Can You Read This?

Fnuelt raderes otefn tkae lticarey fro gre tand!
If yuo aer a Good rdaeer the olny iprmoatnt
tihng is that the frist and lsat ltteer be in the
ghit pclae. Mnay of yuor sbjuctes cnaont
raed wlel euongh to uesdnatnrd yuor csneont
fmros!

Waht are you gniog to do aubot it?
Informed Consent: Moving from Readability to Comprehension

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Where we have come from

• In 1966, Henry k. Beecher, reviewed the ethics of 50 studies and found that consent was mentioned in only 2 studies.
• He wrote, “If suitably approached, patients will accede, on the basis of trust, to about any request their physician may make”
U.S. STUDENTS RANK LOW IN MATH AND SCIENCE

WHAT DOES THAT SAY?
Adult English Literacy in the US

- Average reading level in US: 8th – 9th grade
- National Adult Literacy Survey (NALS, 1992)
  - Over 90 million Americans had inadequate functional literacy
- National Assessment of Adult Literacy (NAAL, 2003)
- 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
Readability and Liability

• If comprehension has been compromised, the consent may be nullified.
  – Medical malpractice case law supports readability as a basis for overriding an executed consent form.
  – “pervert the law of informed consent to allow a physician to discharge his or her affirmative duty by merely securing a signature-even that of a . . . confused or uneducated patient on an abstruse, jargon-ridden, and largely unintelligible preprinted consent form"
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.
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.
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.
Difference in Readability, Grade Levels
(Actual-Target)
IRB Readability Conclusions

- IRBs do not meet their own readability standards.
- Actual reading level were not influenced by readability standards, level of research activity, or local estimates of low literacy.
- Recent OHRP oversight was associated with better readability.
- The language presented by IRBs, even in schools which underwent OHRP oversight remains beyond the ken of the majority of American adults.
- Paasche-Orlow, NEJM 2003
“What part of oil lamp next to double squiggle over ox don't you understand?”
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 (rather than all caps or 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
What other choices do I have if I do not take part in this study?

Your other choices include:

- Getting treatment for [disease] without being in a study
- Taking part in another study
- Getting no treatment
Okay, now listen up. Nobody gets in here without answering the following question: A train leaves Philadelphia at 1:00 p.m. It's traveling at 65 miles per hour. Another train leaves Denver at 4:00... Say, you need some paper?
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
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.

(9th grade)
"I understand that you're a master in the art of camouflage."
Asking Questions in a Shame Society

• Iatrocultural tendencies
  – Difficulty admitting lack of understanding
  – Subtle assertions of dominance through knowledge

• Invisibile Problem

• Give cues to not ask questions

• Make continued education contingent on asking questions
“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.
“I had an epiphany.”
Confirmation of Comprehension

• If you want a result you have to check it
• Teach-to-Goal
  – Teach, assess, continue focused 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
Prior Related Studies

• Taub and Baker (1983) The effect of repeated testing upon comprehension of informed consent materials by elderly volunteers
  
  • Embedded in a longitudinal study n=100
  
  • 11-question test to all in EC, repeated up to 3 times w/brief feedback on incorrect answers

The multi-trial approach improved comprehension scores at all vocabulary levels, but had no effect upon memory @ 2w.
Prior Studies


• Elderly volunteers Part of RCT n=87

• Research participants were given an 8-question test and received brief feedback on incorrect answers; total time for intervention was 15 min or less

Comprehension better @2w
Prior Studies


• Psychiatric patients n=49

• Research participants were tested and received brief feedback on incorrect answers until they were able to score 100%, then reevaluated for understanding 7 d later

• 31 closed and 5 open ended questions

• 37% needed 3 or more rounds of testing
  • All improved from 1st to 7 day
Prior Studies


• Mentally ill and healthy volunteers
• Simulated Randomized n=227

• Research participants were tested up to 3 times with a quiz and received brief feedback on incorrect answers

• Recall (15 point open test) as well as recognition (15 point multiple choice format)

Improved comprehension in all groups
Prior Studies

• Deficiencies in participant knowledge identified with Questionnaire (10 T/F items) and discussed with research participants; 3 such meetings occurred at 6-mo intervals

• Simulated Longitudinal n=3908

Participation in the prototype process was associated with substantial and sustained increases in knowledge across HIV risk groups, race/ethnicity, and educational levels
Prior Studies

- Elderly volunteers n=204 part of RCT
- Simplified form, read to subject, then Teach-to-Goal
- 7 comprehension questions

28% answered questions 1st pass
80% after 2nd pass
4 subjects excluded (no mastery after 6 passes)
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)
Questions about Confirming Comprehension

• Test Burden
  – Subjects
  – Investigators
  – IRB Administrators
  – Specific for each protocol or generic?

• Automated creation of test?
"The test calls for a pirouette, sir. Arabesques don't really tell us enough."