Peaels Raed Tihs

Mnay of yuor sbjuctes cnaont raed wlel euongh to uesdnatnrd yuor csneont fmros! Waht are you gniog to do aubot it?

Paesle rsiae yuor hnad if you wnat to ivrpmoe the ifronemd cnsonet peroscs for yuor paiotentl sujbetcs.

Informed Consent: Moving from Readability to Comprehension

Michael Paasche-Orlow, MD, MA, MPH
Associate Professor of Medicine
Section of General Internal Medicine
Boston University School of Medicine

Literacy

- Literacy is inherently a functional concept i.e., it is competence in a set of skills relating to a specific domain of human endeavors.

Issues About the Concept of Literacy

- Basic literacy skills (reading, writing, arithmetic) very useful
- However, really is no one Literacy
  - corollary: there is no illiteracy
- All are functional - task oriented
- The demands are contextual

Definition of Health Literacy

"The degree to which individuals have the capacity to obtain, process, and understand ~~basic~~ health information services, and skills needed to make informed health decisions and actions.

- Understand how to use glucometer
- Interpret blood glucose results
- Obtain information about an illness
- Participate in discussions of informed consent
- Enroll in health insurance plan

Health Context increasingly complex

- Too much information
- Not enough time
- Heavy cognitive tasks when sick

Conceptual Domains for HL

- Basic Literacy Skills
  - Prose, Document, Quantitative
- Self-care tasks
  - Disease specific
- Interactional
- Navigation

Health Literacy

- ❷ Prevalence and associations
  - Prevalence of HL and associations
    - with demographic characteristics that have been the central focus of the health disparity discourse

- →place your bets

Health Literacy in America

National Assessment of Adult Literacy (NAAL)

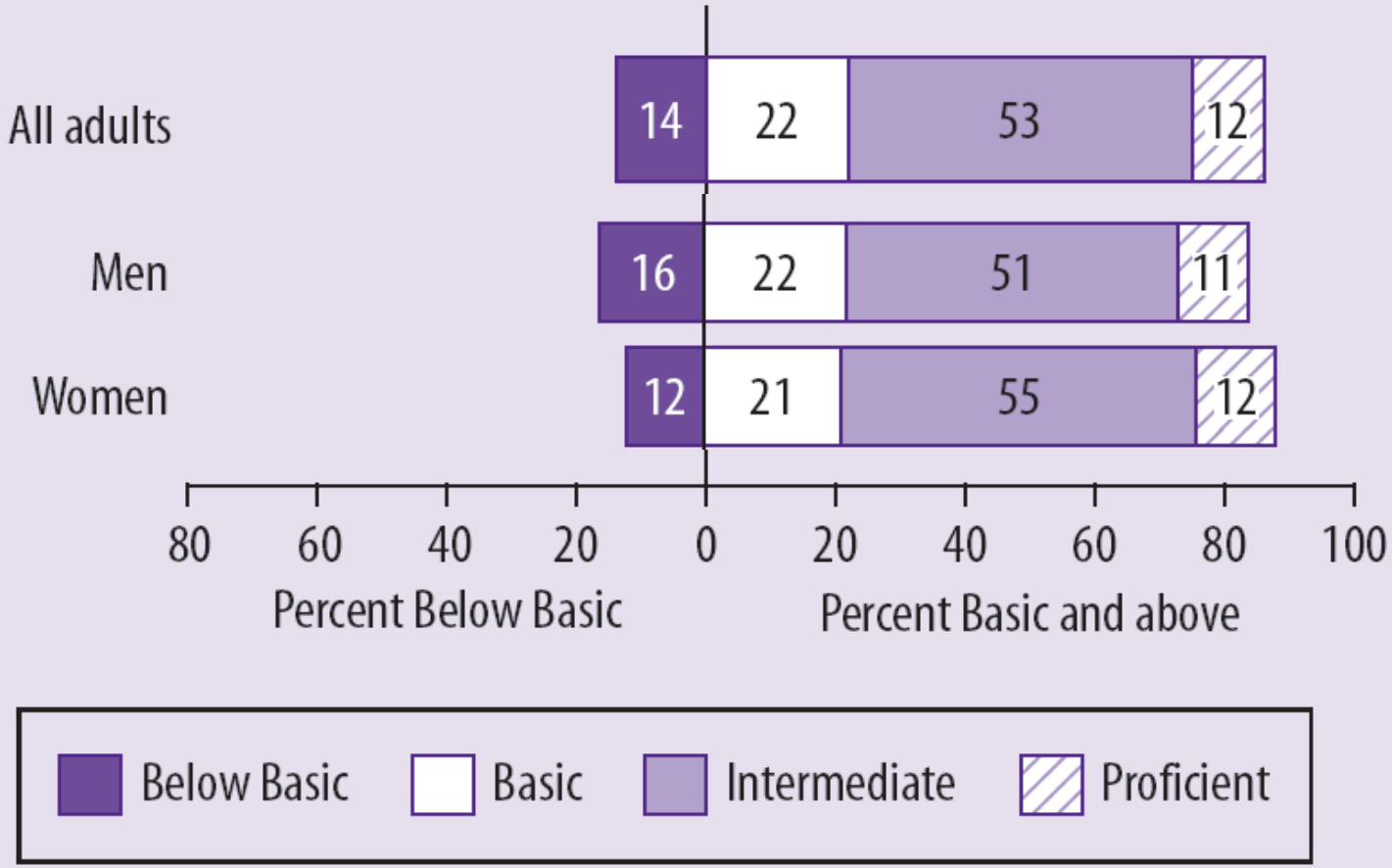
- National household survey, 2003, N~20,000
- Prose, document, and quantitative literacy

From http://nces.ed.gov/naal/

NAAL Levels

- Below Basic: Circle date on appointment slip, Understand simple pamphlet about pre-test instructions
- Basic: Understand simple pt ed handout
- Intermediate: Determine healthy weight from BMI chart, Interpret prescription and over-the-counter drug labels
- Proficient: Define medical term from complex document, Calculate share of employee's health insurance costs

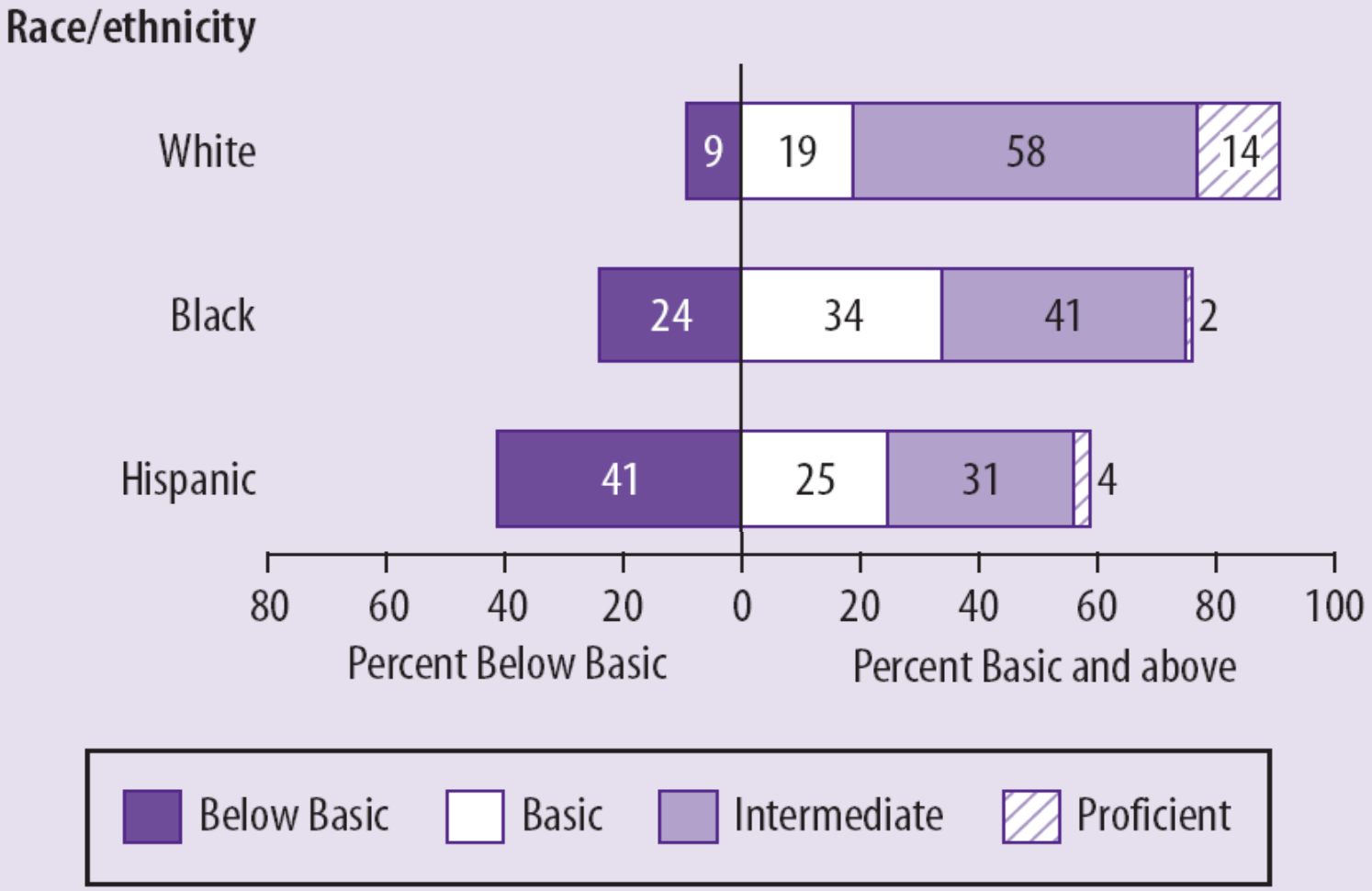
Figure 2-1. Percentage of adults in each health literacy level: 2003



National Assessment of Adult Literacy (NAAL), 2003

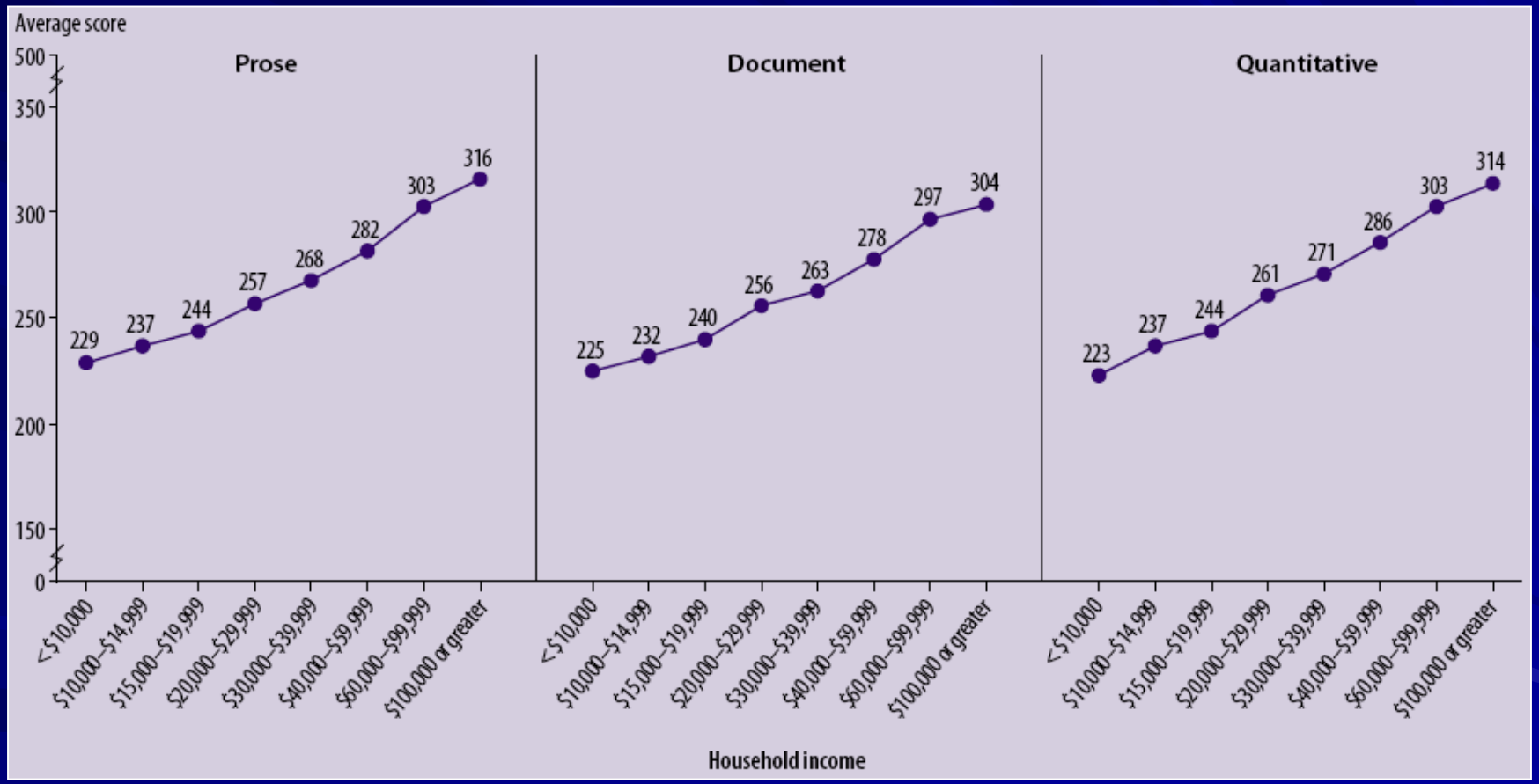

© charlesm

Percentage of adults in each health literacy level, by race/ethnicity: 2003



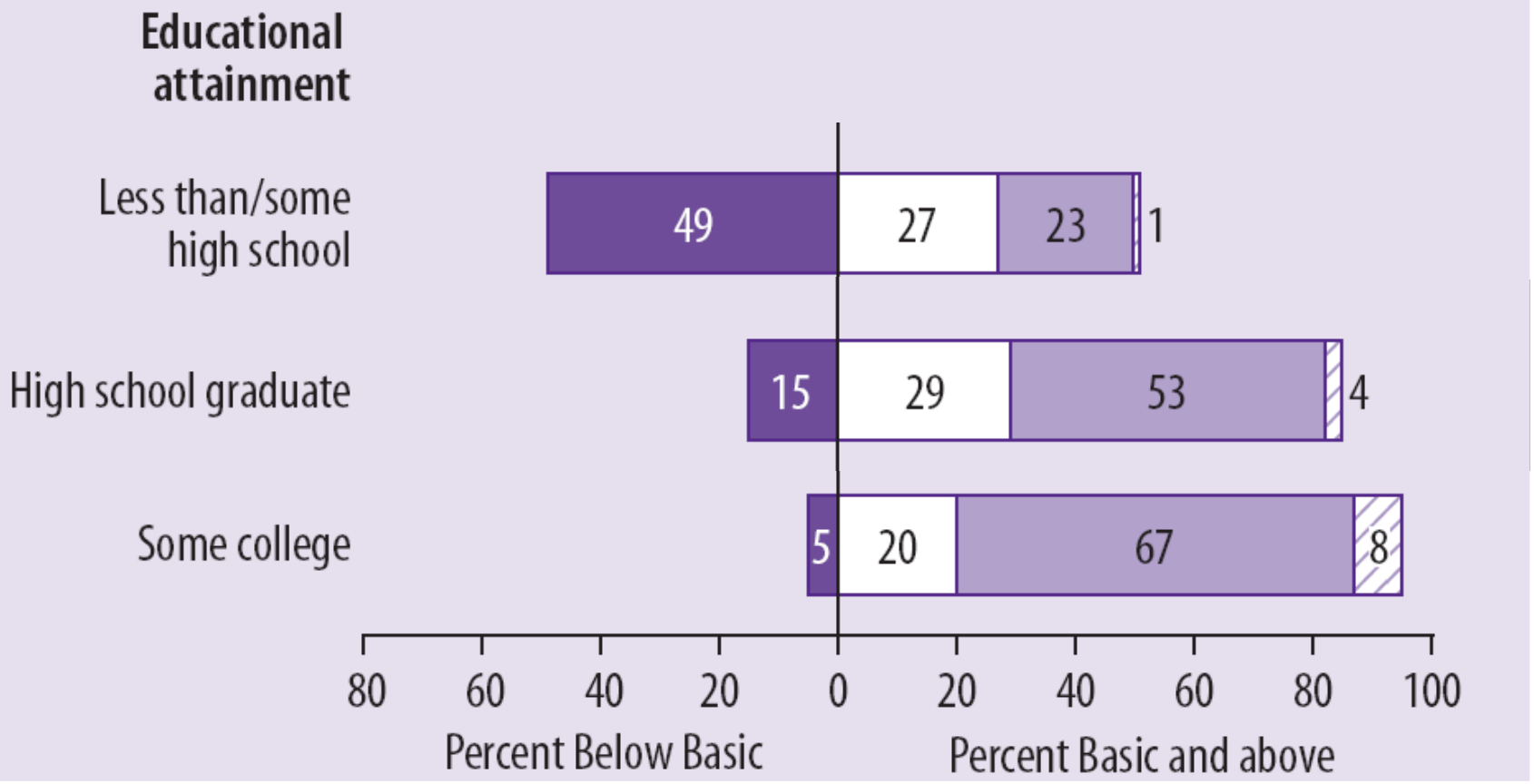
National Assessment of Adult Literacy (NAAL), 2003

Literacy and Income



National Assessment of Adult Literacy (NAAL), 2003

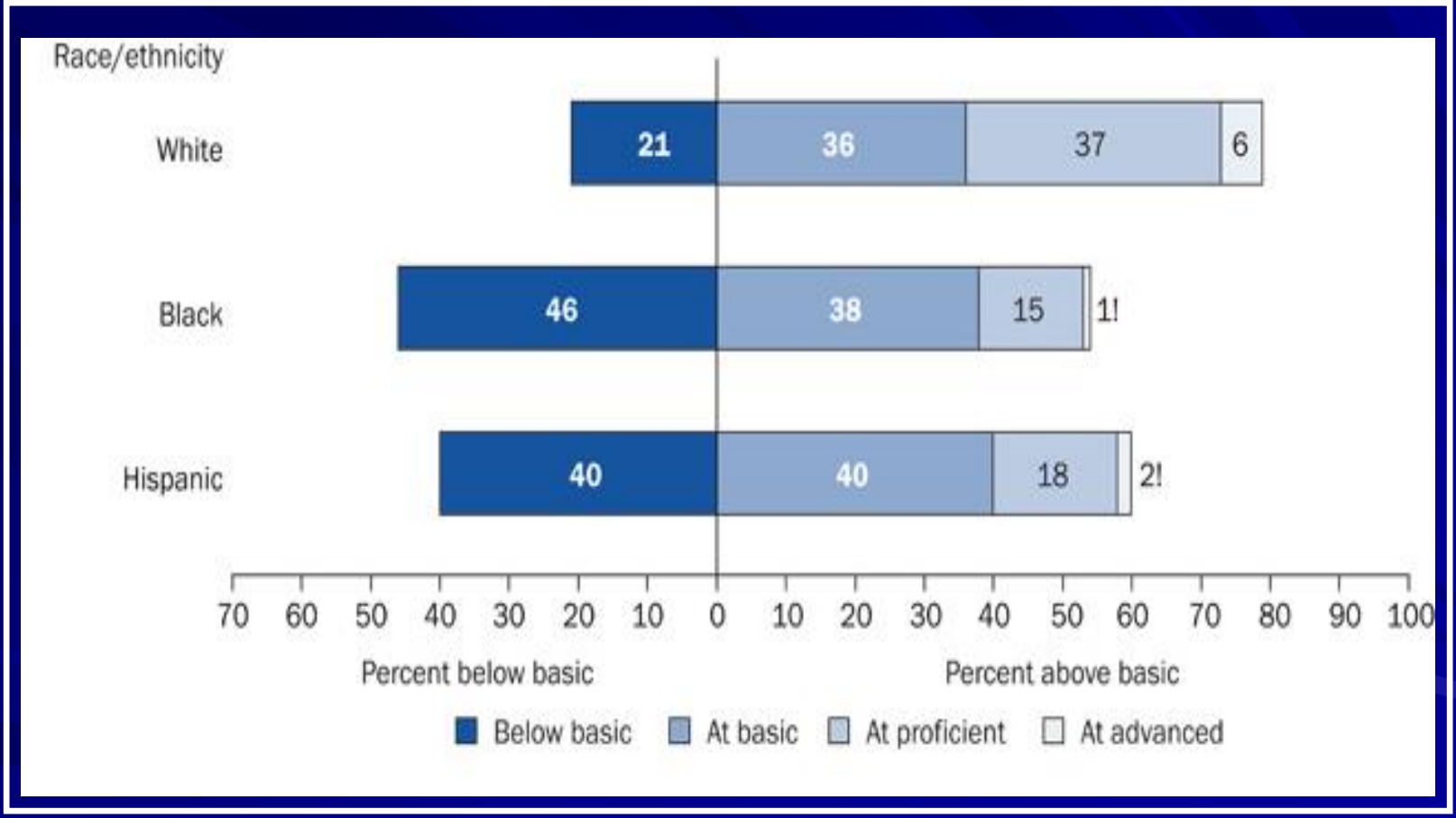
Percentage of adults in each health literacy level, by highest educational attainment: 2003



National Assessment of Adult Literacy (NAAL), 2003


SHCOOL

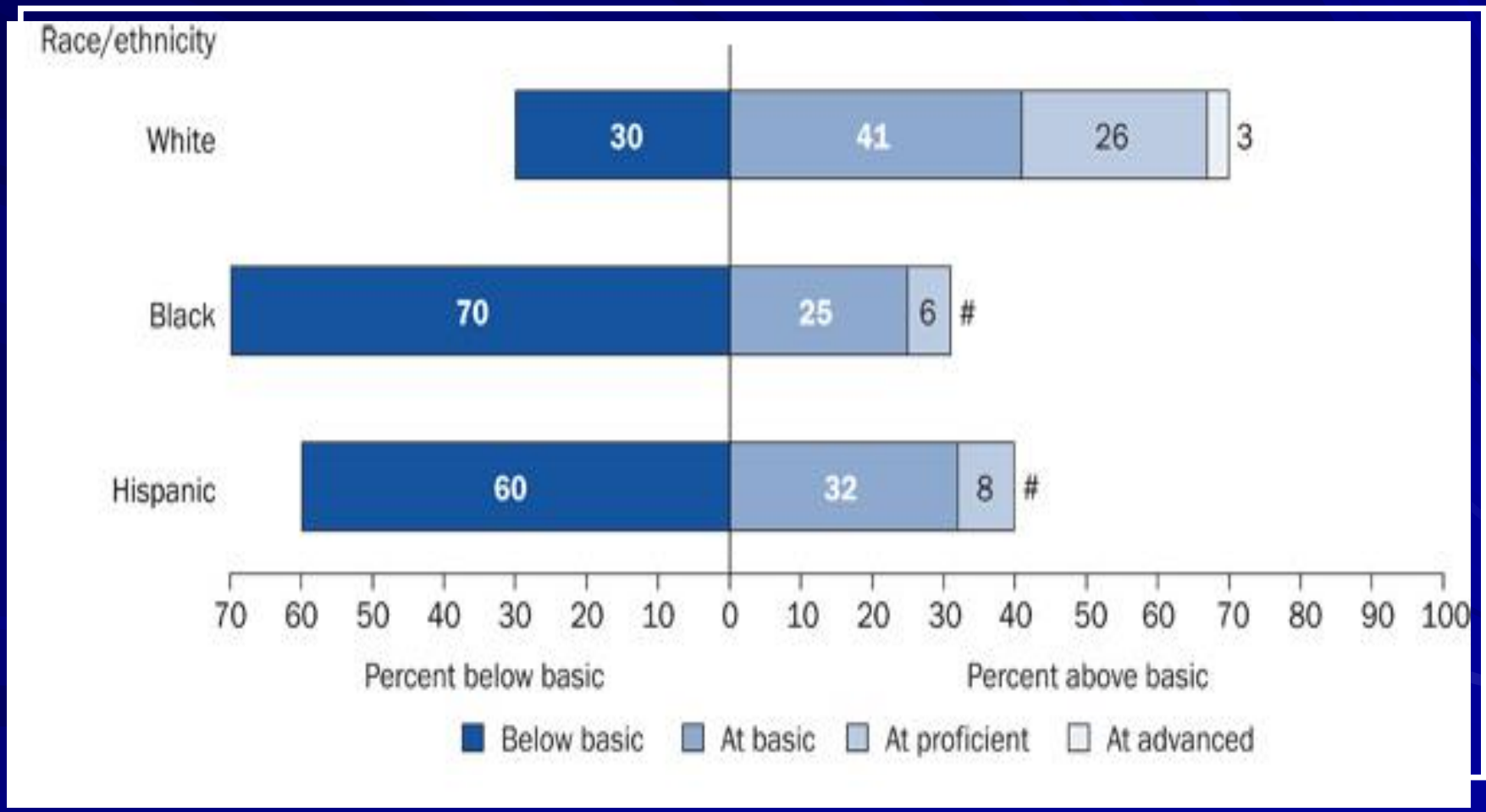
12th-grade students reading achievement, by race/ethnicity: 2005



National Assessment of Educational Progress (NAEP), 2005


I'M AWSOME

12th-grade students mathematics achievement, by race/ethnicity: 2005



National Assessment of Educational Progress (NAEP), 2005

Why does this matter?

Literacy and Health Outcomes

Health Outcomes/Services

- General health status
- Hospitalization
- Emergency department use
- Prostate cancer stage
- Depression
- Diabetes control*
- HIV control*
- Mammography*
- Pap smear
- Pneumococcal immunization
- Influenza immunization
- STD screening
- Cost
- Mortality

Behaviors

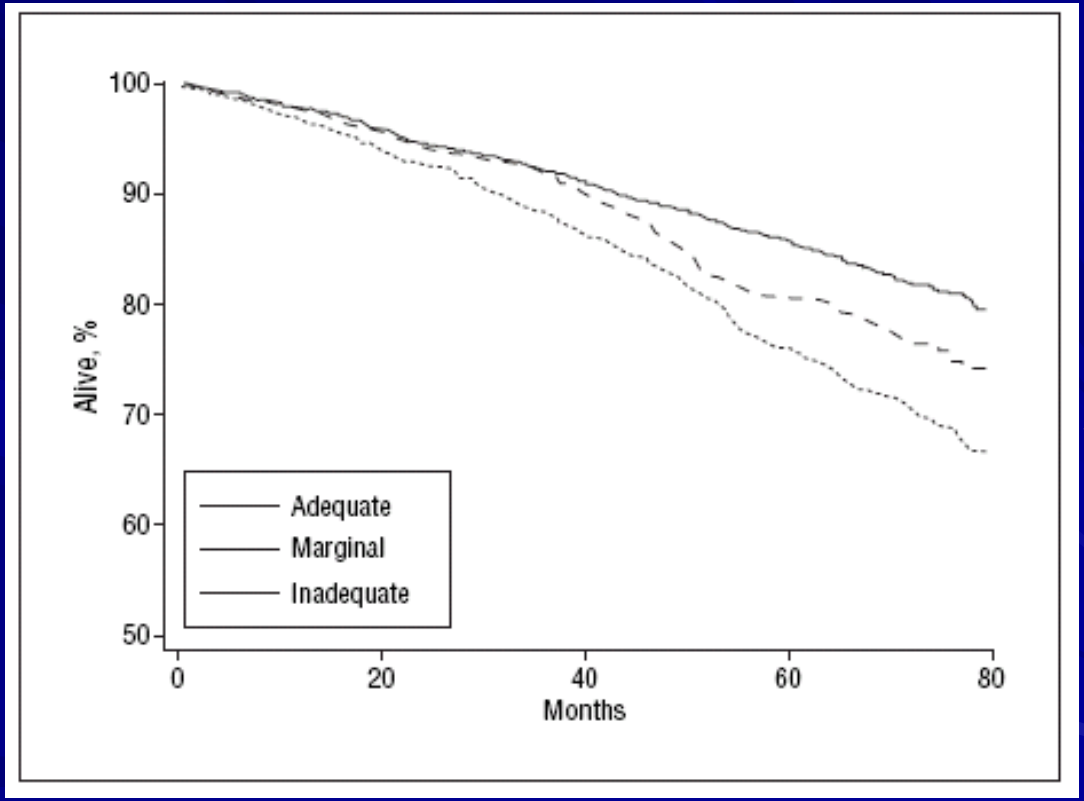
- Substance abuse*
- Breastfeeding
- Behavioral problems
- Adherence to medication*
- Smoking*

Knowledge

- Birth control
- Pap screening
- Emergency department instructions
- Asthma
- Hypertension
- Diabetes
- And many more…

Low Literacy and Mortality

- Limited literacy independently predicts all-cause and cardiovascular deaths in the elderly (39.4% vs 18.9% with HR 1.52, CI 1.26-1.83)



Baker et al, Arch Intern Med 2007;167: 1503-9

Where we have come from

- “If suitably approached, patients will accede, on the basis of trust, to about any request their physician may make”

  – JAMA. 1966 Jan 3;195(1):34-5.

Current Consent Standard

- Ethical Guidelines
- Federal Law
- And yet – consistently observed that many subjects not familiar with core principles of informed consent

Readability and the IRB

- Federal Statutes mandate that IRBs ensure that Informed Consent Forms are written in language subjects can understand (§**46.116, 50.20)**.
- IRBs must approve individualized informed consent forms for each study.
- IRBs often present language templates and/or sample documents to direct investigators.
- IRBs often present language standards for informed consent forms.

Readability and Liability

- **In the research setting readability has been used to negate the power of an executed ICD**
  - **In 1999, after 10 years of legal maneuvering, the University of South Florida and Tampa General Hospital agreed to a $3.8M settlement of a lawsuit brought on behalf of clinical trial subjects.**
  - **The plaintiffs maintained that the informed consent document for the study was written at a grade level that significantly exceeded the reading ability of the class – and this became a key issue in the settlement.**

Informed Consent Form Readability Standards vs. Actual Readability: A Survey of U.S. Medical School Institutional Review Boards

- Relevant data were extractable from 114/123 (93%) medical school websites examined.

  – Paasche-Orlow, NEJM 2003

Readability Standards

- Grade Level Standards in 61/114 (54%): Range 5th-10th (mode 8th) grade.
- Descriptive guidelines in 47/114 (41%): "in simple lay language"
- No language guidelines in 6/114 (5%)

Examples: Voluntary Nature of Participation

"You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care." (4th)

"You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University." (College)

Examples: Benefits (When there are none)

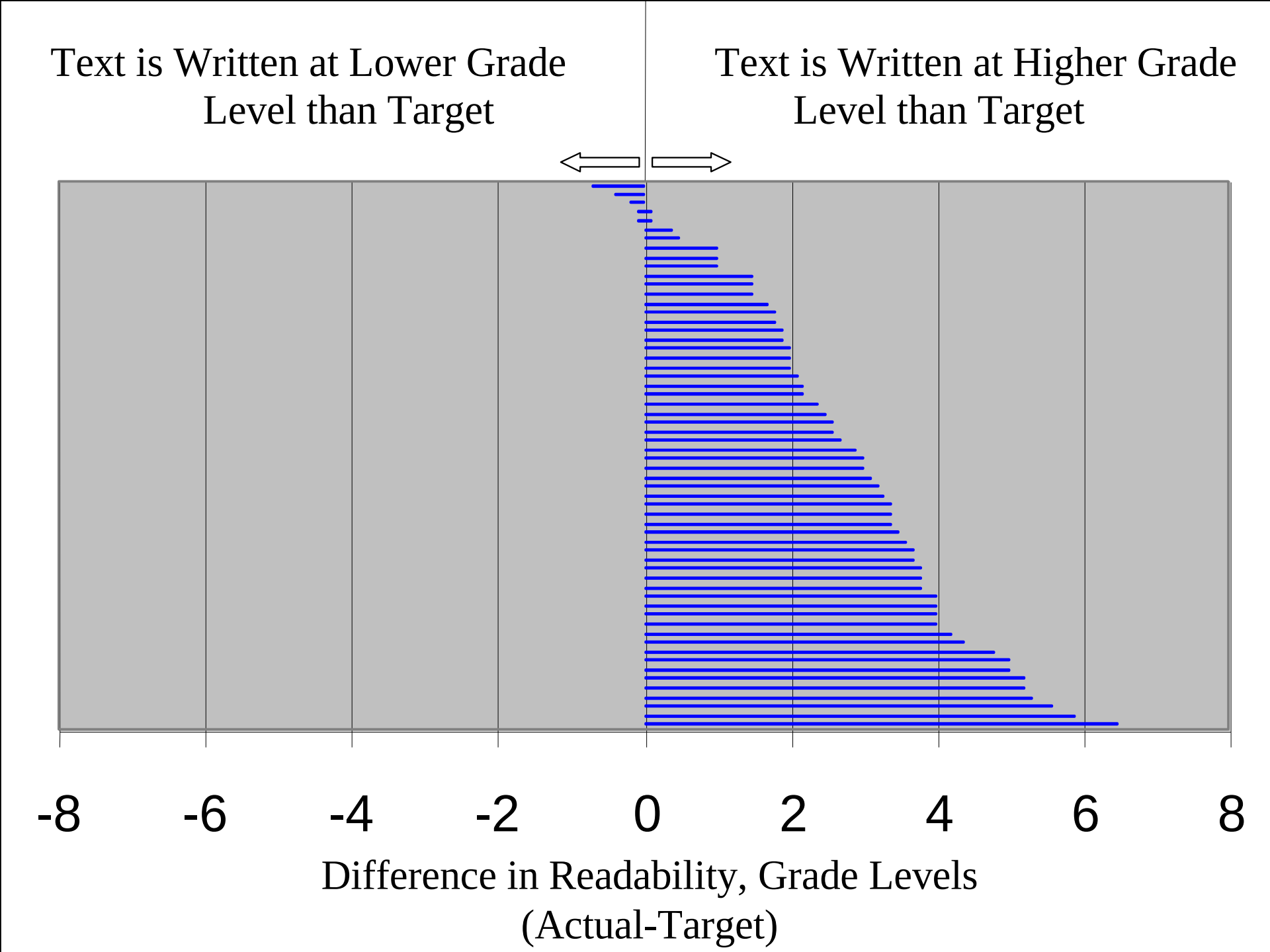
There is no benefit to you from being in the study. Taking part in this study may help patients in the future. (4th)

"There may be no direct benefit to me, however, information from this study may benefit other patients with similar medical problems in the future." (12th)

"The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study." (College)

Observed Readability of Template

- Mean Flesch-Kincaid grade level was 10.6 (95%CI: 10.3 to 10.8).
- Presence of a specified grade level standard did not influence Flesch-Kincaid grade level (10.7 vs. 10.5, P=0.10).
- In schools with specified grade level standards:
  - 5/61, 8% (95% CI: 3 to 18%) met their own standard
  - Mean of 2.8 (2.4 to 3.2) grade levels higher, P<0.001.


Text is Written at Lower Grade Level than Target
Text is Written at Higher Grade Level than Target
-8
-6
-4
-2
0
2
4
6
8
Difference in Readability, Grade Levels (Actual-Target)

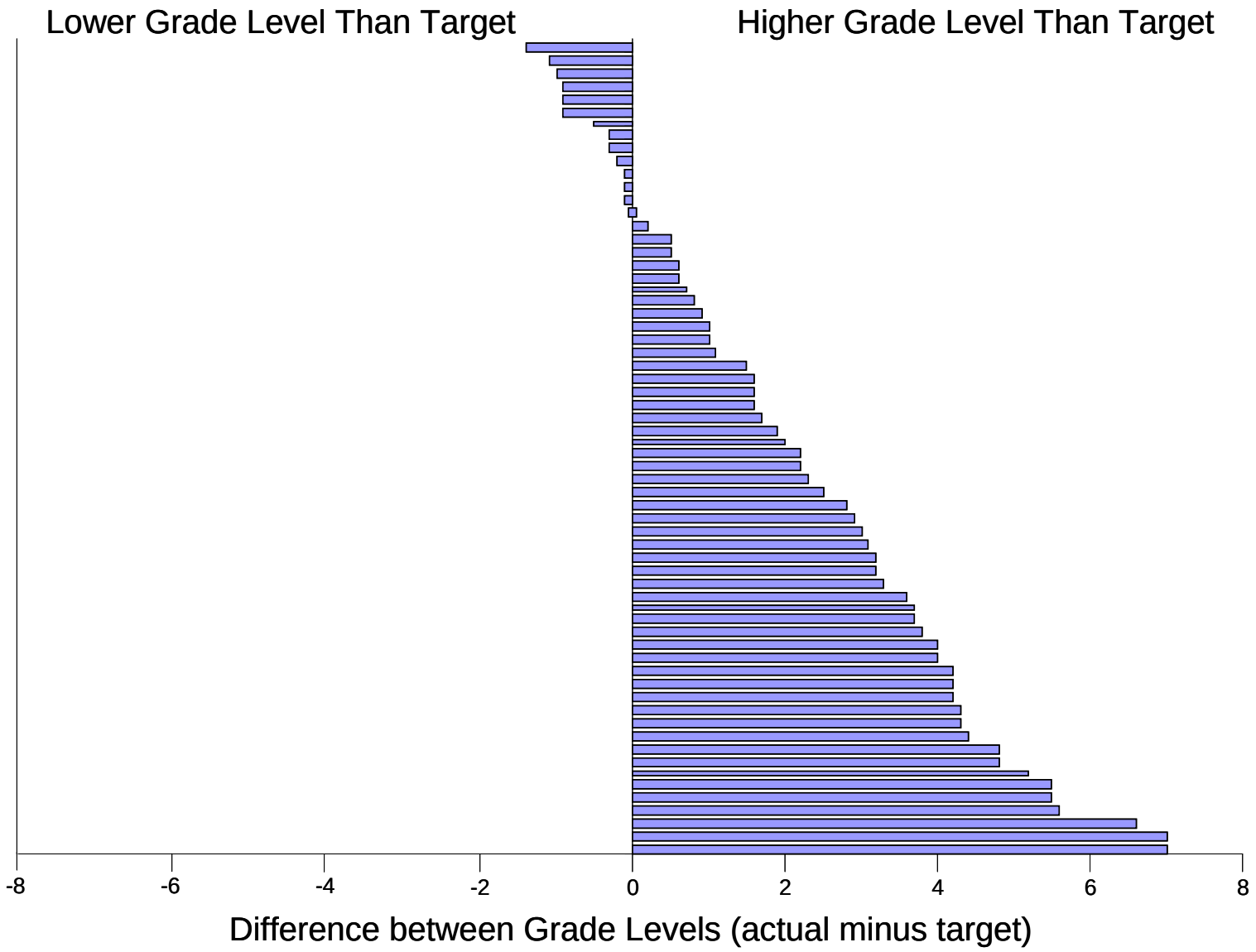
IRB Readability Conclusions

- IRBs do not meet their own readability standards.

Take II: The Redux Observed Readability of Template

- Mean Flesch-Kincaid grade level was 9.8 (95% CI: 9.4 to 10.2)
- In schools with specified grade level standards:
  - 14/64, 12% met their own standard
  - Mean of 2.2 grade levels above standard (95% CI: 1.7 to 2.8)

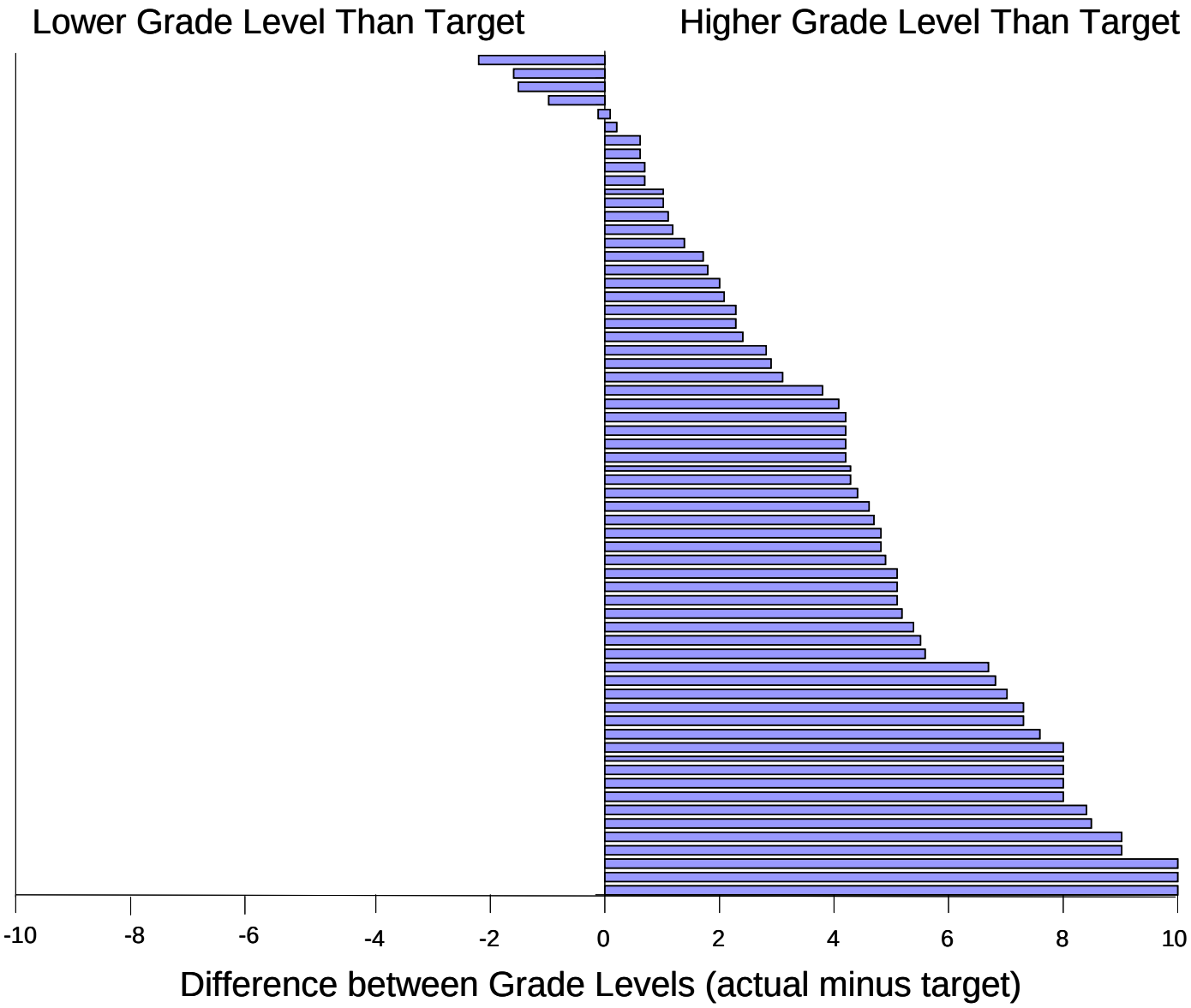
The Redux


Lower Grade Level Than Target
Higher Grade Level Than Target
-8
-6
-4
-2
0
2
4
6
8
Difference between Grade Levels (actual minus target)

Take II: The Redux
Enter the HIPAA

- Mean Flesch-Kincaid grade level for HIPAA template text was 11.6 (95% CI: 11.0 to 12.1).
- In schools with specified grade level standards:
  - 5/64, 8% met their own standard
  - Mean of 4.2 grade levels above standard (95% CI: 3.4 to 5.0)

The Redux – HIPAA!



Readability: Text Recommendations

- Familiar Words
- Define Jargon
- Consistency
- Short Sentences
- Simple Sentences
- Line limit = 50
- One idea/paragraph
- Personal Pronouns
- Second Person
- Active voice - i.e., the subject is the doer of the act

Readability: Text Recommendations

simple outlines, flow charts, diagrams, study schemas, calendars, and other graphics

- Underline, bold, or boxes (NOT IN ALL CAPS *and not in italics*) to give emphasis.
- Layout balances white space, words, and graphics.
- Left margins are justified. Right margins are ragged.
- Upper and lower case letters are used.
- Style of print is easy to read. Only one style.
- Type size is at least 12 point.
- Readability analysis

Readability: Text Recommendations

- Logical sequence
- Visually organize
- Break up large text blocks

- Avoid when possible
  - More than 3 syllables
  - Abbreviations and acronyms
  - Long lists

Avoid writing to the formula

Subjects at all levels of literacy have better Satisfaction, comprehension, and retention with Simple ICD

(Cut to Ezra's room. Cameron enters.)

Ezra: What do you want?

Cameron: House wants to biopsy your skin; he sent me to get it.

Ezra: [With slight surprise.] Oh. And you agreed.

Cameron: I had nothing to do with putting you in a coma or any of the subsequent tests.

Ezra: Which brings us to now.

Cameron: I read some of your articles.

Ezra: There were a lot of them.

Cameron: 1967 Massachusetts Medical Journal. You radiated babies. Just like that. No forms, no questions, nothing. Who knows how many cancers you caused.

Ezra: I don't know. What I do know is we discovered techniques that prevent fatal kidney failures in hundreds of thousands of other kids.

Cameron: You're not sorry.

Ezra: I don't regret what I did. Informed consent, patient rights - holds back research. [Cameron takes the tool to get the sample and slices Ezra, who groans in surprise and pain.] What the hell are you doing?

Cameron: Informed consent is holding back our diagnosis.

Ezra: Good for you. Finally standing up for something; acting on what you believe.

(Cut to clinic. House pops a Vicodin.)

Consent Process not Consent Form

- The task is HARD
- AND Yet – cynical not to try to do better
  - Subjects do POORLY on comprehension tests
- Liability (target of private action and Regs)
- Doing a better job with the ICD can:
  - Facilitate the process
  - Cue the potential subject to engage
  - Cue the research staff to do a good job
  - Effect recruitment? Retention? Subsequent legal action – empirical questions to be sorted out

Design Informed Consent Process for Success

- Framing
- Timing
- Comfort
- Stance

- Anticipatory Guidance

AG - Process

- **Offer to read the document with all research subjects**.
  - Do not make any reference to reading ability. For example, the researcher could say, “Let’s read this document together,” or “If you like, I can read the document along with you to make sure all the information is clear.”

AG - Content

- What aspects of your studies confuse patients?
  - Randomization
  - Therapeutic misconception
  - Risks
  - Research Related Injury

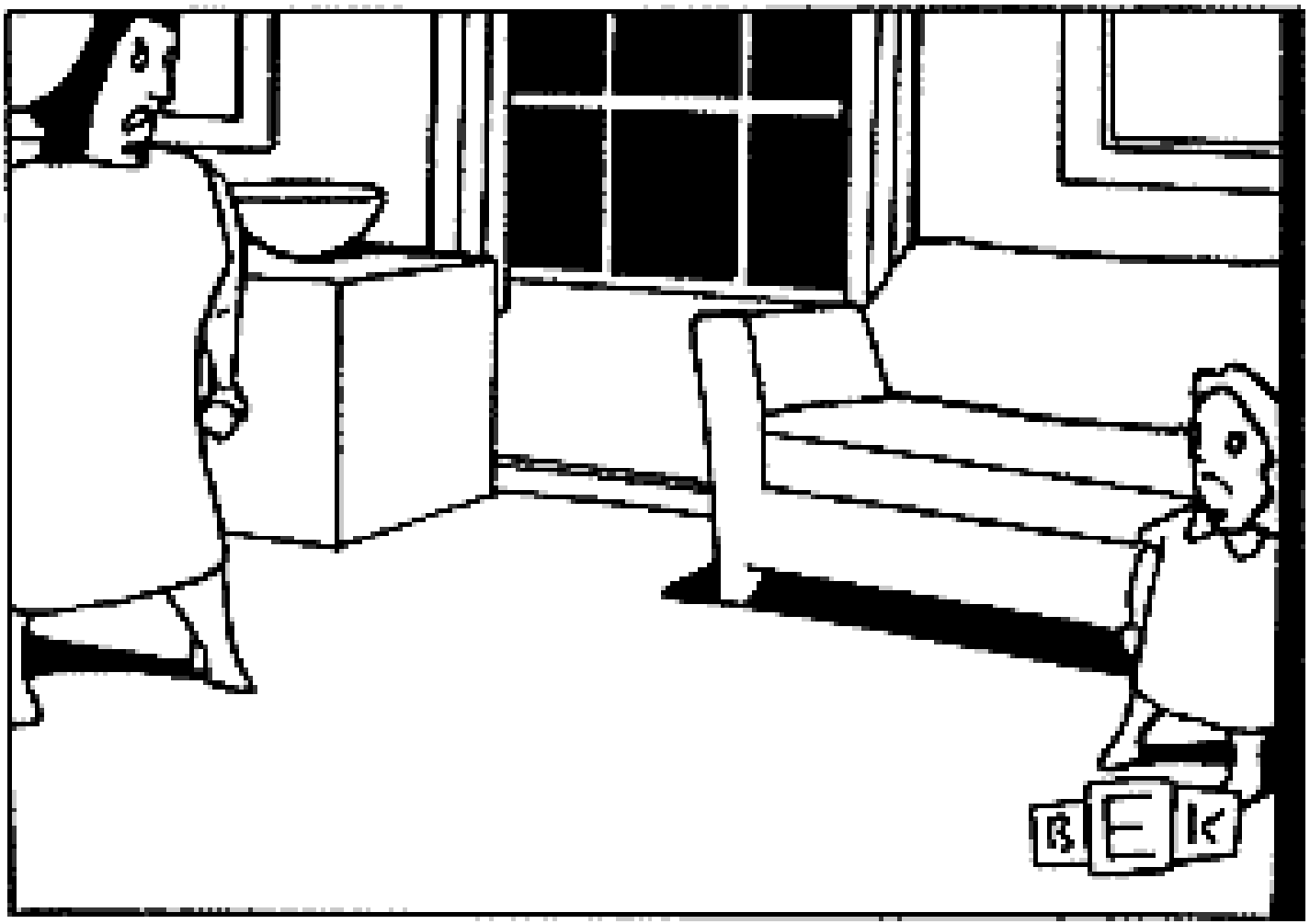
Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

Paasche-Orlow MK, Brancati FL. Am J Med. 2005 Feb;118(2):175-80.

Sample Introduction

- 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 regular medical care in any way.
- Please take all the time you need to make your choice.



"Someday, you'll act like you understand."

Shame Society

- Parikh 1996: Pts w/ low health literacy who admitted having trouble reading when tested:
  - 67.2% had never told their spouses
  - 19% had never disclosed to anyone
- Many patients with reading problems are ashamed and hide their inability to read. Shame is a deeply harbored emotion that plays an important role in understanding how low literate patients interact with health care providers.

Confirmation of Comprehension

- If you want a result you have to check it
- Teach-to-Goal, Teach-Back
  - Teach, assess, continue focued teaching until subject exhibits mastery.
- NQF – safety measure

Confirmation of Comprehension

- Shift goal of RA
- Shift culture of research recruitment
- Provide opportunity to monitor
- Only recruit folks who understand
- Helps shift from form to process
- Provide opportunity to revise process

Questions about Confirming Comprehension

- Always? Or protocols that deserve special scrutiny?
- Nature of the Assessment:
  - Qualitative
    - standardization
    - skill set
    - time
  - Quantitative
    - Avoiding correct answers without comprehension (T/F)

Teach-Back: Part 1

- Start with phrases such as:
  - "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."

Teach-Back: Part 2

- Make sure that the potential research subject has understood all the important elements of the study. Allow the potential research subject to consult the document when answering the questions.
- The purpose is to check comprehension, not memory.
- Listen for simple parroting; if a potential subject uses technical terms ask them to explain further.

Teach-Back: Part 2

Ask open-ended questions such as:

- **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**

"Will anything happen to you if you refuse to be in this study?"

Teach-Back: Part 2

- **Discontinuing Participation**

- "What should you do if you agree to be in the study but later change your mind?"
- "What will happen to information already gathered if you change your mind?"

- **Privacy**

- "Who will be able to see the information you give us?"

- **Contact Information**

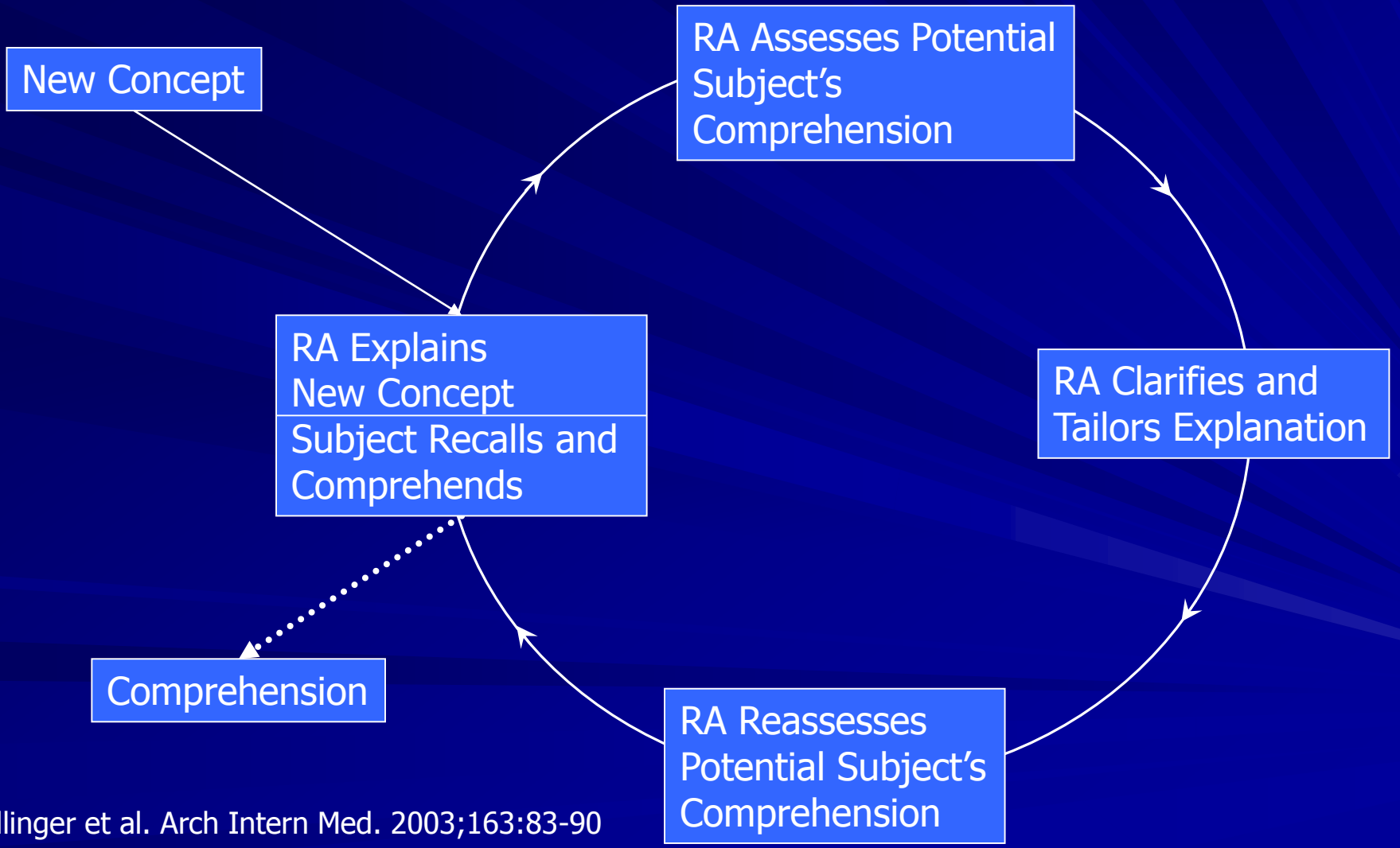
- "What should you do if you have any questions or concerns about this study?"

Teach-Back: Part 3

- Correct any misinformation until potential research subjects indicate that they have understood by correctly answering all the questions.
- Make clear that the need to repeat is due to your failure to clearly convey the information rather than the “fault” of the potential subject.
- For example, you could say, “Let’s talk about the purpose of the study again because I think I have not explained the project clearly.”

Closing the Loop

"I want to make sure I explained everything clearly. Tell me what will happen..."



Schillinger et al. Arch Intern Med. 2003;163:83-90