

Breakout Session: Informed Consent

Additional Resources

Sources:

1. National Cancer Institute: Simplification of Informed Consent Documents.
<http://www.cancer.gov/clinicaltrials/conducting/simplification-of-informed-consent-docs/page5#appendix3>
2. Temple Health. How To Improve Your Informed Consent
<http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage20.html>
3. The Toolkit for Making Written Material Clear and Effective
<http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=/writtenmaterialstoolkit>

**Engaging in Cultural Competence through Awareness,
Knowledge and Action**

March 13, 2014

National Cancer Institute

at the National Institutes of Health

Conducting Clinical Trials

Updated: 06/03/2013

Appendices 3 - 7

Appendix 3: Checklist for Easy-to-Read Informed Consent Documents

Appendix 4: Communications Methods

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Appendix 6: Comprehensive Working Group on Informed Consent in Cancer Clinical Trials

Appendix 7: Informed Consent Template Update Working Group

Appendix 3: Checklist for Easy-to-Read Informed Consent Documents

Text

- Words are familiar to the reader. Any scientific, medical, or legal words are defined clearly.
- Words and terminology are consistent throughout the document.
- Sentences are short, simple, and direct.
- Line length is limited to 30-50 characters and spaces.
- Paragraphs are short. Convey one idea per paragraph.
- Verbs are in active voice (i.e., the subject is the doer of the act).
- Personal pronouns are used to increase personal identification.
- Each idea is clear and logically sequenced (according to audience logic).
- Important points are highlighted.
- Study purpose is presented early in the text.
- Titles, subtitles, and other headers help to clarify organization of text.
- Headers are simple and close to text.
- Underline, bold, or boxes (rather than all caps or italics) give emphasis.
- Layout balances white space with words and graphics.
- Left margins are justified. Right margins are ragged.
- Upper and lower case letters are used.
- Style of print is easy to read.
- Type size is at least 12 point.
- Readability analysis is done to determine reading level (should be eighth grade or lower).

- Avoid:
 - Abbreviations and acronyms.
 - Large blocks of print.
 - Words containing more than three syllables (where possible).

Graphics

Graphics are:

- Helpful in explaining the text.
- Easy to understand.
- Meaningful to the audience.
- Appropriately located. Text and graphics go together.
- Simple and uncluttered.
- Images reflect cultural context.
- Visuals have captions.
- Each visual is directly related to one message.
- Cues, such as circles or arrows, point out key information.
- Colors, when used, are appealing to the audience.
- Avoid graphics that won't reproduce well.

⁶National Cancer Institute, *Clear and Simple*, 23.

⁷National Cancer Institute, *Making Health Communications Programs Work*, 37.

⁸ C. Doak et al., *Teaching Patients With Low Literacy Skills* 2nd ed. (New York: Lippincott, 1996): 3.

⁹ C. Meade, *Consent forms*, 1527.

Appendix 4: Communications Methods

• Time to Read and Discuss the Form

Researchers should encourage the potential research participant to thoroughly read and re-read the consent form and supplemental materials, if provided, and to discuss the proposed research with others before signing the consent form. This may require a delay between the describing of the study and the signing of the consent document.

• Assess Understanding

It may be helpful for the researcher to ask the potential research participant short questions, after the research has been described and the consent form read, in order to assess that the potential research participant has at least a basic understanding of what the research involves.¹⁰ Example questions include:

- Tell me in your own words what this study is all about.

- Tell me what you think will happen to you in this study.
- What do you expect to gain by taking part in this research?
- What risks might you experience by participating in the research?
- What are your alternatives (other choices or options to participating in this research)?

- **Communication Techniques**

Videos, audiotapes, interactive computer programs, and discussions with qualified lay individuals may assist in educating the potential research participant about the clinical trial.

¹⁰S. Titus et al., "Do you understand? An ethical assessment of researchers' description of the consenting process," *J Clin Ethics* 7 (1996): 60-8.

Appendix 5: Supplemental Materials

Information needs vary from person to person and it may be important to supplement the informed consent document with additional material that will increase the participant's understanding of the proposed study. The following list is intended to provide the clinical trial participant, as well as the clinical researcher, with an awareness of the cancer-related information that is available. It may be helpful to talk with local oncology professionals to learn of other resources, including published materials, videos, and Web-based documents.

Types of Information:

Clinical trial/disease information from national organizations

- therapeutic alternatives
- clinical trial information
- disease-specific booklets
- drug information
- nutrition booklets
- questions to ask your doctor
- symptom management

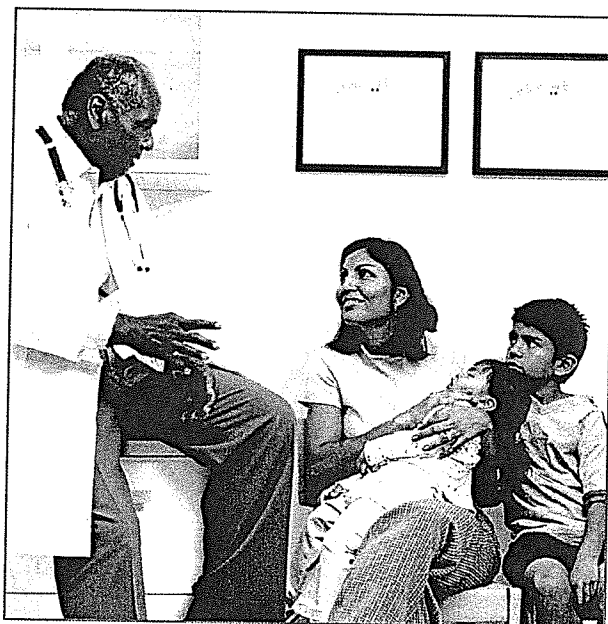
Information from local organizations

- clinical trials programs
- insurance programs/coverage
- Institutional Review Boards
- procedure information; e.g., bone marrow biopsy, insertion of a central line, etc.
- advocate/support programs

[TOOL 3A]

Collected here are a number of tips for drafting simple and clear consent forms and related educational materials. You may want to photocopy this *Style Guide* and place a copy inside each of the separate folders you created for each informed consent form undergoing revision.

These basic recommendations were synthesized based on research studies as well as on the material in excellent public domain guides such as: *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers* from the National Cancer Institute; *Simply Put* from the Centers for Disease Control and Prevention; *Plain Language* from the U.S. federal government.



Use Plain Language

Word choice and sentence length and structure are critical in creating text that is easy to understand. Here are tips to keep in mind while writing:

Words

- Use simple, common words (avoid medical terminology or jargon)
- Pick strong verbs
- Use "you" to address the reader
- Explain technical terms or use the simpler alternative

Examples:

"**Chemotherapy** is the use of drugs to treat cancer"

"**Noninvasive** means without surgery, needles, or cutting skin"

"**arteriovenous fistula** (abnormal opening between any artery and vein)"

"benign (not cancer)"

"**colonoscopy** (internal exam of the bowel using a bendable tube (colonoscope) with an attached camera"

"**hypertension** (high blood pressure)"

- Avoid long words with many syllables
- Avoid unnecessary adjectives
- Avoid legal jargon
- Avoid abbreviations and acronyms if possible
- Use the same words consistently (ie, don't use a synonym just to avoid repetition, and be careful with use of pronouns)

[TOOL 3A]

Sentences

- Keep sentences short (8 to 10 words is good), direct, and succinct
- Use a conversational tone
- Avoid complex sentence structures (e.g., compound sentences, dependent or embedded clauses, lots of commas)
- Consider breaking into a short list when there are more than 3 points to the sentence
- Use concrete nouns and give clear direction

Don't say:

"Following postsurgical safety precautions can reduce the likelihood of wound infections."

Do say:

"After your surgery:

(1) change your bandage daily,

(2) watch for pus or leakage,

(3) call the doctor if there is any change."

- Use the active voice

Don't say:

"The instrument is inserted by the doctor into the vein"

Do say:

"The doctor inserts the instrument into the vein."

Paragraphs

- Avoid long paragraphs (and dense blocks of text) (3-4 lines or 2-5 sentences is good)
- Start a new paragraph with a new thought

Organize the Flow of Ideas

Present one idea at a time

Rule:

If it does not add information or understanding, delete it.

- Sequence the ideas in the order a patient would want them... or...
- Consider using a standardized sequence of categories for all forms

Example:

The Queensland Government format generally recommends:

A] Interpreter/Cultural Needs

B] Condition and Procedure

C] Anaesthetic

D] General Risks of a Procedure

E] Risks of Procedure

F] Significant Risks and Relevant Treatment Options

G] Patient Consent

H] Interpreter's Statement

I] Doctor's Statement

- Use headings and subheading to "chunk" text together
- Keep these sections short
- Make your heads and subheads work to organize and communicate

Don't say:

"Complications of the Surgery."

Do say:

"Infection is the Most Common Complication."

- Use vertical lists to highlight a series of items

Simply Put

A guide for creating easy-to-understand materials



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Consider Culture

Culture affects how people understand and respond to health messages. The best way to ensure that your materials are culturally appropriate is to engage members of the target audience early on in the communication planning phase. They can assist in identifying messages and images that are likely to work best within their culture.

1. Use terms that your audience uses and/or is comfortable with.

For example: If your audience of elderly people with diabetes usually goes to the health department to see a doctor, ask them if they say “clinic,” “doctor’s office,” or something else to ensure that the words being used in your materials will be familiar to the intended audience.

If you need to identify a group of people by race or ethnicity, use a term preferred by that group. Preferred terms may vary even within an ethnic or racial group. Ask a sample audience.

The best way to make sure your materials are culturally appropriate is to talk with members of the audience you are trying to reach



For example: One group may want to be identified as “African American,” while another group may prefer to be identified as “Black.”

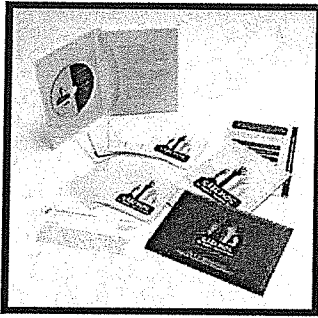
OR

One group may want to be identified as “Native American,” while another prefers “American Indian.”

2. Target messages to each cultural or ethnic group or subgroup.

Groups may have different needs, values, and beliefs that will affect how they interpret your message. Minority groups often have subgroups that differ greatly from one another. What is effective for one minority group or subgroup may not work at all for another.

Using culturally appropriate images, concepts, and language is not enough. Messages should always be tested with the intended audience.



Sabemos (Spanish for “we know”) is a bilingual, culturally appropriate toolkit developed by HHS/CDC to support the efforts of Hispanic parents and community leaders in protecting children from secondhand smoke. The kit was developed based on research acquired during focus groups with parents and leaders from the Hispanic community and key informant interviews. The findings from were used to develop key messages and tools for community leaders working with Hispanic/Latino populations.

Translations Take your Message Further

It is best to develop your materials in the language of your intended audience. However, translating them from English (or another language) is often necessary due to time limitations and/or available resources. This section will provide tips to help ensure that translations of your materials are both culturally and linguistically appropriate.

1. **Messages that work well with an English-speaking audience may not work for audiences who speak another language.** Find out about your audience's values, health beliefs, and cultural perspectives. You can do this by conducting individual interviews, focus groups, or other kinds of audience research, including secondary research (i.e., literature reviews).

2. **Design material for minority populations based on subgroups and geographic locations.** All members of a minority population are not alike. Mexican Americans, for example, may respond differently than Cuban Americans to certain words, colors, and symbols. Likewise, Korean women living in New York City may view a health issue very differently from Korean women living in Los Angeles.

Messages that work well with an English speaking audience may not work for audiences who speak another language

3. **Get advice from community organizations in the areas you wish to reach.** Local groups that work regularly with your audience can give you valuable insight about your audience. They can also recruit participants for surveys or focus group testing and help you gain the trust of your audience.
4. **Carefully select your translator.** Choose a qualified translator who is familiar with your intended audience. A qualified translator is typically a native speaker of the target language, has ten or more years experience in translation, and is preferably certified by a recognized institution. A qualified translator will produce documents that reflect the message and content of the source document. It is important to keep in mind that if the source document is not written clearly or in plain language the translated document will maintain this same attribute. When materials are used for intended audiences with more than one linguistic variation (for example, Mexican-American and Cuban-American) have multiple translators check the translation.
5. **Avoid literal translations.** Allow your translator to select from a wide range of expressions, phrases, and terms used by the audience. This flexibility will result in more culturally appropriate material.

6. **Use the back-translation method.** Once the material has been translated to the intended language, translate it back to English. (This step should be done by someone other than the original translator.) Check to see if the meaning and tone of the message have stayed the same.
7. **Field test draft materials with members of your intended audience.** Field testing will allow you to get feedback from your members of your intended audience and to make changes based on their comments and suggestions.

Beware of these common pitfalls:

- Do not translate English slang phrases or idioms literally.
- Do not translate into a dialect unless it is used by your audience.
- Do not omit foreign language characters or accent marks when publications are written in languages that use those elements. Missing characters or punctuation marks can change the meaning of a word or sentence. Make sure your word processing software and desktop publishing software have all the punctuation used in the intended audience's language.
- If you list a phone number to call for more information, make sure staff fluent in the intended language is available. Or add a qualifier; such as, "Spanish speakers are available between 1:00 to 5:00 pm EST."

Testing for Readability

Readability formulas are useful tools. They provide a general idea of how hard a document will be to read based on the average syllables per word and average words per sentence. However, they do not measure a person's level of comprehension. Comprehension levels are often two or more grades below reading or education level. Comprehension drops even more when a person is under stress.

Readability formulas do not take into consideration the effects of layout or design elements. They cannot predict how well your audience will accept or act upon your message. The use of readability formulas alone does not guarantee well-written, understandable text. They should be used only in conjunction with other means of assessing effectiveness.

1. Reduce reading level before using formulas.

There are several basic techniques to lower the reading level of your document. Begin by reducing the number of words per sentence and by using one and two syllable words when possible. Reducing these numbers can improve reading ease.

Also look for the number of times passive voice is used in your document. Change to active voice when possible. Active voice improves readability.

For example:

This sentence is written in passive voice:

“Heart disease and lung cancer are caused by smoking.”

Using active voice is better:

“Smoking causes heart disease and lung cancer.”

If you think the reading level of your document is too high because of long names of organizations, diseases, or other proper nouns, use a readability formula without those words. It may be that the readability is at the right level, except for the long words. If this is the case, revise your text to remove longer words

If you find that the reading level is still too high even when you don't count the long words, write in “plain language” or use “everyday” language that people are most likely to understand. For ideas on substituting easier words and phrases, take a look at the reference library found at www.plainlanguage.gov/howto/wordsuggestions/index.cfm

One of the best ways to see how a “plain language” approach can improve a document is to look at examples of documents before and after they were edited into plain language. For before and after examples go to: www.plainlanguage.gov/examples/before_after/index.cfm

2. Testing a document's readability level.

There are several ways to determine reading level. You can test a document's reading level by hand or by using computer software. Also, you can achieve consistency in your evaluations by using the same readability formulas through every draft stage. The Flesch-Kincaid Readability Test, the Fry Readability Graph, the Gunning 'FOG' Readability Test (FOG), and the Simple Measure of Gobbledygook Readability Formula (SMOG) are several good tools. See Appendix C for help in using them.

The best way to judge if your material will be understood is to pre-test it with a sample group from your audience

Several word processing software programs, including Microsoft Word® and Corel WordPerfect®, include reading level assessment capabilities. Plain language experts, however, do not consider these computer tests reliable or valid for readability analysis and recommend:

- free-standing software, including Readability Calculations* or Readability Plus* from Micro Power & Light (www.micropowerandlight.com)
- a website using SMOG formula: www.harrymclaughlin.com/SMOG.htm*
- additional tools are listed in Appendix C.

However, remember that readability tests are only one useful tool in assessing readability. The best way to judge if your material will be an effective communication tool is to pre-test it with a sample group from your intended audience.

Readability tests are only one useful tool for assessing readability of written materials.

Material testing and analysis are important considerations. For health communication efforts to succeed, learn what your audience knows or thinks about a subject, and anticipate how they may interpret new ideas. For example, by conducting usability testing focus groups or individual interviews with people from your intended audience before your first draft, you can gauge what they already understand about the topic. And you can test several possible approaches to presenting information. This testing should begin before you write the first word and continue until the final draft.

Find more information on how to conduct usability testing.

Most programs need more than one research method, including pre- and post-testing methods. Many of these methods are thoroughly described in Making Health Communication Programs Work, U.S. Department of Health and Human Services, and in Methodological Review: A Handbook for Excellence in Focus Group Research, M. Debus.

Usability testing is also defined by the Plain Language Association International at www.plainlanguagenetwork.org/plaintrain/Testing.html

* Note: Mention of the software products does not constitute an endorsement by the CDC

Appendix A: Checklist for Easy-to-Understand Print Materials

Message Content

- ☐ Have you limited your messages to three to four messages per document (or section)?
- ☐ Have you taken out information that is “nice to know” but not necessary?
- ☐ Is the most important information at the beginning of the document?
- ☐ Is it repeated at the end?
- ☐ Have you identified action steps or desired behaviors for your audience?
- ☐ Have you post-tested your materials?

Text Appearance

- ☐ Does your document have lots of white space? Are margins at least 1/2 inch?
- ☐ Is the print large enough (at least 12 points)? Does it have serifs?
- ☐ Have you used bold, italics, and text boxes to highlight information?
- ☐ Have you avoided using all capital letters?
- ☐ Is text justified on the left only?
- ☐ Did you use columns with a line length of 40 to 50 characters of space?
- ☐ Have you post-tested your materials?

Visuals

- ☐ Is the cover attractive to your intended audience? Does it include your main message and show who the audience is?
- ☐ Are your visuals simple and instructive rather than decorative?
- ☐ Do visuals help explain the messages found in the text?
- ☐ Are your visuals placed near related text? Do they include captions?

- ☐ If you read only the captions, would you learn the main points?
- ☐ Have you post-tested your materials?

Layout and Design

- ☐ Is information presented in an order that is logical to your audience?
- ☐ Is information chunked, using headings and subheadings? Do lists include bullets?
- ☐ Have you eliminated as much jargon and technical language as possible?
- ☐ Is technical or scientific language explained?
- ☐ Have you used concrete nouns, an active voice, and short words and sentences?
- ☐ Is the style conversational?
- ☐ Have you post-tested your materials?

Translation

- ☐ Are the language and content culturally appropriate?
- ☐ Are the visuals culturally appropriate?
- ☐ Have you had the piece back translated?
- ☐ Is the translator fluent in the same linguistic variation as the intended audience?
- ☐ Have you post-tested your materials?

Understandability

- ☐ Have you tested the complexity of the language used in your material for comprehension?
- ☐ Have you pre-tested your materials with members of your intended audience?
- ☐ Have you post-tested your materials with members of your intended audience?

Appendix C: Formulas for Calculating Readability

Using SMOG

Perhaps the quickest way to check a reading level manually is to use the SMOG estimating formula. G. Harry McLaughlin created SMOG (Simply Measure of Gobbledygook) in 1969 to estimate the years of education needed to understand a piece of writing.

Here's a quick way to estimate reading level.

- Simply count the number of words with three or more syllables in three chains of 10 sentences in different parts of your draft.
- Then look up the approximate grade level in this chart.
- The SMOG formula can predict the grade level difficulty within 1.5 grades in 68 percent of passages.

Total Polysyllabic Word Counts	Approximate Grade Level
0-2	4
3-6	5
7-12	6
13-20	7
21-30	8
31-42	9
43-56	10
57-72	11
73-90	12
91-110	college-level

Developed by Harold C. McGraw, Office of Educational Research, Baltimore County Schools, Towson, MD.

McLaughlin worked with programming expert Alain Trottier to produce a free SMOG calculator. The online calculator can service 30 to 2000 words at this link: www.harrymclaughlin.com/SMOG.htm.

Appendix C: Formulas for Calculating Readability (continued)

Using Fry Formula

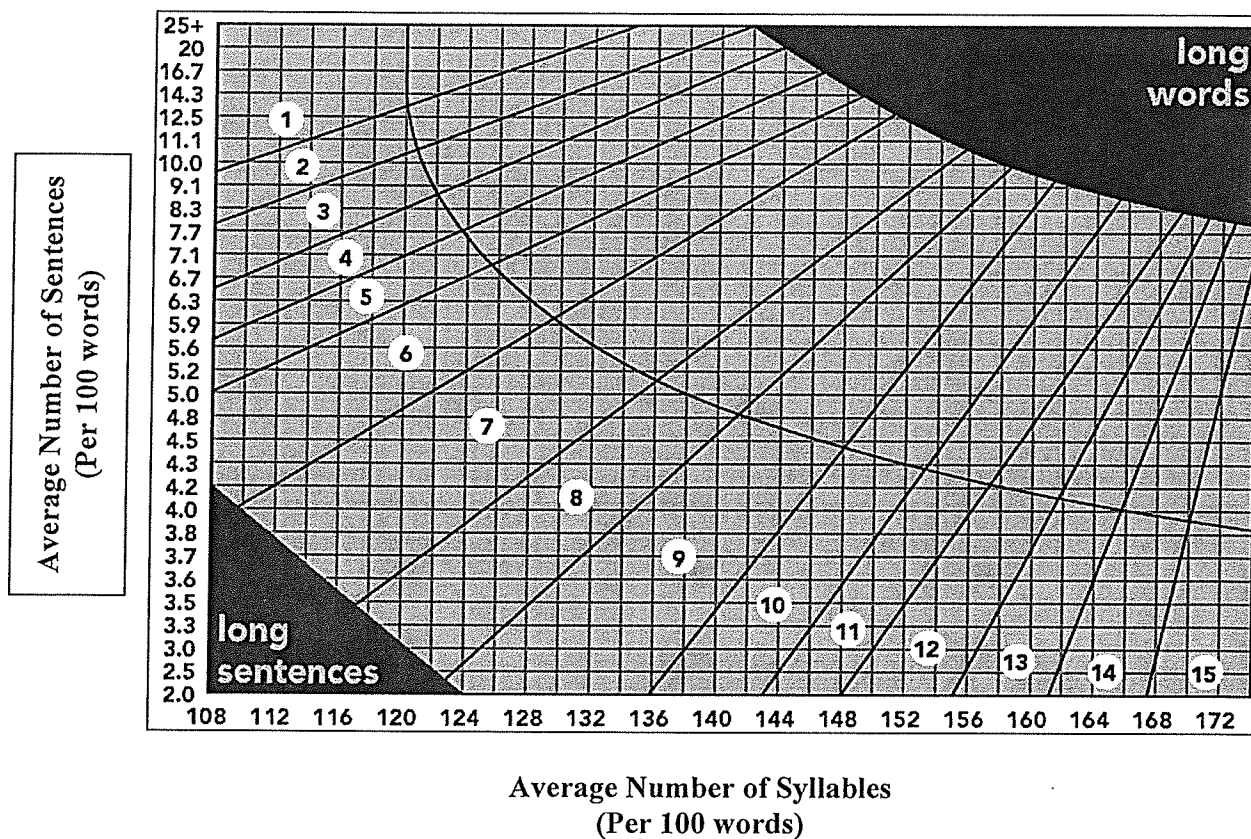
In 1977, Dr. Edward Fry created one of the most widely used readability formulas. Fry calculates the grade reading level by averaging the number of sentences and syllables per hundred words.

Steps for you to follow:

- Randomly choose three samples from your document with 100 words each.
- Count the number of sentences in the hundred words, estimating length of the fraction of the last sentence to the nearest 1/10th.
- Count the total number of syllables in the 100-word passage. Do not count numbers. Do count proper nouns. If you don't have a hand counter available, an easy way is to simply put a mark above every syllable after the first syllable in each word. Then, when you get to the end of the passage, count the number of marks and add 100 to include the first syllable in each word that you did not mark.
- Find the average number of sentences and the average number of syllables for the three samples by dividing the total of all three samples by three.
- Use the graph on the next page to plot the average sentence length and number of syllables. The two lines will intersect at the approximate grade level. If a great deal of variability is found, try putting more sample counts into the average

Appendix C: Formulas for Calculating Readability (continued)

Fry Graph* for Estimating Grade Levels



* From: Fry, Edward. Elementary Reading Instruction. 1977, McGraw-Hill

Appendix C: Formulas for Calculating Readability (continued)

Using Fry on Short Documents

When your document has fewer than 300 words, you can use an adaptation of the Fry method.

1. Count total words, total sentences, and total syllables for the entire text. (Note: hyphenated words count as one word.)
2. Do these calculations:
 - Multiply the number of sentences by 100 and divide by the total number of words. This will give you the average number of sentences per 100 words.
 - Multiply the number of syllables by 100 and divide by the number of total words. This will give you the average number of syllables per 100 words.
3. Plot the averages on the Fry graph to find the readability score.

Here is an example with fewer than 100 words.

Hepatitis A is a liver disease caused by the hepatitis A virus.

Hepatitis A can affect anyone in the United States. Hepatitis A can occur in situations ranging from isolated cases of disease to widespread epidemics.

Good personal hygiene and proper sanitation can help prevent hepatitis A. Vaccines are also available for long-term prevention of hepatitis A virus infection in persons 2 years of age and older. Immune globulin is available for short-term prevention of hepatitis A virus infection in all ages.

82 words

6 sentences

177 syllables

$$6 \times 100 = 600$$

$$600 / 82 = 7.3 \text{ average number of sentences}$$

$$177 \times 100 = 17,700$$

$$17,700 / 82 = 216 \text{ average number of syllables}$$

Plot the two averages on the chart on page 37.

Grade level is 17+.

Appendix C: Formulas for Calculating Readability (continued)

Here are two examples testing 100 words:

Planning a trip to Asia?



These tips will help you stay healthy on your trip.

Example 1:

Before Before You Go: Talk to Your Doctor

#1

4 sentences
154 syllables

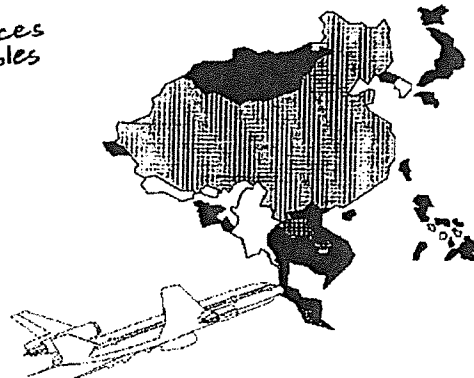


As soon as you start planning your trip, ask your doctor if you need any of these shots or medicines to avoid getting sick. *Even if you were born in Asia, you may still need these shots or medicines:*

- Immune Globulin or the vaccine to prevent Hepatitis A
- Booster shots of tetanus or polio vaccine
- Vaccines for Hepatitis B, Typhoid, Rabies, and Japanese B Encephalitis

Check that all your shots like measles, diphtheria, and rubella are up-to-date.

If you are pregnant, elderly, traveling with a small child, or have a chronic illness, your doctor may have special advice for you.



Example 2:

Prevent Illness from Food and Water

Follow these tips to avoid getting sick from food and water.

- Drink only bottled or boiled water or carbonated drinks.
- Eat only food that is completely cooked.
- Avoid dairy products unless you know they are pasteurized.
- Avoid shellfish and blowfish—these can contain toxins that may not be killed by cooking.
- Do not swim, wade, or wash in fresh water ponds, lakes, or rivers.
- Do not touch dirt or sand with your bare hands or feet.



#2

7.9 sentences
142 syllables

Traveler's Diarrhea: You can get sick from eating food or drinking water that has germs or parasites in it. This is called traveler's diarrhea or TD.

If you get TD, you should take Oral Rehydration Salts to replace lost fluids. You can buy them in food and drug stores almost anywhere in Asia. Most people can treat themselves with these salts, but

talk to a doctor if you:

- ✓ get bloody diarrhea, chills, or fever
- ✓ can't keep fluids down or become dehydrated
- ✓ are pregnant
- ✓ do not get better in 7 days
- ✓ want medicine to make you feel better

Warning: If your child gets TD, see a doctor right away.

Appendix C: Formulas for Calculating Readability (continued)

Using Lexile Readability Analyzer

Lexile Analyzer[®], produced by MetaMetrics[®], allows you to test the readability of your text by generating a Lexile[®] measure. (A free, limited version is available at www.Lexile.com.) The Analyzer measures sentence length and the familiarity of words used. Your word choice will be compared to word frequencies within a large database of literature.

The Lexile[®] measure is a text difficulty score followed by an “L”. The scale ranges from below 200L for beginning-reader material to above 1700L for advanced text.

Lexile [®] Value	Grade Level
300L	2 nd grade
400L	3 rd grade
1300L	12 th grade

Using PMOSE/IKIRSCH Document Readability Formula

Researchers Mosenthal and Kirsch developed a measure for assessing document complexity, called the PMOSE/ IKIRSCH document readability formula. The PMOSE/IKIRSCH formula measures complexity based on three factors:

- The structure of the document,
- The density of the information,
- The relative dependence on information from other documents.

This tool is particularly useful for documents that include forms, tables, graphs, charts, and lists. PMOSE/IKIRSCH measures the readability of information organized in rows and columns. The formula uses the number of rows and columns, the structure, and the number of labels and items to assess the chart or table. Scores range from Level 1 to Level 5 Proficiency. The Proficiency Level can be translated into a grade-level equivalent.

Proficiency	Grade Level	Equivalent
Level 1	Grade 4	>8 years of schooling
Level 2	Grade 8	to high school diploma
Level 3	Grade 12	some education after high school
Level 4	15 years of schooling	college degree equivalent
Level 5	16 years of schooling or more	advanced post college degree

The next page is the Mosenthal and Kirsch’s worksheet that you can apply to your text. Please note that the complexity of word choice is not a consideration in this tool.

Appendix C: Formulas for Calculating Readability (continued)

The PMOSE/IKIRSCH Document Readability Formula

Structure

Score 1 if *simple-list* structure.
Score 2 if *combined-list* structure.
(also includes *pie charts* and *time lines*).
Score 3 if *intersected-list* structure.
(also includes *bar charts* *line graphs* and *maps*).
Score 4 if *nested-list* structure.
(also includes *bar charts* and *line graphs* with *nested labels*).

Document Structure Score _____

Density

Labels Score 1 if 15 or fewer labels.
Score 2 if 16 to 25 labels.
Score 3 if 26 to 35 labels.
Score 4 if 36 to 46 labels.
Score 5 if more than 46 labels.

Number of Labels Score + _____

Score 1 if 75 or fewer items.
Score 2 if 76 to 125 items.
Score 3 if 126 to 175 items.
Score 4 if 176 to 225 items.
Score 5 if more than 225 items.

Number of Items Score + _____

Dependency

Add 1 if document makes reference to information in a related document or as a dependency.

Dependency Score ÷ _____

Total Score = _____

Document Complexity Level

(Circle total score below to determine a document's complexity level)

3 4 5	6 7 8	9 10 11	12 13 14	15
Very Low	Low	Moderate	High	Very High

Adapted from: Mosenthal, P. and Kirsch I. (1998). A New Measure for Assessing Document Complexity: The PMOSE/IKIRSCH Document Readability Formula. *Journal of Adolescent and Adult Literacy*, 41:8, pp 638-657

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Culture affects how people understand and respond to health messages. The best way to ensure that your materials are culturally appropriate is to engage members of the target audience early on in the communication planning phase. They can assist in identifying messages and images that are likely to work best within their culture.

1. Use terms that your audience uses and/or is comfortable with.

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If you need to identify a group of people by race or ethnicity, use a term preferred by that group. Preferred terms may vary even within an ethnic or racial group. Ask a sample audience.

The best way to make sure your materials are culturally appropriate is to talk with members of the audience you are trying to reach



For example: One group may want to be identified as “African American,” while another group may prefer to be identified as “Black.”

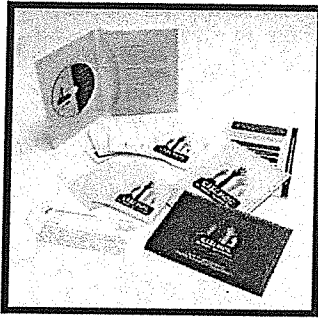
OR

One group may want to be identified as “Native American,” while another prefers “American Indian.”


2. Target messages to each cultural or ethnic group or subgroup.

Groups may have different needs, values, and beliefs that will affect how they interpret your message. Minority groups often have subgroups that differ greatly from one another. What is effective for one minority group or subgroup may not work at all for another.

Using culturally appropriate images, concepts, and language is not enough. Messages should always be tested with the intended audience.



Sabemos (Spanish for “we know”) is a bilingual, culturally appropriate toolkit developed by HHS/CDC to support the efforts of Hispanic parents and community leaders in protecting children from secondhand smoke. The kit was developed based on research acquired during focus groups with parents and leaders from the Hispanic community and key informant interviews. The findings from were used to develop key messages and tools for community leaders working with Hispanic/Latino populations.



TOOLKIT for Making Written Material Clear
and Effective

SECTION 2: Detailed guidelines for writing
and design

PART 4

Understanding and using the “Toolkit
Guidelines for Writing”

Chapter 3

Guidelines for writing style

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services



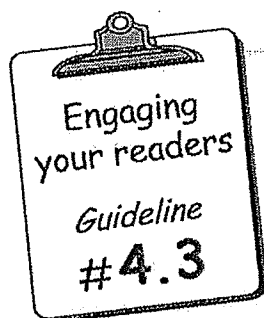
Source: The first two examples in this figure are adapted from work done by Christina Zarcadoolas, Penny Lane, Holly Smith Mirenda, and Mercedes Blanco as part of a project for the Centers for Medicare & Medicaid Services by the MAXIMUS Center for Health Literacy. The last two examples and the discussion of legal language that precedes this figure are reproduced with permission from *The Health Literacy Style Manual* (MAXIMUS, 2005:22). For information about the MAXIMUS Center for Health Literacy, visit <http://www.maximus.com/services/health/health-literacy>.

Use words that are culturally appropriate and respectful

To help readers relate to your material, use words, phrases, and examples that reflect their habits and cultural customs. Here are tips for choosing language that is respectful and culturally appropriate:

- To choose the most effective and culturally appropriate ways to get your messages across, rely on advice and feedback from members of your audience and key informants. They will help you identify and avoid any stereotyped portrayals. It's especially helpful to ask people who represent your intended readers to review your drafts.
- **Sometimes you may need to use more than one word to reflect the diversity or preferences of your intended readers.** For example, if you know that some of your readers use community clinics rather than private doctor's offices, say "doctor's office or clinic" in your materials. Getting feedback from your intended readers is crucial when you are unsure about which words to use. For example, should you say "Black" or "African American" or both? "Hispanic" or "Latino" or perhaps a name that is more specific, such as "Mexican" or "Puerto Rican"? One term or the other may be preferred for certain audiences or certain parts of the country, and even then, some people may disagree. Toolkit Part 11, *Understanding and using the Toolkit Guidelines for Translation*, discusses regional variations in terminology and gives examples.
- Be cautious about using slang expressions or figures of speech because they are likely to be culturally inappropriate for at least some of your readers. Slang expressions may undermine the tone of your material by sounding excessively familiar or even condescending. It is best to avoid them. When figures of speech are unfamiliar, they will frustrate or confuse readers who take them literally. For example, what if someone is unfamiliar with the expression "you'll feel better down the road," and tries to interpret it literally?
- **Use resources to learn more about culturally appropriate communication.** For suggested resources, see the end of Toolkit Part 2, *Using a reader-centered approach to writing and design*.

Are instructions specific and culturally appropriate?



When you give suggestions or instructions, make them specific, realistic, and culturally appropriate for your intended readers.

To keep people from feeling frustrated or discouraged, be sure that the behavior you are urging seems feasible to them. If you raise awareness of risks or problems, tell people what they can do about them.

Be specific

If your materials give vague instructions or advice, you put the burden on your readers to figure out what you mean and how they should apply what you have said. To encourage and guide your readers, be specific.

The book, *Teaching Patients with Low Literacy Skills* (Doak, Doak, & Root, 1996), provides examples and helpful advice on how to be specific in patient education materials. Their advice applies to administrative procedures as well. For example, suppose you are explaining Medicaid enrollment procedures to beneficiaries. Instead of saying, "bring proof of your income," tell them exactly what kind of documents they need to bring, and give examples (such as an illustration of a pay stub). The "Ask Me 3™" campaign is another example. It coaches patients on questions to ask when they go to the doctor.

Be realistic

To empower your readers, be *realistic* as well as specific in what you suggest or tell them they should do. Any behavior change or action you urge needs to be something that your readers may believe they can do. Asking them to do something they can't envision doing will discourage them and could even cause them to reject everything else you say.

Here are some tips about gearing your suggestions and advice to people's capabilities:

- **When something is hard to do, say so, and offer support.** You can acknowledge and reinforce people's good intentions. For example, you can tell smokers who are trying to quit to keep trying, and then offer reassurance about how most people need to make repeated attempts before they quit for good.
- **Offer options for transition to a new behavior.** For example, suppose your materials tell people how to reduce the amount of salt they eat. Readers will find the advice more palatable if you explain how to phase in their new eating habits rather than telling them to make all of the changes immediately. Materials that encourage physical activity might give guidelines for gradual increasing the amount of activity over a period of time.
- **Suggest compromises for behaviors that are highly resistant to change.** For example, suppose that your material explains how to reduce children's asthma attacks by controlling their exposure to pet dander. Even though their health would benefit, it's unrealistic, not to mention cold-hearted, to tell children they must give up a beloved pet. Instead, the material could suggest ways of reducing exposure such as keeping the pet out of the child's bedroom, and shampooing it regularly. It could also warn against getting new pets with dander.

Be cautious about messages based on fear

Health promotion materials often discuss health risks, hoping to make people feel vulnerable and therefore more receptive to changing their behavior. But this approach can backfire if the threat part of the message comes across more strongly than the healthy behavior solution (NCI, 2002). For example, readers might conclude that there's nothing they can do to prevent heart disease, cancer, or high blood pressure, and fatalistically continue their bad habits.

Here are two suggestions:

- **If you raise awareness of risks or problems, give people a way to follow-up.** For example, in material that warns about breast cancer, it's logical to include explicit instructions about self-examinations, as well as advising regular checkups and mammograms.
- **If you include messages based on fear, be sure to test them thoroughly** with members of your intended audience.

Be culturally appropriate

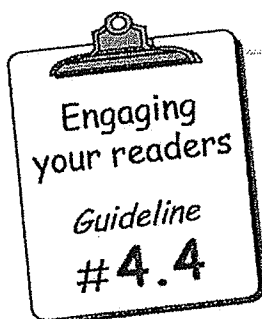
When you are urging particular behaviors, take into account the cultural and linguistic practices of your intended readers. When you give culturally appropriate suggestions, you make it easier for readers to relate to the material and understand what it means, and easier for them to act on what you have advised.

For example, materials that deal with nutrition should reflect the usual eating habits of the intended readers. Be aware of the diversity among your intended readers and make adaptations as needed so that they can easily relate to the material:

- **Food choices.** The food pyramid diagram typically includes a few examples of foods in each food group. Often, these pictures reflect a narrow definition of a western diet. To make a food pyramid culturally appropriate, you may need to expand the examples of foods that are pictured.
- **Cooking practices.** Material with dietary instructions for Hispanics/Latinos who have diabetes provides another example. Instead of telling them to eliminate cooking oil, which would run counter to typical cultural practices and might be unrealistic in any case, the materials advise cutting back on the amount of oil that is used to prepare foods (Health Promotion Council).

Besides making people more receptive, giving culturally appropriate instructions can help prevent medical error. To give just one example, instructions for taking a "teaspoon of medicine" need to take into account the possibility that Asian or Asian American households may have spoons that are much larger than a measuring teaspoon.

Do readers trust the information sources?



Base your material on information sources that your intended readers will trust.

To check on credibility of different sources, ask members of your intended audience and informants.

People tend to reject information that comes from a source they do not trust. Some information sources may have little credibility with your audience, while others will be viewed as quite trustworthy. For example, consumers tend to be skeptical when a health care organization describes its own quality of care. Studies suggest that consumers typically prefer to get information about health care quality from a neutral third party (McGee, Sofaer, & Kreling, 1996; Lubalin & Harris-Kojetin, 1999). For example, they are