Research Ethics
How to Improve Participant Comprehension

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Learning Objectives

- Understand how we memorize new information
- Understand how logic, language, and experience plays a role in comprehension
- Understand how cultural differences play a role in comprehension
- Understand the effect of literacy on comprehension
- How to evaluate participant comprehension of informed consent
If you can’t explain it **simply**, you don’t understand it well enough.

– Albert Einstein
“Do you understand?”

Conditions for Remembering and Learning
Collection
Capacity Limit

Storage
Storage Time Limit
Specific Procedures for Retrieval

Retrieval
Specific Procedures for Retrieval
The Memory System

Sensory Information Processing → Short-term Memory → Long-term Memory
Sensory Information Processing

• Get Participant’s Attention
  • Gaining attention turns on the electrical connections. Participant must activate his/her own memory system.
  • Use many senses such as visual, auditory, tactile references
  • Read pamphlet, listen to tape or view video

• Participant establishes priority/importance
  • Do I like it?
  • Do I want it?
  • Do I need to pay attention to this?
Short-term Memory

• Limited capacity
  • Seven independent items for well-educated and well-trained adults. Five or fewer for those with less education and training.
  • If you go beyond the capacity, the brain will dump all the information and resets to receive the next set of information.
  • Can increase short-term memory by “chunking”.
this getting can
five of vegetables
risk fruits your
and cancer eat
day a cut
Eat five fruits and vegetables a day. This can cut your risk of getting cancer.

https://www.youtube.com/watch?v=5Flz3zP-Z_E (Song about eating five fruits and vegetables a day)

http://www.thekitchn.com/10-photos-that-show-you-your-daily-recommended-servings-of-fruits-vegetables-207261 (Picture of what five fruits and vegetables looks like)
**Figure 5-1**

- What Ketones are
- Why ketones are produced
- What happens when ketones are produced
- Why test for ketones
- When to test for ketones
- How to test for ketones
- What ketone tests are available
- When to call the doctor
- What to do during sick days

**Figure 5-2**

**Ketones: What are they?**

- What ketones are
- Why ketone are produced
- What happens when ketone are produced

**Testing for Ketones**

- Why test for ketones
- When to test for ketones
- How to test for ketones
- What ketone tests are available

**What to do during sick days**

- When to call the doctor
- What to do during sick days
8 Basic Elements of Informed Consent
How are they grouped in the regulation?
8 Basic Elements of Informed Consent

1. A statement that the study involves research, purpose of research, expected duration of participation, description of procedures to be followed and which procedures are experimental

2. Foreseeable risks or discomforts

3. Benefits to subject or to others

4. Whom to contact for questions related to research, participant’s rights and event of research-related injury to participant

5. Statement that participation is voluntary
8 Basic Elements of Informed Consent

6. Alternatives procedures or courses of treatment, if any
7. The extent, if any, to which confidentiality of records identifying the subject will be maintained
8. For greater than minimal risk studies, if there will be any compensation and whether any medical treatments are available if injury occurs
Short-term Memory

• Short storage (retention) time of less than a minute
  • Must move quickly to long-term memory even if you provide written instructions
  • Patients with low literacy skills read word by word, which slows down the reading process.
  • Consequence: Forget many of the words at the beginning of the sentence.
Short-term Memory “Remedies”

- Short sentences
- Common words, non-technical everyday words
- Use same words consistently throughout the document.
  - Your meals, diet, meal plan, diet prescription
  - Research, study, project
  - Medication, drugs, pills
Summary

• Get the participant’s attention (the “hook”)
• Present no more than five items/chunks at a time
• Get to the point quickly
Long-term Memory

• Lasts for days and years
• No limit in capacity
• Two key factors in learning new information
Associate the new information with what the participant already knows

Interact with the new information for reinforcement
Association with Existing Knowledge
(i.e. build on what they know)

• Explain new words by context and examples
  • Randomized (like flipping a coin)

• Ask the participant what it reminds them of
  • Amount of salt added to infant oral rehydration solution (no saltier than the tear)

• Pictures and illustrations
  • Remember faces, but not names

• Demonstrations
  • Losing 25 lbs of weight (pick up 25 lbs of sand or sugar)

• Use mnemonic (e.g., three steps of CPR is CAB)
Involve the Participants by Interaction (Participant directly interact with new information)

- Ask participant to tell you about the new information in his/her own words
- Present a problem: How/when will you do this when you go home? (e.g., medication regimen, fasting before appointment)
- Ask the participant what problems he/she has or expect to have in order to comply
- Ask questions during the teaching/learning session; dialogue with the participant
Involve the Participants by Interaction
(Participant directly interact with new information)

• Create one-page worksheet. Ask questions and leave blanks for them to write-in or check off or ask to circle a selected picture.
• For small groups, foster interaction between members of the group
• Games, interactive television, interactive multimedia instructions
• Have participant circle important information the consent document (e.g., after hours contact number, signs/symptoms requiring immediate attention)
Summary of Long-term Memory

• Associate new information with what the participant already knows
• Facilitate participant’s active interaction with the information
• Repeat or review
Watch Out for Mismatch of Logic, Language, and Experience

Instruction

Logic
Language
Experience

=  

Participant’s

Logic
Language
Experience

Participant’s

Understanding
Acceptance
Behavior Change
Language and Translation

• Translation of English to another language may not be effective due to cultural differences and literacy limitations.
• Work with members from the culture in the overall design and approach (graphics, diet lists, and procedures may not translate into same meaning in other languages).
• Back translate to make sure there were no omissions or additions.
• Use family member as translator (if competent as bilingual)
• Use community services for specific translation needs.
Other Ways to Communicate

• Pictures, models, and demonstration with actual equipment
• Simulation experiences
• Audiotapes in the dialect of the participant’s population
• Stories on audio cassettes appropriate to the culture to make participants more at ease (adults and children)
• Drawing pictures to show how he/she understands the instruction (or choose the appropriate picture).
• Check for body language for hesitation. If so, ask him/her to repeat or rereview the instruction.
Experience

• Ordinary requests that we make in health care system are not within the experiences of other cultures.

• Organization and sequence of giving out information may be different in other cultures
  • Use of stories for instruction
  • Building on extended family networks

• Ask advice from the target population who are bilingual with the best ways to present the information. May want to consider writing in the native language directly and then back translate.

• Get advice from ministers, priests, other religious leaders, school systems, community service agencies, etc.
Logic – Other People’s Values and Beliefs

• In U.S. we educate the participant directly, since we assume that each person manages his/her own healthcare.
• In other cultures, the critical decision making is influenced by others. The target population goes beyond the participants to the decision makers.
• In other cultures, an authority figure give “orders” and is never questioned. Participants from these cultures need encouragement to ask questions. Pamphlets with model questions may be useful.
• Participants must know what to expect from taking part in research.
• Watch out for use of humor. Some cultures may think that the information is not serious or “you don’t care about me”, if you use humor for serious health problems.
Cultural Suitability

• Obtain advice from members of the culture during the planning/development (Community Partnered Participatory Research - CPPR)

• Have written materials in the language of your target population

• Ask healthcare professionals from the culture to help develop research materials (e.g., informed consent, study instruments, translated materials, health education materials).

• Pilot test the written material
## Differences between Skilled and Poor Readers

<table>
<thead>
<tr>
<th>Skilled Readers</th>
<th>Poor Readers</th>
<th>Managing the Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interpret meaning</td>
<td>Take words literally</td>
<td>Explain the meaning</td>
</tr>
<tr>
<td>Read with fluency</td>
<td>Read slowly, miss meaning</td>
<td>Use common words, examples</td>
</tr>
<tr>
<td>Get help for uncommon word</td>
<td>Skip over the word</td>
<td>Use examples, review</td>
</tr>
<tr>
<td>Grasp the context</td>
<td>Miss the context</td>
<td>Tell context first, use visuals</td>
</tr>
<tr>
<td>Persistent reader</td>
<td>Tire easily</td>
<td>Short segments, easy layout</td>
</tr>
</tbody>
</table>
Evaluation to Sign a Consent Form for Research

- Understanding
  - What is the purpose
  - What is expected of you
  - What should you do if you have distress or discomfort.

- Appreciation
  - What is the risk and consequence

- Expressing a Choice
  - What should you do if you do not want to take part in the study

- Reasoning (greater than minimal risk)
  - Are there any other options if you do not take part in the study?

- Make decisions that are consistent with their values and beliefs (unfavorable risk/benefit ratio)
Teach-back

• Explain information clearly using plain language
• Ask the participant to explain in their own words
• Check for understanding, re-explain and check again
10 Elements of Competence for Using Teach-back Effectively

Agency for Healthcare Research and Quality (AHRQ)
PRISM Readability Toolkit
https://www.grouphealthresearch.org/about-us/capabilities/research-communications/prism/
“Do you understand?”

“What would you like to hear more about?”

“Can you tell me how you will take this medicine?”

Conditions for Remembering and Learning
References

- CDU IRB — Evaluation to Sign a Consent Form for Research
- UC Irvine HRP — Decision-Making Capacity Assessment Tool
- PRISM Readability Toolkit
- Informed Consent and Health Literacy, 2015 Workshop Summary, Institute of Medicine of the National Academies