

# Informed Consent in Clinical Research Settings: Fantasy, Illusion or Reality?

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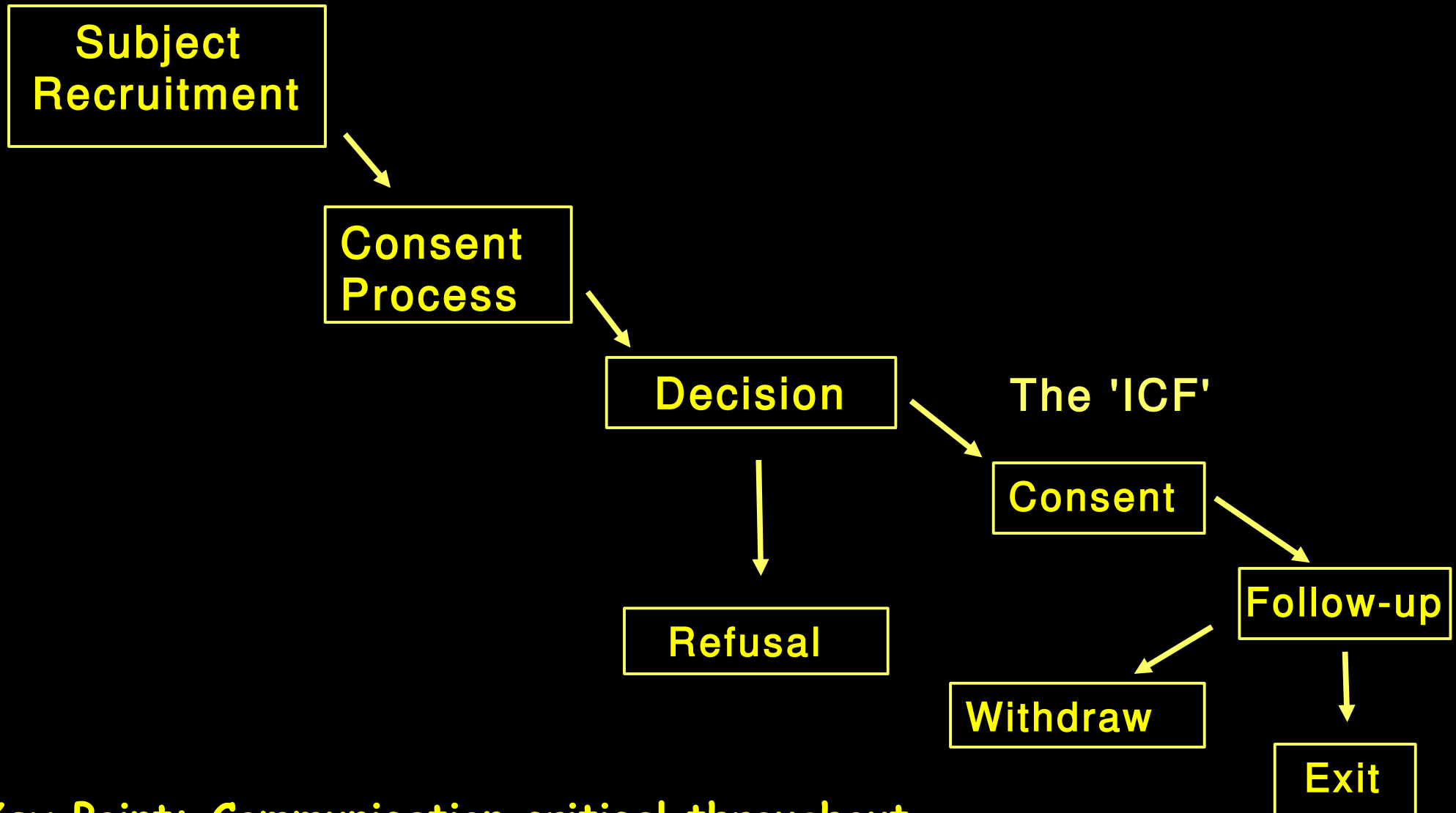
**November 17, 2010**

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# Topics to be covered

- Elements of informed decision-making in clinical settings
- Why should you care?
- What does the research show about informed consent in clinical settings?
- Why are the results so poor?
- What can be done to improve the situation?
- Facilitating informed consent

# Informed Consent: The Process



**Key Point: Communication critical throughout**

# Informed Consent

- Goal from subject's perspective
  - Preserve autonomy
  - Protection from harm
- Requires:
  - Capacity to understand and consent
  - Full disclosure
  - Voluntariness (neither implicit or explicit coercion)
  - A decision i.e. to consent or refuse

**Key Point:** ethical and legal informed consent requires not just disclosure but understanding

# Informed Consent Demands

- Communication of appropriate content
  - The nature of the problem/goal of the research
  - The choices the patient has
  - Likely consequences
  - How to obtain additional information
  - Rights and obligations
- Analysis & reflection (requires: time, location, ability)
- A 'decision' --- 'signing the consent form' the 'ICF'
- Ongoing contact and communication

# What does the research show about informed consent in practice .....

- Study of consent using simplified ICF (Sudore et. al. 2006)
  - Used a modified and simplified ICF
  - After consenting only 28% could answer 7 simple questions about the study
- Cross-sectional study of subjects (N=207) cancer clinical trials (joffe et.al., Lancet 2001)
  - 70% thought proposed treatment had been proven to be the best
  - 74% were unaware they would receive non-standard treatment
  - 25% did not know trials were mainly meant to benefit future patients

# What does the research show about informed consent in practice .....

- RCT study of  $\beta$ -blockers in patients with history of MI (Howard & DeMets, Control clinical Trials 1981)
  - 44% did not know they had been assigned to a treatment group by chance
- A Systematic review of 30 trials using different approaches to enhance understanding as part of consent (Flory and Emmanuel, JAMA 2004)
  - Showed a range of understanding in the intervention groups after the intervention as follows:
    - Mean understanding 74.6%
    - Median 72.5%
    - Range 47-96%

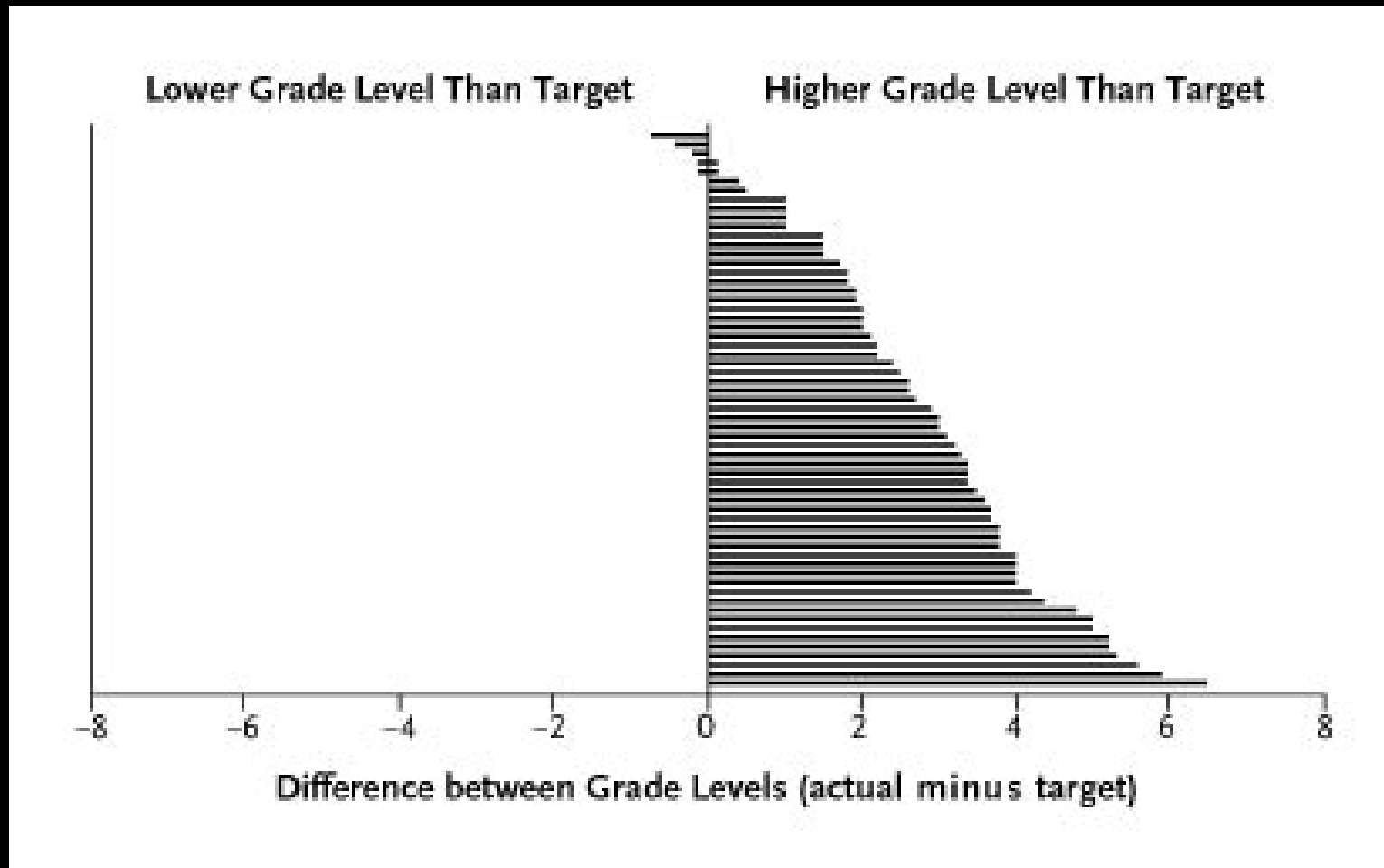
# What does the research show about informed consent in practice .....

- A Study of parental understanding of randomization in childhood leukemia trials (Kodish et. al. JAMA 2004)
  - Physicians used term "randomization" 83% of the time
  - Only 50% of parents understood the term
- Study of 137 oncology consent forms (Grossman, Journal of Clinical Oncology 1994)
  - Only 6% had a readability level at or below 8<sup>th</sup> grade
- Analysis of 107 consent forms from cancer clinical trials (Grossman, American Journal of Oncology, 2004)
  - None were written at the 8<sup>th</sup> grade level or below and only 11% were below grade 10.



# Readability Standards for Informed-Consent Forms As Compared with Actual Readability

Paasche-Orlow, M.K. et. al., NEJM (2003)



Each bar represents 1 of the 61 institutional review boards that indicated a specific grade-level target as a readability standard.

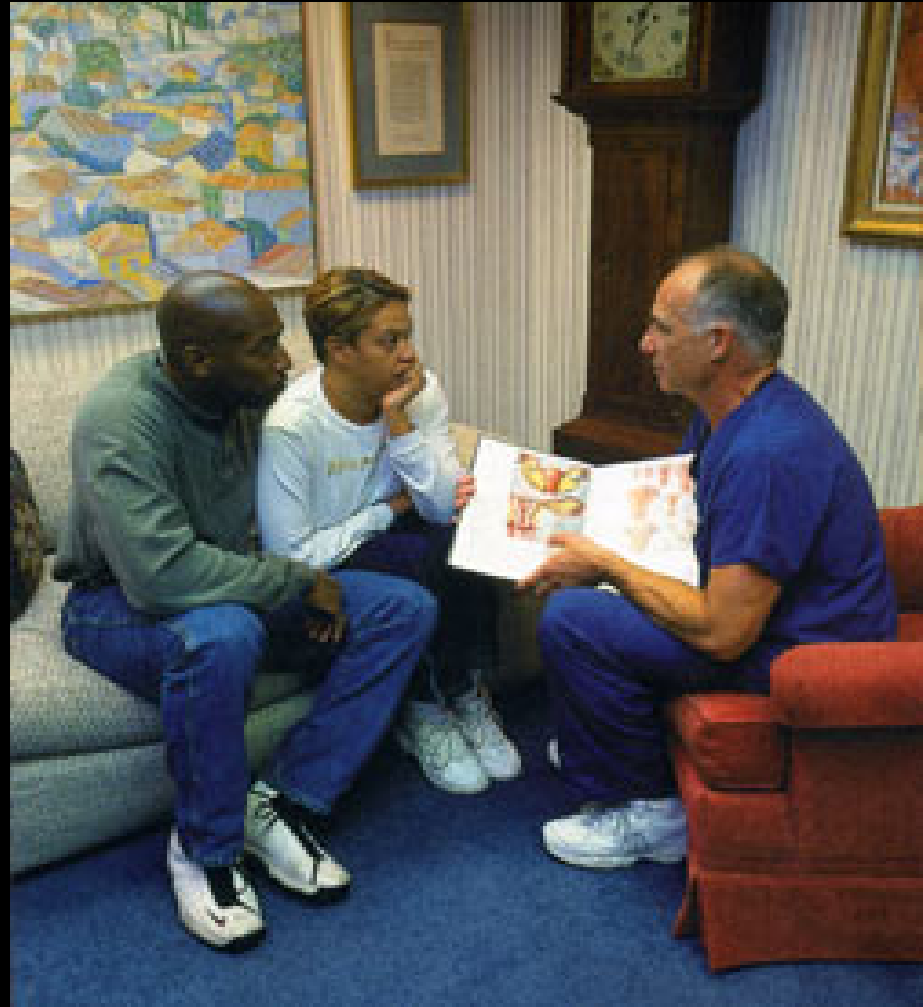
# So what!

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# Answering the “so what” question

- Legal
- Ethical
- Regulatory
- PR
- Threats to validity
  - Internal
  - External

# Communication 101



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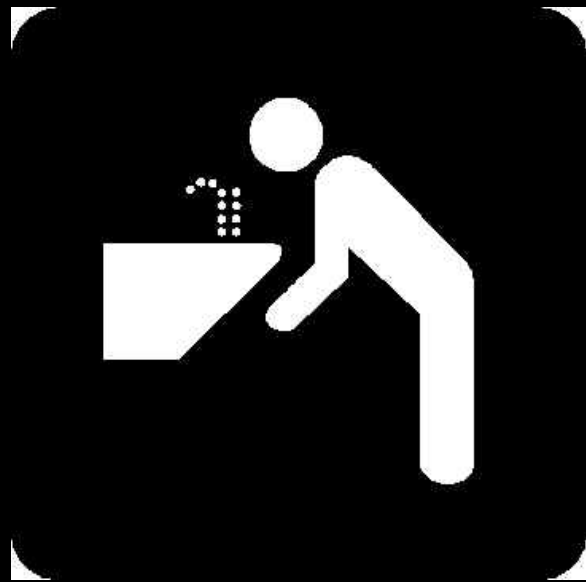
# What is Communication ?

One definition of communication:

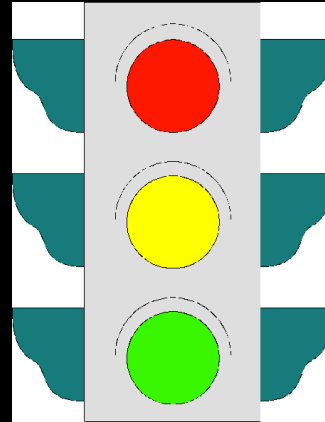
A transactional process involving the exchange of mutually understood symbols conveying information or understanding to another.

# It's about more than the written word

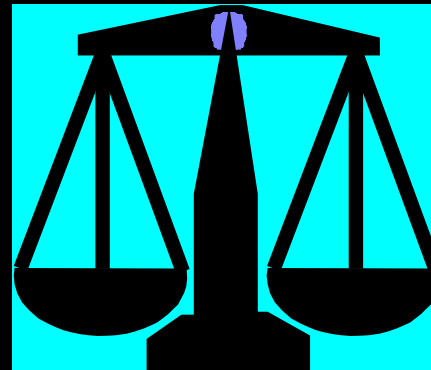
# 1



# 3



# 2



# 4



and what about these.....?

$\alpha$

$\mu$

$\Pi$

$\Omega$

$\Delta$

# and what about these.....?

$\alpha$  (angular acceleration, attenuation constant, Type I error, coefficient of resistance, alpha particle ....)

$\mu$  (population mean, wavelength, micro, osmotic pressure, Pelitier coefficient)

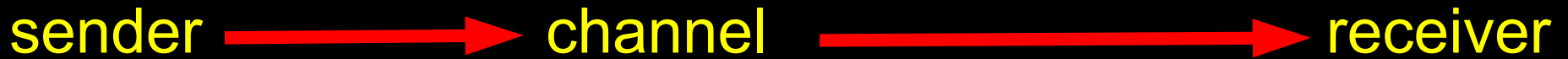
$\Pi$  (proportion, product, 3.14, osmotic pressure....)

$\Omega$  (ohms, volume of phase space...)

$\Delta$  (change, optical tube wavelength, distance between focii of two lens units....)



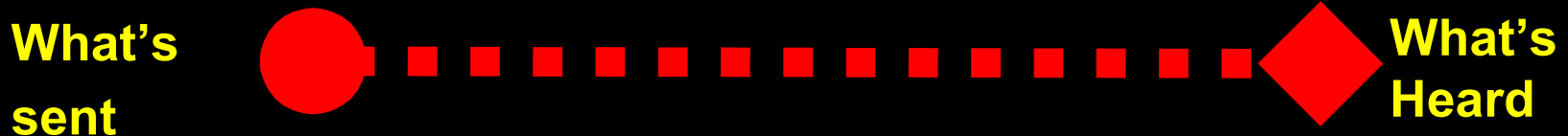
# Health Communication 101



## The 'Ideal' Fantasy World



## The 'Real' World



# Health Communication 101



# Health Communication 101

Sources of Distortion

Sender & Receiver Characteristics  
culture/values/attitudes/beliefs/literacy

sender

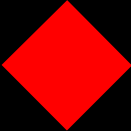
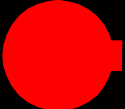


channel



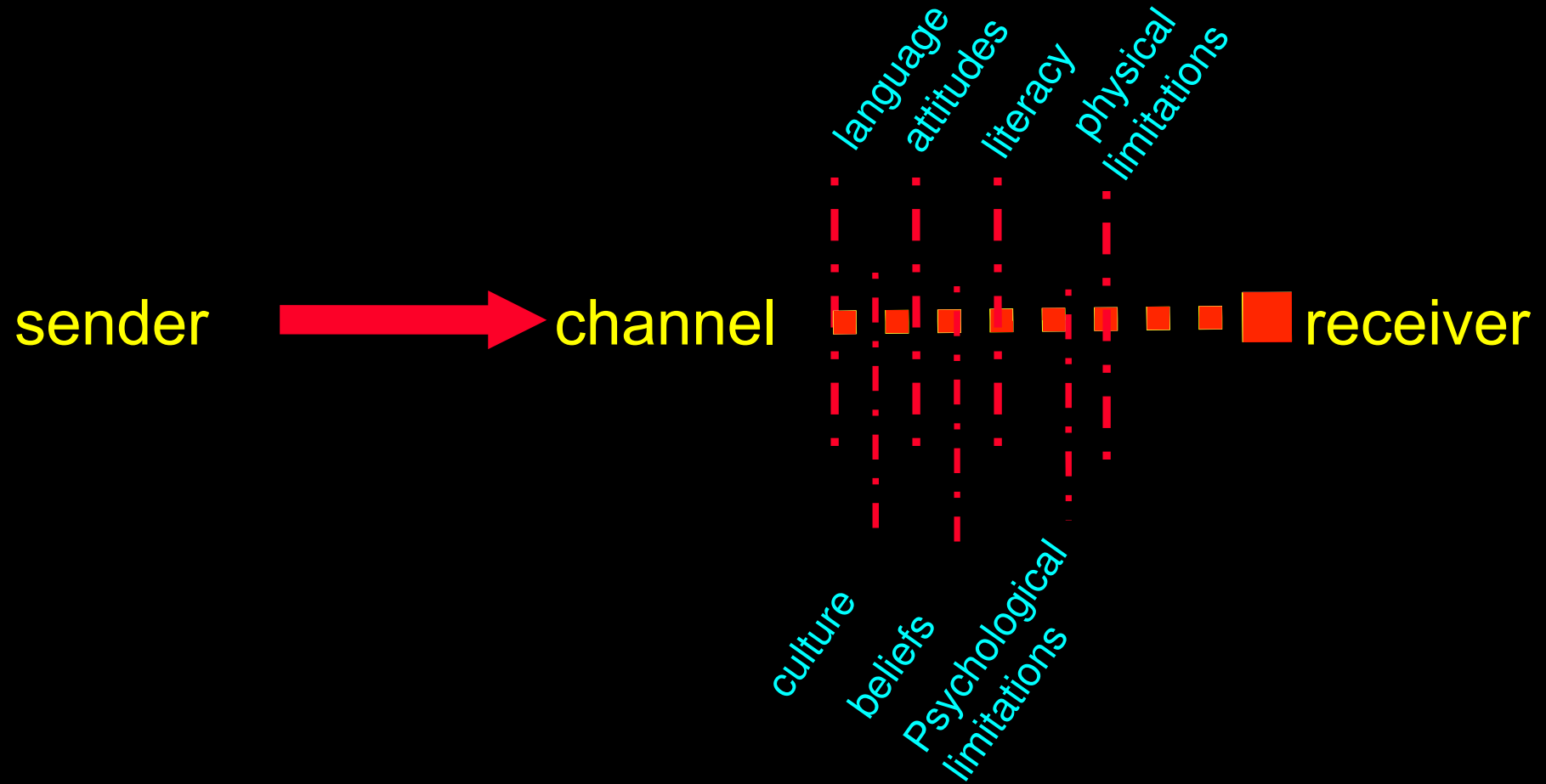
receiver

What's sent



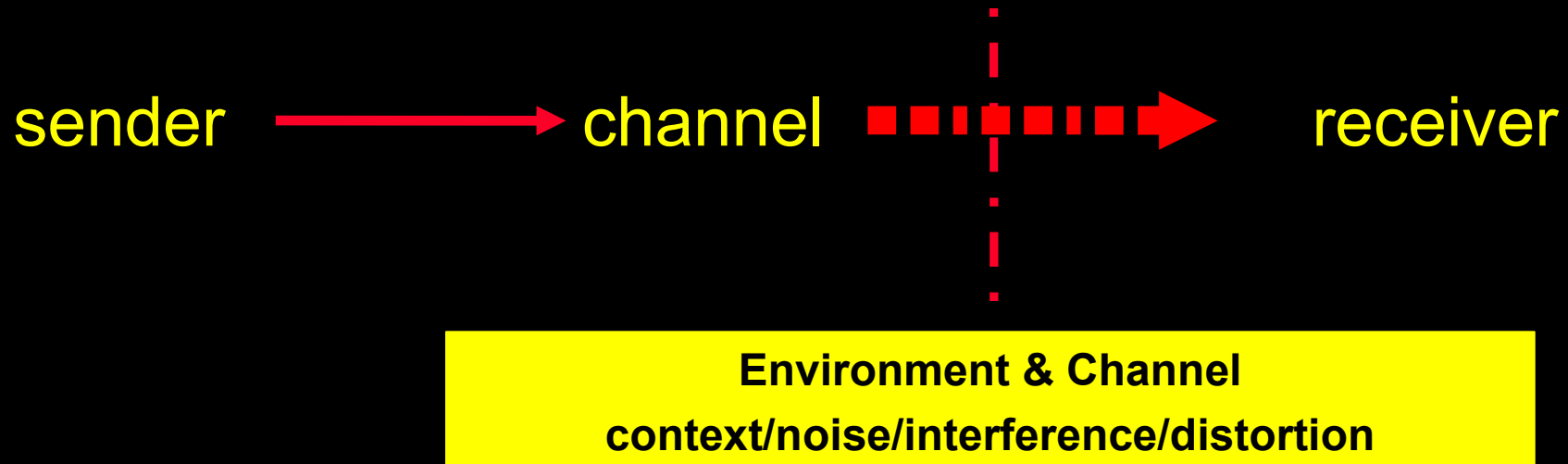
What's Heard

# Sources of Distortion-Personal

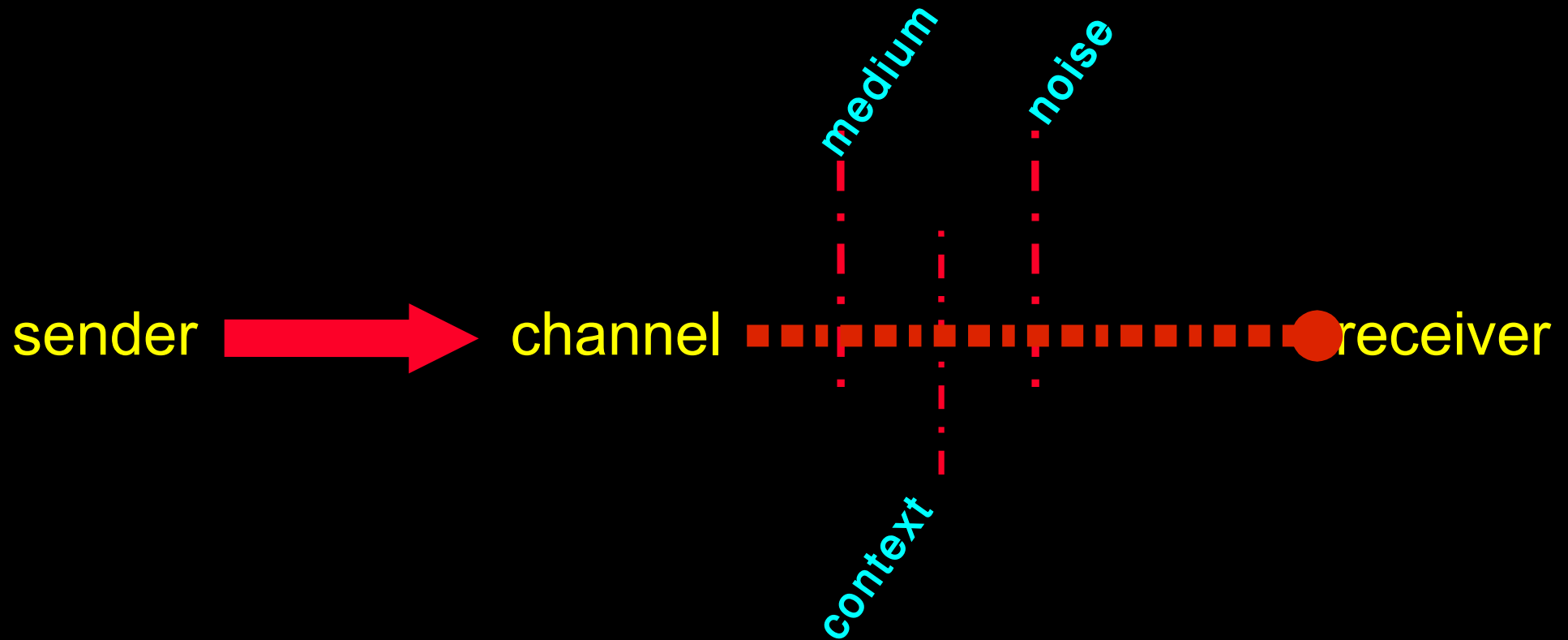


# Health Communication 101

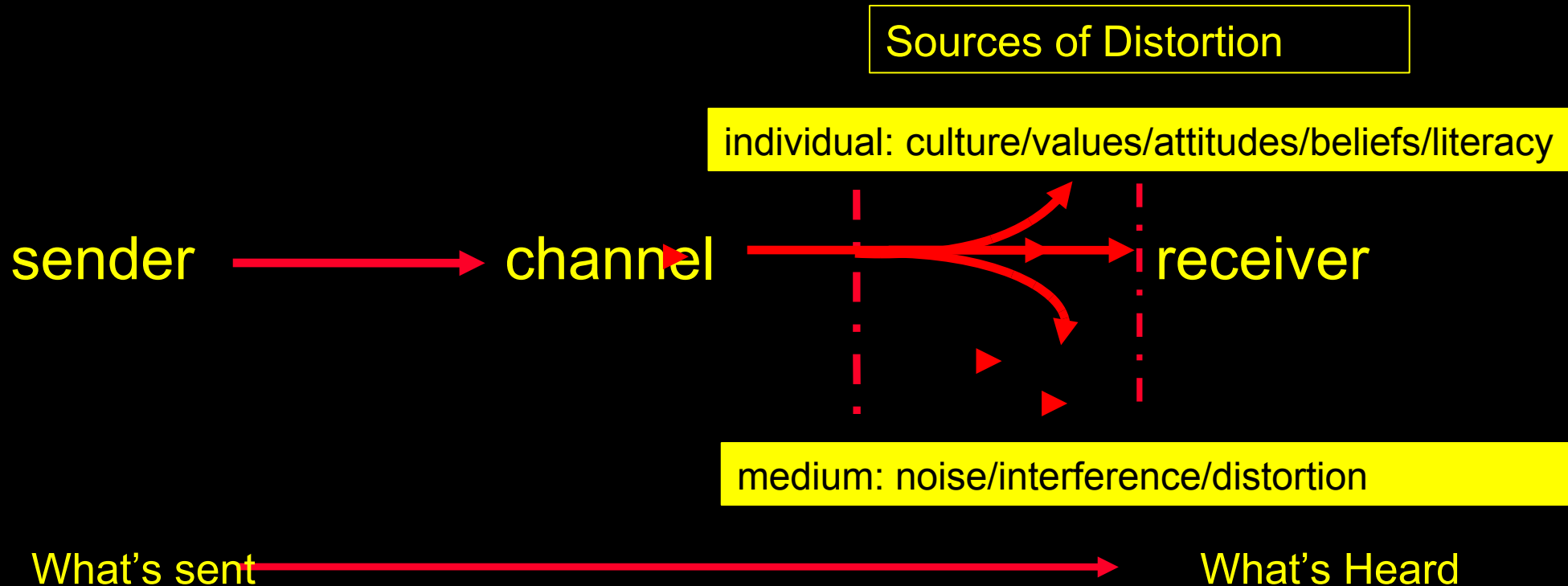
Sources of Distortion



# Sources of Distortion-Environmental

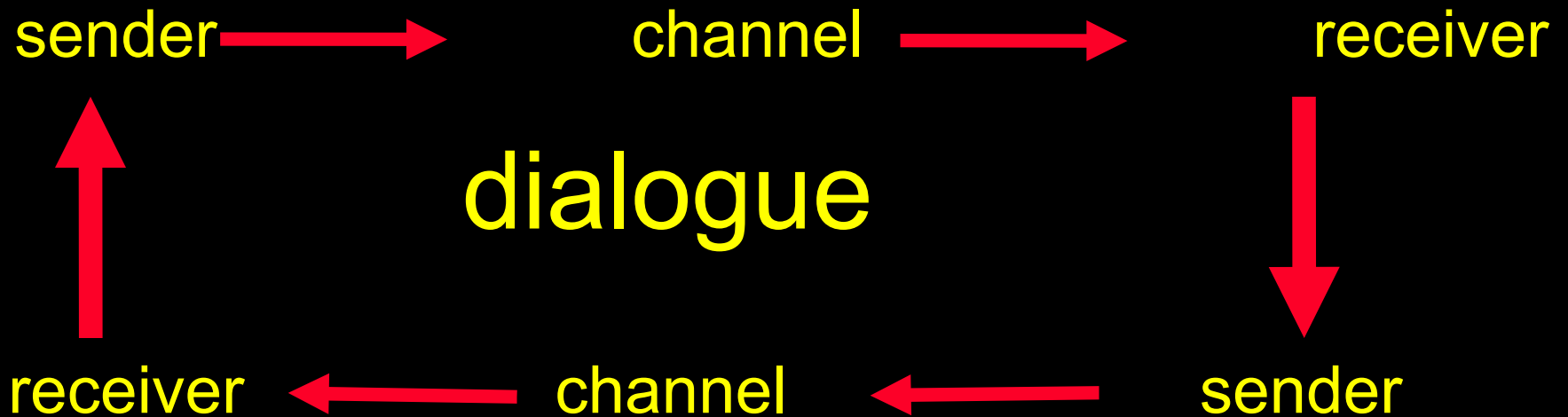


# Health Communication 101



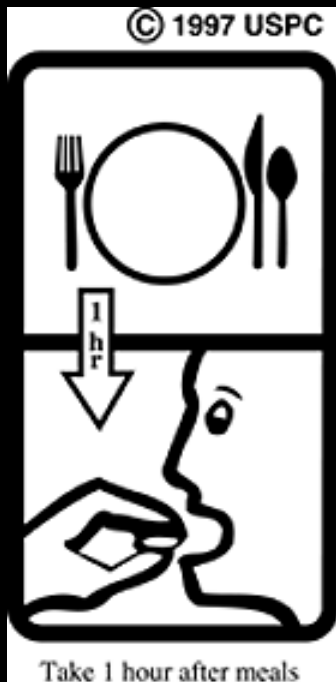
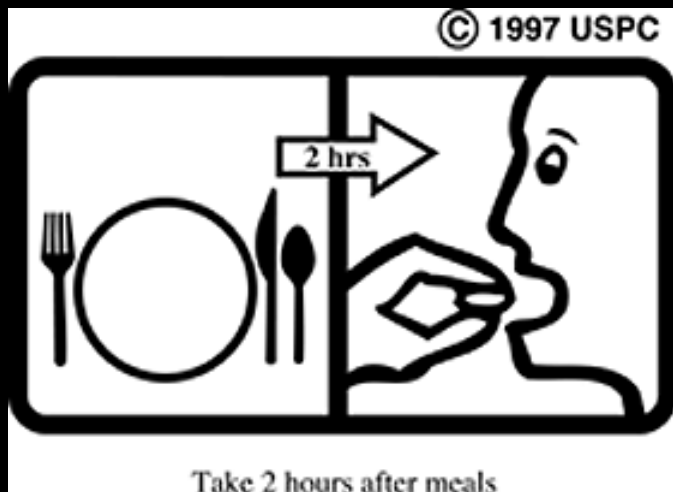
*Key points: What is sent? What channel is used? What do people hear?  
What do they think about what they hear? What do they do?*

# Communication paradigm (two-way)



*Note: Dialogue involves listening*





# Key Points

- Communication is more than reading plain text e.g. verbal-(plain text/oral); nonverbal (drawings/diagrams/symbols/gestures)
- Dissemination is NOT communication
- Translation is NOT communication
- The context may make it impossible for people to "hear"
- Culture shapes attitudes and beliefs, what's heard, and what's acted on
- Beware of assumptions about implicit knowledge or beliefs

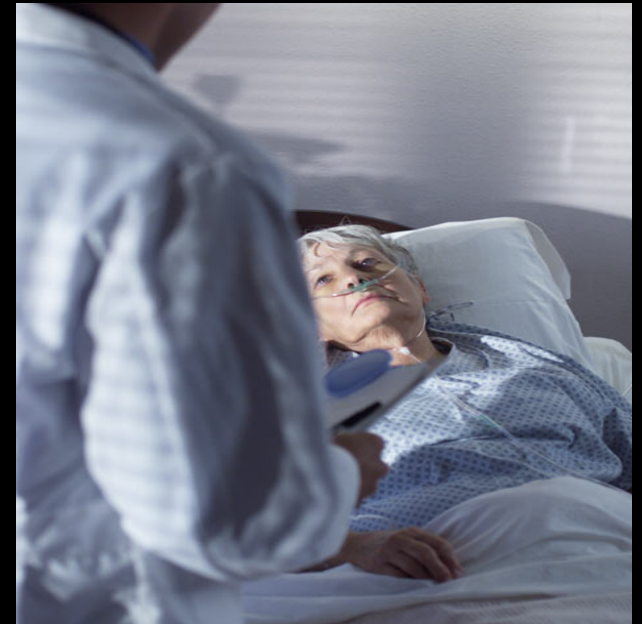
# Informed Consent Demands

- Use of mutually understood words and symbols
- Dialog and discussion
- Communication tailored to the knowledge, skills, attitudes and beliefs of the audience
- Respectful tone
- Supportive and "noise-free" environment
- Neither implicit or explicit coercion

# Barriers to Effective Communication

- Language
- Cultural attitudes and beliefs
- Emotional state/context
- Environmental factors e.g. noise, chaos & confusion, alien environment
- Communication overload
- Health and science literacy

# What is health literacy?



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# Consider this....



The Massachusetts Department of Public Health concerned about the abuse of antibiotics mounts a massive campaign to warn people about the adverse consequences of taking antibiotics to treat viral illnesses. The campaign planners assume that people understand the difference between a bacteria and a virus.



# Consider this.....



A 50-year-old man weighs 275 lbs. His cardiologist advises him that even a 5% weight loss will greatly improve his health. The man has no idea how to determine how many pounds he should lose.

# Consider this...



A two year old is diagnosed with an ear infection and prescribed an antibiotic. Her mother understands that her daughter should take the prescribed medication twice a day. After carefully studying the label on the bottle and deciding that it doesn't tell how to take the medicine, she fills a teaspoon and pours the antibiotic into her daughter's painful ear.

Parker et.al. 2003



# Consider this...



A young mother got prescription for her daughter from the pharmacy with instructions to give her 1 cc two times a day. It came with a dispenser marked ml.

She was too ashamed to call the doctor and ask if it made a difference. So as not to risk giving her daughter too much medicine, she gave her .5 ml instead.

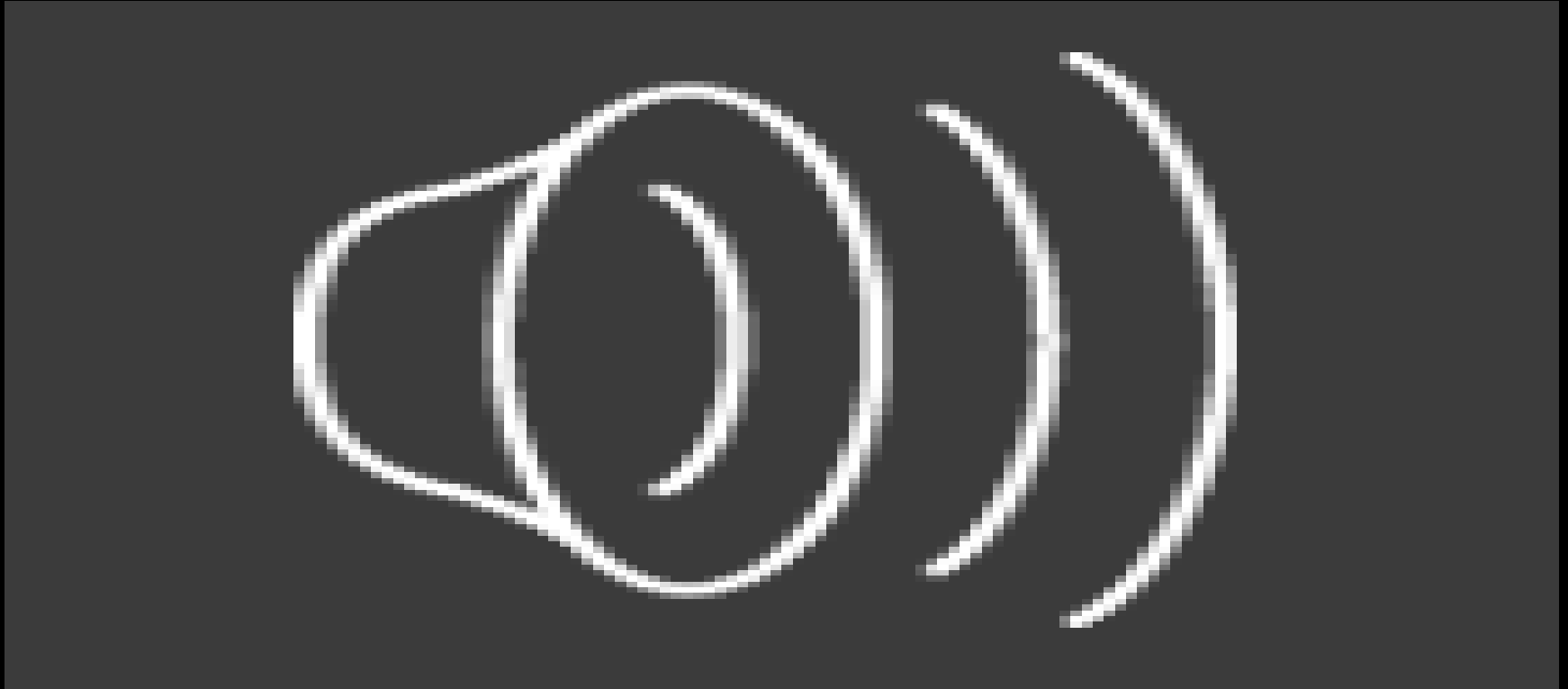
Consider this....



*Mrs. Cordell-Seiple*

Graduated high school reading at 5<sup>th</sup> grade level

**Consider this**



**Mrs. Seiple**

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# Health literacy

*The degree to which individuals have the capacity to obtain, process, interpret and understand basic health information and services needed to make appropriate health decisions.*

*Ratzan and Parker, NLM-NIH 2000*

**Functional health literacy: capacity to obtain, understand and act on information.**

# How Health Literacy functions as a barrier to effective communication and to informed consent



# What do we know prevalence?



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# What Do We Know about the Prevalence of the Problem?

## National Assessment of Adult Literacy

(NAAL 2003)

- N=19,000 national probability sample (38 states)
- Assessed English literacy among adults >16yrs
- Respondents resided in both households and prisons
- assessed how well tasks were performed using written materials

**Key point:** *selection criteria and methodology means sample under-estimates of size of the affected population*

# Key points about the NAAL

- The NAAL data reflect under-estimates of prevalence
- There are certain segments of the population at especially high risk e.g. elderly, uninsured, < H.S. Education
- Health literacy is situational-it does not necessarily correlate with reading or numeracy



# The research shows that people with poor literacy skills...

- Don't receive preventive messages and services in a timely way
- Don't get screened early in the disease process
- Delay seeking treatment
- Miss out on entitlements e.g. free care pool  
Medicaid, free-care, drug benefit programs
- Are sicker, have poorer outcomes, and higher mortality rates

# **The research shows that people with poor literacy skills...**

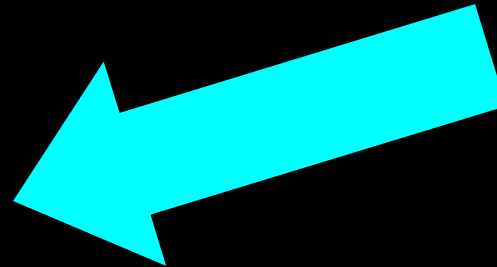
- Get lost and cannot find their way through the system**
- Are labeled as “passive”, “unreliable”, “unresponsive”, “hard to reach”**
- Are more likely to suffer from treatment or medication errors**
- Maybe denied basic rights e.g. the right to make an informed decision**
- May not be able to advocate for themselves**

# Functional Literacy (NAAL)

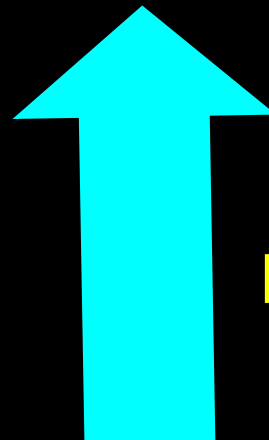
Documents



Quantitative



Functional  
Literacy



Prose

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# NAAL Functional Categories

- Proficient (12%)

Using a table calculate employees health insurance costs for a year.

- Intermediate (53%)

Read, interpret, and follow a prescription label

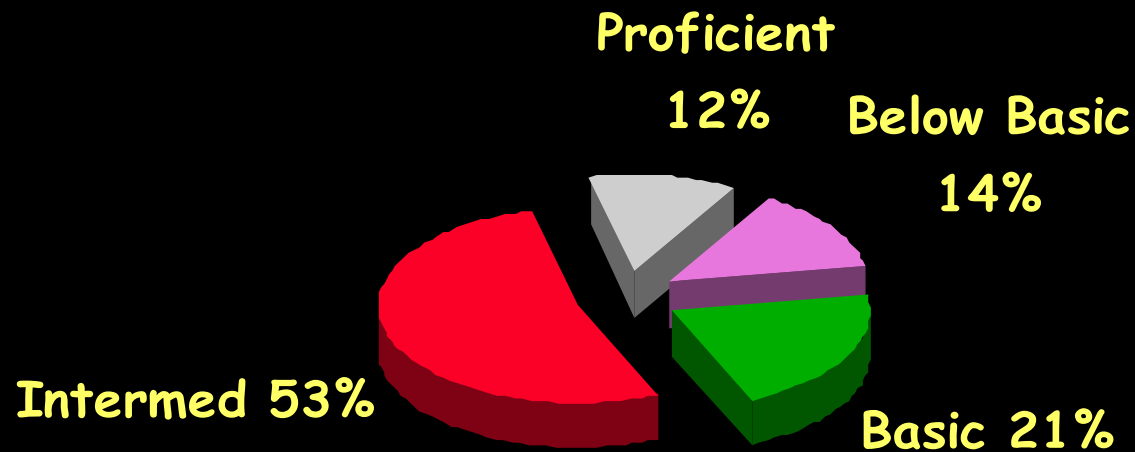
- Basic (21%)

Read a pamphlet about screening and give to reason for screening someone who is asymptomatic

- Below Basic (14%)

Read a set of short instructions identify what can be eaten or drunk before a test.

# Adult Health Literacy Level: NAAL 2003



Percent of U.S. Adult population in each category.

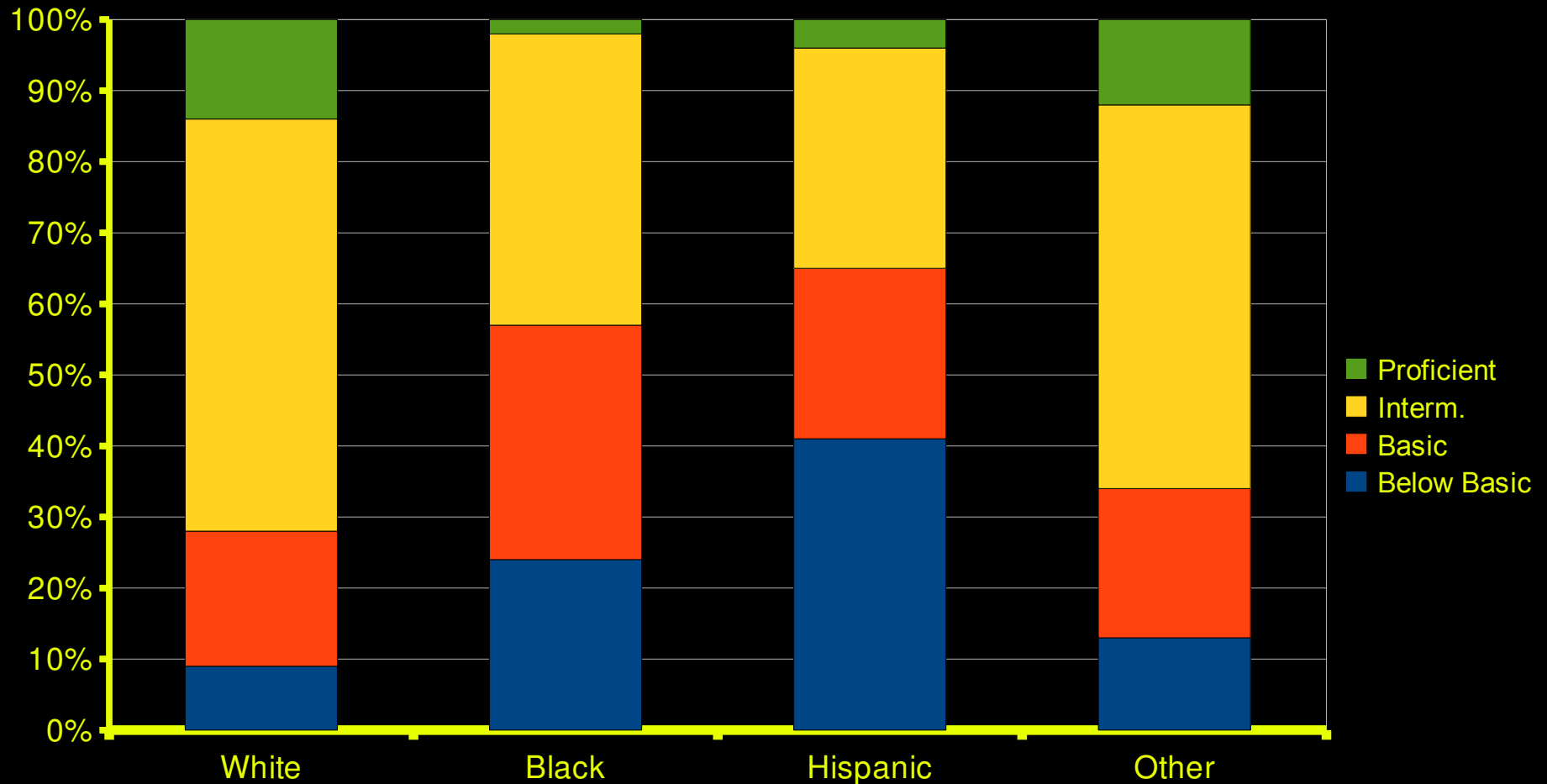
30 million adults “below basic” 47 million adults “basic”

Source: U.S. Department of Education, Institute of Education Sciences, 2003, National Assessment of Adult Literacy

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# Adult Health Literacy Level

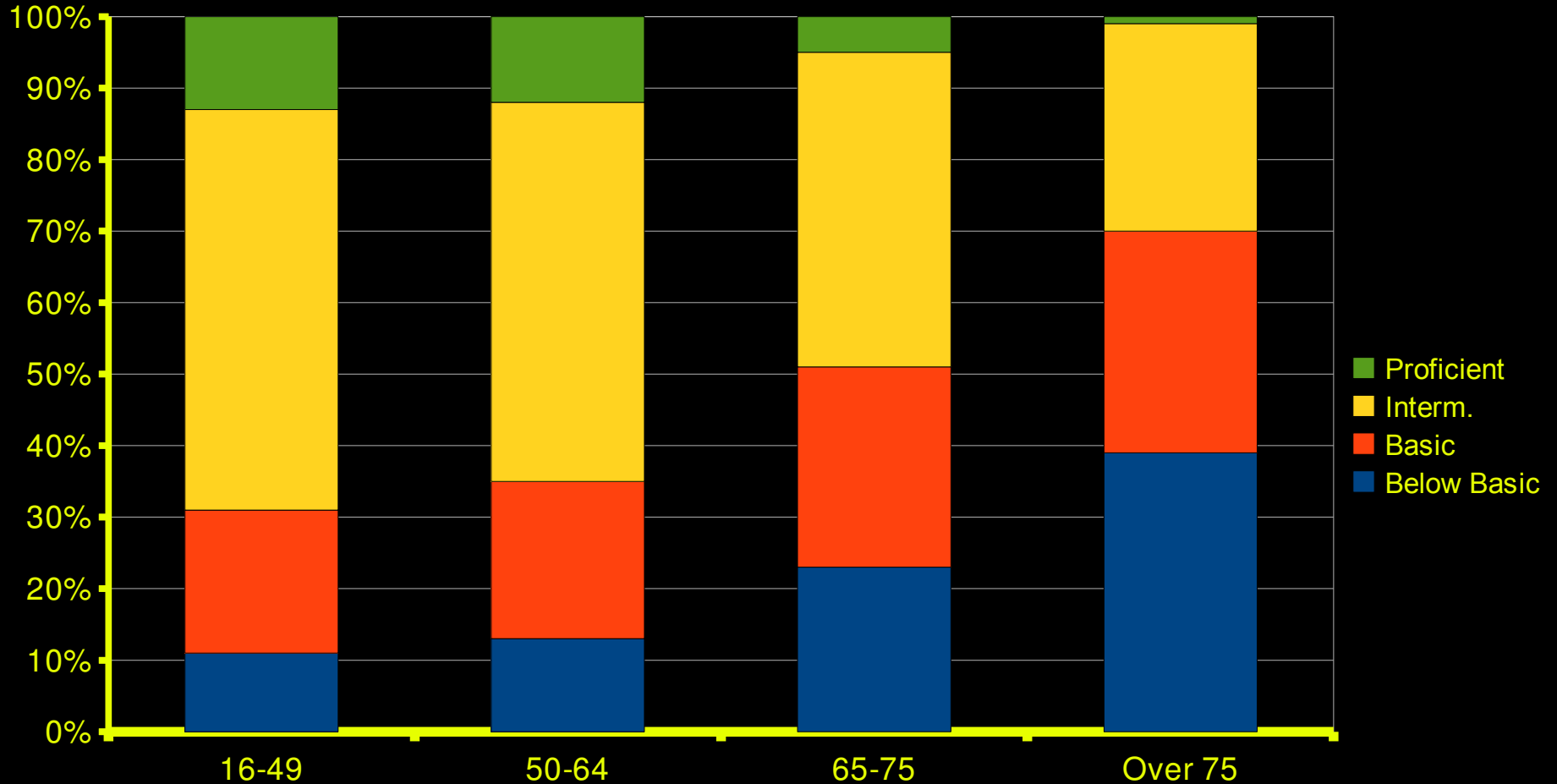
## by Race and Ethnic Group NAAL 2003



Source: U.S. Department of Education, Institute of Education Sciences, 2003, National Assessment of Adult Literacy

# Adult Health Literacy Level

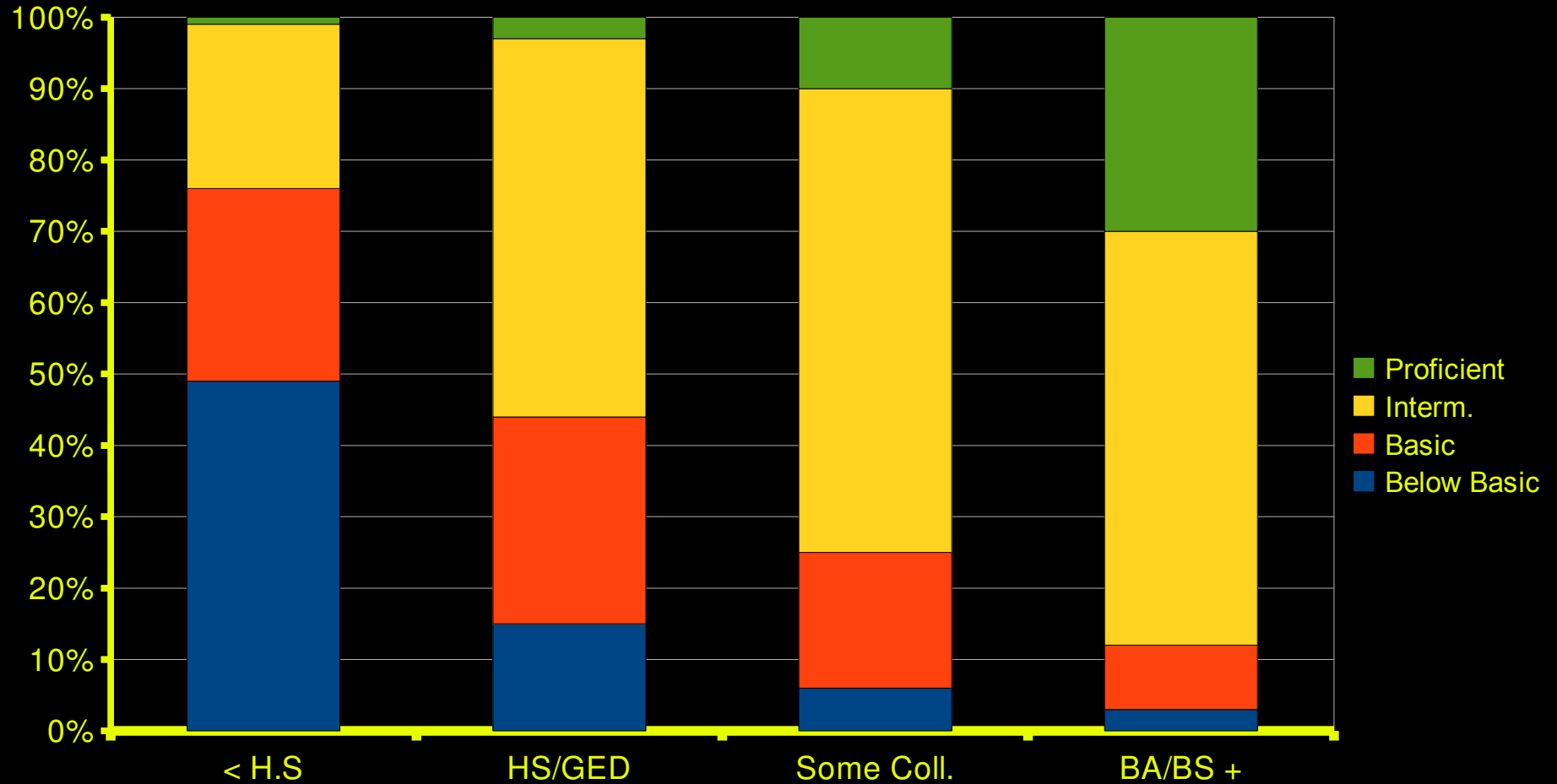
## by Age Category NAAL 2003



Source: U.S. Department of Education, Institute of Education Sciences, 2003, National Assessment of Adult Literacy

# Adult Health Literacy Level

## by Educational Level NAAL 2003

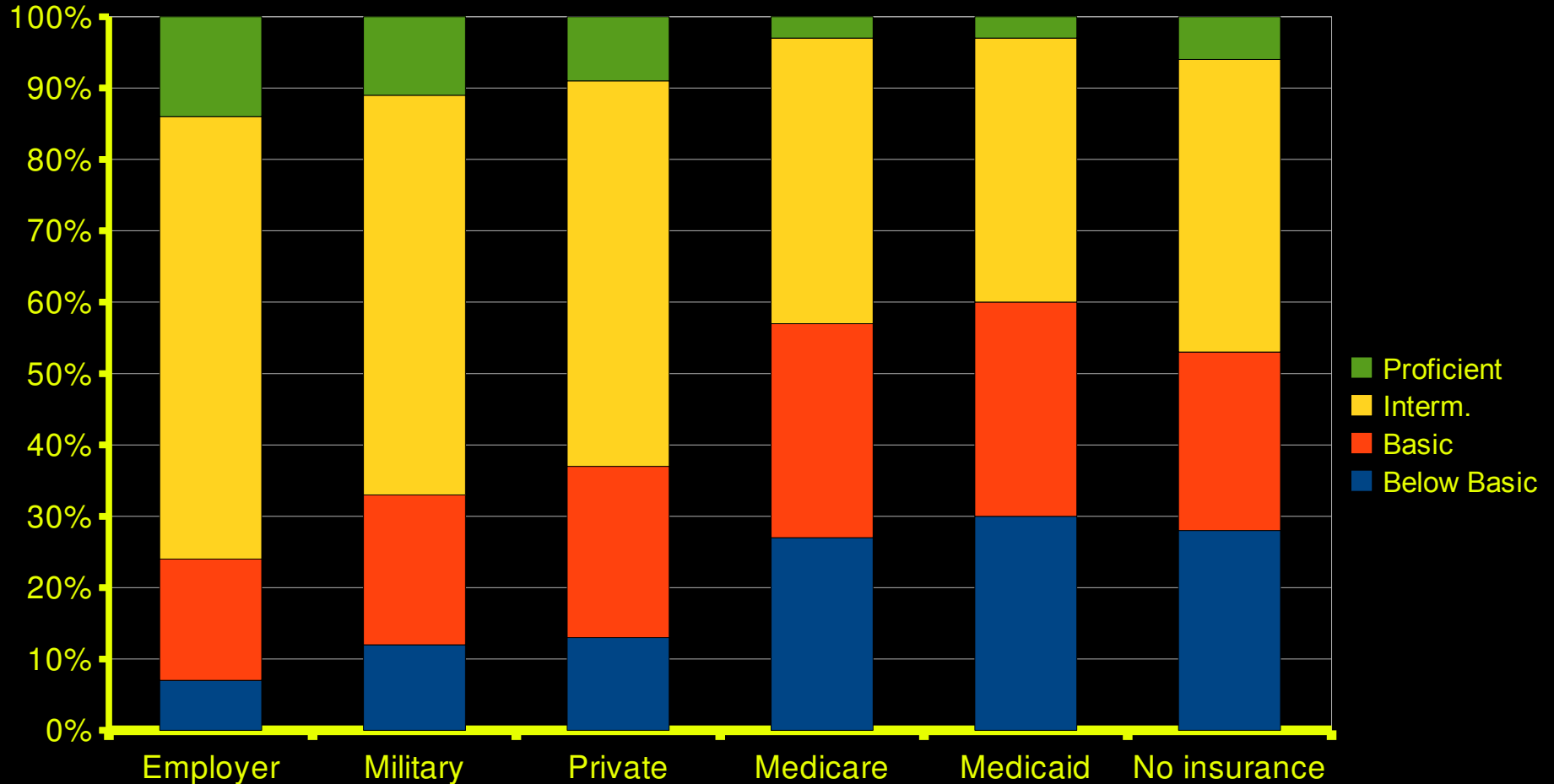


Source: U.S. Department of Education, Institute of Education Sciences, 2003, National Assessment of Adult Literacy



# Adult Health Literacy Level

## by Insurance Category NAAL 2003

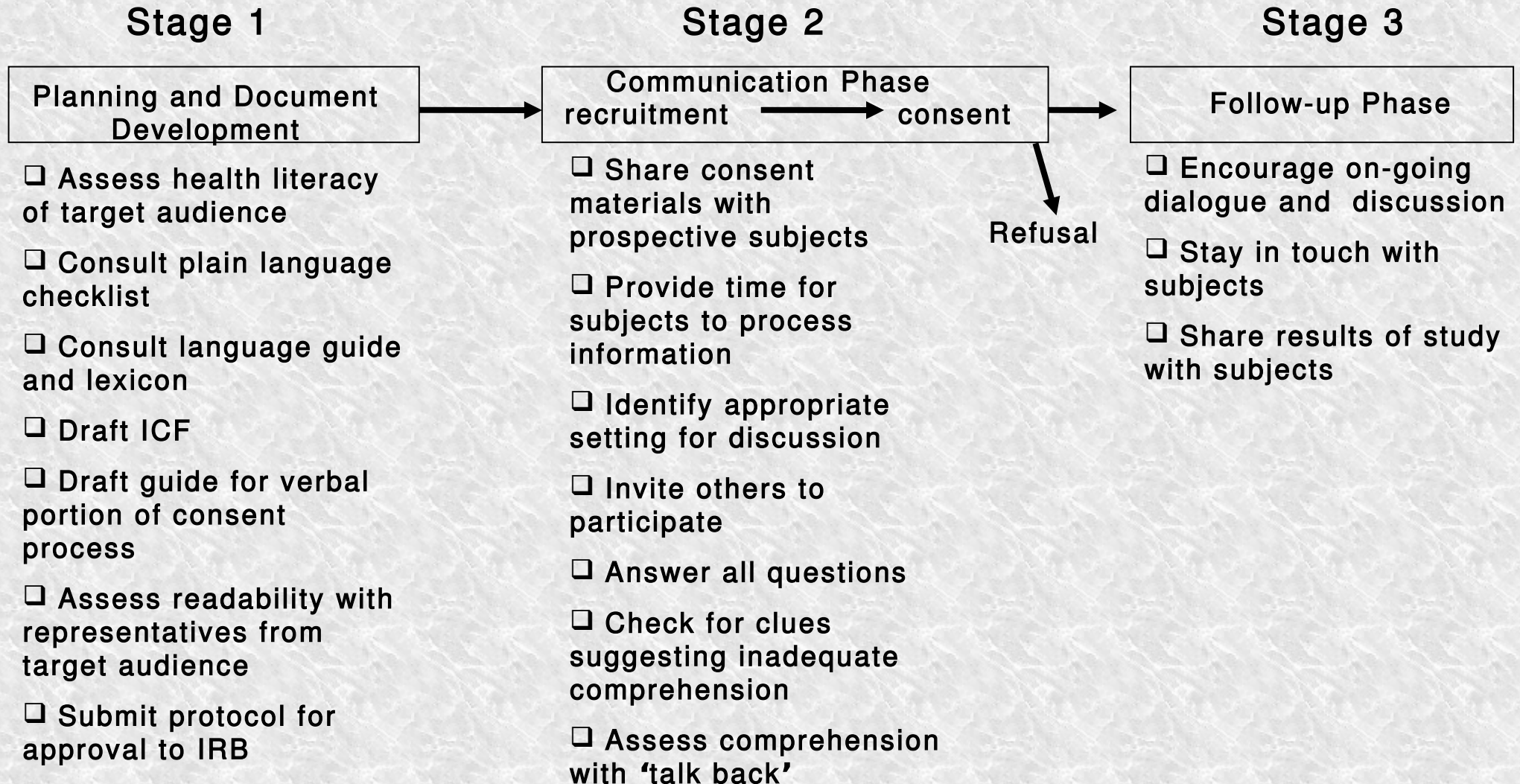


# Seven Steps for Facilitating Informed Consent

- Think beyond 'the form'-the form should be seen as an endpoint of one part of a process
- Train investigators, investigator surrogates verbal and non-verbal skills
- Adopt a 'universal precautions' approach-don't accept the argument that 'our patients are different'
- Abandon 'one-size-fits-all' and 'template' approaches use formative research to tailor communication to the language, skills, knowledge of the audience
- Start with plain language let people "drill down" for more
- Use 'teach back' to assess understanding
- Require investigators to address the "setting" for consent
- Consider multi-media approaches

# Facilitating Informed Consent

## A Longitudinal Process



# Stage 1

## Planning and Document Development



### Verbal

- Use plain, non-medical language as if you were speaking to a family member
- Limit the amount of information given, and repeat as necessary
- Explain the risks of the research thoroughly, remember that people perceive risks differently
- Ask subjects to bring in a list of questions they have
- Use 'teach back' method to ensure comprehension
- Empower subjects to speak without inhibition

### Nonverbal

- Train investigator surrogates to avoid negative non-verbal cues
- Provide adequate time and appropriate space for subjects to reflect and consider participation
- Show or draw pictures, visual images, and/or flow-charts
- Never hover!

### Written

- Use one or two syllable words, short paragraphs, and the active voice.
- Show or draw pictures, visual images, and/or flow-charts
- Provide consent forms in the subjects own language(s).
- Use large font, (at least 12 pt) with serifs.
- Be consistent with fonts: use only 2-3 font styles.
- Use upper and lowercase letters, all uppercase is hard to read.
- Use bullets for lists
- Use headings and subheadings to separate blocks of text
- Include a lot of white space around the margins and in between chunks of text.

## Stage 2



### Verbal

- Use plain, non-medical language as if you were speaking to a family member
- Limit the amount of information given, and repeat as necessary
- Explain the risks of the research thoroughly, remember that people perceive risks differently
- Ask subjects to bring in a list of questions they have
- Use the 'teach-back' method to ensure comprehension
- Empower subjects to speak without inhibition or shame

### Nonverbal

- Hold eye contact
- Face the subject with open body posture
- Nod, smile and vocal qualities of friendliness
- Provide a comfortable, quiet, private environment for conversation.
- Minimize noise distractions in the physical environment by turning off TV and radio.
- Avoid 'hovering' while waiting for the subject to sign the informed consent form;
- Try to leave the room and return to see if s/he has any questions.
- Create a shame-free environment: be respectful, caring and sensitive.
- Allow people plenty of time to read the documents that you have given to them.

### Written

- If explaining medication dosing and scheduling, use identifiers such as time of day references. Example: one tablet in the morning when you wake up
- If available, provide subjects with a glossary of research terms that you can reference during conversation.

# Stage 3

## Follow-up Phase

### Verbal

- Empower subjects to speak ask questions at any time now, or in the future
- Use plain, non-medical language as if you were speaking to a family member

### Nonverbal

#### Positive

- Hold eye contact
- Face the subject with open body posture
- Nod, smile and vocal qualities of friendliness

#### Negative

- Raising eyebrows
- Cover your mouth when speaking
- Avoiding eye contact
- Arms crossed over chest
- Looking at watching while being spoken to

### Written

- Share study results with subjects

# Summary

## Informed Consent in Clinical Research

- A problem of conflicting goals
- A rare occurrence-especially when illness, complexity, and other factors intrude
- Poses a serious threat to rights of subjects but the integrity of the research enterprise
- Can be improved even given the constraints imposed by conflicting goals

# Six Suggestions

1) Best single-one stop shopping site:

<http://www.hsph.harvard.edu/healthliteracy>

2) Clinical Health Literacy and Patient Care: A Manual for Clinicians-  
Dr. Barry Weiss published by the AMA Foundation.

<http://www.ama-assn.org/ama1/pub/upload/mm/367/healthlitclinicians.p>

3) The Health Literacy and Plain Language Resource Guide

[www.healthLiteracyinnovations.com](http://www.healthLiteracyinnovations.com)

4) General topic of interest to clinicians-Helen Osborne-

[www.healthliteracy.com](http://www.healthliteracy.com) and [www.healthliteracyoutloud.com](http://www.healthliteracyoutloud.com)

5) NIFL Listserve. Subscribe at: [www.healthliteracy@nifl.gov](mailto:www.healthliteracy@nifl.gov)

6) AHRQ-Universal Precautions Toolkit

[www.ahrq.gov/qual/literacy/healthliteracytoolkit.pdf](http://www.ahrq.gov/qual/literacy/healthliteracytoolkit.pdf)



# If I want to learn more, which door....?





# Health Literacy and Informed Consent





## Health Literacy and Informed Consent

## Health Literacy and Informed Consent Introduction



Welcome to the online module on Health Literacy and Informed Consent. This module was developed to help investigators and researchers recognize and overcome barriers to effective communication during the informed consent process. Click [here for Faculty and Reviewer Information](#).

The **content** is divided into three main sections:

- Health Literacy: Definition and Background
- Effects of Limited Health Literacy
- Successful Communication during Informed Consent

Funding for the development of this module is from a National Institutes of Health grant entitled: Health Literacy and Informed Consent in Clinical Research Studies NIH # R03 HD0540432-01.

*To learn about the module components and features, click [here](#). This information is also always available by clicking Help (below and on all screens). New learners should also click Help to review navigation and options before proceeding through the screens.*



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## Health Literacy and Informed Consent

## The Realities of Health Literacy

Did anything surprise you about this video clip? Would you have guessed that the woman depicted in this video had a problem reading? She certainly sounded as if she would be very comfortable in a health care environment, yet she signed a form and consented to a procedure that led to an outcome that she did not want. Her reasons for assenting resulted from the shame she felt in not being able to read all of the information given to her.

This video clip highlights the fact that it is impossible to tell if a person has difficulty reading or understanding information simply by looking or listening to them. Reading problems affect people from all walks of life; even celebrities are affected. In 2005, Jacques Demers, former head coach of the NHL Montreal Canadiens, admitted publicly to his illiteracy ([International Herald Tribune, 11/11/05](#))

Health literacy impacts a wide range of individuals, not just those who speak English as a second language or have little formal education. Individuals with poor health literacy may hold high-level positions; they may be professionals with advanced degrees. Yet these people are unable to function adequately in medical and health environments. It is critical to keep this in mind during the informed consent process.



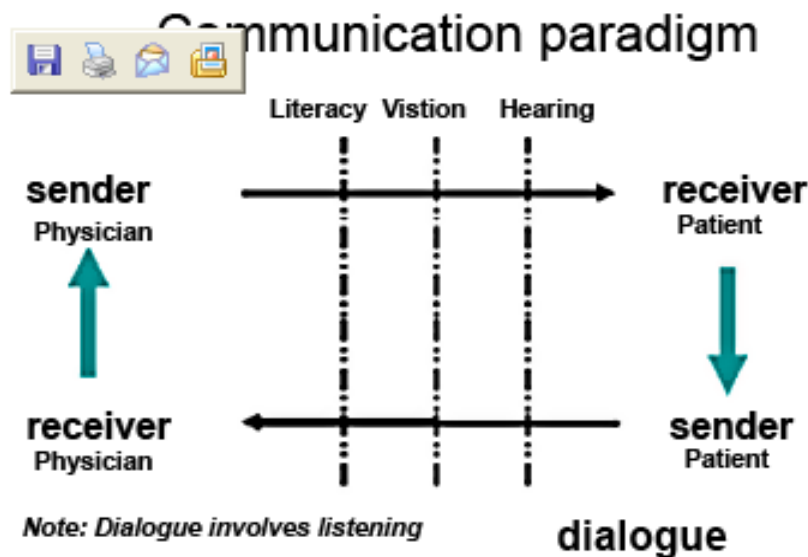
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Health Literacy and Informed Consent

## Introduction

In this module, we address communication issues between potential research subjects and the research investigator. Communication is a two-way process: it involves sending and receiving information between two involved parties. These "messages" can be sent with written words, spoken language, gestures, or a combination of all three methods. There are all sorts of barriers that may disturb the communication process, e.g., a noisy environment, differences in accents and speech, or cultural perspectives. Literacy is just one of several factors that can interfere with clear communication.



Click Next to continue.