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Barriers of Low Health Literacy in Achieving Informed Consent

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The Barriers of Low Health Literacy on Achieving Informed Consent



Honors Thesis

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April 2020

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Abstract

For many members of lower socioeconomic classes in the United States, a routine trip to a doctor's office can be fueled by complete fear and confusion. This is due to a variety of factors, but a major contributor is the low level of health literacy that is often associated with members of lower socioeconomic levels. According to the Center for Disease Control and Prevention, health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." Informed consent documents are used frequently when a patient needs a medical procedure or operation. These documents are signed by the patient affirming that they understand and accept the risks and methods for a procedure. However, if the patient signing these consent documents does not understand the information, there can be significant legal problems and ethical dilemmas that will arise. This project therefore examines informed consent documents given to patients and analyzes the readability and usability of these documents. After examining these documents, recommendations for improving their user friendliness were made to increase comprehension.

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According to the U.S. Dept. of Health and Human Services, “Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” An insufficient level of health literacy greatly affects the ability for an individual to understand health information and therefore maintain a healthy lifestyle. The average U.S. adult reads at an 8th grade reading level (NAAL). If medical documents are written at a reading level higher than 8 this increases the probability that patients will be confused when attempting to learn more about health treatments or outcomes. Ultimately, it falls on healthcare providers and administrators to make these documents easier to understand. One of the biggest examples of this issue lies in the use of informed consent forms. Informed consent documents are frequently used for patients to sign once they arrive at the physician’s office or prior to a surgery or other type of procedure. These documents are created to outline treatments and risks but also for documenting consent (Murray). In many instances, a healthcare provider will summarize the treatment to a patient and then give him or her an informed consent document to read and sign for a written record (Medline Plus). Understanding these documents can become more difficult for individuals with lower health literacy. This subsequently blurs the line on whether “informed” consent has been achieved. Therefore, informed consent documents must be examined and crafted to be accessible for all individuals regardless of their health literacy levels.

In 2003, the first National Assessment of Adult Literacy (NAAL) was performed on approximately 19,000 adults in the U.S. This survey contains the most recent and comprehensive health literacy data. This study was crafted to identify the varying health literacy levels across the country. This helped to show how this issue is stratified across different socioeconomic classes. The results found that approximately one-third of the U.S. population has a health literacy level of basic or below basic. Health literacy at this level means that one-third of the population “would have difficulty with common health tasks, such as following directions on a prescription drug label or adhering to a childhood immunization schedule using a standard chart” (U.S. Department of Health and Human Services).

While low health literacy is an issue that affects a wide range of people, the results show a tendency for minorities and individuals of lower socioeconomic classes to have lower health literacy. Individuals more likely to have low health literacy were those without healthcare or were relying solely on Medicare and Medicaid. Many of these people without health insurance primarily belong to lower socioeconomic classes (U.S. Department of Health and Human Services). Through further research of this data it was concluded that “racial and ethnic minorities have lower health literacy compared to whites” and “Health literacy scores increased by a quarter of a percent for every additional \$1000 in median household income” (Rikard).

There have subsequently been many research studies performed to analyze, critique, and reform medical documents. For example, a study was performed in 2017 that examined approximately 100 informed consent documents used for clinical research studies. This study found that the average reading level of these documents was four

grade levels higher than the average U.S. adult, proving a barrier for effective patient care (Simonds). A different study examined online Medicaid forms and found that reading levels for these documents ranged from 11th to 18th grade (Wilson, 2009). There also have now been research and training programs for physicians and other healthcare workers to improve the consent process (Heerman). This research study is focused on examining the reading level and layout of various types of informed consent documents and making recommendations to improve their comprehension for lower health literate patients.

Methods

This project aims to determine if there is a need for informed consent documents to be written and designed more effectively for U.S. adult readers. For this study, consent documents were collected from a variety of healthcare facilities and were analyzed using three tests.

Collection of Informed Consent Documents.

Beginning in February of 2019, informed consent documents were collected from various medical facilities and hospitals throughout a region in the Midwest. These documents ranged from general consent contracts to consent documents for various medical procedures. A convenience sampling model was used when acquiring these materials. These documents were collected in a variety of ways: through personal connections to healthcare workers, volunteering at healthcare facilities, and through personal visits to these locations. When acquiring these documents, special attention was given to “cast a large net” to ensure diversity of socioeconomic background of the patients who commonly visit these locations. To ensure anonymity of each healthcare location, any identifying information of these documents was removed upon acquisition and each document was given a number. From these methods a total of 13 documents were collected ranging from areas with low socioeconomic status to more affluent sectors. See Table 1 for a more detailed description of each document and its facility’s respective demographic data according to U.S. census data.

Table 1: Collected Document Descriptions

	Document Type	Facility	Population	Median Income
1	Surgical Procedure	Large pediatric hospital	120,486	32,481
2	Blood Transfusion	Large pediatric hospital	120,486	32,481
3	Anesthesia	Large pediatric hospital	120,486	32,481
4	Informational	Private Practice	54,818	71,540
5	Consent for Shots	Private Practice	54,818	71,540
6	General to Treat	Free Clinic	13,553	22,599
7	Stress Test	Small hospital	58,650	99,342
8	Invasive procedure	Small hospital	58,650	99,342
9	Surgical Procedure	Large hospital	85,670	34,350
10	General Consent to Treat	Large hospital	85,670	34,350
11	Botox Consent	Large hospital	150,543	56,516
12	Anesthesia	Medium hospital	120,486	47,522
13	Cardiac Implanted Device	Large hospital	150,543	56,516

*data derived from 2018 U.S. Census Data

Evaluation of Informed Consent Documents.

Guidelines for the evaluation of these informed consent documents follow the criteria proposed by- Wilson et al. in their review of Medicaid application enrollment forms. The documents were analyzed in three separate ways: by readability, layout, and design. These metrics were used to test each document for its potential comprehension level. The first two tests, the Flesch-Kincaid and SMOG tests, determine a document's reading level. The User Friendliness Tool examines the layout and design of each document and how this can cause comprehension issues for lower literacy individuals. All three tests have been used in numerous studies and have been shown to be reliable measures.

To examine reading level, a Flesch-Kincaid test was first performed on each document using Microsoft Word. A SMOG test was subsequently performed to confirm the respective reading level of these documents. Both tests use an accepted algorithm. All documents used were confined to one page but ranged in different formatting features. These formatting choices did not significantly impede this part of document analysis.

In addition to the readability tests, a set of criteria was adapted from the User Friendliness Tool (UFT). This UFT was created by a team of researchers as a standardized criterion for analyzing documents (Arnold). This tool specifies five criteria

on various factors that can be assessed to test the efficacy of a document. This current project focused on the UFT's layout and design criteria and examined the use of white space, bulleted or numbered lists, and font and paragraph size. These metrics are more subjective than the readability tests.

Each document was assigned a number between one and four corresponding to the work a writer or designer would need to do in order to improve the document for a U.S. reader. For example, if a document used an ample amount of white space then the document received a four, meaning there is no work would be needed. If a different document was found to have little to no white space, then it received a one, indicating significant work would be needed to increase the document's white space. This process was conducted for each of these three categories for each document. Table 2 shows the criteria for each element analyzed and the corresponding scores that were given.

Table 2: UFT Criteria

Number	Meaning
1	"a lot of work needed"
2	"some work needed"
3	"little work needed"
4	"no work needed"

Findings

The readability of these collected documents ranged widely from around 8th grade to 17th grade. Results showed that the average reading level was found to be 13. Only one document resulted in a reading level of 8th grade or below using both tests while 10 of the 13 were written at 11th grade or higher. All results can be found in Table 3.

Table 3: Readability Results

	Type	Facility	F-K	SMOG	Average
1	Surgical Procedure	Large pediatric hospital	9.5	12	10.75
2	Blood Transfusion	Large pediatric hospital	10.3	12	11.15
3	Anesthesia	Large pediatric hospital	13.6	14	13.8

4	Informational	Private Practice	9.1	13	11.05
5	Consent for Shots	Private Practice	10.8	12	11.4
6	General to Treat	Free Clinic	18.4	17	17.7
7	Stress Test	Small hospital	9	10	9.5
8	Invasive procedure	Small hospital	11.6	12	11.8
9	Surgical Procedure	Large hospital	15.4	16	15.7
10	General Consent to Treat	Large hospital	16.2	18	17.1
11	Botox Consent	Large hospital	11.4	12	11.7
12	Anesthesia	Medium hospital	12.6	13	12.8
13	Cardiac implanted device	Large hospital	6.4	8	7.2

The UFT used for this study analyzed the layout of these documents and the results can be found in Tables 4 and 5. Recent literature recommends that the use of any font below 11 should be avoided for the reading of printed materials. Of the 13 documents collected only four were found to have a font of 11 or higher with document 10 having a font of 10.5. One of the documents had a font size of only 8. Smaller sized fonts may result in much more difficulty in reading the documents especially in individuals with worse eyesight.

Table 4: Font Size

	Type	Font Size
1	Surgical Procedure	9
2	Blood Transfusion	10
3	Anesthesia	9
4	Informational	11
5	Consent for Shots	11.5
6	General to Treat	11
7	Stress Test	14
8	Invasive procedure	9
9	Surgical Procedure	9.5
10	General Consent to Treat	10.5
11	Botox Consent	7.5
12	Anesthesia	9
13	Cardiac implanted device	8

Another important aspect of printed materials that was examined with the UTF is the use of white space, bulleted lists and the size of paragraphs. The criteria are outlined in Table 2 and the findings can be found in Table 5 below. Through this analysis only three “4’s” were given to these documents. This shows that in only two documents was there enough white space used and only one document used numbered or bulleted lists effectively. This analysis also shows that the use of bulleted and numbered lists is used least frequently, and six documents received “1’s” during the examination.

Table 5: Documents and the Amount of Work Needed

	1 (a lot of work needed)	2 (some work needed)	3 (a little work needed)	4 (no work needed)
White Space	3 (23%)	4 (31%)	4 (31%)	2 (15%)
Paragraphs < 4 lines	3 (23%)	3 (23%)	7 (54%)	0 (0%)
Bullet Lists	6 (46%)	3 (23%)	3 (23%)	1 (7.7%)

Discussion

The most important result from this experiment was that a majority of the consent documents were written at a reading level much higher than they should be. More than half of the documents were written at a reading level above what a senior in high school can read. This creates a major problem with the average U.S. adult reading level of 8th grade. Also, the UTF results show that slight changes in layout and formatting of these documents can improve comprehension greatly.

Below in Table 6 there are examples of simple revisions that could be made to lower the reading level of the documents examined in this study. These revisions have not been reviewed by a legal department or IRB but serve as an example of the ease of improving the language of these documents.

Table 6: Document Revisions

Original Document	Suggested revisions
<p>Document 6: "I further authorize the medical personnel to take cultures and use precautions deemed necessary for infectious cases. If necessary, I also give my permission for the allied health professionals to review my medical record for the purpose of evaluating my overall health needs."</p> <p>Flesch-Kincaid: 13.9</p>	<p>"I allow health care workers to take samples and use safety measures for infectious cases. I also allow allied health care workers to look at my health record for treatment."</p> <p>Flesch-Kincaid: 7.9</p>
<p>Document 11: "Botulinum toxin treatment of frown lines can cause minor temporary droop of one eyelid in 2% of injections. This usually lasts 2-3 weeks. Occasional numbness of the forehead lasting 2-3 weeks, bruising and transient headache have occurred. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual."</p> <p>Flesch-Kincaid: 10.6</p>	<p>"This treatment of frown lines can cause slight short-term drooping of one eyelid in 2% of cases. This mostly lasts 2-3 weeks. Numbness can also occur for 2-3 weeks. You may also have brief headaches and bruising. In a few patients this shot does not work as well as expected."</p> <p>Flesch-Kincaid: 4.8</p>
<p>Document 2: "My questions about the procedure(s) have been answered to my satisfaction. I also understand that if I have more questions at any time before the procedure(s), I can call my doctor's office at ___. I have read and understand this consent form and all of the blanks were filled in before I signed it. By signing, I confirm to the best of my knowledge that the law allows me to consent to the procedure(s) for this patient."</p> <p>Flesch-Kincaid: 8.2</p>	<p>"My questions about the surgery plan have been answered as needed. I know that if I have more questions at any time, I can call my doctor at ___. I have read and understand this form and the blanks were filled in before I signed it. By signing, I agree to this procedure."</p> <p>Flesch-Kincaid: 5.0</p>

Due to the established association between lower socioeconomic level and low health literacy, specific attention should be given to reform documents given to these populations. In this study one unexpected result was the fact that the documents collected in areas with lower median incomes had documents written at a higher reading level than

documents written for more affluent areas. For example, the document collected from the free clinic had an average reading level of 17.7 which is much higher than recommended. This correlation is troublesome. Healthcare facilities that serve lower socioeconomic classes should be focused on tailoring these materials to their patients. Due to the small sample size, no strong conclusions can be made about this correlation in this study, but this creates the opportunity for an additional research with larger sample sizes collected from different areas.

The opportunities for improving this issue seem endless. Implementation of patient surveys for determining health literacy levels, more widespread use of the physician teach-back method, and many other solutions are currently being researched and used in healthcare facilities (Weiss). Also, researchers are beginning to examine which aspects of reformed health materials are most important for improving comprehension (Tamariz).

There are a few limitations for this study. First the documents were collected through a convenience sample, and this may have influenced the type of documents that were acquired. Also, the documents ranged from general consent to treat to documents for more complicated procedures like an implanted cardiac device and were not standardized. Finally, the UFT is a subjective test for analyzing these forms; nevertheless, it can still serve as an indicator for potentially improving medical documents.

In conclusion, this study found that most of the documents analyzed were written at a much higher level than they need to be for all people to understand them. Also, the font size and use of white space in these documents needs to be improved. The use of simpler language and shorter sentences would greatly improve the readability of these documents and would not sacrifice legal credibility (Root 1999). Although these documents all could be improved for comprehension, they all contain some positive elements as well (bullet point lists, fill-in the blanks, etc.) Further research should be conducted to examine how improvements to informed consent documents may increase comprehension, but also to examine how more complicated consent documents may impact patient outcomes.

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