Informed Consent Documents: Increasing Comprehension by Reducing Reading Level

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The purpose of the informed consent process is to ensure that potential volunteers for research studies are informed about risks and benefits so that they can make an informed decision before taking part in a study Written informed consent is critical for communicating such information in research where face-to-face communication is lacking. In the late 1970s, the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) issued rules that required written informed consent to be obtained from individuals taking part in research regulated by or sponsored by these agencies. Clinical studies designed to determine the safety or efficacy of a new pharmaceutical product were the original focus of these rules.

However, the concept of informed consent has been extended to other types of research, including psychological research as well as some types of consumer-related research. This last category involves product preference testing on products such as antibacterial shampoos and soaps, and over-the-counter drug products such as aspirin, etc. Product preference research plays an important part in the development of successful consumer products. Product preference testing is used to determine what attributes consumers want and to obtain their evaluations of various characteristics.

In conducting medical research, psychological research, and some types of product preference research with healthy subjects, the FDA's Institutional Review Board (IRB) rules require that specific information be presented to potential subjects in the consent procedure. For example, subjects must be told about: (1) the purpose of the research; (2) any possible risks; (3) the benefits of participating; (4) other treatments available (when appropriate); (5) the confidentiality of records; (6) who to contact concerning questions or if complications arise; (7) the consequences of withdrawing from the study; and (8) voluntariness of their participation. Such specifications are useful. However, to be truly informed, this information must be presented in such a way that subjects are able to understand it clearly.

Over the past 15 years much of the discussion in the literature relating to informed consent has centered on the informational requirements of informed consent. More recently; there has been some discussion and research on consent comprehension. In an extensive review of research reviewed by IRBs, Gray Cooke, and Tannenbaum[1] found that over 77% of the 1526 consent forms evaluated had readability scores (using the Flesch Readability Yardstick) in the scholarly/academic or scientific/professional range. Other studies have also found that a high percentage of consent forms are written at college level or higher.[2]

Many potential research subjects or patients are not reading at a college level or higher, as a result, it is likely that they do not truly understand the procedure or research in which they are agreeing to participate. This concern has been supported indirectly by a number of studies showing that comprehension of consent form information increases with the education and vocabulary level of participants. In addition, other research has indicated poor recall and comprehension of key information presented in consent forms.[3]

However, few studies have directly compared the comprehension of consent forms written at different educational reading levels. In addition, very limited research on informed consent has been conducted in a consumer preference research context. Our research on informed consent comprehension was conducted as a result of questions raised by the Procter & Gamble IRB about the consent process. This IRB primarily reviews human testing conducted by Procter & Gamble on consumer products in the low risk category:

The primary purpose of this research was to gain insight into the impact the informed consent reading level has on potential volunteer subjects’ comprehension of consent information and their concerns about participating. An additional goal of the study was to examine the impact of delaying for 15 minutes a subject's decision to participate after reading the consent form on both consent form comprehension and concerns about participating. The question was whether the 15 minute delay could affect potential subjects' comprehension of the information presented or their level of concern and thus, their willingness to participate in the research.

Subjects

The sample consisted of 666 consumers between 18 and 72 years of age, with a median age of 49 years. Subjects were sampled from three areas--a West Coast city, a Southern city and a Midwestern city. The only selection criterion was that the subjects had used a mouthwash product during the past 3 months.

Materials

In this study, two versions of a consent form describing a pair test of a new mouthwash product were developed (Appendix A). The same "core" information was presented in both consent forms. However, the Low Reading Level consent form was written at about the 6th grade level (according to the Flesch-Kincaid readability formula) and the High Reading Level consent form was written at about the college graduate level (grade level 16). Earlier versions of these consent forms were informally reviewed by Procter and Gamble's IRB and, with their suggested revisions, were judged as acceptable in terms of presenting the key information required in a consent form.

Readability differences between the two consent form versions were obtained by changing a number of characteristics of the information presented. First, fewer syllables and more commonly used words were employed in the Low Reading Level consent form. This included the use of less technical jargon. Second, shorter and less complex sentences were used in the Low Reading Level version. Third, where possible, parallel sentence construction was maintained in the Low Reading Level version. Together, these differences resulted in the Low Reading Level version being more concise-both in terms of the number of syllables and the number of words.

Procedure

Panelists were presented with either the Low or High Reading Level version of the consent form and were instructed to read it carefully They were led to believe that they would be asked to participate in the study described in the consent form. Subjects were given as much time as needed to read the consent form. After reading the form, all subjects were given the same 21 question multiple choice comprehension test covering the information presented in the consent form. They also answered 3 follow-up questions addressing: (1) concerns about using the mouthwash products; (2) willingness to participate in the study described; and (3) difficulty in understanding the consent forms.

Approximately half of the subjects receiving each version of the consent form answered the comprehension test and the follow-up questions immediately after reading the consent form (No Delay condition) and half answered the questions after a 15 minute delay (Delay condition).

Results

Comprehension. Subjects' comprehension was affected by the reading level of the consent form. Comprehension also decreased as the formal education level of subjects decreased. However, comprehension was not affected by the 15 minute delay.

Overall, comprehension scores (see Table 1a) were higher for the Low Reading Level consent form than in the High Reading Level consent form, $p<.005$. But perhaps the practical effects are more obvious when one looks at large differences in correct answers on key questions, such as: (1) the overall purpose of the test (Low Reading = 77% correct, High Reading = 44% correct); *(2)* potential side effects (Low Reading = *72%* correct, High Reading = 58% correct); and *(3)* the results of refusing to participate (Low Reading = 64%, High Reading = 43%) (see Table lb).

The greater difficulty of the High Reading Level consent form was also indicated by the follow-up question (see Table *2)* on ease of understanding the consent form. A *higher* proportion of subjects in the Low Reading Level consent form condition *(64%)* than in the High Reading Level condition *(33%)* believed the consent form was somewhat or very easy to understand; and a *lower* proportion of subjects in the Low Reading Level condition *(9%)* than in the High Reading Level condition *(20%)* believed the consent form was somewhat or very difficult to understand.

For further understanding of reading effects, subjects were divided into three groups according to their education level-high school graduate or less, attended college, and college graduate or higher. Table *3* shows that comprehension scores increased with education, $p<.001$, with the two college groups having significantly higher scores. As indicated above, all education groups had higher comprehension with the Low Reading Level Consent Form than with the High Reading Level form.

Concern About Research. Subjects were asked two follow-up questions to evaluate their level of concern about participating in the research (see Table 4). If there was a 15 minute delay before completing these questions, subjects' level of concern increased and their willingness to participate decreased. This may indicate that subjects require some time to reflect on the possible implications of the information presented in the consent form in order to fully appreciate it.

This is consistent with findings of Gertson and McNamara[4] that a significant number of their subjects changed their decision to participate between the first and second session of the study

Reading difficulty did not seem to affect concern about participating in the research. There were no significant differences between subjects reading the High and Low Reading Level consent forms on either concern about using the test products or willingness to volunteer for the study described in the consent form.

Conclusions

Overall, the results indicate that the reading level of the consent form affects subjects' comprehension of the information presented. In addition, subjects with lower levels of education have poorer understanding of the consent information even when it is simplified.

Concerns about using the test product were higher and willingness to participate was less if some time was allowed after the presentation of the consent form. Unfortunately, we cannot say for certain why this occurred. However, it is possible that subjects need some time to appreciate the information presented in the consent form.

Recommendations

The primary purpose of informed consent procedures is to assure that potential research subjects can knowingly decide whether or not to volunteer to participate in research. To do so, they must clearly understand the consent information presented.

Based upon our findings, we recommend that researchers and IRBs increase the comprehensibility of their consent documents. This can be accomplished in part by writing consent forms at a lower reading level. The reading level can be reduced by: (1) using shorter and simpler sentences, (2) improving organization of the information, (3) using more familiar terminology, and (4) defining technical terms in layman's language.

In most cases, consent forms should be *written* below the 7th or 8th grade reading level.' Even this may be too high if the subjects have lower educational backgrounds or verbal skills. There are other ways to further increase the likelihood that subjects will understand the information in the consent form. It has been found that combining oral and written presentation increases comprehension.[5] Others[6] found that comprehension is better if the subjects have more time to review the information presented in the consent form. The current research further suggests that such a delay also allows potential subjects an opportunity to further evaluate the implications of participating in the research. Overall, comprehension is better if the information is presented in a clear, brief, and direct manner.[7]

High Reading Level Consent Form

Preceding your agreement to participation in this experimental investigation, it is important that the following explanation of the investigation be read in its entirety and signed. The following specifies the purpose, methodology, benefits, potential risks, discomforts, and precautions of the research investigation in which we are soliciting your voluntary participation.

We are requesting that you participate in a study to determine the acceptability of a new mouthwash product. This mouthwash preparation is formulated with a new ingredient devised to counteract malodorous breath and provide for the refreshment of the oral cavity. In this investigation, the mouthwash preparations you will utilize are comprised of some or all of the following ingredients: cetylpyridinium chloride, domiphen bromide, sodium saccharin, benzoic acid in addition to other flavor and color additives. It should be noted that the actual products that you evaluate either may or may not contain the new experimental ingredient.

This new mouthwash formulation was extensively evaluated for safety in human and animal clinical investigations and its constituent ingredients were determined to be safe if the product was used in accordance with the instructions. Nonetheless, in a subgroup of individuals, this formulation was determined to cause inconsequential swelling of the tissue of the oral cavity, as well as irritation of the gums and mouth. In addition, certain reactive individuals developed a mild cutaneous rash in the oral cavity. Should an adequately substantial amount of this product be orally ingested, it can culminate in some stomach discomfort, nausea, dyspepsia or dizziness. There are no additional risks you are anticipated to incur as a result of your participation in this investigation.

Nonetheless, if in the course of the current investigation you experience an infirmity, discomfort, or sustain an impairment which is medically determined to be a function of your participation in the study, you will be provided with appropriate medical attention at no expense to yourself.

For the duration of this experiment, we request that you replace your customary mouthwash products with the experimental mouthwash products with which you are being supplied. In the course of using these products, they should be expectorated after cleansing the mouth. You should use the bottle labeled "USE FIRST" for the initial one week period, then you should use the bottle

marked "USE SECOND" for the subsequent one week period. In addition, we request that you maintain a record throughout the course of the investigation of how frequently you rinsed your mouth with each of the mouthwash products. Upon your return in two weeks, you will be requested to complete a questionnaire pertaining to your evaluation of the two formulations being tested.

These two test mouthwash products should not be utilized by individuals other than yourself; that is, they should not be used by other family members or acquaintances.

The information accumulated during the course of this investigation will in its entirety remain confidential. The records of the investigation will be made available only to the personnel working directly on this project, the research sponsor's auditors and, under certain circumstances, personnel of the Food and Drug Administration who are legally authorized to gain access to such records.

As a participant in this investigation you should not anticipate receiving any benefits from your participation with the exception of the use of the test products under investigation and the receipt of a coupon for a complimentary product.

Should you experience any difficulties resulting from the use of these products during the course of the investigation call (513) 721-346 collect. In the event that you should wish to ask questions pertaining to the investigation, you are instructed to call Dr. Dan Young collect at (513) 6275017 during working hours (8:00 a.m.-4:00 p.m. EST).

Your participation in this investigation is entirely voluntary and your refusal to participate in the study will culminate in no penalty or loss other than the forfeiture of the complimentary product and the test products. In addition, you have the option of discontinuing your participation in the investigation at your discretion with only the forfeiture of the complimentary product.

I have read and understand the preceding information concerning the investigation and, additionally I comprehend the nature and the purpose of the aforementioned procedures and such risks as are involved in their performance. I understand that I will derive no direct benefits from this investigation and that I may withdraw my consent and cease participating at any time I choose. I was provided the opportunity to pose questions regarding any facet of the information provided, and I understand that I may ask additional questions as they might occur.

I am over eighteen years of age and freely and without reservations give my informed consent to participate as a subject in the research investigation described above. I will be provided with a duplicate copy of this consent form.

Panelist's Signature Date

Low Reading Level Consent Form

Before you agree to take part in this study, you must read and sign the following.

This is a study to see how much people like a new mouthwash. This mouthwash is made with a new ingredient for fighting breath odors and freshening your mouth. The mouthwash you will use in this study is made with ingredients commonly used in mouthwash products. It also may or may not contain the new ingredient.

This new mouthwash was tested for safety in animal and human studies. It vas found to be safe if used as directed. However, in a few people it caused a little swelling of the mouth and soreness of the gums and mouth. Also, a few sensitive people developed a slight rash in their mouth. If you swallow too much of this mouthwash, it can cause some stomach upset or dizziness. There are no other risks expected. However, if it is medically determined that you became ill, injured, or felt discomfort because of this study, you will be given free medical care for the problem.

In this study, we want you to use the mouthwash we give you instead of your usual brands. You should not swallow the mouthwash. Spit it out after rinsing your mouth. Use the bottle marked "USE FIRST" for the first week. Then use the bottle marked "USE SECOND" for the second week. Also, write down how many times you use each mouthwash. When you return in two weeks, we will ask you to answer questions about the two mouthwash products.

Only you should use these two products. Other family members or friends should not use them.

All the information you give us during the study will be kept confidential. The records will be available only to the people working on or auditing the project. In some cases, Food and Drug Administration staff can also see the records.

The only benefits to you for taking part in this study are using the free mouthwash and receiving a coupon for a free product.

If you have any problems during the study due to these products call (513)721-3460 collect. Should you wish to ask questions call Dr. Dan Young collect at (513) 627-5017 during working hours (8:00 a.m.-4:00 p.m. EST).

Taking part in this study is completely up to you. You can refuse to be in the study. You may also withdraw from the study at any time. If you withdraw or refuse to be in the study you will not lose anything except the free products.

I read the above information and understand it. I was given a chance to ask questions. Also, I know that I may ask other questions as I think of them. I am over eighteen years of age and I freely agree to participate in this study A copy of this form will be given to me.

Your Signature Today's Date

Table la. Overall Comprehension By Consent Form Reading Level.

	Low Reading Level Consent Form		High Reading Level Consent Form
Base Size	328		333
Total Comprehension (Mean Correct)	14.0	**	13.4

'** Differences are significant at the 95% confidence level.

Table lb. Comprehension on Specific Items By Consent Form Reading Level.

	Low Reading Level Consent Form		High Reading Level Consent Form
Base Size:	328		333
	%		%
Effect if swallow mouthwash	72	**	58
Other possible side effects	73	**	63
What do if have questions	37	**	21
Results if do not participate	64	**	43
The purpose of study	77	**	44

**Differences are significant at the 95% confidence level.

Table 2. Ease of Comprehension By Reading Level Condition.

	Low Reading Level Consent Form	High Reading Level Consent Form
Base Size:	328	338
	%	%
**Ease of Understanding The Consent Form:		
Very Difficult	2	2
Somewhat Difficult	7	18
About Average	28	47
Somewhat Easy	25	12
Very Easy	39	21
	100	100

**An overall X^2 test indicates a significant difference at the 95% confidence level between the collective rating distributions of the subjects receiving the "Low Reading Level Consent Form" and those receiving the "High Reading Level Consent Form."

Table 3. Mean Comprehension By Education Level.

	Education Level of Panelists		
	High School Or Less	Attended College	Graduated College
Base Size:	251	166	249
Total Comprehension (Items Correct):	12.88	13.95**	14.31**

**Significantly higher at the 95% confidence level than the "High school or Less" group.

Table 4. Concern About Product Use and Willingness to Participate By Delay Condition.

	Delay in Testing	
	No Delay	**15 Min. Delay**
Base Size:	318	324
	%	96
**Concern About Using The Mouthwash:		
Very Concerned	24	35
Somewhat Concerned	20	21
Slightly Concerned	33	26
Not Concerned	23	18
	100%	100%
**Willingness to Participate in Study:		
Definitely Would Not	19	27
Probably Would Not	6	8
Might or Might Not	8	14
Probably Would	36	31
Definitely Would	31	20
	100%	100%

**An overall X^2 test indicates a significant difference at the 95% confidence level between rating distributions of subjects in the "No Delay" condition and those in the "15 Minute Delay" condition.

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