Health Literacy, Plain Language and Informed Consent

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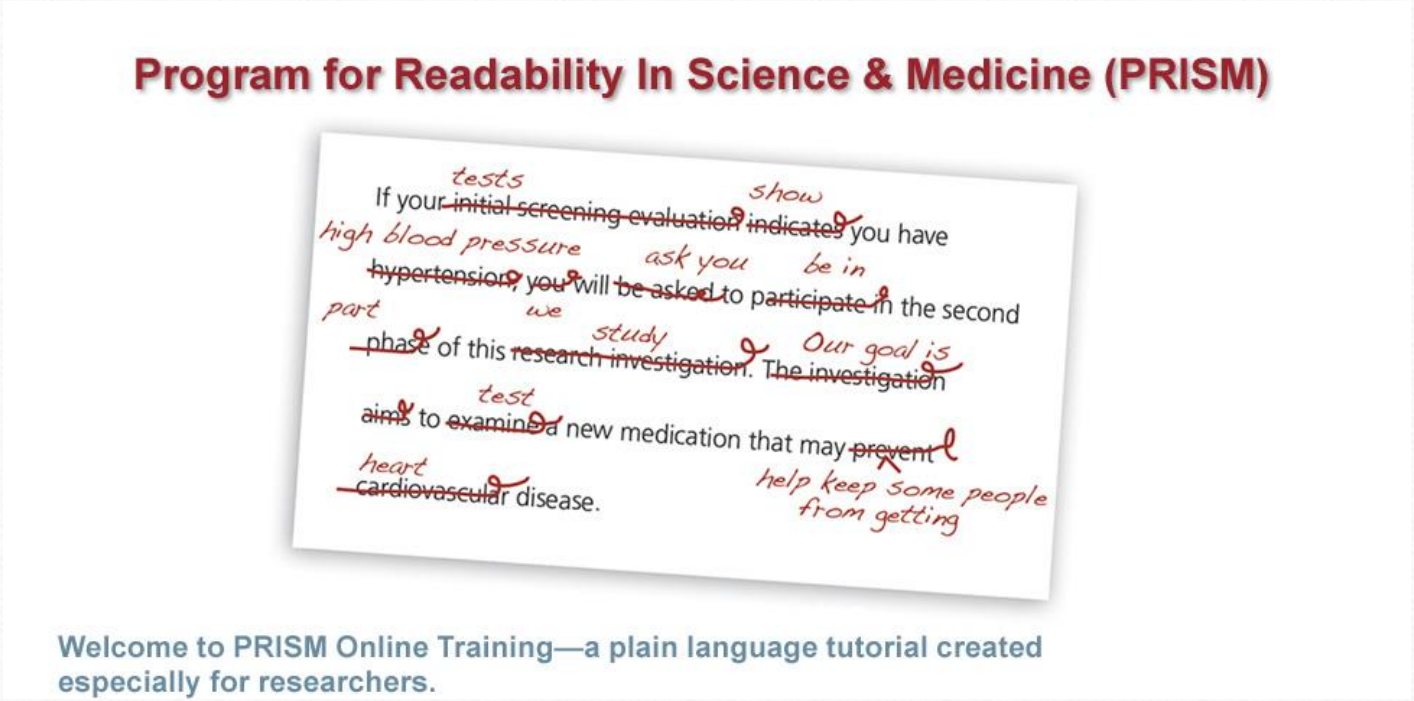
PRISM Online Training

https://prism.kpwashingtonresearch.org/start.htm



Why is readability important?

The link between readability and health literacy

Most printed health information exceeds high-school level reading skills.

About half of American adults read at or below an 8th-grade level.

An epidemic of "low health literacy": Half our population may not be able to read or understand health information, including informed consent documents.

What does this mean for health researchers?

Research volunteers should have clear information about participation and risks.

Complex consent forms raise questions related to research ethics.

Many institutional review boards (IRBs) require easy-to-read consent forms.

Goals for our session

Give you tools & strategies for improving readability

Explain why using plain language is important

Demonstrate plain language writing strategies

Point you to other readability resources

Provide skills & knowledge you can use immediately

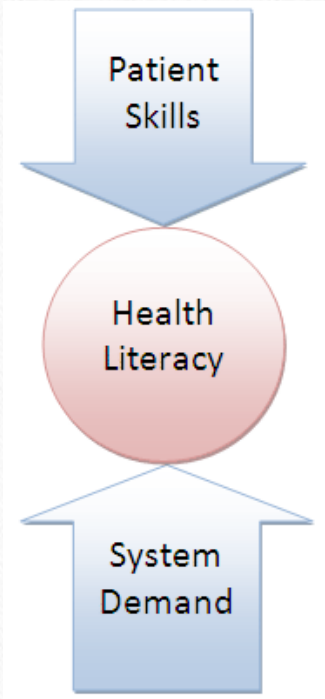
What is Health Literacy?

Health literacy is the communication component of health care:

- An early definition(AMA, 2005): "The ability to find, understand and act on health information:

Newer understanding: An interaction between patients and the health care system

An interaction between patients and the health care system



What health literacy is not

- **Not the same thing as general literacy-** anyone can have trouble figuring out a complex self-care routine
- **Not only about reading-** communication involves a range of skills and cultural characteristics
- **Not a fixed state-** individual abilities vary depending on stress, prior experience, information salience, etc.

Limited health literacy can affect anyone at anytime.

Health Literacy Epidemic

Half of American adults (~ 93 million people) have "low health literacy"

(Institute of Medicine, *Health Literacy: A prescription to end confusion*, 2004)

Widespread communication gaps - most people have had trouble:

- Remembering "doctor's orders"
- Understanding treatment choices
- Taking medicine correctly
- Wayfinding in a clinic or hospital
- ***Reading a consent form for health care or health research***

What is readability?

In general, readability is the ease with which text can be read.

The primary factors involved are:

- Vocabulary (the complexity)
- Sentence length and structure
- Amount of information
- Page design and formatting
- Logical order and well-organized content
- Degree to which content is meaningful and interesting

How to measure readability?

Many formulas are based on word and sentence length:

- None are 100% accurate, but most are good approximations
- Flesch-Kincaid and others give a grade-level score
- Flesch Reading Ease is based on a 0-100 scale ("very confusing" to "very easy")

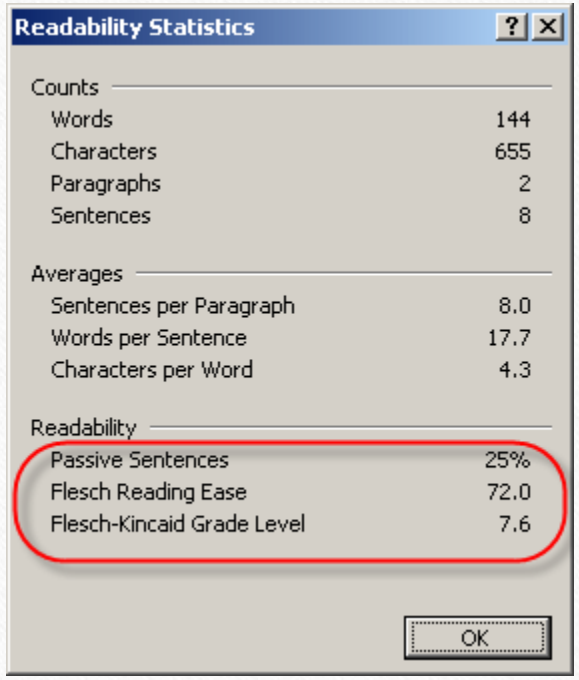
Important caveats about readability formulas:

- They don't assess organization, formatting, and page density
- Most of these tools measure word length, but some short words aren't well understood
- Automated tools may be less accurate
- The most accurate results can require time or money

Readability scores in Microsoft Word

Flesch Reading Ease and Flesch-Kincaid Grade Level

- Both based on word length and sentence length
- Perhaps are less accurate, but are fast, free and a good starting point



Readability scores in Microsoft Word: The Flesch Reading Ease score

Based on number of words per sentence and number of syllables per word.
0-100 point scale, with 100 being most readable

PRISM goal = 70 or above

A rough qualitative translation:

- 90-100 = Very easy
- 80-89 = Easy
- 70-79 = Fairly easy
- 60-69 = Standard
- 50-59 = Fairly difficult
- 30-49 = Difficult
- 0-29 = Very confusing

The Flesch-Kincaid Grade Level score

- Quite popular in readability literature
- Roughly the same algorithm as the Flesh Reading Ease, but translated to a grade level score
- Scores greater than 12th grade are college level

Other Readability Scores or Tools

- Fry Graph Readability Formula
- SMOG Readability Formula (Simple measure of Gobbledygook)
- SAM Suitability Assessment of Materials
- Design Readability Scorecard

Readability in the Research Setting

- How readable are research consent forms?
- Why haven't we met our reading level goals?
- Why should we care?
- Helpful resources for the research setting

How do research consent forms measure up?

Most IRBs endorse 6th-8th grade reading levels for consent forms

2003 Study of consent form readability

- 8% of research consents at US medical schools meet their own standards.
- Average reading level was 10.6 to college-level (depending on formula used) Paasche-Orlow, et al., New England Journal of Medicine, 348:8, Feb 20, 2003

Consent form readability requires our attention

Many IRBs are growing more attuned to low readability—and requiring study teams to improve their consent forms.

Federal regulations require consent forms and other recruitment materials that are "understandable to the subject."
Protection of Human Subjects. Federal Regulations Title 45, 46.109 and 50.20 (1993)

Not just language choice (e.g., Spanish versus English). We need to make sure the information makes sense.

Why aren't we already meeting our targets?

Consider the unique challenges you face:

•Your audience is usually the scientific community
— so plain language writing may not be intuitive
•Medical jargon PLUS specialized research terminology
•Clinical trials often involve complex and variable procedures
•Complicated legal clauses may be mandated by the institution, sponsor, or IRB
•And other language mandated by the institution, sponsor, or IRB

It's not as easy as "just doing it."

What tools can help us meet our targets?

The PRISM Readability Toolkit

- **A grab-and-go suite of complementary resources**
- **In the public domain since 2006**
- **Unexpected traction in the research community**
- **PRISM Toolkit download**

What's in the PRISM Readability Toolkit

Contents

- Health literacy and readability in the research context
- Principles of plain language
- Using readability formulas
- Quick reference guide
- Editing checklist
- Template language
- Resources for consent forms
- Resources for HIPAA forms

Appendices

Checking readability in Microsoft Word™
Alternative wording suggestions
Examples of improved readability
Examples of improved formatting
Links to other resources

Toolkit excerpt: Template language

Sample language for common consent topics, such as randomization.

We will use a computer to assign you at random to 1 of the [insert #] study groups. This means we will put you into a group by chance, like [flipping a coin/drawing names out of a hat]. You will have an equal chance of being in placed in [either/any] group.

Flesh-Kincaid Grade Level = 4.6
Flesh Reading Ease = 90.1 or "very easy"

PRISM Resources for Informed Consent Documents

Toolkit Excerpt: Alternative Word List

- Developed with help from health education writers at Group Health (now Kaiser Permanente)
- Plain language alternatives to more than 700 complex terms PRISM Alternative Word List

Navigation links: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
A TOP	
abdomen	stomach, tummy, belly
abrasion	scrape, scratch
absorb	take in fluids, soak up
abstain from	don't, don't use, don't have, go without
accompany	go (along) with, come with
accomplish	carry out, do
accordingly	so, for that reason, as a result
accrue	add, gain, build up
accumulate	add, build up, collect, gather
accurate	correct, exact, right
acquire	get

What is Plain Language?

Plain language is a synonym for clear communication:

- Does your audience "get it" the first time they read or hear it?
- Is it focused on what they need to know?
- Does it include terms, techniques, and concepts they can relate to?
- Plain language is a tried-and-true method shown to improve outcomes and cut costs

What plain language is NOT

Plain language is…

***not* dumbing it down.**

- Succinct—but not the same as "See spot run."
- It's using clear, meaningful messages that "land right."

***not* offensive to well-educated people.**

- People of all education levels prefer concise information.
- We all appreciate clarity when outside our area of expertise.

***not* impossible.**

- Successful initiatives in law, health care, finance, the federal government, and several states, including Washington

Putting health information in plain language

Before

Your initial evaluation may take up to one hour.

During the evaluation, your therapist will provide appropriate testing and discuss various treatment strategies designed to help you reach your optimal state of health and function.

It is advised that you wear comfortable and loose clothing for this initial evaluation. If your legs or feet are being examined, gym shorts are recommended.

Grade Level = 10.0,
Reading Ease = 49.8 or “difficult”

Putting health information in plain language

After

Your first appointment may take up to one hour.

Your therapist will do some tests and talk to you about your treatment options.

Please wear comfortable clothes that fit loosely. If we are looking at your legs or feet, please wear shorts.

Grade Level = 3.6,
Reading Ease = 87.4 or “easy”

Putting research information in plain language

Before

If your initial screening evaluation indicates you have hypertension, you will be asked to participate in the second phase of this research investigation. The investigation aims to examine a new medication that may prevent cardiovascular disease.

Grade Level = 15.0,
Reading Ease = 19.3 or "very confusing"

Putting research information in plain language

After

If your tests show you have high blood pressure, we will ask you to be in the second part of this study. Our goal is to test a new medication that may help keep some people from getting heart disease.

Grade Level = 6.6,
Reading Ease = 82.9 or "easy"

Four Principles of Plain Language

1. Use terms your audience can easily understand

2. Write in a conversational style, as if you were speaking

3. Organize & filter content with your readers' needs in mind

4. Format your document so that it looks easy to read,
   so that it will grab your reader's interest and attention

Principle 1: Use terms your audience can easily understand

Writing strategies that support this principle

- **Choose common, everyday words**
- PRISM Alternative Word List
- **Replace or define medical and research jargon**

  Use examples, analogies, and visual aids
- **Check the reading level**

  Remember all methods have their limitations. Use the method as an estimation, rather than an exact score.

Principle 2: Write in a conversational style

Writing strategies that support this principle:

Use active voice. In passive voice, the subject is acted upon. In active voice, the subject performs the action.

- Passive: “You will be asked questions about your health.”
- Active: “We will ask you questions about your health.”

Write in the first person using pronouns like "we" and "you.“

Read your document out loud, to help improve clarity and flow.

Principle 3: Organize and filter content based on readers' needs

Writing strategies that support this principle:

•Use short sentences — about 15 words on average.

•Use succinct, single-topic paragraphs.

•Cover key points early and provide summaries.

•Consider your audience's cultural characteristics — literacy level, age, ethnicity, or health conditions.

•Ask someone unfamiliar with your project to read your materials.

Principle 3: Organize and filter content based on readers' needs

Before

- Can you take five minutes to provide information that will help plan an important study to aid people with arthritis pain and problems getting a good night's sleep? I am an investigator at XXX Research Institute who is planning a major study to test new ways of helping people with arthritis pain and sleep problems.

  Grade level = 13.0
  Reading ease = 53.4 ("fairly difficult")

Principle 3: Organize and filter content based on readers' needs

After

- Can you take five minutes for a study about helping people with arthritis get a good night's sleep? If you have arthritis, you may know what it's like to have trouble sleeping. I am a researcher at XXX Research Institute. I'm writing to ask for your help with a major study about arthritis pain and sleep problems.

  (A number of words were removed from the first sentence to get to the main point more quickly, and the term investigator was replaced with the less intimidating term of researcher)

  Grade level = 6.3
  Reading ease = 75.9 ("fairly easy")

Principle 4: Format your document for easy reading

Writing strategies that support this principle:

- Use ample white space and margins.
- Break up chunks of dense copy.
- Put lists in bullet format.
- Use meaningful headings to identify topics with clear headings - think of "road signs."
- Draw attention using bold, large font, or extra space. (Limit use of italics, all caps, or underlining)

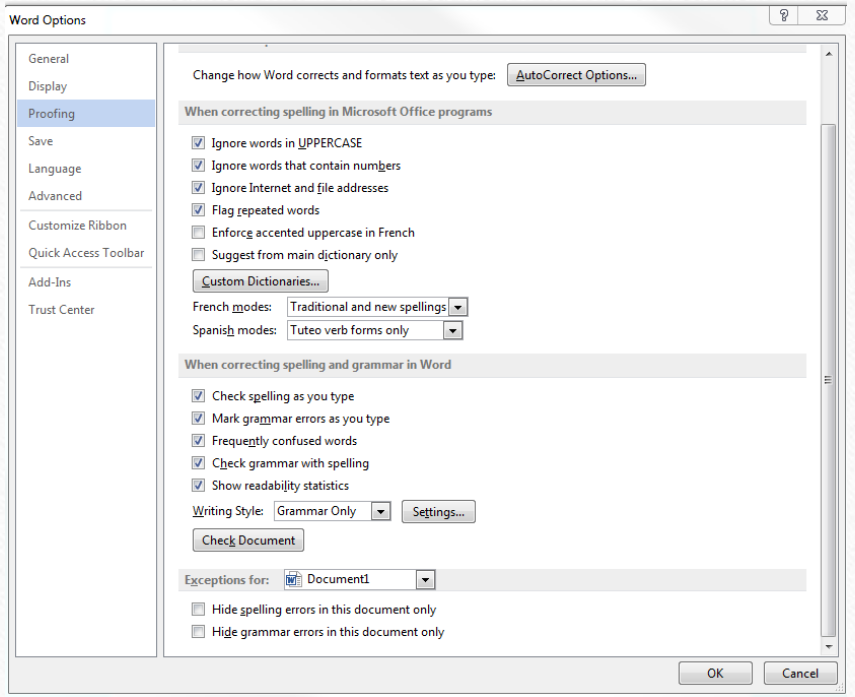
Using Plain Language in Research Materials: Three Resources from the PRISM Toolkit

PRISM Quick Reference Guide

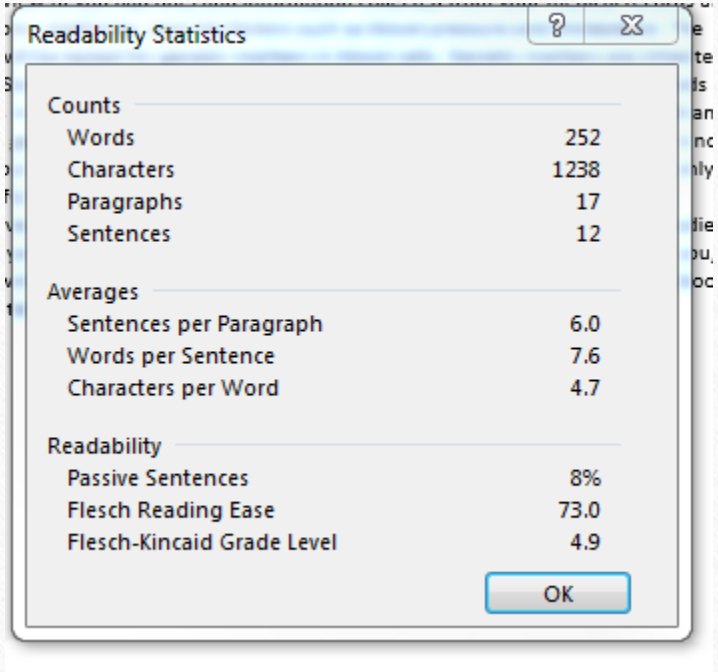
PRISM Editing Checklist

PRISM Readability Resources

Microsoft Word Readability Score Option- Word 2013: File: Options: Proofing: Show readability statistics



Example: after going through spelling and grammar checks



Now, let's practice!

- Revise a passage from an informed consent form
- Run the revised passage through Word's Spelling and Grammar Check feature.
- Review the Before and After versions, and compare to our revision