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Informed consent documents for BRCA1 and BRCA2 screening: how large is the readability gap?

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Abstract

The decision to undergo testing for the BRCA1 and BRCA2 mutations, which are associated with an increased risk of breast and ovarian cancer, can have long-term consequences on women's lives. Women who decide to undergo such testing are required to sign informed consent documents, which indicate that they understand the test and its risks and benefits. These documents are generally written for advanced-level readers. However, the reading abilities of many women are substantially lower than the level of the consent forms, resulting in a 'readability gap'. This disparity suggests that women may not fully understand the documents they are asked to sign. The 'readability gap' poses the serious issues about informed consent, raising questions about institutional review boards and the effectiveness of the documents that are currently in use.

Keywords: Informed consent; Readability; Breast cancer

1. Introduction

In many instances, informed consent amounts to nothing more than a signature on a piece of paper. In other cases, the process is – and should be – more complex. The level of complexity of the consent process should reflect, among other factors, the risks associated with a procedure, its newness and complexity, and the individual's role as research participant or patient. Depending on the situation, that information may be very complicated, and the consequences might also be life altering. For example, informing a woman's decision to undergo testing for BRCA1 and BRCA2 genetic mutations associated with increased risk of breast cancer (among other types of cancer) should reflect the gravity of the consequences [1,2]. In that decision, women should have both correct and complete information, and the information should be communicated in a comprehensible way. In signing the consent form, those women are asked to affirm that they – in the common wording of many consent forms – fully understand the terms and have had adequate opportunity to ask questions. This descriptive study assesses the readability of informed consent documents

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for BRCA1 and BRCA2 testing, and compares them with the literacy levels of women who might choose to be tested.

2. Background

Although informed consent is generally taken as one process, it is composed of both informational and consent elements [3,4]. If one of those elements is missing, then the participant's consent is not valid. The informational elements of informed consent are composed of the disclosure and the comprehension of information. The Common Rule joins these two elements by requiring that the disclosure be made in 'language understandable to the subject' [5], interpreted by many institutional review boards (IRBs) as meaning a reading level of no higher than the sixth grade [6].

The readability of documents, such as consent forms, is central to understanding them [7,8]. Consent forms used in research and clinical settings are often designed and written by physicians, researchers, and lawyers who have a clear understanding of the medical and legal issues. However, the end-users of the documents – the general public – are less likely to be familiar with those types of issues. Moreover, the education level of most of the public is lower than that of the physicians and lawyers who author many consent forms. As a result, the public is often given consent forms that are written at reading levels beyond its abilities to understand. Thus, Morrow's [9] observation of almost 20 years ago continues to be true: the regulations developed to ensure informed participation may be responsible for the current state of many consent forms, which are so complex that informed cooperation is very unlikely.

Literacy of the US adult population was the subject of a 1992 national study conducted with support from the National Center for Education Statistics [10]. The designers of the study evaluated three components of literacy: prose, document, and quantitative literacy. Prose literacy focused on texts such as editorials, news stories, poems, and fiction, as well as the ability to understand and use information from these sources. This literacy component is most relevant to assessing informed consent documents. Unfortunately, it appears that a significant portion of the American adult population lacks sufficient prose literacy to understand many informed consent documents. Researchers found that almost 92 million adults – 48 percent of the adult population – were either barely literate or had poor literacy skills.

Education levels also are indicative of reading abilities. Data from the March 1996 Current Population Survey [11], shown in Table 1, indicate that educational attainment decreases as age increases. Among women between 25 and 34 years of age, 43 percent have no more than a high school education, compared with more than 70 percent among 65- to 74-year-old women.

The process of informed consent has developed to ensure that participants in medical research have a sufficient understanding of procedures, risks, benefits, and their rights as research participants. Yet given the low levels of prose literacy among much of

Table 1
Women's educational attainment by age group[a]

Age group	Less than High School graduate (%)	High School graduate (%)	Some college (%)	College graduate (%)	Advanced degree (%)	Total (%)
18–24	22	29	41	8	0	100
25–34	12	31	30	22	5	100
35–44	11	34	29	18	8	100
45–54	14	36	27	15	9	100
55–64	23	41	21	10	6	100
65–74	30	41	19	7	3	100
75 +	41	33	15	8	3	100

[a] Source: March 1996 Current Population Survey.

the public, informed consent documents may not be effective in communicating that information. The disparity between educational materials and the public's reading level is so great that in a review of cancer education materials produced by the American Cancer Society and the National Cancer Institute, only 27 percent of the subjects were expected, based on their reading skill, to understand the full set of educational materials assessed [12].

3. Materials and methods

We conducted a search of the National Institutes of Health CRISP database to retrieve the abstracts of all currently funded research projects that might involve BRCA1 or BRCA2 testing. After reviewing the abstracts to identify likely prospects for offering BRCA1 or BRCA2 testing, we contacted principal investigators to obtain a copy of their informed consent documents and any relevant training and counseling materials that are used. Of the 23 studies identified, six were not relevant to our interest.

We obtained informed consent documents from eight research institutions. Of the eight research institutions providing information, five were conducting BRCA1/BRCA2 testing in the context of clinical research and three offered testing as a part of its clinical services. Some of the studies providing consent documents used multiple forms as a participant progressed through the study. In those cases, we included in our analysis the consent form that most fully addressed the actual procedures involved in BRCA1/BRCA2 testing and the associated risks and benefits. In addition to consent forms from research institutions, we received consent forms from two organizations that offer BRCA1 and BRCA2 testing on a commercial basis. The consent forms used in the research studies are required to provide specific pieces of information included in the Common Rule about the procedure, risks and benefits, and rights as a research participant. Testing for BRCA1 and BRCA2 mutations in other settings do not have the same legal obligations. (A recent review of the contents of consent forms for BRCA1 and BRCA2 testing has been conducted by Durfey et al. [13]).

To further our comparison of the information about BRCA1 and BRCA2 testing, we analyzed two publications made available by the National Cancer Institute: 'Genetic Testing for Breast Cancer: It's Your Choice' and 'Questions and Answers: The BRCA1 Breast Cancer Susceptibility Gene' [14,15]. Although these additional sources are not informed consent documents, they are relatively common sources of information that women might use to obtain basic information about BRCA1 and BRCA2 testing.

3.1. Evaluating readability

The readability of the documents was analyzed using the Flesch–Kincaid Grade Level and Flesch Reading Ease Score. These indicators are estimated by word processing programs, such as WordPerfect and Microsoft Word. (WordPerfect calculates other indexes, such as Sentence Complexity and Vocabulary Complexity Indexes, which are not discussed in this paper because they are not standard measures of readability.)

The Flesch–Kincaid Grade Level determines the appropriate reading level of a text, based on grade in school [16]. The scale is a function of the average length of sentences in a text and the average number of syllables per word, and is calculated by the following formula: $(0.39 \times \text{average sentence length}) + (11.8 \times \text{average number of syllables per word}) - 15.59$. WordPerfect calculates a maximum grade level of 16 (college graduate). 'Standard' writing normally equates to a seventh-to-eighth grade level. Below a sixth grade level indicates a simple document; above a tenth grade level may be too complex for the general public [17].

The Flesch Reading Ease Score [16] is also based on the average number of syllables per word and average number of words per sentence, and is calculated with the following formula: $206.835 - (0.846 \times \text{average number of syllables per word}) - (1.015 \times \text{average sentence length})$. The score has a range of 1–100, with a higher score indicating that more people can easily understand the document. According to Flesch – and still used today, 'standard' writing has a score between 60 and 70 [17]. Flesch Reading Ease Scores of 0–30 characterize scientific journals and scores of 30–50 characterize other academic journals. At the opposite extreme, a reading ease score of 80–90 characterizes pulp

fiction, and a score of 90–100 is typical of comics [16].

4. Results

The results of the analysis of the documents are summarized in Table 2. On average, the consent forms obtained from research institutions contained 1793 words, and had an average sentence length of 20.57 words. The mean score on the Flesch–Kincaid Grade Level was 13.00 (a year beyond high school graduation), with values ranging from 11.54 to 14.16. The Flesch Reading Ease Index for the research documents was 45, placing it into the same category as many academic journals [16].

The readability indicators for two informed consent documents obtained from commercial organizations that conduct BRCA1 and BRCA2 testing were somewhat more favorable. These informed consent documents were longer, with an average of 1853 words and 19.68 words per sentence. The mean Flesch–Kincaid Grade Level was 11.78, which is 1.2 grade levels lower than the research institution forms. The mean Flesch Reading Ease Index was 52.

Although the sample sizes are too small to detect statistically significant differences, most of the indicators for the commercial organizations' consent forms suggest that they are more likely to be understood by a larger portion of the adult population. Overall, none of the consent documents was written within the standard writing range of the Flesch–Kincaid Grade Level or Flesch Readability Ease Index. Of the documents used in research institutions, only one was written with a Flesch–Kincaid Grade Level of less than 12 (high school graduate level). The grade levels of the remaining consent forms in that group ranged from 12.5 (i.e. beginning college level) to 14.2 (i.e. more than 2 years of college). The two documents from commercial sources had Kincaid–Flesch Grade Level scores of 10.4 (high school sophomore) – and approaching the standard writing range – and 13.2. Similarly, the Flesch Reading Ease Index values were higher for the commercial sources than the research sources, although one of the consent forms in the commercial group and one in the research group approached the standard writing range.

The two informational documents published for the National Cancer Institute were structured in a question-and-answer format and covered much of the same material included in informed consent docu-

Table 2
Readability data for consent forms and informational documents

Parameter	Research institutions ($n = 8$)		Commercial organizations ($n = 2$)		NCI publications[a] ($n = 2$)	
	Mean (S.D.)	Range	Mean (S.D.)	Range	Mean (S.D.)	Range
Average number of words per document	1793 (782)	835–2932	1853 (135.5)	1717–1988	2910 (53.5)	2857–2964
Average number of words per sentence	20.57 (1.90)	17.76–25.75	19.68 (3.18)	16.5–22.85	22.63 (1.59)	21.04–24.21
No. complex words (three or more syllables)	350 (139)	149–558	325 (27.5)	298–353	651 (29)	622–680
Flesch–Kincaid Grade Level	13.00 (0.78)	11.54–14.16	11.78 (1.42)	10.36–13.2	14.82 (0.64)	14.18–15.45
Flesch Reading Ease	45 (7.07)	36.1–56.9	52 (4.1)	47.8–55.9	39.2 (1.1)	38.1–40.3
Average number of syllables per word	1.73 (0.07)	1.61–1.81	1.65 (0.01)	1.64–1.65	1.81 (0)	1.81
Average number of sentences	86.6 (35.5)	40–136	95.5 (8.5)	104–191	129.5 (11.5)	118–141

[a] NCI publications included in the analysis are entitled: 'Questions and Answers: The BRCA1 Breast Cancer Susceptibility Gene' and 'Genetic Testing for Breast Cancer: It's Your Choice'.

Table 3
Content summary of documents analyzed

Informed consent documents (required by Common Rule)	Questions and Answers: The BRCA1 Breast Cancer Susceptibility Gene[a]	Genetic Testing for Breast Cancer: It's Your Choice[a]
Involves research	What is BRCA1 gene	How BRCA1/2 affect risk of breast and ovarian cancer
Purpose of study	How it affects breast cancer	Frequency of alterations in ethnic populations
Duration of participation	Its importance in causing BC	What positive test result means
Description of procedures	Role in non-inherited BC	What negative test result means
Identifying experimental procedures	Do all women with mutation develop BC?	Options for people with positive test
Forseeable risks or discomforts	Passing gene to children	Benefits of screening
Benefits to subject and other	Availability of test	What happens if results placed in medical records
Alternative procedures	BRCA and age of onset of BC	Risks of employment and insurance discrimination
Confidentiality of records	Reducing risks	Cost and timing of testing
Compensation/treatment if injured	How BRCA1 identified	Other risk factors for breast and ovarian cancer
Contact about research and subject's rights	How BRCA1 increases susceptibility	
Contact in event of research-related injury	BRCA1 links to other cancers	
Participation is voluntary	Moral, legal, social, and ethical implications	
Refusal to participate will not result in penalty or loss of benefits		
May discontinue at any time		

[a] 'Questions and Answers: The BRCA1 Breast Cancer Susceptibility Gene' and 'Genetic Testing for Breast Cancer Risk: It's Your Choice' are prepared for the National Cancer Institute.

ments. Table 3 provides a comparison of the content of the documents analyzed in this paper. The average length of the two NCI documents was 2910 words, with an average sentence length of 22.6 words. The mean Flesch–Kincaid Grade Level was 14.82, and the mean Flesch Reading Ease Index was 39.

Overall, informed consent documents and other materials relating to BRCA1 and BRCA2 testing are written at a high reading level. Many of the concepts associated with genetic testing for breast cancer are complex. Yet complicated ideas can often be explained in nontechnical language and without the use of long and complex sentences. Some of the common words in explaining BRCA1 and BRCA2 testing, such as 'hereditary', 'likelihood', and 'alterations' are themselves multisyllabic, and thus, contribute to the high readability index values. Although these words – and the concepts that they communicate – may be understood by the scientific and legal communities that conduct the research and write the consent forms, many of the participants who are involved in the research and are likely to have lower education levels and may have difficulty understanding a phrase like 'inherited genetic alterations'.

5. Text comparisons

Many of the components of an informed consent document used in research are required by the Common Rule and follow guidelines developed by organizations such as the American Society of Clinical Oncology [18]. As a result, many informed consent documents contain very similar information but articulate those points in different ways, which are reflected in different levels of readability. To illustrate how this range might affect comprehensibility, we compare specific passages from documents with higher and lower readability.

5.1. Background/purpose

Many informed consent documents provide a background or purpose statement about the procedure being conducted. In the case of BRCA1 and BRCA2 testing, these statements often mention that some breast cancer is inherited. Most informed consent forms do not include a percentage of how often breast cancer is attributable to mutations to these two genes, although the scientific community

generally accepts between 5 and 10 percent. Consider the two excerpts from informed consent documents that are currently in use:

> *Recently a great deal of knowledge has been accumulated regarding genes that may be responsible for genetic predisposition to develop breast cancer. Although only about 5% of newly diagnosed breast cancer cases are known to be associated with hereditary predisposition, occurrence of cancer at a younger age is one of the hallmarks of hereditary disease.*

> *Most breast cancer is not inherited; however, about 5 to 10% of breast cancer is thought to be due to a change (called a 'mutation') in a gene inherited from a parent. One of the genes that can cause hereditary breast cancer is called BRCA1. Another is called BRCA2.*

Both examples communicate the point that a relatively small percentage of breast cancer is hereditary. The first example, which is taken from a consent form with a Flesch–Kincaid Grade Level of 13.4, uses longer and complicated words and phrases. The writer uses a grammatical structure that emphasizes the age-related information rather than the percentage of cases due to mutations. Both points are relevant to informing participants, but linked together as they are places a relative, and not necessarily correct, priority on their importance.

The second example is drawn from a consent form with a Flesch–Kincaid Grade Level of 10.4. It is easy to follow and uses words that are part of everyday language. The two independent clauses in the first sentence make the information of equal importance and communicate information that is linked: most breast cancer is not inherited from a parent. The text also names the two types of mutations for which the participant will be tested, and provides a brief clarification of 'mutation'.

5.2. Risk

The BRCA1 and BRCA2 tests are based on the analysis of blood samples. In mentioning the risks of such tests, informed consent documents should include the risks of having blood drawn. Consider the following passages from the two documents previously discussed:

> *Blood-drawing involves some minimal risk, including local bruising and transient pain. Occasionally, there are technical problems with the laboratory analysis, making it desirable for us to obtain a second set of blood specimens from you.*

> *The risks associated with drawing blood are minimal. There may be discomfort and temporary bruising at the site. Infections can occur rarely.*

In the first example, 'local' and 'transient' may confuse readers. Moreover, the term 'blood-drawing' is used less frequently than 'drawing blood', and may be a more difficult concept to understand. The text goes beyond the discussion of the physical risks associated with drawing blood, and includes risks of testing errors. The adjectives 'technical' and 'laboratory' contribute little to the text, while the phrase 'a second set of blood specimens' could be simplified to 'more blood', which uses fewer words and is conceptually more straight forward.

The second example includes a more complete list of the physical risks, and does not include information that does not pertain to the discussion of risks. For example, it mentions the possibility of infection as a risk. It uses shorter sentences and familiar terminology. 'Discomfort' may better describe the sensation of being stuck with a needle than 'transient pain', and 'temporary bruising' emphasizes a short-term consequence.

Insurance discrimination

Perhaps one of the most critical points in deciding to obtain BRCA1 or BRCA2 testing is the possibility of insurance discrimination [19–21]. Consider how the following examples communicate this information:

> *A positive result may also make it more difficult to obtain or keep health or life insurance. The results of this test should be kept confidential and will not be put in your regular medical file or*

released to anyone without your written permission.

You should realize that once you have been personally informed of a test result, regardless of whether it is entered into your medical records, that you may be required to reveal the result as a part of an application for health, life, disability or other insurance coverage. Some insurance companies may consider an inherited change in a cancer susceptibility gene to be a 'pre-existing condition', and on that basis may decide not to cover you, to limit your coverage, or to charge you a higher premium for coverage.

The first example is taken from a research-based informed consent document with a Flesch–Kincaid Grade Level index of 13.0. The statement uses familiar words and does not introduce any complex ideas. It is located as the second of three paragraphs that discuss the risks of BRCA1 and BRCA2 testing. Although the statement is very concise, it does not offer any explanation about why problems with insurance might occur.

The second example is taken from the research-based informed consent with a Flesch–Kincaid Grade Level of 11.5, which is the lowest among the research documents. (However, the Grade Level for the cited passage is higher – 16.0 – illustrating the range of readability within all the consent forms.) The sentences are long and difficult to follow. The explanation of a 'pre-existing condition' may be understood by some people who would read the document, but others may be unfamiliar with the expression. (A similar discussion of 'pre-existing condition' is found in several other informed consent documents.) Within the document, the information is placed as the response to a question: What are the risks of loss of confidentiality and discrimination? This structure gives the reader a clear idea of the topic to be discussed.

The issue of insurance discrimination is addressed in many of the other popular sources of information on BRCA1 and BRCA2 testing. Although the NCI documents are intended to be informational rather than consent to be tested, they communicate much of the same information found in informed consent statements. The final example is taken from 'Genetic Testing for Breast Cancer Risk: It's Your Choice', prepared for the National Cancer Institute.

If a genetic alteration is found that increases the risk for developing cancer, it would affect the status of a person's health, life, and disability insurance by causing that individual to be unable to qualify for new insurance, increasing premium rates, or decreasing the amount of coverage. Some insurers view the affected individual as a potential cancer patient whose medical treatment would be costly to the insurance company [16.0].

The fact sheet prepared for the National Cancer Institute also follows a question-and-answer format. Written with a Flesch–Kincaid Grade Level of 14.2, this information is written at a reading level that exceeds much of the public. The first sentence is long and the passage has many multisyllabic words. The quoted text is included as part of the response to: What are the risk for insurance and employment discrimination? The fact sheet explains the reason for insurance discrimination by stating that persons with a positive result may be viewed as 'potential cancer patient', which is a more precise explanation than 'pre-existing condition'. The response to the question then mentions that the 'degree of discrimination can vary from state to state'. This passage provides a different type of information than the informed consent documents, and illustrates how different sources communicate the similar information.

6. Discussion

The process of informed consent exists to ensure that participants have a clear understanding of procedures, risks and benefits, and their rights as research subjects. In the case of testing for the BRCA1 and BRCA2 mutations, the informed consent should be conducted in tandem with genetic counseling. Because there is generally neither an audio nor video recording of these counseling sessions to verify that women undergoing BRCA1 and BRCA2 testing are sufficiently informed, and because not all counselors adhere to the same guidelines [22], it is critical that the written informed consent documents be complete and readable.

In conducting this analysis, we have reviewed as many consent documents from research and commercial organizations as we could obtain. The potential number of forms is not very large and the forms we obtained may be different from those we did not obtain. Institutions where the research is conducted may also place constraints, such as page limits, on informed consent documents. In attempting to be brief, the writers of these forms may rely on fewer sentences that are longer and more difficult to understand.

There are limitations of using measures such as the Flesch–Kincaid Grade Level and the Flesch Reading Ease Index as indicators of readability. Being based on relatively basic aspects of a text – sentence and word length – these indicators do not take into consideration the flow of ideas or the writer's style. Attempting to write a text using shorter words and sentences so that it has a lower grade level may, in fact, require that readers infer more information, contributing to lower comprehension [23–25]. Nevertheless, these standard indicators provide a starting point for evaluating the readability of texts. They provide an objective assessment of materials without requiring the use of human readers [26]. It is in this regard that we use these indexes to assess the readability of the materials obtained from our search. These indicators tell us that of the eight documents obtained from research settings, seven are written at a reading level beyond that of a high school graduate.

The age distribution of breast cancer cases due to BRCA1 and BRCA2 is younger than that of breast cancer cases in the general population, where age-specific breast cancer rates increase rapidly as women grow older [27]. Women with BRCA1 or BRCA2 mutations are more likely to develop cancer at a younger age than the general population of women. Struewing et al. [28] report that the difference in the risk of developing breast cancer among carriers of the mutations and non-carriers is statistically significant by age 35. As a result, it is likely that more younger women will undergo testing than older women. Although younger women, on average, have a higher educational level than older women, a sizable percentage of women under age 35 (approximately 46 percent) have no more than a high school education.

The relatively high levels of literacy needed to comprehend the informed consent documents coupled with the low educational attainment and literacy levels among the large portion of the adult population of the United States suggest that a serious disparity exists. Many women may not have a sufficient understanding of the content of the informed consent documents that they are signing. The Common Rule requirement that 'language understandable to the subject' be used in the disclosure of information may be violated on a regular basis.

Institutional review boards are charged with the task of ensuring that informed consent is obtained and appropriately documented. Although most IRBs have a diverse composition, they may overlook the education and literacy levels of the populations they are charged to protect. To ensure that the rights of participants are protected, IRBs need to be more aware of both the reading levels of research participants and the readability of consent documents.

Respecting the right to make an informed decision about participating in a clinical study should involve more than signing an informed consent document. The results of this analysis indicate that the consent forms that are used for BRCA1 and BRCA2 testing are written at a reading level that exceeds the ability of the average prospective participant. Although many women may be willing to sign the form anyway, the informed consent process becomes more effective if it builds on women's own knowledge base, rather than someone else's, and enables them to obtain the information they want to know [29]. Such an approach would engage women in an active consent process, and empower them to be more responsible decision makers [30], which is the ultimate goal of the process.

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