] or patient recall tests of information in the consent form.[12-14] In a pilot study by Mariner and McArdle, readability formulas were shown to be an inadequate measure of consent form comprehension by patients.[15] Results of patient recall tests are difficult to interpret without control groups to compare recall of well-understood information.[16] A different method of evaluation must be used for accurate assessment of consent form readability.

Waggoner and Mayo devised a research study that used a questionnaire format to evaluate the comprehension of common words and phrases found in informed consent forms. If subjects cannot understand the words and phrases used in the consent form, they may not be fully informed when they sign the consent. Through their survey, Waggoner and Mayo identified often used consent form terminology that the general population does not appear to understand. [17]

Dr. Waggoner's study is more relevant to subject understanding of consent forms than previous research, but the accuracy of the data is limited by the fact that the study population was not restricted to people who had participated in clinical research. This group may have a different knowledge level than the general public. In addition, questions were posed verbally, and some of the questions asked respondents to define words without context. Written presentation of terms within a context similar to a consent form could affect comprehension. We explored this question through written survey research conducted in the summer of 1995.

**Study Methods**

The study population (those who received surveys) consisted of 146 people who had previously enrolled in research studies at Gundersen Clinic in LaCrosse, Wisconsin. Only recent studies were used, with names given at the discretion of the investigator. Children were not included. Surveys returned on or before 18 August 1995 were evaluated. Overall, 86 surveys were returned before the deadline.

Prior to being sent, surveys were grouped into one of three categories (groups A, B, and C) depending on what the subject's health status was in relation to the study in which he or she had been enrolled. Those subjects in group A had been enrolled in protocols designed to evaluate treatment for chronic, life-threatening diseases. In group B, the subjects had been enrolled in protocols for chronic but not life-threatening diseases. The final group included those subjects who had been enrolled in protocols that entailed research not related to their health condition. The breakdown of surveys sent by group is as follows: group A=22, group B=18, and group C=106.

The survey consisted of a brief introduction, a request for basic demographic information, and 15 open-ended questions. A cover letter explaining the study goals and methods and a business reply envelope were sent along with the survey form. Demographic data requested were age, gender, education level, and employment status, each to be indicated by marking the appropriate category in a multiple choice scale. For statistical analysis, subjects were grouped by age (18-40, 41-65, and over 65 years) and education level (high school diploma or less, some college or vocational training, and college degree or higher).

Survey questions were designed to test common words from consent forms. The selection of words to test was based on frequency of use in forms at this institution, probable difficulty, and use by previous research studies. A sentence containing the term was given for context, followed by a question asking the subject to define the term. In an attempt to balance brevity (to maximize response rate) and thoroughness, 15 words were chosen for the two-page survey.

Scoring was done on a 3-variable format based on degree of correctness. A high score of two was given for display of full knowledge of the term. A score of one was given when answers showed familiarity but did not fully

explain the term, and zero was given when subjects did not know the word. Subjects were not expected to give a dictionary definition. Rather, this method enabled consistency in scoring answers that were partially correct.

After scoring, the data were entered into a computer database for analysis. Percentages of fully correct, partially correct, and incorrect answers were used to evaluate subjects understanding of the consent form terms. The chi-square method was used to determine if study group, age, or education level correlated significantly with scores.

**Results**

**1. "The purpose of this study is to determine the efficacy of a new drug. What is efficacy?"** Overall, 86 percent of respondents had complete knowledge of this term. Although not a high-scoring question, this was much higher than expected. A previous study reported that only 33 percent of respondents to an interview survey knew the term.[17] There was no statistical difference found when knowledge was compared by group, age, or education.

**2. "Do not apply the cream to any lesion. What is a lesion?"** Only 1 respondent had no knowledge of the word *lesion.* Of the remainder, 34 (40%) displayed complete knowledge, and 51 (59%) knew the word but not entirely. Many respondents simply answered that a lesion was a "cut," not acknowledging other types of lesions. The scores varied significantly by the study group (p=.026), with only 29 percent of the chronic, not life-threatening group showing complete knowledge, where 50 percent of the chronic, life-threatening group and 39 percent of the healthy group gave full definitions.

**3. "Take the medication *orally.* How is the medication taken?"** A study of patient comprehension of medical vocabulary reported that one in four patients interviewed at the Primary Care Center of the Yale New Haven Hospital believed that orally referred to "how often" medication is taken.[18] For this written survey, orally proved to be the most well understood term, with 99 percent of the respondents giving a correct definition. There were no differences in responses by group, age, or level of education.

4. **"The *protocol* has been reviewed by the ethics committee. What is a protocol?"** This question had the fewest answers with complete knowledge shown (only 5). One-third of all respondents had no knowledge of what a protocol is. There was significant difference in scores by education level (p=.002), with higher scores for those respondents with higher education. As a frequently used word not only in consent forms, but also in conversations with subjects, it is alarming that research subjects did not understand the term.

5. **"There are many *benefits for* those who take part in this study. What does the word benefit mean?"** This question was intended as a reference level for the survey. Of the 86 subjects, 80 (93%) gave a full definition of the word.

6. **"This is an *open-label* study**. **What does open label mean?"** Only 13% understood this term completely. Sixty respondents (70%) had no knowledge of what *open-label* referred to. The younger subjects had better knowledge of the term (41% showing complete knowledge), as well as the more educated, although education was only marginally related to knowledge of this item (p=.056).

7. **"Do not take any *non-steroidal anti-inflammatory drugs (NSAIDS).* What are NSAIDS (give an example)?"** Just under half of those who returned the survey were able to give an example of an NSAID, while one-third did not know the word at all. Those with more education were able to give more complete answers (p=.051).

8. **"Some *adverse reactions* may occur as a result of the medication. What are adverse reactions?"** Research study subjects showed good knowledge of this term, 90 percent answering with complete definitions. Only 2 of the 86 total responses appeared to have no familiarity with "adverse reactions," and no statistical differences were found by group, age, or education level.

9. **"I will not receive *compensation* for medical treatments for side effects unless caused by *negligence*. What is compensation?"** Compensation is understood by 59 percent of responders to be reimbursement in monetary or other form. Another 38 percent cited cash payment, and 2 subjects did not know the word.

10. **"What is *negligence*?"** Not as well understood as compensation, this word posed problems for some of the subjects. Only 85 percent answered the question fully and correctly.

11. "I **will either get the trial drug or the *placebo*. What is a placebo?"** Study participants scored much higher on this question than predicted by previous surveys. Waggoner and Mayo reported that only 75 percent could define the term, [17] but in this survey 81 percent gave a complete definition, and an additional 11 percent had some familiarity with the term *placebo.* Subjects 41 to 65 years old appeared to have better knowledge than both older and younger groups, with 93 percent writing complete definitions. Education was also related to knowledge of *placebo* (p=.012), with the higher educated having higher scores.

12. **"My involvement in the study will not affect *subsequent* care. What is subsequent care?"** This term was found in most of the consent forms sampled at this institution. Although 94 percent were familiar with the term, there was a significant difference across the study groups (p=.003). Of the group with chronic, life-threatening diseases, only 38 percent had complete knowledge of the term, and one in four had no knowledge of the word *subsequent.* This may be due to the small sample size of groups A and B.

13. **"During the study I will use a reliable method of *contraception*. What does contraception refer to?"** A surprising 10 percent could not give any correct definition for contraception, and only 76 percent gave full definitions. The younger participants had much better knowledge of this term, 100 percent of those 18-40 years old responding with complete answers, while 78 percent of those 41-65 and only 55 percent of the over 65 age groups could do the same.

14. **"If I have ever had chicken pox, I am *ineligible* for the study. What does ineligible mean?"** This was a high-scoring question. Ninety-four percent had complete knowledge, 1 percent some familiarity, and 5 percent no knowledge. Statistical difference by group (p=.02), as well as trends by age (p=.08) and education level (p=.06) were found.

15. **"I can *withdraw my consent* at any time. What does it mean to withdraw consent?"** Respondents had high comprehension of this term as well, with 83 of the 86 responses being correct and complete.

## Limitations

As with previous research on the readability of informed consent documents, this study tested only one component affecting comprehension by subjects. Sentence length, structure, format of the document, environment, and time given for reading, as well as other materials given to the patient also affect how well a patient understands the consent process and protocol.

The small sample size of 86 subjects limits the data. This reflects a return rate of approximately 59 percent. The 41 percent who did not return the survey may be more or less knowledgeable than those subjects who did. In particular, this may introduce a self-selection bias. Those subjects who did not return the survey may have been those who had more difficulty understanding the words.

Finally, subjects may have a more complete knowledge of the terms than their response implies. Only what was written could be scored, not what might be implied or known but not written out. Conversely, although requested not to get assistance, subjects may confer with spouses or dictionaries to figure out the best answer.

## Discussion

This survey identified some words that should not be used in consent forms without explanation, in particular medical and clinical research terms. It was also found that in many cases, subjects have an idea of what a word means, but do not have a complete or inclusive definition. This can prove dangerous in consent forms, as subjects are not likely to ask about phrases they think they know and may sign the form without complete understanding.

The most significant factor in determining score on the survey was education level. Since the grade level of clinical research subjects is not generally known when the consent form is written or even as it is presented to the subject, the forms should be written to be understood by the subjects with minimal educational background. It has been estimated that national illiteracy rates may range from 13 to 55 percent, and that the reading levels of patients are "about three to four grade levels below educational level." [19] Therefore to make a form readable for a high school graduate, it should be written at the ninth grade level. Considering the potential for a subject to be functionally illiterate, it is clear that the written consent form cannot be used as the only source of information for the subject. Many authors have made this point in previous writings, and it merits emphasis in the debate over informed consent forms.[20]

Some discrepancies with previous research were found. These may be due to regional differences (Waggoner and Mayo did not sample from the midwest in their survey), study population differences (this is the first survey of research study participants), or survey format (written, with a sentence given for context). A more extensive survey of a larger population of research participants would be valuable in evaluating subject comprehension of consent form terminology.

## Summary

Through a mailed survey, clinical research subjects' understanding of informed consent document terminology was evaluated. The data obtained are of practical value, as they will enable more readable consent forms for future research.

A brief (one page, two sides) questionnaire was sent to former or present clinical research subjects. The questionnaire contained instructions and a demographic survey, followed by the survey questions, composed of typical sentences from consent forms with a word or phrase in bold print. The subjects were asked to define the bold word to the best of their ability. Upon return, each question was scored individually by degree of correctness. Data were accumulated and grouped for analysis.

The results show that research subjects have poor or incomplete understanding of medical and research terminology. The most significant factor in predicting knowledge of these terms is the education level of the subject. Age and state of health were also significant in some instances.

## Acknowledgments

The authors would like to thank Brenda Rooney, PhD, and Bud Hammes, PhD for their help in developing and completing this project, and the Gundersen Medical Foundation for provision of funding and support.

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*IRB: A Review of Human Subjects Research* 17, No. 5-6 (1995): 16-19