Health Literacy Tips to Improve Patient Education and Informed Consent

Connie Arnold, PhD
Associate Professor of Medicine

Terry C. Davis, PhD
Professor of Medicine and Pediatrics

South Carolina Clinical & Translational Research Institute (SCTR)

MUSC

May 7, 2014
DISCLOSURE STATEMENT

Research funding:
- NIH, LA Clinical and Translational Science Center
- American Cancer Society
- American College of Physicians Foundation
- Agency for Healthcare Research and Quality

Stocks:
- Johnson & Johnson
- Abbott Laboratories
Exercise

What do good patient education materials and consent forms look like?

Hand out materials and judge and report.
When Evaluating Materials: Ask 7 Questions

1. Is title patient centered?
2. Is layout user-friendly?
3. Do illustrations tell the story?
4. Is key message clear, easy to pick out?
5. What is behavioral objective?
6. Is information manageable?
7. Is it culturally appropriate?
Common Problems with Health Information

- Organized using medical model not patient-centered
- Scientific/bureaucratic not personal/conversational
- Often too long, too much information
- Illustrations complex, confusing or “don’t look like me”
- Lack of attention to ‘tone,’ patient emotions & culture
- Lack of patient and provider input and evaluation
- Distribution and sustainability not thought out
  - How and when will patients get the information? Who gives it to them? When is teachable moment? Plan to update?
- Lack of awareness of what’s on Google/blogs
Hidden Problems With Videos

• Often too long (limit to 2-3 minutes)
• Too many “talking heads”
• Focus on disease not the patient
• Lack of attention to ‘tone’, patient emotions
• Who will show it? Where? Teachable moment

Little is known about efficacy of using multimedia tools over print media
Developing Health Information
Before You Begin...

• Identify intended audience and put yourself in their shoes

• What information do they need & want?

• What is your key message?

• What is your behavioral objective?

• How will your patients find, receive, & use the information.
Write Clearly - Create Meaningful Content

*Initial sentence - Vague, general concept:*

“It is important to get plenty of exercise in order to stay healthy.”

*Revised sentence - Specific, actionable*

“Walking 3 times a week for 10 to 20 minutes will help you stay healthy. It will also help you feel better and have more energy.”
Easy Ways to Improve Layout and Reading Ease

- White space “breathing room”
- At least 12-point font (Times New Roman, Arial)
- Avoid ALL CAPS, cutesy fonts
- Use headers, bullets, lists
- Write short, simple, direct sentences
- Use active (not passive) voice
- Break text into manageable chunks (“lump & clump”)
- One idea per short paragraph
  - Limit paragraph to 3-4 lines
Exercise: 
Write these statements in active voice

1. You will be asked to measure and record your weight every day.

2. A Medicaid application can be obtained by contacting your local County Department of Job and Family Services.
Try Your Hand At Writing Literacy-Friendly Handout
Streptococcal pharyngitis (strep throat)

Your doctor has diagnosed you as having streptococcal pharyngitis, or “strep throat.” Strep throat is caused by Group A beta hemolytic streptococcus, a common bacteria in the nose and throat that can cause sore throats (pharyngitis) and skin infections. Symptoms of strep throat include pain and redness in the throat, difficulty swallowing, fever, and swollen glands in the neck. Sometimes there is a rash going along with the sore throat, in which case patients are said to have “scarlet fever.” Strep throat occurs most commonly in children.

The symptoms of strep throat go away by themselves, even without treatment. Without treatment, however, a small percentage of patients with strep throat will develop rheumatic fever, a serious disease of the heart and heart valves. When patients get rheumatic fever, heart valves may be damaged and in the future, the patient may need open heart surgery to replace a heart valve. Although rheumatic fever is uncommon, in recent years there have been more cases reported.

The treatment for strep throat involves taking penicillin, an antibiotic that kills the streptococcus bacteria. The reason for treating strep throat is not to make the sore throat get better quicker. Rather, the reason for treating strep throat is to prevent the development of rheumatic fever. Treatment with penicillin for 10 days almost always prevents rheumatic fever. It is important that you take the penicillin for the full 10 days, even if you are feeling better before the medicine is used up. That’s because taking the penicillin for less than 10 days may not protect you against rheumatic fever. Patients allergic to penicillin can take on of several other medications.

Can You Limit ED Discharge Instructions?

(274 words, 10th gd.)
Treating Strep Throat:
One Option for Clear Instructions

• You have strep throat.

• You need to take penicillin.

• Take the medicine every day for 10 days – even if you feel better before then.

• Stopping the pills before 10 days can result in serious heart problems.

(38 words, 6th gd.)
Pictures Help Tell the Story

• Locate them next to relevant text
• Place captions under images
• Use color if possible - draws the eye and adds appeal

Image from http://www.umm.edu/patiented/articles/ecg_000172.htm
Pictures May Be Worth a Thousand Words, but Which Thousand?

Are pictures:

- Serving a purpose—not just decorative?
- Clear and realistic?
- Familiar and likely to be understood?
What Makes This Page User-Friendly?

- Title
- Bullets
- Short sentences
- 1 idea per paragraph
- Picture conveys message

There's No Place Like Home

Eating at home is better for you than eating out. Restaurants add more fat and sugar to meals than you would if you were cooking for yourself.

Try these ideas for eating at home:
- Sit down when you eat. When you eat standing up, you tend to eat more food, and not think about what you are eating.
- If you live with other people, eat together. Talking makes you slow down and feel full with less food.
- Leave the extra food in the kitchen. When the serving dishes are farther away, people tend to feel less hungry for seconds.
- Try not to cook fried foods. Save these for special occasions.
Design ‘Mock Up’

- Start with piece of paper
- Write patient-centered title
- Write main message at top
- Emphasize with visual
- What is the call to action?
- Visual appeal and “tone”?
- Culturally sensitive?
Templates Provide Useful Framework

- Uniform look, consistent message
- Makes development easier
- Easily reproducible
- Standard structure helps patients navigate the material
American College of Physician’s Patient Self-Management Guides:

A good model to engage people in their health

Guides focused on:

• Patient not disease
• ‘Need to know and do’

Help patients change health behavior:

• Increase knowledge and confidence managing disease
• Help patients solve self-care problems
Focus Is On Doing

• ‘You Can Do It’ checklist at end of each chapter

• Concrete examples of successful action plans

• Emphasis on small steps and patient choice
User Friendly Does Not Mean “Dumbed Down”

- Adults with high education and income still prefer brief, to-the-point materials.

- Most patients looking for “what I need to know and do”.

- Patients who want more detailed information appreciate links to websites.

- Web sites need to be user-friendly, easy to navigate and understand.

How to do the test

When you are ready to have a BM (poop), bring the test kit into the bathroom with you. You will do the test 2 times using 2 different BMs.

Do not do the test if you have:
- Hemorrhoids that are bleeding.
- Blood when you pee or see blood in the toilet.

Get things ready.
- Take any cleaners out of your toilet. Flush the toilet 2 times.

Use the bathroom.
- After your BM, wipe. Do not put the toilet paper in the toilet. Put it in the blue bag from your kit.

Start the test.
- Get the card, lift the tab where it says “sample 1”.
- Before you flush the toilet, gently wipe the brush over your poop for 5 seconds.
- Shake the brush lightly to remove any clumps.
Bottom Lines in Developing Materials

• Aim for <8th grade level. Limit information
• Focus on PATIENT’S need to know and **DO**.
• Use plain language – make it conversational
• Format for reading ease- include pictures
• Pilot test with target audience (pts & providers)

In practice:
  – *Use materials as teaching tools - point out key points*
  – *Use ‘teach back’ to confirm understanding*
What about consent?

- Clinical research is increasing - 2.3 million patients a year sign consent forms
- There is growing regulatory scrutiny (purpose of IRB’s and lawyers is compliance with regulations)
- Federal funding agencies concerned that patient comprehension is poor
- No template for easy to read material or standard method to assess comprehension.

Cohn E, J of Nursing Scholarship, 2007
Current Consent and HIPAA Documents
Bad news/Good news

Most NOT designed:
• to inform patients about the research in terms that they can understand
• facilitate discussion between the investigator and patient
• to assure comprehension
• include non-English speakers

Good news: can be modified/simplified more than commonly believed

AHRQ 2008
The Balance Challenge in writing consent forms: considering both IRB and Patients

- Identify IRB requirements – what are they looking for?
- What templates /standard wording is required?
  - What can be simplified?
- What is your key message?
- What information do patients need & want?
- Consider how their literacy, motivation, attention, and distractions may affect their comprehension.
What about your consent forms?

- Can patients read and understand them?
- Is the content meaningful to them?
- Do they help patients make a decision about whether or not to be in the study or the requirements for participation?
- Are they written in plain language?
- Are they formatted for reading ease?
- Do they have a manageable amount of information?

AHRQ, 2008
“This paper by its very length defends itself against being read”

- Winston Churchill

Would you or your patients read this?
Writing Tips to Improve Reading Ease

• Use plain language (limit jargon)
• Write short, simple, direct sentences
• Use active (not passive) voice
• Break text into manageable chunks (“lump & clump”)
• One idea per short paragraph
  – Limit paragraph to 3-4 lines
Unnecessary and complicated language. Long sentence

You have been selected as a possible participant in this study because you have a moderate to very-high risk pulmonary embolism, and it is not known if retrievable vena cava filters reduce mortality or reduce recurrence of nonfatal pulmonary embolism or if complications of vena cava filters outweigh the benefits in such patients.

Plain Language in a shorter sentence

You are invited to be in the study because you have had a pulmonary embolism (clot that goes from your legs to your lungs).
Plain Language = Understandable Language

**Unnecessary and complicated language**

In order to draw statistical conclusions about the study, data from your medical records may be shared among researchers and research staff involved in the study, both here at our hospital and with other members of the collaborative group.

vs.

**Plain Language, short sentence**

In order to get results about the study, your medical records may be shared among the research staff.
The goal of the tissue bank or repository is to support the LSUHSC-S Dept. of Surgery research in order to improve our understanding of those molecular factors that contribute to cancer and that may lead to prevention, early detection, and cure.

vs.

The goal of this research is to learn what makes cells turn into cancer.
<table>
<thead>
<tr>
<th>Words to watch</th>
<th>Plain Language Exercise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse events</td>
<td>Bad reaction</td>
</tr>
<tr>
<td>Alternative Procedure</td>
<td>Other choices</td>
</tr>
<tr>
<td>Authorize</td>
<td>Give your OK in writing</td>
</tr>
<tr>
<td>Benefit</td>
<td>Will being in this study help me in any way</td>
</tr>
<tr>
<td>Clinical trial</td>
<td>Research study</td>
</tr>
<tr>
<td>Determine</td>
<td>Decide, find out</td>
</tr>
<tr>
<td>Notify</td>
<td>Tell us</td>
</tr>
<tr>
<td>Participate</td>
<td>Join</td>
</tr>
<tr>
<td>Randomized</td>
<td>Selected by chance</td>
</tr>
<tr>
<td>Voluntary participation</td>
<td>It is your choice to be in this study</td>
</tr>
</tbody>
</table>

http://firstclinical.com/glossary/
Writing Tips to Improve Reading Ease

• Use plain language (limit jargon)
• Write short, simple, direct sentences
• Use active (not passive) voice
• Break text into manageable chunks (“lump & clump”)
• One idea per short paragraph
  – Limit paragraph to 3-4 lines
Active Voice

• The medicine should be taken at 10 am everyday. (Passive Voice)

• Take your medicine at 10 am everyday. (Active voice)
Exercise:
Write these statements in active voice

1. You will be asked to measure and record your weight every day.

2. A Medicaid application can be obtained by contacting your local County Department of Job and Family Services.
Paragraphs:
Limit length. One idea per paragraph.

Too much (9 lines):
You are being asked to take part in this study because you have prostate cancer that is only partially responding to hormone therapy. Abiraterone acetate is a hormonal tablet that has been approved by the Food and Drug Administration (FDA) for more advanced prostate cancer patients who have received chemotherapy. It is considered investigational for your type of prostate cancer. We will be looking to see if abiraterone acetate improved the effectiveness of standard hormonal shots or injections. (The prostate specific antigen (PSA) is a blood test used in prostate cancer screening and also to follow prostate cancer. In this study, we will follow your PSA level to help determine if abiraterone acetate is beneficial. The main goal of this study is to see if abiraterone acetate with prednisone reduces PSA.

Appropriate (3 lines):
You are being asked to take part in this study because you have prostate cancer. Researchers at X hope to learn if a hormonal tablet (abiraterone acetate) is helpful with prostate cancer. The effect of the prostate cancer will be measured by a blood test (prostatic specific antigen or PSA).
Purpose of Study:

This is a research study. You are being asked to participate in this study because you have chronic obstructive pulmonary disease (COPD). One of the main problems with COPD is that it causes people to be short of breath with exercise. It also is a disorder that causes increased inflammation in the body. The treatments of COPD are relatively limited, and new medications are needed to improve the ability to exercise. Inhaled iloprost is an inhaled nebulized (a medication delivered through a mist into the lungs) medicine Federal Drug Association (FDA)-approved for the treatment of pulmonary arterial hypertension (high blood pressure in the lungs). It is not approved for use in COPD, and its use in these patients should be considered experimental. Using inhaled iloprost may reduce the volumes of air in your lungs during exercise, which may help you breathe better. It may also reduce the amount of inflammation in the body.

11th grade level
• **This is a research study.** You are being asked to take part because you have COPD (chronic obstructive pulmonary disease).

• There are not many ways to treat COPD. New medicines are needed to improve patients’ ability to breathe better especially during exercise.

• This study will test a new medicine (inhaled iloprost) to help you breathe easier. It is a mist which you breathe in (inhale) using an inhaler (nebulizer).

• The FDA has said it is ok (approved) to use with patients with high blood pressure in the lungs. The FDA has not said it is ok (approved) for COPD.

• It is being tested because it may help you breathe easier.
Check the reading level

• Aim for $\leq 8^{\text{th}}$ grade
• Average education level of US adults $\geq 12^{\text{th}}$ grade yet average reading level is $\sim 8^{\text{th}}$ grade

But... remember reading level is the tip of the iceberg in developing good materials
Readability Statistics on Microsoft 2007 & 2010
• Go to File Tab; select Options
• Click on Proofing
• Check “Show Readability Statistics”
• Go to Review Tab
• Select Spelling & Grammar
• Readability Results will show after spelling has been checked
Lexile –

Easy Internet Program to calculate reading Level

www.lexile.com

• Scores based on sentence length and word frequency in popular literature

• Scores range from 0 (beginner level) to 2000 (higher values indicate higher reading difficulty. Aim for <900

• Save text as Plain Text file
  
  Go to www.lexile.com
  Click on Lexile Analyzer
  Upload file and press analyze

Values can be easily translated to reading grade levels.

Lexile Value of 300 → 2nd grade
Lexile Value of 400 → 4th grade
Lexile Value of 1300 → 12th grade
Clean Layout Improves Reading Ease

- White space
- Bullets, lists
- Bolding
- Simple headers
- Short Sentences

What else do I need to know?

- Some side effects will stop when you finish treatment.
  - Your hair will grow back.
  - Your stomach won't be upset.

Some side effects might last forever.

- You must not get pregnant while you are getting treatment.
- You must not take birth control pills.
- If your treatment does not work, your doctor may change it.

There is a very small chance that a side effect could cause death.

What good can come of this?

- If your treatment works, it may:
  - Keep your cancer from coming back.
  - Make it a longer time before your cancer comes back.
  - Give you a longer life.
  - Help you to feel better.
Which page are you more likely to read?

**Definition of Consent Form**

This consent form gives detailed information about the research study which you will be able to discuss with your doctor. It is not meant to frighten or alarm you; it is an effort to make you better informed in order for you to make a decision as to whether or not you wish to participate. This process is known as informed consent.

This is a research study. A research study includes only patients who choose to take part. Please take time to make your decision. However, before you agree to take part, you must understand the statements in this informed consent document. After that, please ask all the questions you want, especially to help you understand completely what will happen if you take part in this study. You will be told of any important new information about the antibiotics used in this study which could change your decision to take part in this study.

Your doctor has diagnosed you with a skin infection. Skin infections happen when your skin is infected with germs called bacteria. Symptoms of a skin infection may include discharge (“pus”) from the skin, warmth, pain, tenderness, redness, swelling, and/or fever. The standard treatment for many skin infections is antibiotic drugs.

*Therefore, you should immediately inform the study doctor or staff if you have a history of allergies or problems when taking any antibiotics or other medications.*

Your doctor has decided that you must stay in the hospital for several days to receive antibiotics by vein to treat your infection. The antibiotics used to treat skin infections in this study must be given into your vein.

**What else do I need to know?**

- Some side effects will stop when you finish treatment.
  - Your hair will grow back.
  - Your stomach won't be upset.
  - Some side effects might last forever.
- You must not get pregnant while you are getting treatment.
- You must not take birth control pills.
- If your treatment does not work, your doctor may change it.
- There is a very small chance that a side effect could cause death.

**What good can come of this?**

- If your treatment works, it may:
  - Keep your cancer from coming back.
  - Make it a longer time before your cancer comes back.
  - Give you a longer life.
  - Help you to feel better.
Bullets, lists and Less Text

Monitoring Board. If there appears to be a clear advantage of filters plus anticoagulants or anticoagulants without filters, or if there appears to be an unwarranted risk from filters, the study will be discontinued. Unless that happens, results of the investigation will not be known by participating physicians or patients until 5 years after the beginning of the investigation. At that time, results will be published, which usually takes another year. You will not be identified in the publication. We will furnish you with a copy of the publication if you ask for a copy when they become available.

4. POTENTIAL BENEFITS:
The potential benefits to you for taking part in this study are that if randomly selected to receive a retrievable venous valve filter in addition to anticoagulants, the filter may have your life by preventing a recurrent pulmonary embolism, or it may prevent a recurrent nonfatal pulmonary embolism, which could have damaging effects. On the other hand, if randomly selected to receive anticoagulants without a filter, it may be that mortality and the incidence of nonfatal pulmonary embolism are the same as in the patients who received filters, and you would be spared the risks of complications of filters and the discomfort of filter insertion and retrieval.

In addition to the possible direct benefit to you, your participation in this study may contribute to the understanding of whether retrievable venous valve filters should be routinely inserted in patients with moderate to very-high risk pulmonary embolism. If the risk reduction of the combination of death or recurrent nonfatal pulmonary embolism is lowered from 25% to 15.6%, the number of patients with pulmonary embolism who die or suffer nonfatal recurrence in one year would decrease in United States from 26,480 to 20,650. Therefore, 5,800 patients yearly in United States would benefit from a reduced mortality or reduced illness from nonfatal recurrence of pulmonary embolism.

5. POTENTIAL RISKS
Pulmonary embolism carries risks. The usual symptom is shortness of breath that can occur at rest or during exertion. In most patients, the clot in the arteries of the lung dissolve by natural processes, and the patients recover fully. In some patients, however, some or most of the clots in the arteries of the lung fail to dissolve. Such patients may continue suffering shortness of breath at rest or during exertion. Some patients suffer a recurrence of pulmonary embolism despite treatment with anticoagulants (blood thinners) and despite treatment with thrombolytic agents (clot-dissolving drugs). Recurrences of pulmonary embolism can cause further shortness of breath which may or may not resolve, depending on the extent to which the clots in the arteries of the lung dissolve by natural processes or by thrombolytic drugs (clot-dissolving drugs). Clots in the arteries of the lung that fail to dissolve may lead to high blood pressure in the pulmonary arteries. This could lead to heart failure or death. If pulmonary embolism is massive (large clots in major branches of the arteries of the lung), the patient could die from the effects of the clots. In this investigation we will determine if retrievable venous valve filters reduce the incidence of recurrent nonfatal or fatal pulmonary embolism, and we will determine the risks of such retrievable venous valve filters.

The potential risks of participating in this study relate to complications of retrievable venous valve filters. Risks also relate to failure to insert filters in those who may need them. There is insufficient evidence for and against filters.

What is informed consent?
- It is an agreement to take part in a study.
- The research staff will help you with this consent form.
- It gives you facts about the research study so you can decide if you want to take part or not.
- The form will explain the study, tests or procedures you may receive and the benefits and risks.
- It also tells you your rights as a research volunteer.

Why are you being invited to take part in a research study?
- You are invited to be in the study because you have had a pulmonary embolism (clot that goes from your legs to your lungs).

What are your rights?
- You can choose whether you want to be in the study or not.
- You can ask all the questions you want. Feel free to ask the research staff to explain the study to help you decide if you want to participate.
- If you choose not to be in the study you will not be penalized. It will not affect your health care.
- You can agree to be in the study and then change your mind later.
- After the study begins, we will give you any new information that we learn about the research. Then you can decide if you want to continue being in the study.

Why is this research being done?
- There are new metal basket-like filters that can be put in your veins that may help prevent another pulmonary embolism.
- We do not know if these metal filters can help people like you.
- Everyone in the study will be given blood thinners just like they would if they were not in the study.
- This study is looking to see whether people with a higher risk of pulmonary embolism who are given a metal filter in addition to blood thinners do better, worse, or the same as people who just get treated with blood thinners.

How long will the research last?
- We expect you will be in this study for about 6 months. The research project is expected to last 5 years.
Misuse vs. Proper Use of Bullets

The results of this study will be published and presented at professional meetings, but the identities of all research participants will remain anonymous.

7. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW
   - Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
   - You have the right to say no.
   - You may change your mind at any time and withdraw.
   - You may choose not to answer specific questions or to stop participating at any time.
   - Choosing not to participate or withdrawing from this study will not make any difference in the quality of any treatment you may receive.
   - Whether you choose to participate or not will have no effect on your evaluation or medical care.
   - You will be told of any significant findings that develop during the course of the study that may influence your willingness to continue to participate in the research.
   - If you decide to withdraw from the investigation, you should continue treatment with anticoagulants until your physician indicates that they can be safely discontinued. If you were randomly selected for a rare event filter, your physician should remove it as soon as known that the risks of recurrent pulmonary embolism are low. Failure to continue anticoagulants could result in a recurrent pulmonary embolism and death. Failure to appropriately remove the filter could lead to clotting of the filter resulting in severe swelling of the legs. Other complications of filters might occur (see section on potential risks), and such complications could be avoided by removal of the filter at the appropriate time.
   - Treating physicians may decide, based on your clinical course, that you will benefit from a filter. In that event, you will be removed from the study and managed by a physician (outside the study) as necessary.

8. COSTS AND COMPENSATION FOR BEING IN THE STUDY
   - Routine costs of this clinical trial will be billed to you or to your health insurance company in the usual way. However, some health insurance plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for.
   - Taking part in this study may or may not cost you or your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the costs.

   You will not receive money or any other form of compensation for participating in this study.

9. THE RIGHT TO GET HELP IF INJURED
   - If you are injured as a result of your participation in this research project, (INSERT NAME OF INSTITUTION) will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs

Risks of x-ray contrast
   - When the radiologist puts the filter in and takes it out he will inject a dye (radiographic contrast material) to see the vein. Allergic reactions to the dye are rare (less than 1 out of 100 times).
   - If you have kidney disease, the dye could damage your kidneys. We will do blood tests to check your kidneys before giving you the dye.

Risks of local anesthetic (numbing medicine)
   - The radiologist will give you a shot of numbing medicine when he puts the filter in and takes it out.
   - The risks of this medicine are numbness or tingling and nerve damage.
   - Allergic reactions could result in death. This is rare.

Risks of sedation
   - When the filter is being put in your vein or taken out, the radiologist may give you a medication to make you less anxious. It is possible to become too sedated and stop breathing. If this happens you would be put on the ventilator in the intensive care unit, or even die. This is rare.
   - Allergic reactions to the medicines could result in death. These are very rare.

What are the costs of being in the study?
   - Since this study is comparing two treatments that are “usual care” for patients who have had a pulmonary embolism, we will bill your health insurance for costs of usual medical care.
   - We will help you check with your health plan or insurance company to find out if they will cover the costs. Any deductibles or other costs that are not paid by your insurance will be your responsibility.
   - If you do not have insurance and are unable to pay for the care you received in this study, we will cover the costs for putting the filter in and taking it out.
   - Under Medicare rules, we cannot pay costs unless you qualify for “indigent care.”
   - Please talk with Dr. Walter for more information about your particular situation.
   - Being in this study may lead to additional costs to you or your insurance company. Please ask about any added costs or potential insurance problems.

What are the benefits of taking part in this research? Will being in this study help you in any way?
   - We cannot promise any benefits to you or others for being in this study.
   - If you are chosen to get a filter, it may reduce your risk of getting another pulmonary embolism.
Develop Content from patient ‘s perspective

- Use conversational tone
- Get to the point
- Make key messages easy to pick up
- Focus on need to know and do vs. nice to know
- Use pictures to help convey message
- Get patient and provider input
Is Tone Bureaucratic or Patient-Centered?

Does the document:

• Focus on study or consider the patient

• Is it conversational, respectful?

• Address the reader – use personal pronouns

**Good Example**

We are asking you to be in a research study.

You do not have to be in the study.

You can quit at any time.

Your choice will not change your medical care in any way.

Please take as much time as you need to make your choice.

**Bad Example**

DE**FINITION OF CONSENT FORM**

This consent form gives detailed information about the research study which you will be able to discuss with your doctor. It is not meant to frighten or alarm you, it is an effort to make you better informed in order for you to make a decision as to whether or not you wish to participate. This process is known as informed consent. This is a research study. A research study includes only patients who choose to take part. Please take time to make your decision.
Don’t forget about Numeracy

Percentages and probability are challenging for many

- Approximately **half** of U.S adults are unable to calculate a tip.
- **20%** of college-educated adults **don’t** know what is a higher risk – 1%, 5%, or 10%

Ways to Encourage Clearer Understanding

Provide numeric likelihoods of risks and benefits.

– Describing risks solely with words such as, “You have a low chance of experiencing a side effect” has been proven ineffective.

– Patients vary in their interpretation of what low and high risk are.

– Individuals with lower numeracy skills should be given numbers that are accessible to them.
Provide absolute risks, not just relative risks.

- Drug X could reduce your risk of breast cancer by 50%? *(Relative risk presentation)*
- Drug X could reduce your 5-year risk from 4% to 2%? *(Absolute risk presentation)*

Drug has same effect in both cases, but in first description it sounds much better.

Controversy about Absolute vs. Relative Risk

- Changes in risk appear larger when presented using relative vs. absolute.*

- Relative risk can inappropriately lead patients to believe treatment is more effective than it is.*

- Physicians more likely to recommend treatment if information presented using relative risk.**


More ways to help patients understand the numbers

Keep denominators constant for comparisons.
– It is difficult for patients to compare across treatments when different denominators are used (e.g., 1 in 1000 vs. 1 in 500)

Keep time frames constant.
– Use the same time frame when presenting risks and benefits.
Use pictographs and other visual aids when possible.

- Pictographs have been shown to be the best graph for communicating both gist and verbatim knowledge.
- BUT in our recent research subjects with low literacy more easily understood pie graphs.
Ways to Help with Better Numeracy Understanding cont...

Provide both positive and negative frames.

– People with less numeracy skills are more influenced when a treatment is described in positive or negative terms. Try to use both – “60% of men who have surgery to treat prostate cancer will be impotent. This means 40% of men will not.

Be careful how you interpret the meaning of important information.

– Describing information in terms of goodness or badness can affect people’s risk perceptions.
Developing User-Friendly Consent Forms

- It’s not rocket science, but harder and more tedious than it seems.
- User friendly does not mean ‘dumbed down.’
- Patients with high education and income still prefer brief, simple, easy to read materials.
Steps to Improve Consent Process

- Prepare and allow sufficient time for session.
- Slow down and connect with patient
- Communicate using everyday language and conversational tone
- “Walk” patient though the form
- Arrange quiet, private non-cluttered space (let patient include who they wish)
- Verify and document comprehension

AHRQ, 2008
Prepare for consenting process

• **Schedule time** to clearly understand study and be able to communicate it in a conversational, relaxed manner.

• **Practice** – role play with your P.I. and team. Get feedback to improve communication.

• Pair with team member to consent several patients. The partner is there as a help - adding missing points and later giving private feedback.

• Prepare a flip chart to aid discussion (pictures?)

AHRQ, 2008
Communication is key

- Take a few minutes to **connect** with your patient.
- **Slow down** – allow enough time
- Speak in **conversational** manner – use plain language and friendly voice tone.
- Avoid bureaucratic, stuffy approach.
- **Use document** to point out key messages.
- Consider what your words and body language might be signaling.

AHRQ, 2008
Tell me in your own words

- **Goal of the Research and Protocol**
  - “Why are we doing this research?” “What is the study about?”
  - “What will you be doing if you agree to be in this study?”

- **Benefits and Compensation**
  - “Will being in this study help you in any way?”

- **Risks**
  - “Is there anyway being in this study will be bad for you or hurt you?”

- **Voluntariness**
  - “Can you decide you do not want to be in the study?”
  - “Will that change your healthcare?”

AHRQ, 2008
Teach Back is Effective

• Discontinuing Participation
  – “What should you do if you change your mind?”
  – “What will happen to information we have gotten if you change your mind?”

• Privacy
  – “Who will be able to see the information you give us?”

• Contact Information
  – “What should you do if you have any questions or concerns about this study?”

Allow the subjects to consult the document when answering the questions. The purpose is to check comprehension, not memory.
Verify and Document

• Correct misinformation

  – Subjects not able to comprehend study protocol, despite repeated attempts to explain the details, should not be enrolled.

  – Document completion of teach-back process on consent & authorization certification form.

AHRQ, 2008; *See handout
Pushback

• Legal clauses protect institution against lawsuits.
  – Making informed documents incomprehensible does not afford protection against lawsuits.*
  – There has been no successful case against researchers because the consent form did not use technical language.

• Regulations require technical terms.
  – Regulations support the use of plain language.

• It will take too long to verify comprehension.
  – Assessing comprehension can identify subjects who need further instruction or will not be able to participate.

*Diaz vs. Hillsborough County Hospital Authority, 2000
$3.8 M class action – failure of consent, form too complicated
Tips on working effectively with IRB and HRPP

- Realize that they also want effective forms and improved patient comprehension.

- Ask for help when unclear – the IRB is not the enemy. Develop friendly, working relationships with staff.

- Realize that some wording will be required by the IRB and some things cannot be changed. There is no point in arguing.

- Any changes you make to survey instruments, protocol, or materials must be resubmitted to the IRB every time there is a change.
More Tips on working with IRB and HRPP

• Know the rules on reporting Adverse Events.

• Stay on top of your paperwork, check on a regular basis consent forms, HIPAA, surveys – does everything match up.

• Security is the name of the game. Password protected, encrypted data. Where are you storing hard copies? How are you sending electronic data?

• As the PI you are responsible for everything that goes on with your study.
Bottom lines for consent

Allow sufficient time to fine tune form and prepare for the process

Consent Document
• Aim for < 8th grade. Write & format for reading ease
• Limit jargon – use consistent terms
• Pilot test with a few patients

Consent Process
• Connect with the patient and make it conversational
  Use teach back to confirm understanding
• Remember that participation is the patient’s choice
Consultation

Department of Medicine and Pediatrics
LSU Health Shreveport

Terry Davis, PhD
TDavis1@lsuhsc.edu
(318)675-8694

Connie Arnold, PhD
Carnol@lsuhsc.edu
(318)675-4324
Resources
Templates and Terms


Patient Education Development

**CDC (2013) Clear Communication Index**

[www.cdc.gov/healthcommunication/ClearCommunicationIndex](http://www.cdc.gov/healthcommunication/ClearCommunicationIndex)


**CMS (2011) Toolkit for making written materials clear and effective**

Evaluation of Reading Level for Written Materials

• Flesch Kincaid Reading Level and Flesch Reading Ease:
  – Automatically bundled with Microsoft Word
  – Tests sentence complexity

• Vocabulary Profiler:
  – Helps determine uncommon words
  – Very useful for non-native English speakers
  – ex: http://www.sfu.ca/~msevier/WebVocabularyProfilerCS.htm

• Lexile Level
  – Analyzes both sentence complexity and word frequency
  – http://www.lexile.com/analyzer/

• Fry Readability Formula
  – Randomly select three separate 100 word passages
  – Count the number of sentences in each 100 word sample to the nearest tenth
  – Count the number of syllables in each 100 word sample
  – Plot the average sentence length and the average number of syllables on a Fry Graph to determine the grade level
The “SMOG” Readability Test
(Short Version)

For materials containing > 30 sentences:
1. Count off 10 consecutive sentences at the beginning, middle, and end of the text.
2. Count the number of words with 3 or more syllables in the 30-sentence sample.
   Answer:
3. Use the answer to step 2 to look up the reading grade level in the chart.

For materials containing < 30 sentences:
1. Count the number of sentences: ________
2. Count the number of words with 3 or more syllables in the sample: ________
3. Divide the number of sentences in the sample into 30 (i.e., 30/25) and multiply this number by
   the number of words from step 2.
   Answer: ________
4. Use the answer to step 3 to look up the reading grade level in the chart.

Note:
- A sentence is defined as a string of words punctuated with a period, exclamation point, or question mark.
- Hyphenated words are considered one word.
- Numbers should be considered as if they were written out (i.e., both “22” and “two twenty-five” should be
  considered to have 3 or more syllables).
- Proper nouns should be considered.
- Abbreviations should be considered in their unabbreviated form.

“SMOG” Conversion Chart

<table>
<thead>
<tr>
<th>Number of words with 3 or more syllables in a 30 sentence sample</th>
<th>Approximate Reading Grade Level (plus or minus 1.5 grades)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 3</td>
<td>4</td>
</tr>
<tr>
<td>4 - 6</td>
<td>5</td>
</tr>
<tr>
<td>7 - 12</td>
<td>6</td>
</tr>
<tr>
<td>13 - 20</td>
<td>7</td>
</tr>
<tr>
<td>21 - 30</td>
<td>8</td>
</tr>
<tr>
<td>31 - 42</td>
<td>9</td>
</tr>
<tr>
<td>43 - 55</td>
<td>10</td>
</tr>
<tr>
<td>56 - 72</td>
<td>11</td>
</tr>
<tr>
<td>73 - 99</td>
<td>12</td>
</tr>
<tr>
<td>99 - 110</td>
<td>13</td>
</tr>
<tr>
<td>111 - 123</td>
<td>14</td>
</tr>
<tr>
<td>124 - 136</td>
<td>15</td>
</tr>
<tr>
<td>137 - 152</td>
<td>16</td>
</tr>
</tbody>
</table>

Reading level of this material: ________ Grade (plus or minus 1.5 grades)

http://prevention.sph.sc.edu/tools/SMOG.pdf
A Fun Way for Spotting Difficult Words

www.lextutor.ca/vp/eng

- Vocabulary Profiler color codes words in English
- 1000 most frequently used words (Blue)
- Second 1000 frequently used words (Green)
- Academic words frequently used in academic texts (Yellow)
- Less frequently used words which are not found on the other lists (Red)
Researchers at hope to learn if adding at targeted therapy trastuzumab herceptin to standard treatment with chemotherapy for early stage hernumber low breast cancer from returning tastuzumab is called a targeted therapy because it targets the tumor cells by blocking the hernumber protein on the surface of the cancer cell to slow down or stop cancer growth. Trastuzumab is a standard treatment for hernumber positive breast cancer. In this study, trastuzumab is considered to be investigational because it has not been studied for use in treating hernumber low breast cancer. Studies that already have been done with trastuzumab focused on breast cancers that were strongly hernumber positive; however, in some of these studies, tumor samples were checked in a central laboratory to confirm the hernumber testing results. Some breast cancers that were thought to be hernumber positive were actually hernumber low. The researchers then looked at the results of treatment in patients with hernumber low tumors. They found that trastuzumab seemed to have benefit in keeping the cancer from returning even when the hernumber levels were in the normal range. The number study is being done to learn more about trastuzumab or treat hernumber low breast cancer.
Checklists to Evaluate User-Friendliness (Suitability)


# Suitability Assessment (SAM)*

<table>
<thead>
<tr>
<th>Content</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Purpose is evident</td>
<td>_____</td>
</tr>
<tr>
<td>b) Content about behaviors</td>
<td>_____</td>
</tr>
<tr>
<td>c) Scope is limited</td>
<td>_____</td>
</tr>
<tr>
<td>d) Summary or review included</td>
<td>_____</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Literacy Demand</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Reading grade level</td>
<td>_____</td>
</tr>
<tr>
<td>b) Writing style, active voice</td>
<td>_____</td>
</tr>
<tr>
<td>c) Vocabulary uses common words</td>
<td>_____</td>
</tr>
<tr>
<td>d) Context is given first</td>
<td>_____</td>
</tr>
<tr>
<td>e) Learning aids via “road signs”</td>
<td>_____</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Graphics</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cover graphics show purpose</td>
<td>_____</td>
</tr>
<tr>
<td>b) Type of graphics</td>
<td>_____</td>
</tr>
<tr>
<td>c) Relevance of illustrations</td>
<td>_____</td>
</tr>
<tr>
<td>d) List, tables, etc explained</td>
<td>_____</td>
</tr>
<tr>
<td>e) Captions used for graphics</td>
<td>_____</td>
</tr>
</tbody>
</table>

*Doak, 1996
### Suitability Assessment (SAM)*

<table>
<thead>
<tr>
<th>Score each 0 – 2:</th>
<th>Total SAM score:</th>
<th>Total Possible score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 if not suitable, 1 if ok,</td>
<td>2 if superior, N/A</td>
<td>Percent score:</td>
</tr>
</tbody>
</table>

### 4. Layout and Typography

<table>
<thead>
<tr>
<th>Score</th>
<th>a) Layout factors</th>
<th>b) Typography</th>
<th>c) Subheads</th>
</tr>
</thead>
<tbody>
<tr>
<td>_____</td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
</tr>
</tbody>
</table>

### 5. Learning Stimulation, Motivation

<table>
<thead>
<tr>
<th>Score</th>
<th>a) Interaction used</th>
<th>b) Behaviors are modeled and specific</th>
<th>c) Motivation – self efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>_____</td>
<td>_____</td>
<td>_____</td>
<td>_____</td>
</tr>
</tbody>
</table>

### 3. Cultural Appropriateness

<table>
<thead>
<tr>
<th>Score</th>
<th>a) Match in logic, language, experience</th>
<th>b) Cultural image and examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>_____</td>
<td>_____</td>
<td>_____</td>
</tr>
</tbody>
</table>

---

*Doak, 1996*
Other Helpful Materials

• Doak CC, Doak LG, Root JH. *Teaching Patients With Low Literacy Skills*, 2nd ed., 1996