Strategies To Make Informed Consent Understandable

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2009
Health Literacy
Gaining National Attention

IOM (2004)

- **90 million** adults have trouble understanding and acting on health information
- Complex text must be simplified and attention paid to language
- Providers need health literacy training

Healthy People 2010

- Objective 11-2: Improve health communication/health literacy

JCAHO (2007)

- “What Did the Doctor Say?”: Improving Health Literacy to Protect Patient Safety (2007)
“Public health emphasis is on getting information ‘out’ to people not whether it has been understood and used.”

“Health care professionals do not recognize that patients do not understand the health information we are trying to communicate.”

Dr. Richard Carmona, U.S. Surgeon General

Mentioned health literacy in 200 of last 260 speeches
What’s The Problem?

Patients’ Education, Literacy, Language
Unnecessarily Complex Health Information
LA high school drop out rate is 47%

Problems Are Not Going Away
Low Literacy Rates By Parish

% Adults with Level 1 Literacy Skills

- > 30%
- 20% to 30%
- 15% to 20%
- < 15%

U.S. Department of Education
Who Has Low Literacy?

Medicaid recipients 43%
(over 1/3 births)

Medicare recipients 44%

Patients w/ chronic disease 44%

Low literacy LINKED to:
• Poorer health
• Less use preventive care
• Poorer control of chronic disease
• Lower quality care
• Medical errors
• Poor outcomes
• Disparities

AHRQ Evidence Report 2004
U.S. Dept. of Education 1993
What is it Like?

• These instructions simulates what a reader with low literacy sees on the printed page
• Read instructions out loud.
• You have 1 minute to read.
• Hint: The words are written backwards and the first word is “cleaning”
GNINAELC – Ot erussa hgh ecnamrofrep, yllacidoirep naelc eht epat sdaeh dna natspac revenehw uoy eciton na noitalumucca fo tsud dna nworb-der edixo selcitrap. Esu a nottoc baws denetsiom htiw lyporposi lohocla. Eb erus on lohocla sehcuot eht rebbur strap, sa ti sdnet ot yrd dna yllautneve kcarc eht rebbur. Esu a pmad tholc ro egnops ot naelc eht tenibac. A dlim paos, ekil gnihsawhsid tnegreted, lliw pleh evomer esaerg ro lio.
Cleaning – to assure high performance, periodically clean the tape heads and capstan whenever you notice an accumulation of dust and brown-red oxide particles. Use a cotton swab moistened with isopropyl alcohol. Be sure no alcohol touches the rubber parts as it tends to dry and eventually crack the rubber. Use a damp cloth or sponge to clean the cabinet. A mild soap like dishwasher detergent will help remove grease or oil.
Low Literate Diabetic Patients Less Likely to Know Correct Management*

Need to Know: symptoms of low blood sugar (hypoglycemia)

Need to Do: correct action for hypoglycemic symptoms

*Williams et al., Archive of Internal Medicine, 1998
Health Literacy of America’s Adults

- Proficient: 12%
- Below Basic: 13%
- Basic: 22%
- Intermediate: 53%
- High School Grad: 53%
- Hispanic: 13%
- Medicaid: 48%
- Medicare: 9%

n=19,000

Health Literacy of America’s Adults

- **Below Basic:** Circle date on doctor’s appointment slip
- **Basic:** Give 2 reasons a person with no symptoms should get tested for cancer based on a clearly written pamphlet
- **Intermediate:** Determine what time to take Rx medicine based on label
- **Proficient:** Calculate employee share of health insurance costs using table

*67% probability individual can perform task*
Video

It’s easy to make a mistake
Informed Consent
Research, Medical/Surgical Treatment

• A communication process – not just a form
  – “The document is really just a reference for the patient.” - Dr. Bob Frenck

• Both form and process can be improved

• Problems with forms noted in literature – 1980’s

• Process problem
  – Investigators often see purpose as “consenting patients” rather than helping them decide whether or not to participate
A Perfect Storm?

• Clinical research is increasing - 2.3 million patients a year sign consent forms

• There is increasing regulatory scrutiny

• Purpose of IRB’s, researchers and lawyers, is compliance with regulations

• Patient comprehension is poor

• No standard method to assess comprehension

Cohn E, J of Nursing Scholarship, 2007
What Is Given More Weight: Comprehension or Compliance

Mark Houchhauser, 2008
Problems of Informed Consent

• Documents are long and written at a reading level beyond the capacity of many patients

• IRB’s do not meet their own standards for readability in boilerplate language they require

• Patients may not understand fundamental concepts required for participation in research

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

- Winston Churchill
AHRQ Responses To Objections To Making Consent Forms More Understandable

• Legal clauses need to protect our 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.

* Diaz vs. Hillsborough County Hospital Authority, 2000 $3.8 M class action – failure of consent, form too complicated
Responses Continued

- Small font, long paragraphs are needed to keep the documents short.
  - Large font, white space, headings to break the text into manageable pieces make documents easier to read.
  - Well done documents do not have to be long.

- Most people are familiar with medical terms.
  - Most adults do not understand medical terms.

- We have used these documents for years. Patients wouldn’t sign if they didn’t understand.
  - Research shows most patients do not understand all information contained in consent documents they sign.
Responses Continued

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

• There is no reason to focus on written materials because informed consent is a process and investigators will communicate what is needed.
  – High quality consent materials can lead to an improved consent process and provide information that subjects can refer to later.

AHRQ 2008
How to Evaluate Reading Ease of Consent Documents

First

• Check reading level
  – Flesch-Kincaid (computer)
  – Lexile (state of the art)

Second

• Aim for <8th grade
• Asses reading ease and “user-friendliness”
Flesch-Kincaid Estimation of Reading Level

Go to ‘Tools’.

‘Spelling’

Under Options check ‘Readability Statistics’.
Lexile

Estimation of Reading Level

- Lexile scores are based on sentence length and word frequency in popular literature. Higher values indicate higher levels of reading difficulty.
- Scores range from below 0 (representing a beginning reading level) to 2000. Aim for <900.
- The Lexile Analyzer (internet program), calculates the Lexile score for each sample.
- Instructions:
  - 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
    400 = 3rd grade
    1300 = 12th grade
### Reading Level ≠ Comprehension

% Patient Comprehension by Literacy

<table>
<thead>
<tr>
<th>Prescription Label Instructions</th>
<th>Literacy Level</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glyburide, 5 mg</strong></td>
<td><strong>High</strong></td>
<td><strong>Low</strong></td>
</tr>
<tr>
<td>Take two tablets by mouth twice daily.</td>
<td>&gt;=9th</td>
<td>&lt;=6th</td>
</tr>
<tr>
<td><em>(6th grade level)</em></td>
<td>71%</td>
<td>33%*</td>
</tr>
<tr>
<td>Take 2 pills by mouth at 8 am and 2 pills at 6 pm.</td>
<td>90%</td>
<td>76%</td>
</tr>
<tr>
<td><em>(8th grade level)</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p<0.001, ‡ p<0.01

Davis T, *JGIM*, In press.
Is Form Easy To Read?

• Uses familiar words (no jargon, abbreviations, acronyms)
• Short, simple sentences (8-10 words)
• Active voice
• Address the reader – uses personal pronouns

WHY IS THIS STUDY BEING DONE?
This study is being done to find out how LSU doctors can best communicate important information to mothers who are about to give birth to a very premature baby (mothers who are 20 to 24 weeks pregnant). Since you are at least 26 weeks pregnant, you are not at risk for a very premature baby (born at 20 to 24 weeks).

You are being asked to take part in this study because you are pregnant and a patient of a high risk clinic. We want to find out what parents understand after the doctor has talked to them about what might happen with very premature babies. The purpose of our study is to find out how we can best counsel pregnant patients about extremely premature babies.

If you are willing to take part in this study, the doctor will talk to you about an imaginary situation of you having an extremely premature baby. Then a research assistant will ask you several questions and ask you to say a few words. We want to learn more about what patient education and counseling will be helpful to mothers in that situation and what words to use.

The counseling does not mean your doctors think you are about to deliver your baby. We are giving you this information only to learn if the information we give is clear and easy to understand.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 100 women will take part in this study.
Does Title Aid Comprehension?

SWOG Title

• “Phase III Comparison of Combination Chemotherapy (CAF) & Chemohormonal Therapy (CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary-Node Positive Receptor-Positive Breast Cancer. Intergroup.”

Simplified

• “Breast Cancer. You Can Help Your Doctors Find Better Treatments.”

Is Layout User Friendly?

- White space
- Font at least 12-point

**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.

**Define 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 gram-positive 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.

- Avoid ALL CAPS
- Limit paragraphs to 3-4 lines

Is The Information Manageable?

Does document

• Avoid information overload

• Focus on “need to know & do” vs. “nice to know”

• Use headers, bolding, boxes, underlining

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**About this document**

This document tells you about the study. If you decide to be in the study and to let us use and report on health information about you:

- You will sign the document, and
- We will give you a copy of the document to take home.

**What is the goal of the study?**

We want to learn if we can improve health care for people with [condition]. We are asking people like you who have [condition] to help us.

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.
A Picture Is Worth 1000 Words

• Illustrations aid reading ease
• Pictures help explain text, enhance text

If you use pictures/graphics:
• locate text and graphics together
• put captions under graphics

Colors appeal to readers.
Consent Documents

- Reading ease improved in last 10 years but more is needed
- HIPAA forms - 15th – 16th grade (if read, 9 minute reading time)
- CCHMC forms
  - Med/Surg: 10th – 12th grade
  - Research: 11th – 13th grade
- Average U.S. patient 7th – 8th grade reading level
- Most forms use headers, some paragraphs are short
- Some put “need to know” information up front
- Problems still exist
  - Sentences too long and complex
  - Too many phrases, “nice to know vs. need to know”
- Do patients understand the information in the forms?
CCHMC Research Form

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
(revised 07/23/08)

STUDY TITLE: TRIAL OF EARLY AGGRESSIVE THERAPY IN JUVENILE IDIOPATHIC ARTHRITIS (TREAT JIA Trial)

SPONSORS NAMES: NIH (NIAMS) and Amgen

SPONSOR STUDY NUMBER: 1 R01 AR49762-01A2

INVESTIGATOR INFORMATION

Principal Investigator:
Hemine Brunner, MD, Cincinnati Children's Hospital Medical Center, Division of Rheumatology, 3333 Burnet Avenue, Cincinnati, OH 45229.
Phone: 513 636-7882 during regular business hours and 513 636-4200 evenings and weekends and ask for the Rheumatologist on call.

[Signature]
Date: ____________

Subject Name: ___________________________ Date of Birth: ______/____/____

Throughout this document, references to "You" may stand for either the research study subject or for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify whether the research study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

INTRODUCTION:

You have been asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks, and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will in no way interfere with your care by the study team.

If you have any questions about this study or about the procedures, benefits, or risks, please ask your physician or the study coordinator. They are there to answer your questions. You should not participate in this study if you are pregnant. If you are not sure whether you are pregnant, you may be asked to take a urine test to determine if you are pregnant at any time during the study.

If you choose to participate, you must sign this consent form. You may not sign the form on behalf of another person. If you are under 18 years of age, your parent or legal guardian must sign this consent form on your behalf.

TREATMENT GROUP B: If you are assigned to Treatment Group B, you will get methotrexate in the same way as in Treatment Group A plus a drug called etanercept once a week as an injection (average 20 mg, maximum of 40 mg). Etanercept blocks a substance in the body called tumor necrosis factor (TNF). TNF has been shown to be abnormally high in children with juvenile rheumatoid arthritis (JRA). Etanercept is used in the treatment of children with arthritis with very good results, however, it is usually not given until after treatment with methotrexate has failed. The dose of etanercept used in this study is the dose that has been approved by the Food and Drug Administration (FDA) to treat children with arthritis. You will also take a liquid every day called prednisone (caps 0.5 mg/kg/day, maximum 60 mg/day). Prednisone is a drug known as an anti-inflammatory steroid, and its purpose is to reduce inflammation. The prednisone will be reduced steadily and then stopped after 1 month. We will check you at each study visit to see if you are better, the same, or worse.

We will do this by asking you to answer questions, have a physical exam, a joint exam, complete questionnaires to determine how you are doing, and get blood tests. These tests are similar to or the same as those that doctors would use to check any child who is being treated for JIA. A certified joint assessor, who will not know what treatment you are getting, will perform the joint exam at each study visit. You should not discuss with the assessor the treatments that you think you are receiving. Your usual doctor will perform the other evaluations at each study visit. You will receive an at-home diary card at every visit for medication times and compliance, adverse events, and additional medications taken. Blood will be drawn at each study visit to check the status of your JIA activity and to see if either the medicine or the disease is causing abnormal laboratory results. The amount of blood drawn at the first visit will be about 3 teaspoons and at each of the following visits will be about 2 teaspoons. If you are able to get pregnant, you will have a urine test to see if you are pregnant at all study visits and at any time during the study that your doctor is concerned that you may be pregnant.

The study will last for up to 12 months. During the study, visits will occur monthly or every other month. During the first 6 months (Part A) you will receive the medications according to which group you were assigned. At 6 months we will check to see if your arthritis is significantly better if it is not, or if your arthritis is not completely gone (inactive disease) at the 6 month visit, then you will be offered treatment with open label etanercept and prednisone. Open-label means that you will know what medications you are receiving. This may be a re-treatment with these medications.

If you or your family becomes economically inactive at the 6 month visit (or at any other visit in Part A) you will enter Part B of the study. Part A of the study is to see if you will continue to have "inactive disease". Part B of the study will last up to 6 months. During
RIM
Rituximab in Juvenile Dermatomyositis (JDM) and Adult Polymyositis

The goal of this study is to see if a drug called Rituximab can help children with JDM improve the symptoms of their disease.

What is this study trying to find out?
- The study doctors believe that the symptoms of JDM may be related to the presence of B cells in the blood.
- Rituximab will be given to your child to reduce the number of B cells, which they hope will improve your child's condition.

Who is eligible?
- Children over five years who have been diagnosed with JDM for more than six months and have ongoing weakness despite treatment with standard therapies.

What will happen to your child during the study?
- This study will involve 14 study visits over 45 weeks:
  - Ten of the visits will last approximately three hours and will take place in Treatment Center 14.
  - Four of the visits will include infusions; these will take place in the CCRG here at Cincinnati Children's and will last approximately five hours.
- Everyone in the study will receive two Rituximab infusions, and two placebo (fake, not real Rituximab) infusions. Neither you nor your doctor will know when you are receiving the actual Rituximab and when you are receiving Placebo.

Is there any cost to participate in the study?
- Neither you nor your insurance company will be charged for any study procedure or medication.
- As a reimbursement for your travel and time, you will receive $75.00 for each of the four infusion visits and $35.00 for all other visits.

Who can you contact for more information?
- **Principal Investigator**
  - Dr. Daniel Lovell
  - (513) 636-8071
- **Research Coordinator**
  - Jenn Ramala
  - (513) 636-8029
CCHMC Research Forms Reviewed

Strengths
  – Used good headers – questions
  – Conversational tone

Room for improvement
  – Length: 13-21 pages
  – Average sentence length: 20-22 words
  – 1st half page – sponsor, study #, PI information (not organized for patient’s need to know and do)

Needs bullets
  – Shorter paragraphs
  – Cut some of repetitive information
  – Too much “nice to know” vs. need to know
<table>
<thead>
<tr>
<th>Form – 16th grade</th>
<th>Patient Reading Level</th>
<th>n=183</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;8th grade</td>
<td>&gt;9th grade</td>
</tr>
<tr>
<td>Purpose of form</td>
<td>46%</td>
<td>84%</td>
</tr>
<tr>
<td>Purpose of study</td>
<td>19%</td>
<td>47%</td>
</tr>
<tr>
<td>Difference tx 1,2,3</td>
<td>8%</td>
<td>22 %</td>
</tr>
<tr>
<td>What determines treatment</td>
<td>5%</td>
<td>44%</td>
</tr>
<tr>
<td>List 3 side effects of study drugs</td>
<td>65%</td>
<td>84%</td>
</tr>
<tr>
<td>Why important to tell doctor if you have these side effects</td>
<td>23%</td>
<td>97%</td>
</tr>
</tbody>
</table>

Davis, J Nat Ca Inst, 1998
**Does Simplifying Forms Improve Consent for Clinical Trails?**

<table>
<thead>
<tr>
<th></th>
<th>SWOG</th>
<th>LSU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reading Level</td>
<td>16&lt;sup&gt;th&lt;/sup&gt; grade</td>
<td>7&lt;sup&gt;th&lt;/sup&gt; grade</td>
</tr>
<tr>
<td>Sentence Average</td>
<td>21 words</td>
<td>12 words</td>
</tr>
<tr>
<td>Length</td>
<td>3438 words</td>
<td>524 words</td>
</tr>
</tbody>
</table>

Davis, J Nat Ca Inst, 1998
CONSENT FORM

Phase III Comparison of Combination Chemotherapy (CAF) & Chemohormonal Therapy (CAF + Zoladeq or CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary Node Positive, Receptor-Positive Breast Cancer, Interrog.

Name of Subject: 

Age: 
Date of Birth: 
Sex: 
F Research Project No: SWOG 8851

Date: 
Location: Shreveport 
Service: LSUUMC

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.

Purpose of Study and Selection of Subjects

You are invited to participate in a research study on the adjuvant treatment of breast cancer. Adjuvant treatment is giving chemotherapy after surgical removal of all evidence of your cancer in an attempt to prevent the tumor from recurring. Researchers at LSUUMC hope to learn what is the best type of therapy to give women who are premenopausal (before change of life) and whose tumor bears a certain chemical known as estrogen receptor.

You were selected as a possible participant in this study because you have breast cancer which has been surgically removed and cancer cells were found in one or more of the lymph nodes in your armpit as well as in the breast. In addition, your tumor bears the chemical trait of having estrogen receptors (a hormone receptor) and you are premenopausal.

Description of Experimental Part of Study Including Procedures To Be Used

If you decide to participate, you will be randomized to one of three types of treatment. Since it is not known what type of treatment is best at the present time, your treatment will be decided similar to tossing a coin or picking names out of a hat. This is called randomization.

To be randomized, your doctor will call the Statistical Center in Seattle, WA and your treatment will be decided by computer after you have been registered onto the trial. Neither you nor your physician can predetermine which treatment you will receive. You will be randomized to receive one of the three plans (ARM 1, 11 or III) described below.

ARM I consists of Chemotherapy with the agents Cyclophosphamide, Doxorubicin and S-FLU (CAF).
ARM II consists of the same chemotherapy with CAF plus the investigational drug Zoladeq.
Patients Preferred Simplified Form But It Did Not Improve Comprehension

Davis, J Nat Ca Inst, 1998
Recent Review of Studies to Improve Informed Consent

- Shortened forms may be more likely to be read
- Simplified consent forms improve patient satisfaction but not comprehension
- Multimedia has not improved comprehension
- Consent educator using repetition and ‘teach back’ has promising results

Cohn, J of Nursing Scholarship, 2007; Dunn, 2001
# Efficacy of Research Consent Formats

n=233 head start parents (53% read ≤ 8\textsuperscript{th} grade)

<table>
<thead>
<tr>
<th>Format</th>
<th>% Comprehension Low Risk</th>
<th>% Comprehension High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (11\textsuperscript{th}, 12\textsuperscript{th} grade)</td>
<td>48</td>
<td>46</td>
</tr>
<tr>
<td>Simple language and pictures</td>
<td>56</td>
<td>49</td>
</tr>
<tr>
<td>Narrated video</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Laptop (PPT, pictures)</td>
<td>52</td>
<td>49</td>
</tr>
</tbody>
</table>

- No significant differences in recall by format
- Parents reading ≤ 8\textsuperscript{th} grade – simpler forms more effective
- More information recalled for low risk study

Hidden Problems With Videos

- Often too long (limit to 4-6 minutes)
- Too much time “talking heads” vs. story or case
- Not patient-centered
- Visuals can be too scientific, complex
- Lack of attention to ‘tone’, patient emotions
- Who will show, when, where
- Does not attend to teachable moment

*Little is known about efficacy of using multi-media tools over print media*
Developing User-Friendly Materials

- Is not rocket science
- But harder and more tedious than it seems
- AHRQ Toolkit (English and Spanish) can help
- Patient input needed (for comprehension, organization, clarity)
User Friendly Does Not Mean “Dumbed Down”

- Patients with high education and income still prefer brief, simple, easy to read materials
The Nuts and Bolts of Writing Consent Forms in Plain English

- Use familiar words; define medical, legal or scientific words
- Use consistent words/terms throughout the form
- Use personal pronouns (I, you)
- Avoid abbreviations and acronyms
- Avoid words with 3 or more syllables,
- Write short simple direct sentences in active voice

NCI “Simplification of Informed Consent Documents”
Put Thought Into Document Design

- Present study purpose early in text
- One idea per short paragraph
- Keep headers simple and close to text
- Use bold, boxes or underlining to highlight important points
- Use easy-to-read print style (Times New Roman)

Hochhauser 2007

HOW LONG WILL I BE IN THE STUDY?
If you decide to participate in this study, it will involve a total of about 45 minutes to 1 hour spread out over 2 visits.

WHAT ARE THE RISKS OF THE STUDY?
Your participation in this study does not involve any risks to your health and will not affect your medical care.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?
Your involvement in this study will help LSU research doctors know the best way to communicate instructions for management of high blood pressure.

WHAT OTHER OPTIONS ARE THERE?
You do not have to participate in this study if you do not want to. Your health care will not be affected if you choose not to be involved.

WHAT ABOUT CONFIDENTIALITY?
Any information obtained during this study and identified with you as a subject will remain confidential and will be disclosed only with your permission. Your information, in all cases, will be treated as confidential.

WHAT ARE THE COSTS?
There is no cost to you for participating in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You will not be penalized or lose any of your rights as a patient if you decide not to participate. If you decide to participate, you are free to quit at any time. Your decision will not affect treatment of you by your doctors at MLK Health Center or at LSU.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have any questions, please ask us. If you have any additional questions about the study or a research-related injury later, Dr. Terry Davis at (318) 675-8694 will be happy to answer them. If you have any questions about your rights as a research participant or other concerns you may contact the chairperson of the Institutional Review Board (which is a group of people who review the research to protect your rights) at (318) 675-5409 or the Dean of LSUHSC-S at (318) 675-5240.
HIPAA Plain Language Thesaurus*

- Adverse event – Bad reaction
- Alternative – Choice
- Amend – Change
- Authorization – Your written permission
- Determine – Decide
- Disclosure – Information you give us
- Obtain – Get
- Notify – Tell us/tell you
- Hereby/herein – Don’t use

*Houchhauser, 2007
How To AVOID Information Overload?

Things To Consider

• What is patient’s “need to know”?
• Does the patient need to know all the IRB needs to know?
  – Basic concepts (6 visits, etc.) – need to do
  – Risks/benefits
  – Alternative
  – Voluntary
  – You can stop and it will not effect your care
  – What is experimental?
  – Who to contact if I have questions?
• How much information on standard care needs to be included?

Hochhauser 2008, Pasch-Orlow 2008 (private conversations)
Recommendations To Improve Consent Process

- Read AHRQ Toolkit
- Review your document BEFORE discussion
- Conduct discussion in private place (let patient include who they wish)
- Slow down, use plain language – no jargon
- Focus on patients’ “need to know and do”
- Give patient time to review document
- Verify and document comprehension (see handout)

AHRQ 2008
Paradigm Shift Needed to Adequately Inform Patients

- Current Paradigm: patients are responsible for saying “I don’t understand”
- Most patients are passive and don’t ask questions
- Unless we confirm understanding we don’t know what they comprehend
- Shift paradigm to investigators responsibility to confirm understanding

Michael Pasche – Orlow, 2008
Using Teach-Back Method

- “I want to make sure we have the same understanding about this research.”

- “It’s my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project.”

- Avoid asking:
  - Do you understand?
  - Do you have any questions?

*Remember—what’s clear to you is clear to you!*

AHRQ 2008, AMA 2007
Teach – To – Goal*

Ask open-ended questions to make sure that the patient has understood all important elements:

• **Goal of the Research and Protocol**
  – “Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study.”

• **Benefits and Compensation**
  – “What do you expect to gain by taking part in this research?”

• **Risks**
  – “What risks would you be taking if you joined this study?”

• **Voluntariness**
  – “What do you think will happen to you if you refuse to be in this study?”

*AHRQ, 2008; 2008 Toolkit
• Discontinuing Participation
  – “What should you do if you say you will be in the study but later 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.
Teach – To – Goal Continued (Verify and Document)

• Correct misinformation until patient confirms understanding.
  – “Let’s talk about the purpose of the study again. I don’t know if I have explained it clearly.”

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

• Document completion of the teach-back process on a consent and authorization certification form.

AHRQ, 2008
Teach – To – Goal Is Effective

• Use of modified consent process with vulnerable patients (n=204)

• Consent method: Simplified Form + Teach – to – Goal
  – 6th grade form read slowly to patient
  – Patient asked 7 comprehension questions (T/F)
  – Re-read section(s) of consent patient did not comprehend
  – Question(s) re-asked

• % Patients answering all questions correctly:
  – 1st pass through 28%
  – 2nd pass through 80%
  – 3 – 6 passes 98%

• Patients likely to require > 2 passes:
  – older
  – minority
  – female
  – less education/literacy
  – born outside U.S.

Sudore R, J Gen Intern Med, 2006
Take Home Messages

- Written consent needs to be user-friendly
- Resources are available to help design materials
- Patients and providers need to be involved in development
- Focus oral communication on patients need to know and do. Confirm understanding.
DHHS Resources


• HIPAA Thesaurus: http://www.hrsa.gov/servicedelivery/hipaa.htm

• Readability of HIPAA Privacy Notices: http://www.privacyrights.org/ar/HIPAA-Readability.htm

Other Helpful Materials

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


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