

A Proposal to Consider Changes to Patient Consent Forms

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I. Summary

Denver Health consent forms: something that impacts many people within the range of Denver Public Schools (DPS). Denver Health clinics are located in 207 DPS schools and are accessible to any student attending said schools. Because clinics are so widely accessible, the understandability and processability of their consent forms are vital to obtaining informed consent from — and appropriately satisfying the needs of — DPS students and their parents. When reading the contest form from 2019 the first page was understandable and comprehensible. However, the second page and all other following pages had a greatly increased reading level and became more difficult to understand with clear regressions in the formatting and fonts. This issue does not apply solely to consent forms. Other medical documents tend to rank at a level which is not understandable by individuals without elite levels of education. This creates communication challenges and misunderstandings between medical professionals and patients. For a variety of reasons, whether that be a difference in language or a writing level that is above the readers' level of comprehension. This is a social problem that needs to be solved because it impacts a large variety of people and can cause parents and others to consent in a situation in which they otherwise would not. To make these changes, we plan to present our findings to Denver Health, with a focus on pushing changes to create consent forms that are readable by the entire audience of adults whose children are served by Denver Health's School-Based Health Centers (SBHCs). To format the consent forms in a more readable way, we propose to make a change to vocabulary (using easier-to-understand terms), adding visuals, and modifying the format to create consistency throughout the entire document.

II. Introduction

As members of the Manual High School community, it is important to us that the needs of our peers and families are met. Denver Health's SBHC is the primary way in which students of our school receive medical care on campus. With the consent forms being generally written for all clinics of a similar type at any campus, we also want the issue attended to in other locations. If parents and students cannot understand what they consent to, the medical practice performed can hardly be considered ethical. While we have no desire to solve the general issues in the medical community regarding consent, it is important to us that all of the people with whom we have contact or who are in similar situations as our own are cared for in a proper and ethical manner.

III. Needs/Problems

Consent forms and the debate surrounding actual informed consent has been an ever-pressing issue, addressed at many levels, and always with the intent to make sure that medical practice is ethical and patients are taken care of in an appropriate manner. Ironically, many of the efforts aimed at doing so are not directed at the general population; this could be cited as a reason why no change has been made. In other words, in most cases where the concerned, yet benefitting, party tries to make a change, they do not invoke any desire for change in the affected population, but rather in the population that benefits. While we aim to make the same proposal to a similar group of people, our particular issue —or more specifically, the level at which our issue occurs — has not been addressed before. That issue, of course, is that the consent forms in the School-Based Health Center (SBHC) on our campus do not meet the needs of the population that the clinic aims to serve.

Informed consent is rarely defined in a specific way. For the purpose of defining the issue in greater detail, giving informed consent is simply when a patient signs a consent form or gives legal consent in another way after being entirely informed of the risks and benefits of whatever operation or procedure in which they are consenting to partake. Their vulnerabilities must also be considered. For example, if a parent would not otherwise enroll their child in an experiment but needs money and the experiment offers compensation, it should be stated in the consent form that parents should consider the experiment without the monetary benefits it offers. Informed consent also has to consider social justice: "social justice is defined as 'equal access to wealth, opportunities and privileges within a society'"

(Rogers, 2019). Because not all readers will have access to the same resources, SBHC consent forms cannot be written in a format that does not consider differences in the ability of its audience.

In the same way, readability must be defined. In the simplest way, readability is the level of ease at which a document can be read, understood, and processed by the reader. This includes visual appeal — mainly how much text is on a page and how often visual aids or headings (for example) are used to break up large sections of text — as well as reading level and vocabulary use. Readability tests (such as the ones used to measure readability for the purpose of the following arguments) measure grade level or give a sort of percentage based on total words, total sentences, and total syllables (Murphy, 2018). Others also measure sentence length and the reading level of vocabulary used.

As previously stated, consent forms provided for the use of SBHCs are not readable. Their reading level far exceeds the recommended reading levels for patient material (i.e. consent forms) and the average reading level of adults in the United States.

A number of sources aim to address this issue and prove that enhanced readability makes a better consent form. What these studies also provide is an insight into the scope of the problem of consent form readability. As found by Adam Eltorai and a group of other researchers, the average reading level of consent forms was generally around 15th-grade. The primary issue with this is that the average reading level of an adult in the US is 8th-grade and “the National Institutes of Health (NIH) and the American Medical Association (AMA) recommend the readability of patient materials be \leq 6th-grade reading level” (Eltorai et al., 2015). In other words, all documents provided for patients should be written at a 6th-grade reading level or lower. This, of course, includes consent forms. The average reading level of the 2019 SBHC consent form scores at just below the average calculated in the study at a reading level of 14 (this is an average of all 7 pages combined) (*Readability Formulas*, 2020). The highest reading level of any one page of the consent form, however, was 19th grade. For context, this is 13 years of education past the recommended reading level.

To further explore the issue, nearly one-third of people in the US have poor literacy skills (Tait et al, 2005). As a result, Tait et al. claim that “since poor literacy has been consistently associated with poor health status, a significant number of these individuals will at some time become eligible to participate in clinical research.” Not only does this apply to clinical research, but also to any medical services that would not otherwise be required if not for poor health status. The services that the SBHC provides might be essential to the children of some of those individuals. As a result, it would be critical that the parents with poor literacy understand what they are signing, and therefore that the consent forms are

readable. Currently, this is not the case. Additionally, “nearly 50% of adults ‘experience considerable difficulty in performing tasks that required them to integrate or synthesize information from complex or lengthy texts’” (Eltorai et al, 2015). Certainly, a seven-page document fits into the category of “lengthy.” Being able to put together (“synthesize”) all of the information from a consent form is key to informed consent and therefore ethical medical practice. If parents have difficulty doing so, or do not read the document because of its length, they are not giving informed consent.

What these studies recommend avoiding is present in the SBHC consent forms. Tait et al. indirectly suggest, for example, that consent forms should be modified to include more visuals, a decrease in reading level, and more spread-out text. This was a result of “improved understanding among parents who received the ... consent document [that was hypothesized to be more readable]” (Tait et al., 2005). Eltorai et al. make a similar point. The previously-mentioned high reading level and lack of visuals both greatly decrease the readability of the SBHC consent forms. Additionally, a guide for writing readable consent forms advises that such forms “avoid large blocks of printed text,” and, “use photos, graphics or tables if they will help clarify procedures” (*Informed Consent*, 2016). Currently, large blocks of text are prevalent in SBHC consent forms and tables may be confusing (see Appendix I and Appendix II). No visual aids are included. For parents, this means that the majority of them will sign the form without reading it. They won’t understand the implications of what they’ve signed and may have otherwise private information exposed to an unwanted organization. They may lose some necessary benefits that they would have otherwise received.

Especially in a clinic that aims to serve all types of students, prioritizing understanding for all parties involved should be key. At the moment, however, the SBHC consent forms provide limited accommodations for an expansive audience and lack major features of highly readable and processable documents. This means that a majority of adults who are required to sign the forms are not giving fully informed consent, and are potentially signing away rights that they would not have otherwise.

IV. Goals/Objectives

Our main goal is to indirectly increase the readability of the consent forms used for Denver Health’s School-Based Health Centers (SBHCs), in addition to exposing the issue of readability to those who write consent forms. As a result of a convincing presentation, we would like to see three main changes in the way that these consent forms appear:

- An increase in readability as far as format:
 - The use of visuals to aid in reader understanding (currently, there are none)
 - An increase in the size of headings to 16-point font and spacing set to a minimum of 1.5x and a maximum of 2x
 - No in-sentence lists
 - An increase in the understandability/organization of tables
 - Consistency in formatting throughout the document
- A decrease in the reading level of the consent forms to a maximum of an 8th-grade level, measured using readabilityformulas.com, including lesser use of medical terms and generally complex language
- A decrease in the length of consent forms to a maximum of three pages, still printed on 8.5" x 11" paper

V. Timetable

Activity	Implementation Time	Responsibility
Finish project proposal	8 hours, done by December 7th	Monea Brown, Nayeli Flores, Morgan Pulling
Create and title presentation	10 minutes, done by December 7th	Monea Brown
Add content: graphics, descriptions, arguments, etc.	8 hours, done by two days before the presentation date	Monea Brown, Nayeli Flores, Morgan Pulling
Re-check spelling, grammar, and format	30 min, done one day before the presentation date	Morgan Pulling
Present findings on consent form readability to Denver Health	10-20 minutes	Monea Brown, Nayeli Flores, Morgan Pulling

VI. Key Personnel

Client	Manual students, families, and staff; Denver Health stakeholders
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Sponsor	Whitney Weathers
Project manager	Morgan Pulling
Team	Monea Brown, Nayeli Flores

VII. Evaluation

To determine the effectiveness of the project, the group as a whole will perform daily evaluations of the clarity and conciseness of our writing, and make changes so that the presentation is considered compelling, accurate, and understandable. The end result should be a presentation with high understandability for the intended audience (people who direct and write consent forms) who may not have a complete understanding of the high reading level at which they write their documents. The presentation should meet the following requirements for professionalism and quality:

- Consistent use of formal and academic language
- Consideration of opposing viewpoints
- Ability to maintain an engaged audience (using graphics to enhance understanding)

To aid in an accurate evaluation of the product, our group will entail the use of both our own and outside opinions on the condition of the product to make improvements.

VIII. Next Steps

The following steps should be performed in an effort to begin modifying SBHC consent forms to increase readability and reader comprehension:

- Replace medical terms with terms familiar to a non-medical audience, and reduce the maximum syllables per word to three
- Create a consistent format using the same headings, body text, and overall style (preferably the same or similar format as the first page)
- Increase the use of visuals to aid in reader comprehension
- Reword some sentences to create a better explanation of the information

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APPENDIX I:

DENVER HEALTH
DENVER SCHOOL-BASED HEALTH CENTER SERVICES (DSBHC)
GENERAL PARENTAL/GUARDIAN
CONSENT FOR TREATMENT

Parent: _____
 DOB: _____
 ID#s: _____

Sign consent for my student: First Name _____ Middle _____ Last Name _____ Gender _____ DOB _____

I authorize necessary and/or advisable care provided by the DSBHC. I understand the following services may include:

physical exams • immunizations • routine lab tests • care for acute illness and injury • prescription medications • care for common childhood/adolescent physical concerns (asthma, sore, menstrual problems) • care of certain chronic conditions such as asthma and seizure disorder • pregnancy testing • diagnosis and treatment of sexually transmitted infections • family planning, adolescent counseling, the administration and management of birth control • prenatal/postpartum care services • drug and alcohol prevention counseling and education • mental health services including individual, family and group therapy • follow-up care as needed.

Dental services available in the DSBHCs include evaluation, diagnosis, prevention and limited dental treatment including: screenings • routine cleanings • x-rays • fluoride varnish application • sealants, bite diagnosis or assessment • composite space for the replacement dental material is for determining necessary dental hygiene services only. An examination to evaluate the oral cavity and maxillofacial area, not provided by a licensed dentist.

Release of Information: I understand my student's medical record is protected health information and all records for my student's medical records require a signed consent by student's parent/guardian. DSBHC may disclose health information for payment, treatment, and health care operations as described in Denver Health's Notice of Privacy Practices. As allowed by Colorado law, my student may request confidential visit marking of health information from the rest of their confidential. Access to my student's medical records from a confidential visit will remain confidential and release of medical records to parent/guardian or any interested party requires a signed release of information from the student. I give my permission to DSBHC staff to examine and/or copy my student's school records including immunization records, attendance, and any records that are necessary for DSBHC staff to provide the care and/or treatment to my student.

I understand that the Colorado Department of Public Health and Environment (CDPHE) provides funding for the health services my student receives at a school-based health center, and is equally able to receive information regarding services provided to patients. CDPHE reserves confidential data for all patients, and this consent does not specifically identify any individual patient.

DSBHC Fees, Billing, Authorization, and Consent: On behalf of my student, I assign to Denver Health and Hospital Authority ("DHHA") any and all benefits that either my student or I may be entitled to receive for healthcare services provided by DSBHC from any payer of benefits including any private, entity, insurance (company health benefit plan, or governmental healthcare program). DHHA has authorization to file claims with, and collect payments from, the payer of benefits, and the payer of benefits to make payment directly to, and solely to the order of, DHHA. I agree to assign DHHA in submitting and collecting claims from the payer of benefits in any reasonable manner requested. I authorize DHHA and its care providers to disclose to the payer of benefits any information from my student's medical and billing records necessary to obtain payment. I understand that once information is released DHHA will be unable to control its confidentiality.

Student's School _____ Grade _____ DPE/Health ID # _____
 Student's Home Address _____ City/Zip Code _____
 Student's Race/Ethnicity (circle all that apply) (optional)
 Hispanic/Latino American Indian White Black/African American Asian Other _____

Parent/Guardian (Name) _____ Phone Number _____
 Father/Guardian (Name) _____ Phone Number _____
 Emergency Contact (Different than above) _____ Phone Number _____
 Name of Student's Primary Care Provider _____ Provider Phone Number _____

Insurance Information - My student has health insurance coverage: YES NO
 Health First CO (Medicaid) ID # _____ CHS ID # _____ DSHS/CHAF

Name of Private Insurance _____ Policy/Member # _____
 Group # _____ Policy Holder's Name _____ Relationship to Student _____
 Employer of Policy Holder _____ Policy Holder Date of Birth _____

CONSENT: I have received the DSBHC packet that explains the services provided by DSBHC. I understand this consent will remain valid for 12 months from the date of my signature. I understand that I am responsible for notifying DSBHC with any changes in guardianship and/or insurance. I have the right to revoke this consent for my student at any time with written documentation to DSBHC stating this.

Signature Parent/Guardian: _____ Date: _____
 Print Name of Parent/Guardian: _____
 DS-004 (3/11)

APPENDIX II:

**DENVER HEALTH
DENVER SCHOOL-BASED HEALTH CENTER
IMMUNIZATION CONSENT FORM**

Name: MMR, Page 1 of 1

Student's Name: _____ Date of Birth: _____
Last First Middle MM DD YY

Student's School: _____ Grade: _____ Gender: _____

Parent or Legal Guardian name: _____

Vaccinations are offered at Denver Health School Based Health Centers to protect your student against many serious diseases. Prior to vaccinating, Denver Health checks multiple databases and records to confirm that students are only given vaccines they have not received.

Vaccines are designed to prevent life-threatening, debilitating illnesses, and cancer. These include:

Disease	Vaccine	Disease	Vaccine	Disease	Vaccine
Tetanus	Tdap/Td/DTaP	Polio	IPV	Chicken Pox	Varicella
Diphtheria		Hepatitis A	Hep A		
Pertussis		Hepatitis B	Hep B	For children under 5 years old	
Measles	MMR	Meningococcal Meningitis	MCV4/Men B	Severe diarrhea	Rotavirus
Mumps		Human Papillomavirus	HPV2	Bacterial Diseases	TSS
Rubella		Influenza/Flu	IV	Pneumonia	PCV13

NOTE: Each of these vaccines is recommended by the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP).

1. List the name(s) of the vaccine(s) you do **NOT** want your student to receive here: _____

2. Has your student ever had a serious reaction to a vaccine?
 Yes. If so, what was the reaction and to what vaccine? _____
 No

I give my permission for my student to receive vaccines at the School-Based Health Center, except for the specific vaccine(s) listed above. I request that those vaccines be given to the student named above, for whom I am authorized to make this request. I further agree to have information shared with my student's primary care provider. I also agree to have my student's immunization record stored in my student's school health record, the Denver Health electronic record (eHR), and the Colorado Immunization Information System (CIIS). Vaccine Information Statements (VIS) about the diseases prevented and the risks and benefits of the vaccines given have been offered and my questions answered.

The Center for Disease Control (CDC) maintains a current list of Vaccine Information Statements (VIS) for each vaccine. For the most current VIS, please visit: <https://www.cdc.gov/vaccines/imz/downloads/vis.html>.

Please place an (X) next to one of the following options:

____ YES, I DO authorize Denver Health School-Based Health Centers to vaccinate my student.
 ____ NO, I DO NOT authorize Denver Health School-Based Health Centers to vaccinate my student.

 Parent or Guardian Signature Relationship to Student Date (MM/DD/YY)

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