

A Proposal to Rethink the Way Patients Consent

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1. Summary

Our group's primary focus is to address social injustice, specifically related to readability in medical consent forms at Denver Health. The issue researched proved that the medical Denver Health consent form readability level is too high for patients to comprehend. Through this project, we seek to lower the readability of these consent forms to a sixth-grade reading level for the average patient to understand. To address this problem, we will use virtual surveys to test the comprehension of the patients. Every two days the readability level of the consent forms will be adjusted and new surveys will be made to compliment the updated consent forms. On December 18th, our group's work will conclude. In our presentation, we aim to spread ideas about how we can change the level of reliability of the consent forms and make a change. The annotated bib is located in the appendix as well as other documents used in this proposal.

2. Introduction

As a group of students attending Denver Public Schools, our primary purpose is to address a social injustice, such as readability in medical consent forms at Denver Health. As a group, we learned most patients that receive medical support cannot read or comprehend what the consent forms are addressing because the readability levels of these consent forms are too advanced. Reflect on an experience when you're at the doctor's or in a hospital where you couldn't read or comprehend what the forms were describing. This is an issue that has grown to be more common, which must be brought to light and fixed. As a group, bringing attention to this issue interests us because readability impacts legal medical situations. If a patient signs the consent form and does not understand what the information means, then they don't know what they gave permission for. This is an example of unjust treatment to the patient. Since our mission of this proposal is to serve justice to patients, it is important that all Denver Health consent forms are at a sixth-grade reading level.

3. Needs/Problems

To improve the common grounds of readability, a few concerns were detected to recover this on-going issue regarding all patients receiving medical help. Studies proved the United States' average reading level is at 6th-grade. Assisting the national need in medical-based environments, education for patients is not approached fairly to be taught to comprehend medical consent forms. Access to education above sixth-grade is not always a reality, therefore, the vocabulary is regularly not understood, simply because they're not educated on those terms. For expanded health-care, proposing an efficient purpose for all organizations is required to successfully support patients and the comprehension of consent forms.

First of all, the United States' current national literary average is the 8th-grade level. Individuals are expected to provide their signature on packets for consent but a lot of patients skip forward on the terms and conditions and/or additional information that could possibly be extremely concerning. Considering medical help is constantly in need, 24 hours a day for seven days, this issue must be addressed very quickly. Furthermore, every day a minor is entering the world of adulthood, meaning that they're responsible for receiving and providing their own medical aid. This issue has been addressed by Anvita (2010) enhancing the fact that the text itself in medical consent forms is too complicated, it is the ability to understand the information given. According to Avinta's experience, she wrote about, it is demonstrating the complexity of interpretation, causing possible risks and benefits that a patient signs away to. The possibilities are endless for health-care and it must be considered as a priority for all U.S. residents to be well

informed of their future in medicine and why they're in the circumstance they're in but fully understanding.

Additionally, as the lack of comprehension continues, the target audience, the patients, are impacted, usually without a second thought because it's the easier option to trust providers, such as doctors or nurses because they know what they're doing. Receiving a higher education influences stronger vocabulary usage and has a higher chance of understanding the information given. A study that required a variety of readings and literacy levels were given out to test the national average: The findings revealed that the readability scores ranged from a low of tenth grade to a high of fourteenth grade and that all the material exceeded the accepted standard reading level of eighth grade. These results suggest that the items included in this study would not satisfy the medical information needs of people with poor reading skills" (Baker et al., 1997). Relying on the audience intended, the information may clearly be interpreted, but the majority of the country's population does not have the opportunity to pursue more advanced education. Instead of taking the time to read the very time-consuming consent packet, patients will sign, and that is the issue we must address and fix immediately. Imagining a patient in a severe situation and they are given medication, with official consent, is also very impactful on the surrounding population, mainly the patient's family. It is significant to the family because they may not know the cause of the severe issue, what the medication does, why he/she is taking it, and what possibilities can come out of the reaction from the medication. To add on, the ability to understand significant information requiring a signature to confirm consent is a right that each resident should possess. Medical professionals conducted an experiment to determine the recent study for readability levels in the United States. Because the average US adult reads at an 8th grade level, the National Institutes of Health (NIH) and the American Medical Association

(AMA) recommend the readability of patient materials be \leq 6th grade reading level. Patient materials have been repeatedly shown to be too complex” (Eltorai, et al., 2015). This is a moral responsibility to consider the educational reality of clients and the process of relating to a position that is understood, especially in the context of medical help. This article is a direct example of medical professionals strongly advising the readability level to lower to the literacy level to 6th-grade. Therefore, with professional experiments and professional suggestions, addressing the current reading level is the best option to improve society’s comprehension.

In order to fix the problem, allowing excessive research is measurable, however, it must be used to influence the effectiveness of adapting readability for the betterment of the people in the country of the United States. According to Brennan (1996), medical forms are reported at a college-junior level: “Results of this study reveal that 70% of the language comprising informed consent forms is written at a level for juniors in college to understand... implies that roughly 37% of the United States adult population could read and comprehend them.” Meaning, a portion of the population can read the consent form but more than half is not aware of the consent form information. Though the portion of the population that can understand the form, easily simplifying the text will support patients that deserve the right of comprehension for their own life necessity.

Collectively, medical professionals must take accountability for their clients not understanding what consent they’re required to provide. The need is to adjust the readability in consent forms at Denver Health and more health-based environments. Being adaptable to society’s constant change may be difficult but addressing the inability of patients to understand the consent being given is a priority.

4. Goals/Objectives

- Address medical professionals to improvise with the knowledge their patients need to know during their session
- The goal is for patients to address the unknown information provided to implement for our team to consider over
- Draft a consent form most realistic to the final decision

5. Time Table

	Description of Work	Start and End Dates	Responsible For
Phase One	Read and analyze the consent forms from Denver Health	Nov. 30th - Dec. 2nd	Project Manager and Team Members
Phase Two	Write an outline rough draft of the project/edit and revise	Dec. 3rd - Dec. 7th	Project Manager and Team Members
Phase Three	Create the final PowerPoint presentation.	Dec. 8th - Dec. 18th	Project Manager and Team Members

6. Key Personnel

Client	Denver Health Administrators
Sponsor	Mr. Tricarico or Nurse Lucy Roberts
Ms. Weathers	Mentor
Project manager	Skye James
Team	Ariana Rivera and Destiny Jojola

7. Evaluation

- Experiments
- Front-desk/receptionist check-up
- In-school/minor testing
- Virtual Surveys, testing, and additional volunteer programs
- Every two days, new experiments will be conducted to see if the updated versions of consent forms are readable
- D. Jojola and A. Rivera are responsible for collecting the outcomes and refer to S. James. S. James determines the next steps

8. Next Steps

- Patients participate in experiments- add opinions, explain the experience, and provide suggestions
- Collect data on the comprehension of the consent forms by implementing young adults (ages 17 and below) to test their understanding in school environments
- Finalize updated consent form

9. Appendix

Works Cited

Anvita, Pandiya. (2010) Readability and Comprehensibility of Informed Consent Forms for Clinical Trials, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146080/>

In the article, Antiva (2010) discusses the concept that the readability of a text is not the only issue when it comes to consent form; the author asserts that being able to comprehend the difficult document is also an issue.: “However, this document must not only provide the necessary information, but it must also be provided in a way that can be understood by the patient. Non-conclusive information suggests that research participants frequently may not understand the information presented during the informed consent procedure” (Avinta, 2010).

Anvita unravels both the readability and comprehension issues patients deal with when coming to consent forms with research to back up her experience. The source does not only address the issue with being able to read consent forms but being able to understand what the forms are presenting to a patient including medical information to the patient, convey complexities, possible risks and benefits, treatment options, rights to withdraw, and so on. Regarding

readability and/or social justice comprehension and readability should be at a level where anyone can understand and read a form with no hesitation.

Baker, L. M., Wilson, F. L., & Kars, M. (1997). *The Readability of Medical Information on InfoTrac: Does It Meet the Needs of People with Low Literacy Skills?* Oclc.org; American Library Association.

https://go-gale-com.aurarialibrary.idm.oclc.org/ps/i.do?p=ITOF&u=auraria_main&id=GALE%7CA53408600&v=2.1&it=r&sid=summon

In the article, Baker et al. (1997) discuss the experiment given based on 250 readings given and the conclusion given was exceeding the current eighth-grade standards, which represents the inconsistency in society's readability levels. However, the diversity must be considered to appropriately discover the national average readability level: "The findings revealed that the readability scores ranged from a low of tenth grade to a high of fourteenth grade and that all the material exceeded the accepted standard reading level of eighth grade. These results suggest that the items included in this study would not satisfy the medical information needs of people with poor reading skills" (Baker et al., 1997). The purpose is to address the on-going issue of relevance, comprehension, and generational differences regarding literacy, therefore the results collected from the experiment are effective, yet, not powerful enough to finalize a decision to increase, lower, or not change the United States' readability score. Despite the results for each experiment conducted, the population is constantly adapting, hence readability levels persistently changing. Education referring to literacy must be addressed in the United States to maintain a fair and balanced education for each citizen to interpret the information given, specifically regarding medical documents in this situation.

Brennan, D. (1996). *Informed Consent Forms: Are They Readable?* Retrieved from

https://opensiuc.lib.siu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsr edir=1&article=1223&context=uhp_theses

In this article, Brennan brings awareness to the high readability levels of medical consent forms, also discussing the research done on the overly high readability and why this is an issue. Brennan writes, "Research has indicated that forms utilized to acquire informed consent may be too hard for the typical patient to comprehend...Results of this study reveal that 70% of the language comprising informed consent forms is written at a level for juniors in college to understand. This finding implies that roughly 37% of the United States adult population could read and

comprehend them" (Brennan, 1996). Since Brennan is a college-educated individual, this means they have the ability to read at a higher level than the average adult in the U.S. But because Brennan is stating why there is an issue with the readability levels of consent forms this isn't problematic. This article is imperative to our research because it adds weight to the argument that the readability levels of medical consent forms are too high for the average American to comprehend.

Denver Health School-Based Health Center. (n.d.). School-Based Health Centers Consent Form in English.

<https://www.denverhealth.org/-/media/files/departments-services/school-based-health-centers/school-based-health-centers-consent-form-english.pdf?la=en&hash=B1B9CD9F5099A497564674705EB36D49B510CA19>

Eltorai, A. E. M., Naqvi, S. S., Ghanian, S., Ebersson, C. P., Weiss, A.-P. C., Born, C. T., &

Daniels, A. H. (2015). Readability of Invasive Procedure Consent Forms. *Clinical and Translational Science*, 8(6), 830–833. <https://doi.org/10.1111/cts.12364>

In the article, doctors conducted an experiment to adjust the readability levels in the United States, beginning with the current eighth-grade level and going to a sixth-grade and below reading level. Eltorai et al. (2015) confirm the common issue for medical consent forms being too complicated for readability status and must be changed for the development of appropriate interpretation. The purpose is to address medical consent that is not comprehensible and must be adjusted: “Because the average US adult reads at an 8th grade level, the National Institutes of Health (NIH) and the American Medical Association (AMA) recommend the readability of patient materials be \leq 6th grade reading level. Patient materials have been repeatedly shown to be too complex” (Eltorai, et al., 2015). Based on several analysis experiments conducted, the final result led to a lower national reading level for medical and health-based setting patient information. The doctors visibly represent the desire in society for patients to read and understand the information given. This is important to refer to society as a social justice movement and fairness for all educationally, financially, and other common social indifferences as minors soon to experience adulthood.