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Informed consent in the context of health/research illiteracy: What can we do?

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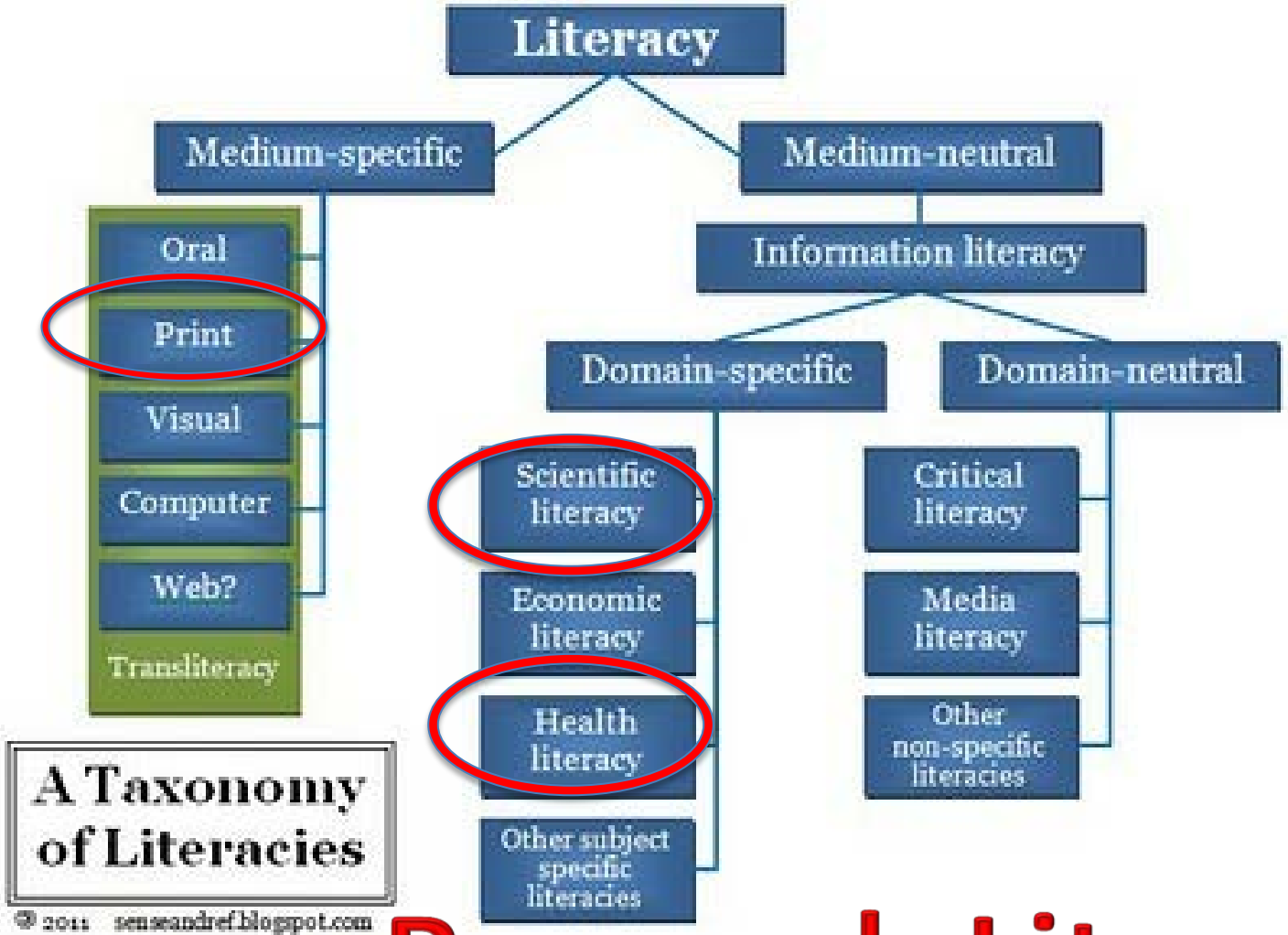
Many types of literacy



Research Literacy?

What is health literacy?

- "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." (Ratzan and Parker 2000)
  - drug bottles, appointment slips, medical education brochures, doctor's directions, consent forms

Health literacy involves more than reading skills

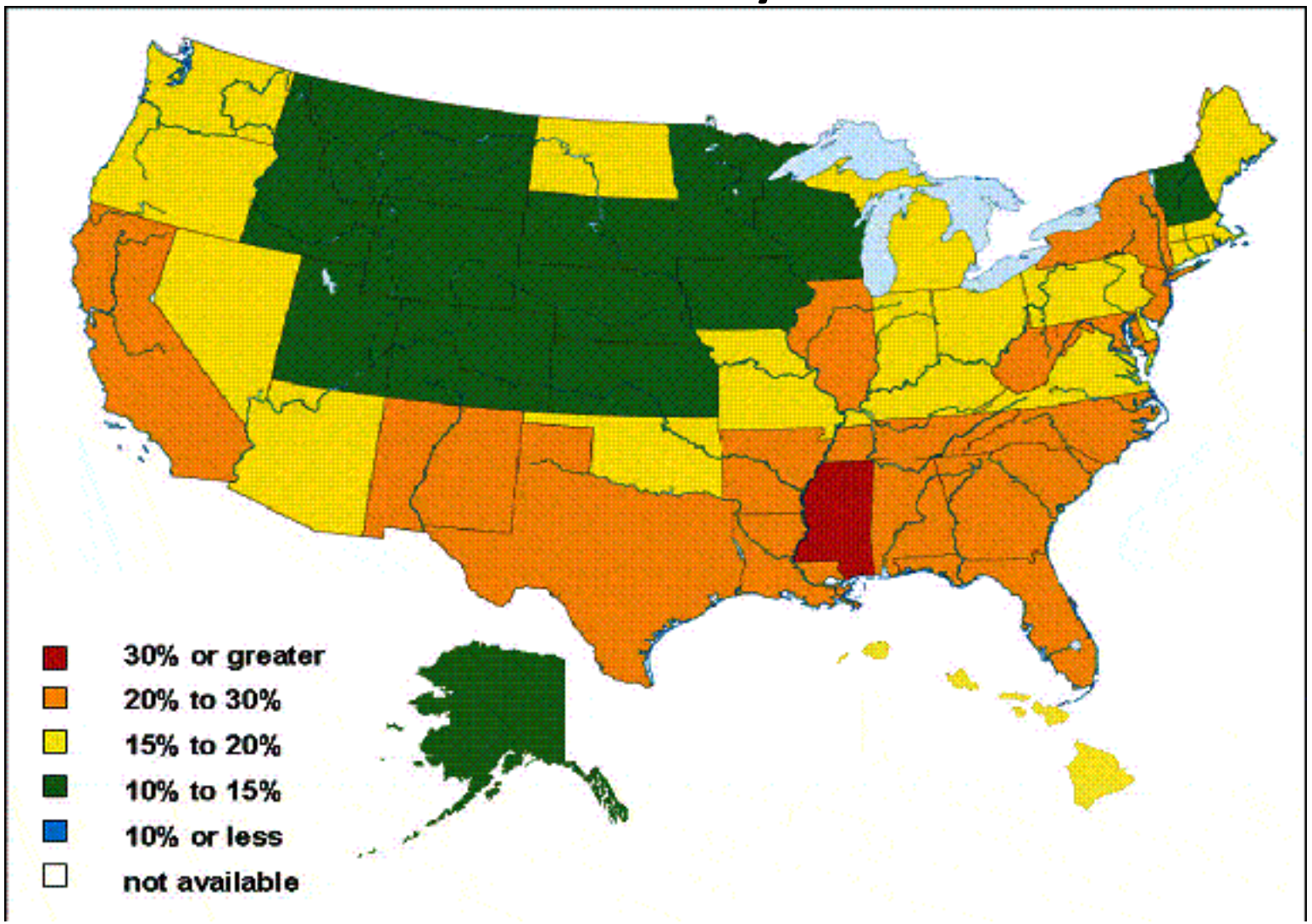
- reading ability
- background knowledge of health-related domain
- familiarity with language and types of materials
- cultural similarities in approaches to health and healthcare
- oral communication skills

IOM Report, *Health Literacy: A Prescription to End Confusion* (2004)

Not good news. . .

- More than 47%, or 90 million U.S. adults have difficulty locating, matching, and integrating information in written texts
- Of these, 40-44 million have difficulty finding information in unfamiliar or complex texts like newspaper articles, editorials, medicine labels, forms or charts.
- Approximately half of Medicare/Medicaid recipients read below the 5th grade level
  - IOM Report, *Health Literacy: A Prescription to End Confusion* (2004)

% of each state's population at level 1 literacy



Importance of health literacy

- AMA: poor health literacy is “a stronger predictor of a person’s health than age, income, employment status, educational level, and race”

Report on the Council of Scientific Affairs, Ad Hoc Committee on Health Literacy JAMA Feb 10 1999

Cognitive dissonance

We know this

But we do this!

Scientific literacy

- “the knowledge and understanding of scientific concepts and processes required for personal decision making, participation in civic and cultural affairs, and economic productivity.”

National Academies

How many Americans answered correctly. . .

• The center of the earth is very hot	• 78%
• All radioactivity is man-made	• 73%
• It is the father's gene that decides whether the baby is a boy or a girl	• 62%
• Electrons are smaller than atoms	• 45%
• Antibiotics kill viruses as well as bacteria	• 54%
• Does the earth go around the sun, or does the sun go around the earth	• 71%

n=2,010.

From National Science Foundation, Division of Science Resource Statistics, Survey of Public Attitudes Toward an Understanding Science and Technology (2001)

But what we really are looking for is. . .

.

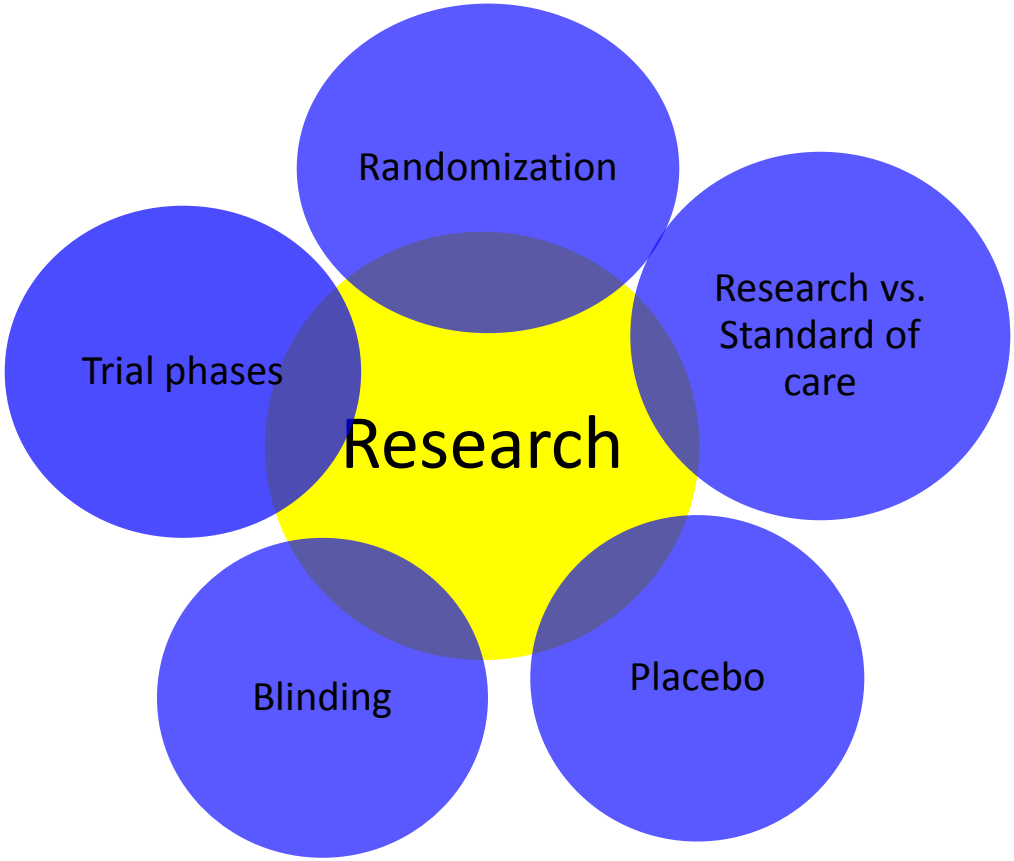
Research literacy

Research literacy

- an understanding of the mathematical and scientific terminology and tools fostering the ability to interpret and apply medical information and the clinical study process that produces that information
    - http://www.dcpatient.us/2012/01/research-literacy-and-the-democratization-of-data/

Huh?

What research concepts do potential participants need to understand?



Why do they misunderstand?

- Science is complicated (genetics, risk, research methods, etc.)

—Domain specific scientific literacy

- badly written patient communications
- social context and emotional stress
- cultural differences (decisionmaking, authority, etc.)

What can we do?

① Improve general research literacy

② Distinguish consent *form* from consent *process*

③ Augment form with process that heeds empirical research on consent

(1) Improve general research literacy outside of consent context

- Why?

- What is research?
  - placebo
  - phase 1, 2, 3
  - therapeutic misconception
  - randomization
- What is THIS research?
  - purpose of study
  - risks/benefits
  - procedures
  - confidentiality

How?

- Give talks at public libraries
- Have public movie/discussions at university
- Have exhibits about research at Science Centers/Museums
- Give talks in school classrooms
- Talk to the media
- Others?

(2) Distinguish consent *form* from *process*

Make the form as good as it can be

- lay language
- appropriate reading level
- remove unnecessary standardized content
- active voice
- 2nd person (you)
- short sentences
- clear page layout and formatting
- images: pictures, diagrams, calendars, flow charts

Tools to improve form

- NCI http://www.cancer.gov/clinicaltrials/learningabout
- AHRQ http://www.ahrq.gov/fund/informedconsent/
- CDC Plain Language Thesaurus for Health Communication http://depts.washington.edu/respcare/public/info/Plain_Language_Thesaurus_for_Health_Communications.pdf
- And Many Many more!!!

Form only goes so far. . .

- Do not overemphasize importance of form
- Evidence
  - does not (alone) consistently improve understanding
  - one randomized trial showed significant improvement with shortened form (4-2 pages)

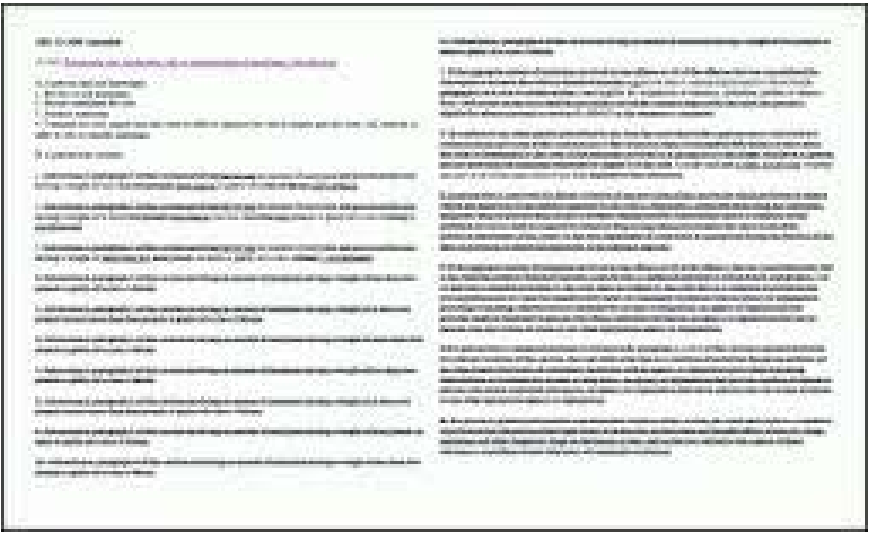
– Flory and Emanuel (2004)

(2) Augment form with. . . Multimedia

- especially effective for the mentally ill
- May increase retention of information
- Can be more standardized
- Can include:
  - hyperlinked explanations
  - videos of procedures
  - videos of people involved
  - videos of participants saying yes and no
  - examples of questions to ask at appointments

Would you rather look at

This?



Or This?

But, don’t rely solely on multimedia

- Does not consistently improve participants understanding. . .Why?
  - Efficacy based on content, not just form
  - Often still one-way information
  - Can be expensive and burdensome on researchers to provide

Augment form with. . . .Conversation

- Most effective consent process is face-to-face

1) extended discussion (need not be researcher or physician, can be nurse, coordinator, etc.)
2) Teach-back method
3) Teach-to-goal method

Teach-back method

- Periodically check if potential participants understand key points by asking them to "teach it back"
  - "Can you explain to me the purpose of this study?"
  - "What will you have to do in this study?"
  - "What types of risks are there in this study?"
  - "Who will have access to your records in this study?"
  - "What can you do if you want to withdraw from the study?"
- Key point: Avoid yes/no questions like "Do you understand?"
- http://www.nchealthliteracy.org/toolkit/tool5.pdf

Teach-to-goal method

- If person answers incorrectly, restate or reshow content of interest and then return to question in a few minutes
- Goal not to test potential participant, but to ensure that he or she understands key points
    - Kripalani et al (2008)

But no matter what you do. . .

- Qualities of potential participants make more of a difference than any consent interventions
  - Low educational attainment/literacy
  - mental illness
  - advanced age
  - minority status

  - If limited resources, may want to target at-risk groups
    - Flory & Emanuel (2004)

Persistent Misunderstanding

- Therapeutic misconception and unrealistic optimism
- Studies have shown these may stay no matter what you do

- Your obligations have limits
- Follow your conscience

Do your best, it is worth it!

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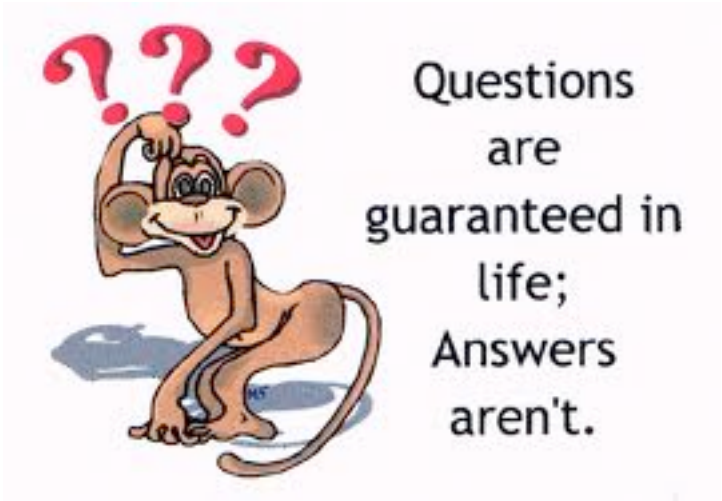
Questions?



Thank you.