Informed Consent: From Form to Process

National Cancer Policy Forum Workshop

Contemporary Issues in Human Subjects Protections

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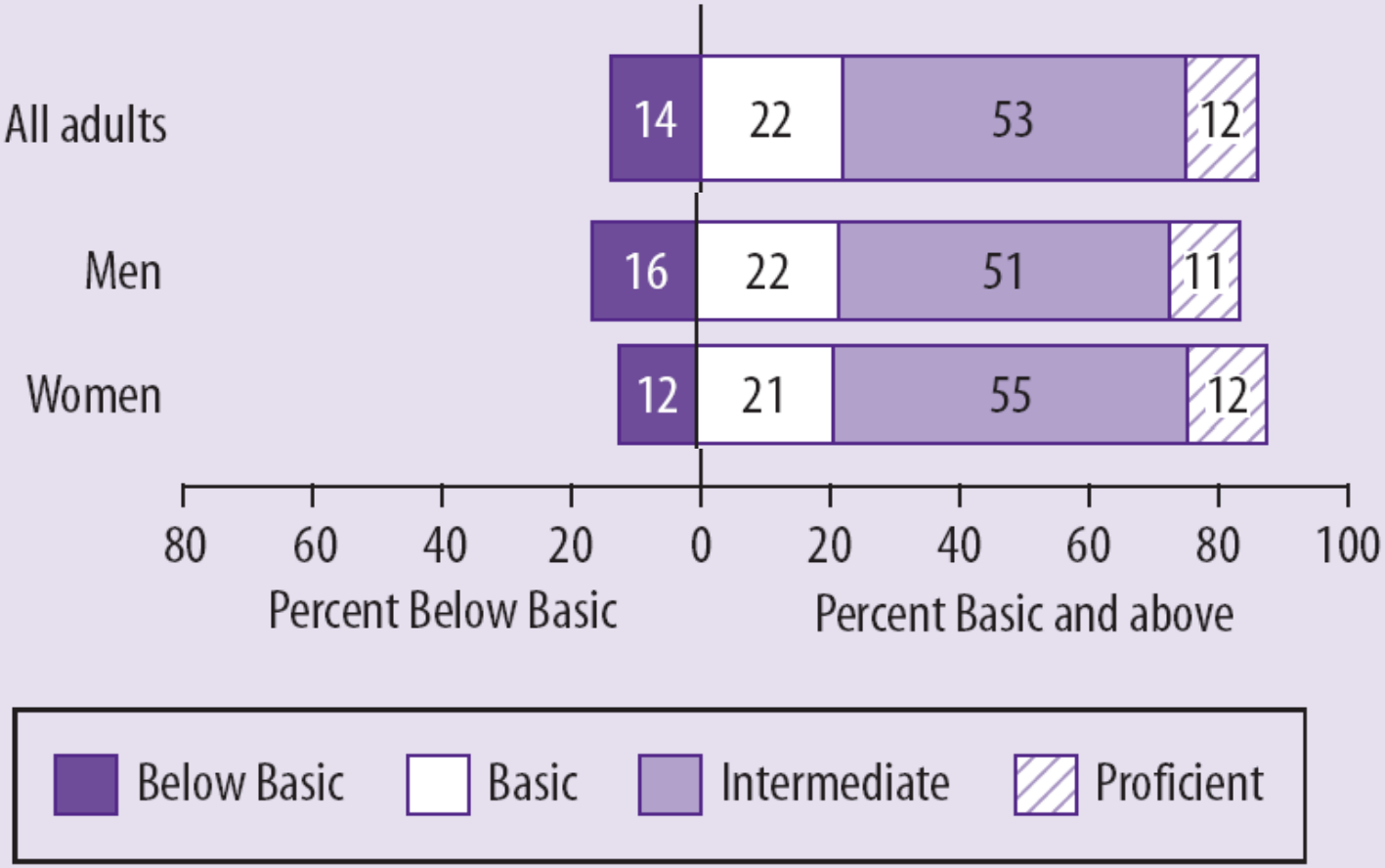
Adult English Literacy in the US

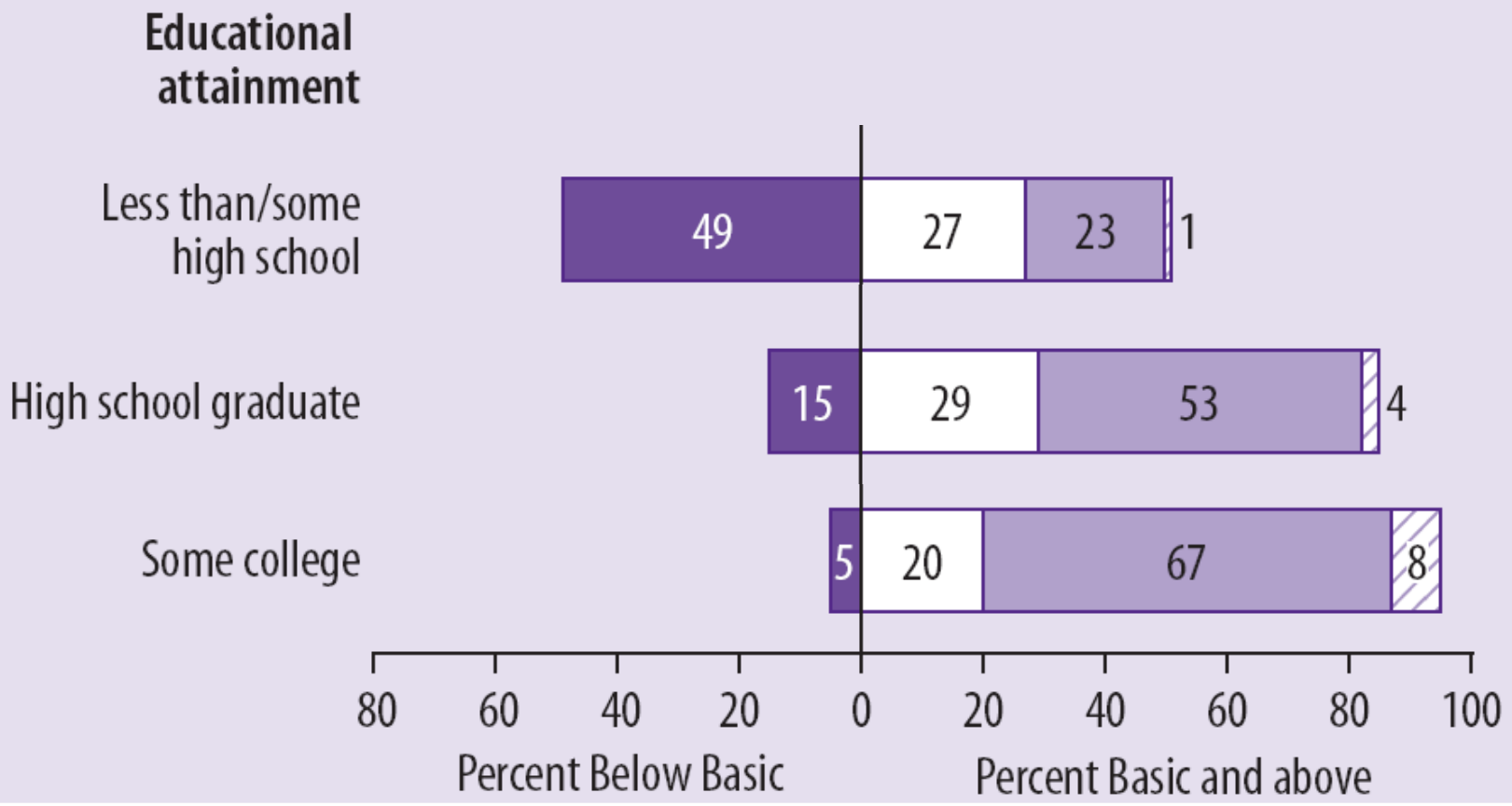
- Average reading level in US: 8th – 9th grade
- National Adult Literacy Survey (NALS, 1992)
- National Assessment of Adult Literacy (NAAL, 2003)
- PIAAC (2012)
- Prevalence across 85 medical studies:
  - 26% low health literacy
  - 20% marginal health literacy
  - More common among elderly, minorities, immigrants, chronic disease
    - Paasche-Orlow, JGIM 2005

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



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

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.

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.

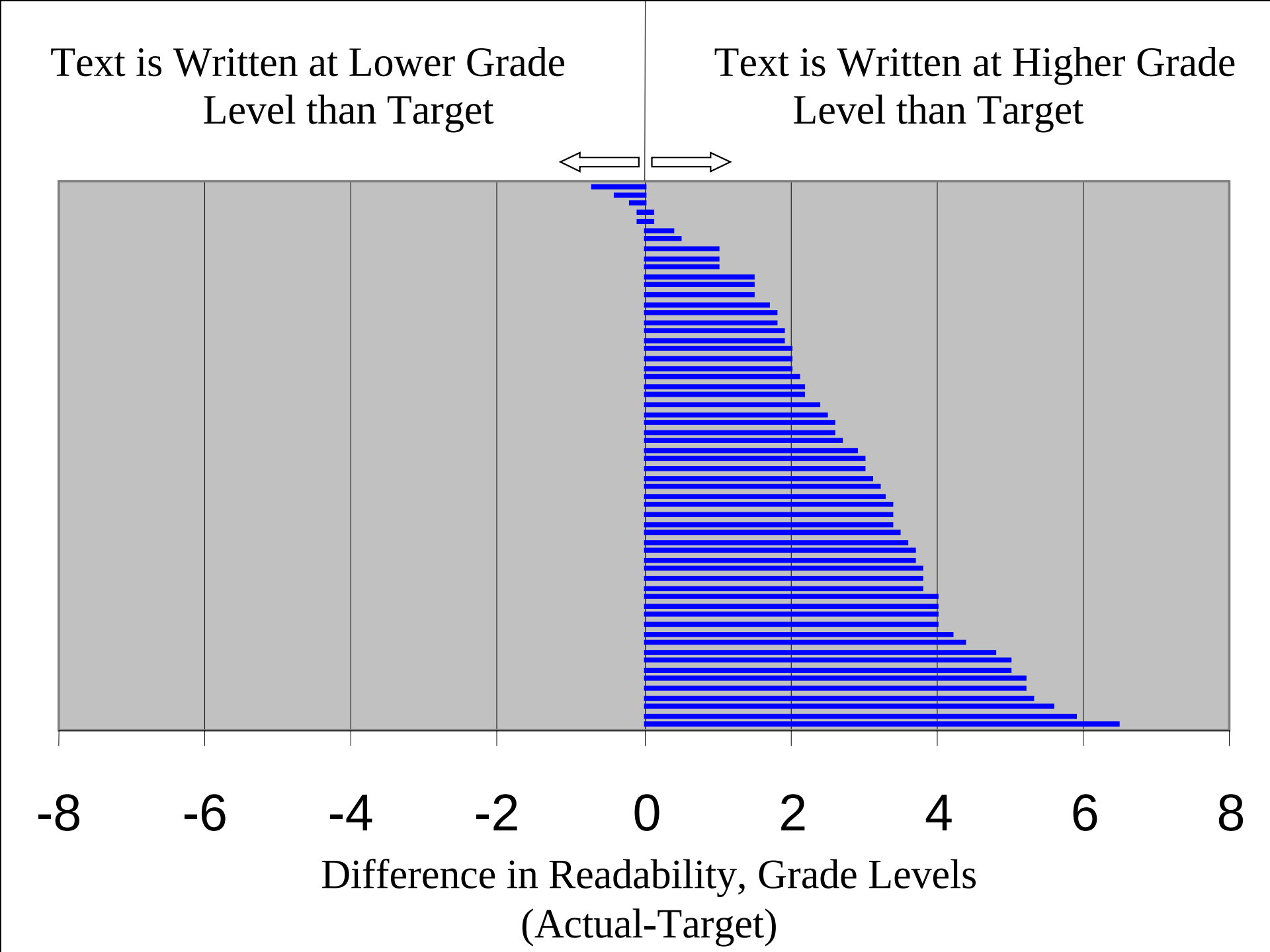
  – Paasche-Orlow, NEJM 2003

Readability Standards

- Grade Level Standards in 61/114 (54%): Range 5^{th}-10^{th} (mode 8^{th}) grade.
- Descriptive guidelines in 47/114 (41%): "in simple lay language"

Observed Readability of Template

- Mean Flesch-Kincaid grade level was 10.6 (95%CI: 10.3 to 10.8).
- 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, $P<0.001$.

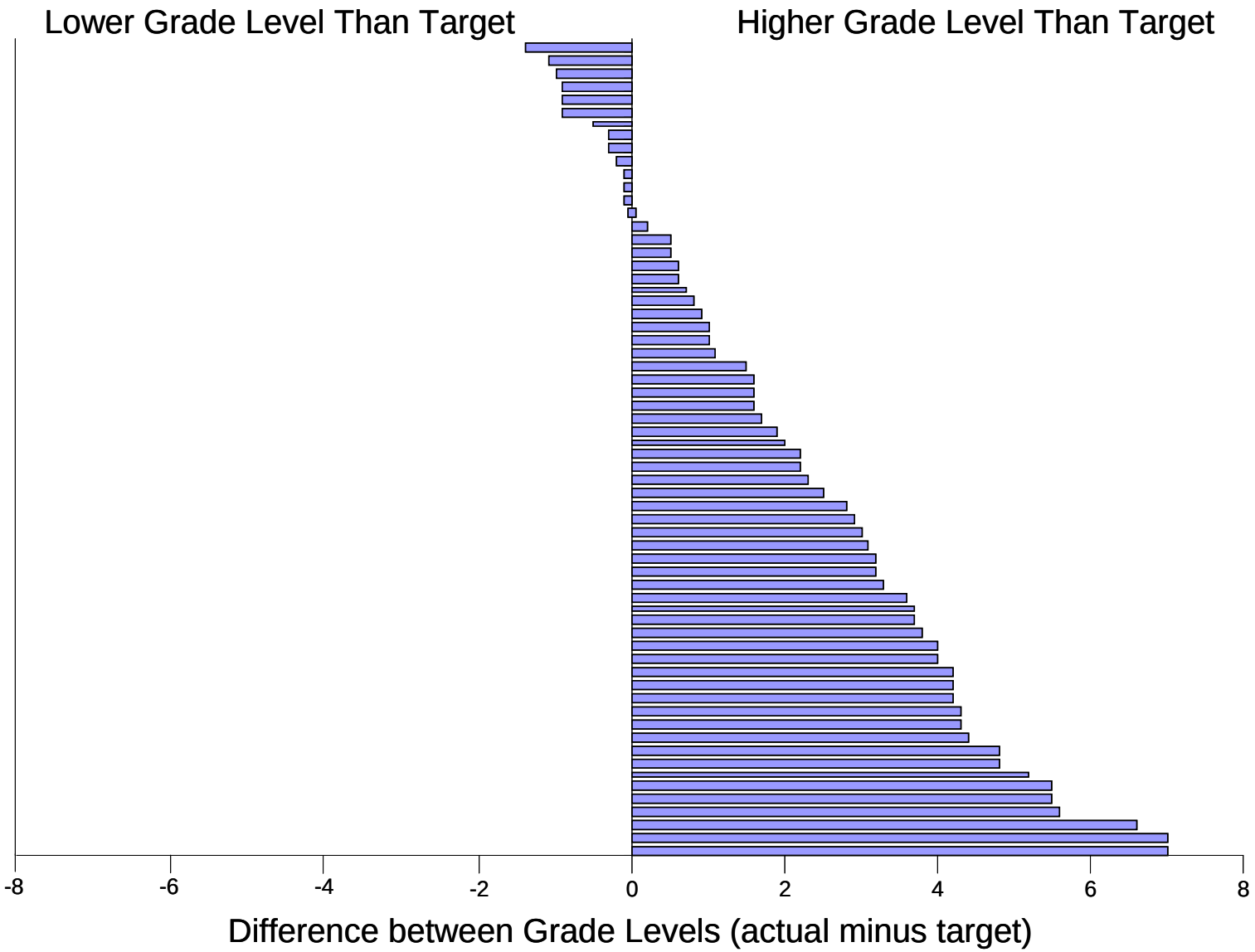

Text is Written at Lower Grade Level than Target
Text is Written at Higher Grade Level than Target
-8
-6
-4
-2
0
2
4
6
8
Difference in Readability, Grade Levels (Actual-Target)

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)

– Paasche-Orlow, IRB 2013

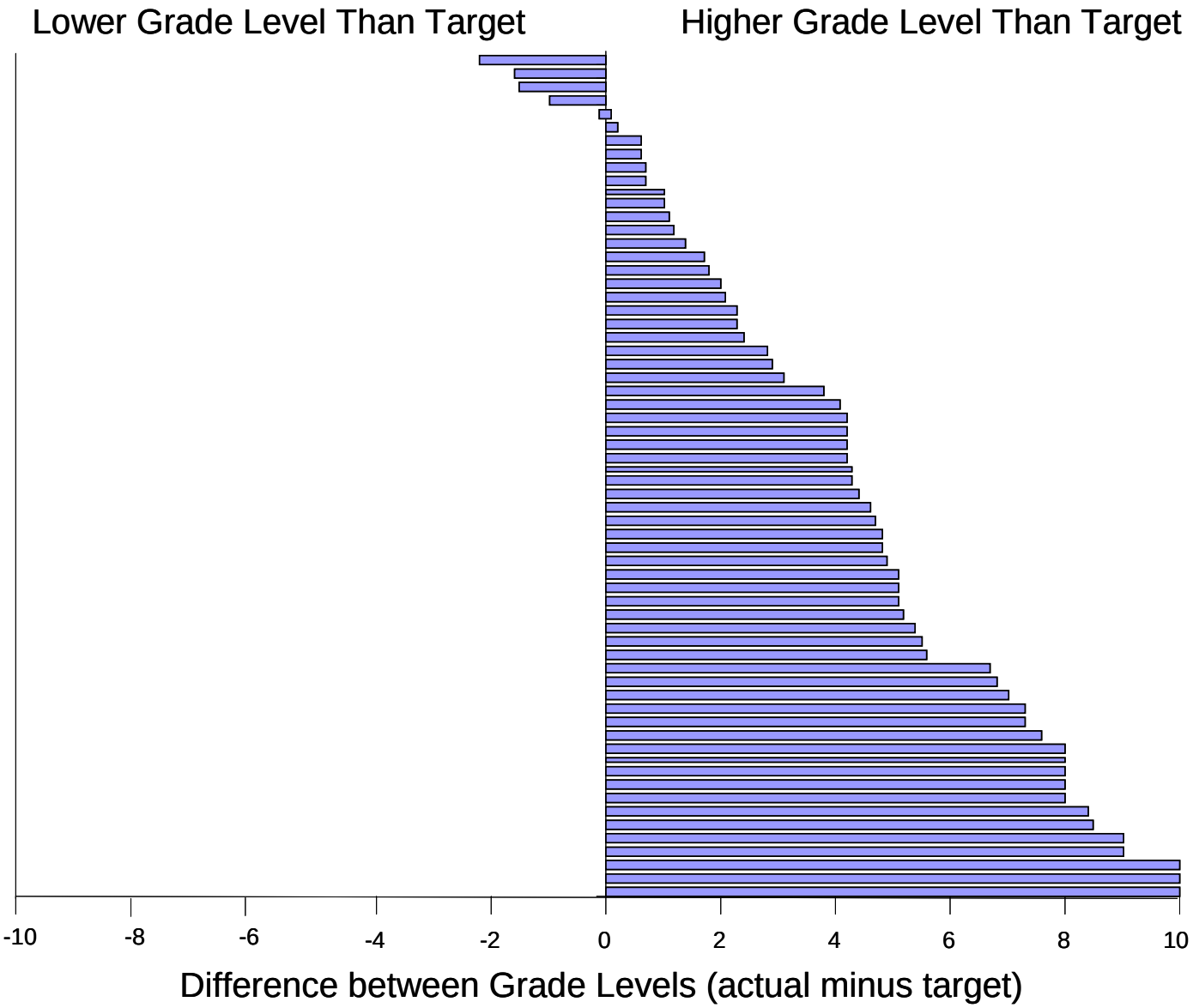
The Redux


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 -- 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!



Consent Process not Consent Form

- It would be cynical not to do better
  - Subjects do POORLY on comprehension tests

  Rec 1. →→ Shorten the forms

  Rec 2. →→ Simplify the forms

- Readability will only be part of the answer
  - Many areas of confusion (**randomization, equipoise, COI, voluntariness, therapeutic misconception,…)
  - Without checking, just will not know!

Shift the paradigm from persuasion to pedagogy

- Values Clarification
  - Flip the default! {“Any questions?”}
  - Embrace positive ethical duty to ensure substantive comprehension
  - Rec 3. →→ Require Confirmation of Comprehension as an entry criterion

Shifting toward pedagogy

- How do research staff learn about the consent process?
  - What supervision or quality control is provided?
- Professional Development
  - Rec 4. →→ National survey of training, supervision, documentation approaches
  - Rec 5. →→ Establish model training program
    - (**Teacher's Guides)

Confirmation of Comprehension

- If you want a result you have to check it
- Teach-to-Goal, Teach-Back
  - Teach, assess, continue focused teaching until potential subject exhibits mastery
- NQF – safety measure for clinical consent

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 choose not 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

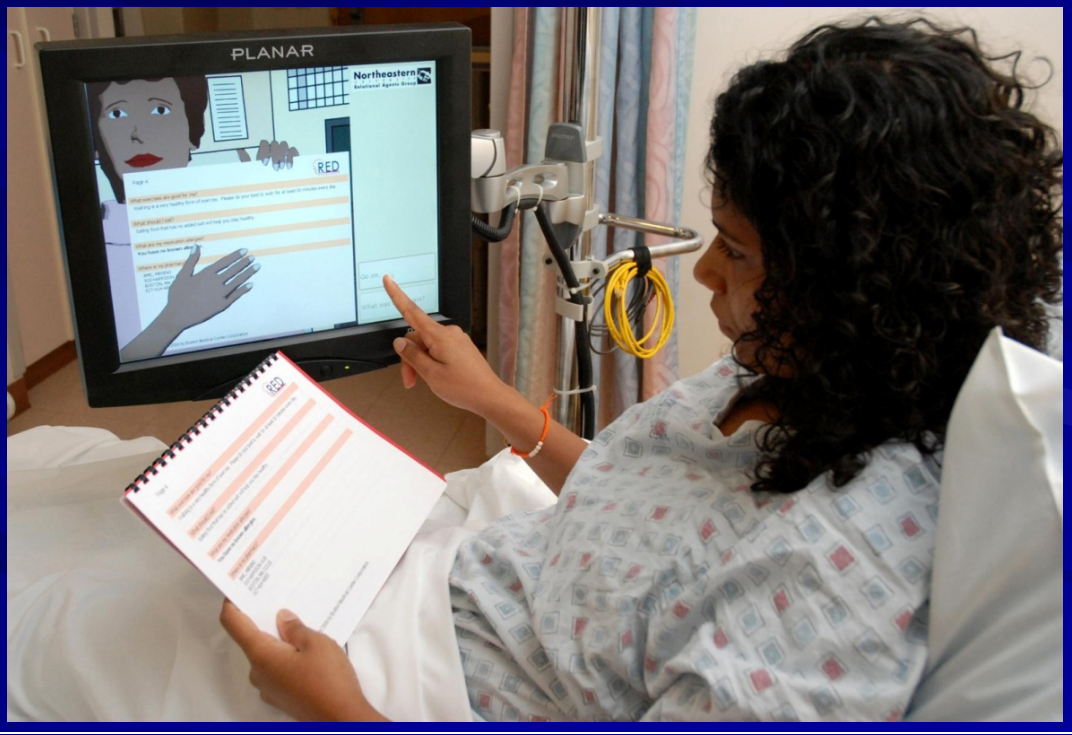
- Correct any misinformation until potential research subjects indicate that they have understood by correctly answering all the questions.
- Make clear that the need to repeat is due to your failure to clearly convey the information rather than the “fault” of the potential subject.
- For example, you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

Confirmation of Comprehension

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

New Health IT tools to augment the Consent Process

- "Embodied Conversational Agent" as health educator
- Emulate face-to-face communication using touch screen
- Develop alliance w/ empathy, gaze, posture, gesture, tailored information, evaluate comprehension, message team



R01 CA158219 - Research Ethics and Safety Promoted by Embodied Conversational Technology

Examples

- Clip #1 – Introduction, note alliance
- Clip #2 – Protocol
- Clip #3 – Risk (specified point estimate)
- Clip #4 – Risk (range) and notification
- Clip #5 – Withdrawal, note check of comprehension