Overcoming Barriers to Providing Informed Consent to Limited English Proficiency (LEP) Patients
Objectives

- Informed Consent and Basic Rights for All Patients: A Quick Review
- Before Translation: Health Literacy and Informed Consent
- How NOT to Get Lost In Translation
- After Translation: Including LEP Patients in Research Protocols
Clarification of Terms

- **Translation**: written
- **Interpreting**: oral
Interpreter Services at YNHH

- Interpreter Services provides approximately 40,000 interpretations per year.
- 10-year old program provides in-person (Spanish and Portuguese), phone interpreting and written translation services.
- Team members include: 13 Spanish Interpreters, 1 Portuguese Interpreter, 2 Dispatchers, 1 Translation Coordinator.
Interpreter Services at YNHH

1% Each Portuguese, Mandarin, Turkish, Arabic, Croatian, Polish, Vietnamese, French, Dari Persian, Russian

ASL 2%

Spanish 86%

The remaining requests are divided among 40 different languages
How to Include LEP Patients on Research Protocols Without “Loosing It”
Informed consent is a process and not a document. The final objective is NOT as signature.

The final objective is the research subject’s clear understanding of the study and its implications for their health.
Refresher: What is Informed Consent?

What do we need to include:

1. Explanation of the study
2. Possible benefits and risks of participating
3. Description of the procedures that will be performed
4. Description of who will see their personal medical information
Refresher: What is Informed Consent?

What do we need to include:

5. Explanation that their legal rights are not waived.

6. Explanation of compensation in case of risk

7. Contact information in the case of injury, questions about the study, or questions about their rights as research subject.

8. Information about the right to withdraw from the study
When thinking about patients who do not speak English, let’s do a mind experiment:

Case of treatment in China......
What is the rule about including non-English speakers in your research protocol?

1. You MUST have the consent form translated into the language of the person.

   ✓ Must be done by qualified translator
   (more to come)

   ✓ Must be done with “lay” language that is understandable to the patient
What is the rule about including non-English speakers in your research protocol?

2. You MUST have a qualified bilingual staff person who speaks that patient’s language available at all times for questions or research-related injury reporting. (more to come)
What part can Interpreter Services play?

1. IS can offer an in-person or over the phone interpreter if the patient is receiving care in the hospital. But only if the study treatment is part of their care in the hospital.

2. IS CANNOT translate the consent form (but they can you find resources)
My objective today:

1. Hints about how to improve your consent documents for all patients (but especially when translating) in relation to plain language.

2. Hints about how to have translations done most effectively.

3. Hints about how to know who is qualified to be a bilingual staff member.

Refresher: What is Informed Consent?
Health (ll)Literacy and Plain Language
What is Health Literacy?

One definition:

The ability to read and comprehend prescription bottles, appointment slips, and the other essential health-related materials required to successfully function as a patient.

Why should we worry about health literacy?

Almost half of all US adults have either basic or below basic prose literacy skills – that means they can only perform simple everyday reading (signs or labels) or they are simply illiterate.
Health Literacy: Basic Facts

People with low health literacy are less likely to:

- Understand written and oral information given by doctors, nurses, pharmacists and insurers.
- Follow directions for procedures or how to take medications.
- Understand how to work the complex medical system.
- Understand their rights or the risks associated with their treatment (informed consent).

CHCS, 2005
Health Literacy: is it really that important?

Yes!! The most vulnerable groups have the lowest health literacy (racial/ethnic minorities, immigrants, the elderly, the mentally disabled)

In a study of 979 low-income patients, most could not understand basic health care information.

◊ 26% could not understand when the next appointment was scheduled
◊ 65% could not understand from the instructions to take medicines on an empty stomach
◊ 75% could not understand if they were eligible for financial assistance.

Williams et. al., 1995.
Health Literacy: how can you tell who has trouble reading?

- People who have low reading skills are notoriously secretive about their problem.

![Bar chart showing lack of disclosure of reading difficulty by patients who admit low literacy.](chart.png)

Who Was NOT Told

- Spouse, 67%
- Children, 52%
- Relatives, 58%
- Co-workers, 89%
- Friends, 62%
- No one, 15%
A Partial Solution: Plain Language

- Plain language is a movement, both in government and in the private sector, that seeks to increase the clarity and simplicity of written documents.

- Plain language involves content, appearance, organization, structure, and writing style.
Do you remember what it was like to not read easily?

The Bumble Turtle

I don't know where I'm the world.
I do if it happens to meet the bumbleurtle.

Do you want to know why? It's quite a story.

I was sitting on the porch one morning thinking I'd have to dig some worms. I had finished the chores on my father's farm and now I wanted to go fishing.
Do you remember what is was like to not read easily?

The Turtle Turtle

I done'f know where to the mor'n I goin', I start to meet the turtle. Done'f comin' to know my old'f way. I done'f know what to do. When I was sittin' on the porch one mornin' I had a thinkin'. I'd have to get some mornin'. I had to finish the cross on my letter's form and now I wanted to go fishin'.
The Principles of Plain Language

1. Content:
   - Written at a 5th-6th grade of reading difficulty (Do NOT use MS Word to measure this)
   - Does not use passive voice
   - Uses simple vocabulary and avoids technical jargon.
   - When technical words are used, they are clearly defined at the beginning of the document
   - Sentences are short
Examples of Plain Language

Covered entities must describe the right of patients to make amendment of a protected health record if patient believes that health information is incorrect or incomplete.

If you think there is something wrong or missing in your health record, you can ask that it be changed.
Examples of Plain Language

Side effects of Oral Contraceptives
Vaginal Bleeding

Irregular vaginal bleeding or spotting may occur when you are taking the pill. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding that is much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate a serious problem.

Bleeding Side Effects

You may have some spotting or light bleeding between periods, especially after you miss any pills.
The Principles of Plain Language

2. Appearance

✓ Looks easy to read
✓ Action message comes first and is easy to understand
✓ Information is “chunked” – Use bullets!
✓ Text written in Serif font (Times Roman, Garamond), no smaller than 12 or 14 point – does not use caps
✓ Line length should be no more than 3 to 5 inches. Columns are useful.
RISKS AND DISCOMFORTS

As with any treatment, it is possible that Experimental Drug and Experimental Drug may cause reactions. The study medications, Experimental Drug and Experimental Drug, may cause all, some, or none of the side effects listed below. Because Experimental Drug is a new drug, we do not know all of its side effects. Rare or previously unknown or unforeseeable side effects, which may be serious, may occur. Every effort will be made to monitor you closely to identify and treat any side effects you may experience. If new side effects are discovered, your doctor will know about them and share that information with you. Any new information will be given to you or your legal representative, so that you can decide whether you want to continue in the study. If you decide that you no longer want to take part in the study you can do this without any penalty or loss of benefits to which you are entitled.

Risks of Experimental Drug

To date, over 1500 patients with advanced malignancies have been treated with Experimental Drug in several studies that have been conducted or are underway. Overall, the most frequent side effects associated with Experimental Drug have been:

- Likely (50% or more): fatigue.
- Frequent (10-50%): nausea, diarrhea, upset stomach, taste disturbances, inflammation of mucous membranes (including mouth sores), vomiting, constipation, yellowing of the skin, loss of appetite, joint/back pain, pain in extremities (hand and feet), high blood pressure, inflammation of the skin, headache, blisters and/or rash in hands and feet which may be painful, increased blood levels of digestive enzymes (lipase and amylase), hair color changes, shortness of breath, swelling, muscle aches, dehydration.
- Occasional (1-10%): nosebleeds, clinically significant decreases in white blood cells (infection-fighting cells), clinically significant decreases in red blood cells (oxygen carrying cells), clinically significant decreases in platelets (which help stop and prevent you from bleeding), inability to sleep, cough, fever, increased/more frequent eye tearing, hair loss, decreased kidney function, increased levels of liver enzymes, decreased heart muscle function, increased levels of heart muscle enzyme.
- Rare (less than 1%): bleeding requiring transfusion (including bleeding into the tumor), clots in blood vessels (including the vein that brings blood to the liver), infec
Risks and Discomforts

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Because Experimental Drug is a new drug, we do not know all of its side effects. Rare, unknown, or unexpected side effects, which may be serious, may happen. We will try to monitor you closely to treat any side effects you may have. If new side effects happen to other patients, your doctor will know about them and tell you. We will give you or your legal representative any information, so that you can decide whether you want to keep taking part in the study. If you decide that you do not want to take part in the study you can do this without any penalty or loss of benefits to which you are entitled.

Risks of Experimental Drug

To date, over 1500 patients with advanced cancer have been treated with Experimental Drug in several studies. Overall, the most common side effects are:

Likely Side Effects:

About half of all patients who took this drug had: fatigue (they felt tired).

Frequent Side Effects:

About 10% to 50% of patients had these side effects:

- nausea
- diarrhea,
- upset stomach
- taste disturbances
- inflammation of mucous membranes (including mouth sores),
- vomiting,
- constipation,
- loss of appetite
- joint/back pain
- pain in extremities (hand and feet)
- high blood pressure
- inflammation of the skin
- headache
- blisters and/or rash in hands and feet which may be painful
- increased blood levels of digestive enzymes (lipase and amylase),
- hair color changes
- shortness of breath
- swelling
- muscle aches
- dehydration
Examples of Plain Language

**IMPORTANT FACTS**

**IMPORTANT SAFETY INFORMATION ABOUT ZYRTEC**

ZYRTEC may make some people feel drowsy. Be careful doing things where you need to be alert, such as driving a car or using dangerous machinery. Do not drink alcohol or use other medicines that make you drowsy while taking ZYRTEC.

**ABOUT ZYRTEC**

ZYRTEC is a prescription medicine used to treat:

*Seasonal (outdoor) allergies.* During certain times of the year, high levels of ragweed, grass, and tree pollen that cause allergy symptoms may be in the air.

*Perennial (indoor) allergies.* All year long, things such as dust mites, animal dander, and molds can be around. They can cause allergy symptoms.

*Continuing (chronic) hives.* Hives are red, itchy bumps on the

**BEFORE YOU START ZYRTEC**

Tell your doctor or your child's doctor:

- About all medical conditions, especially if you or your child:
  - Have or had any kidney problems or are on dialysis
  - Have or had any liver problems
  - Are pregnant, think you might be pregnant, or plan to become pregnant
  - Are breastfeeding
- About all medicines you or your child take. Include prescription and over-the-counter medicines, vitamins, and herbal products.

**POSSIBLE SIDE EFFECTS OF ZYRTEC**

The most common side effects of ZYRTEC are:

**Adults and children 12 years and older:**

- feeling drowsy
- feeling tired
- dry mouth

**Children 2 years to 11 years:**

- headache
- stomach pain
- feeling drowsy
- sore throat

These effects are usually mild to moderate. ZYRTEC has other side effects.
Examples of Language That Seems Plain...But Isn’t

There are many terms that are common, almost second nature to providers but that mean little to patients.

◊ Orally
◊ Apply locally
◊ Diabetes
◊ Incision
◊ Excision
◊ Ambulate
◊ Efficacy
◊ Taper

◊ Intercourse
◊ Indicated for...
◊ Confidential
◊ Risk factors
◊ Insignificant
◊ Physical activity
◊ Nutrition
◊ Infection
2. Plain Language and Translation
Garbage In – Garbage Out

Translation amplifies the problems in poorly written materials.

Immigrant groups tend to have low levels of literacy. They will have difficulty even if documents are written in plain language.

Jargon, technical terms and idiomatic expressions present special problems for translation – don’t leave it up to the translator!
Preparing the Document for Translation

- Take out jargon completely
- Define technical terms simply and descriptively. Use commonly understood vocabulary in the definition.
- Short sentences are translated more precisely
- Provide precise instructions to the translators concerning the tone and style
- Request input from the translators concerning the cultural implications of the text.
Cultural Diversity and Health Care

“Biomedical”

“Traditional”
How Our Documents Reveal Our Culture

Assumptions in our Model of Healthcare:
- Make it Better
- Control Over Nature
- Do Something
- Intervene Now
- Strong Measures
- Plan Ahead – Recent is Best
- Standardize – Treat Everyone the Same
- Full disclosure – the individual decides
- Based on statistical evidence

Assumptions in More Traditional Models
- Accept With Grace
- Balance/Harmony with Nature
- Wait and See
- Cautious Deliberation
- Gentle Approach
- Take Life As It Comes – “Time Honored”
- Individualize – Recognize Differences
- Based on traditional methods/knowledge of healer

(Kleinman, 1999)
How Our Documents Reveal Our Culture

◊ There is a rational, research based logic built in to the way we explain medical information.

◊ Ex: “Research by the AHA has found an association between obesity and the incidence cardiovascular disorders.”
  - What does “incidence” mean?
  - What does “association” mean?
  - Does it cause it or not?
  - Why should I care who the AHA is?
Budget for Translation!!!

◊ When planning and budgeting, start making translation a common expense that you include in your calculations.

◊ Translation are charged usually by the word. Expect to spend anywhere from 0.15 to 0.40 cents per word, depending on the language.
Who should translate:

- ALWAYS use a qualified translator.
- A qualified translator is NOT simply anyone who speaks the language – they MUST be trained in translation.
- Go to reputable sources for recommendations: HIC, YNHH Interpreter Services, Yale Spanish Department, ATA Website (pick certified interpreters)
Who should NOT translate:

- Support staff who say they speak Spanish (or any other language)
- Physicians or nurses who say they speak Spanish
- Anyone who has not been certified or evaluated or who has not translation experience.
Let’s do an exercise...

If you have teenagers, you may have an unfair advantage when taking this quiz....

How well-versed are you in understanding “street”???
How did you do?

• It’s hard to ‘cheese’ when you can’t get the lingo.

• Imagine trying to make a decision about your health when you can’t even understand the words...
Access to Bilingual Staff during the Research Study
For projects in which you intend to enroll LEP participants, you must have a bilingual staff member available to provide information on:

1. the research study
2. the rights of the participant as a research subject
3. research-related injury
How do you know if a person is bilingual?

Important advice:
Don’t trust anyone when they say they “speak Spanish”.
Make sure!
How do you know if a person is bilingual?

• If the applicant was born and educated in Latin America, chances are...they are bilingual
How do you know if a person is bilingual?

• Ask a native-born Latin American to speak with this person to give you their opinion – preferably someone with a medical background.
How do you know if a person is bilingual?

- Language evaluation is available through several companies. Language Line charges around $150 to evaluate language ability.
How do you know if a person is bilingual?

Hiring a person with faulty fluency in the target language is dangerous:
1. It endangers the patient’s rights
2. It endangers the patient’s health
3. It endangers your research results
Contact Information

I would be happy to answer any questions. Feel free to contact me at:

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