WHAT DOES IT TAKE TO REMEMBER INFORMED CONSENT?

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Can prospective subjects understand informed consent if they can’t remember it? Ethically and legally, if subjects can’t remember much about the research did they really give “informed” consent? We shouldn’t be surprised if subjects remember most about clinical trials shortly after the consent process and least weeks or months later. How much subjects remember has little to do with consent form readability but much to do with basic memory processes. While informed consent researchers often refer to “memory” as a single process, informed consent involves all three types of memory.

Three types of memory
Table #1 lists the three types of memory, the duration of each memory, and key features of each memory.

WM: Working Memory
Working memory is the brain’s ability to temporarily store and process small amounts of information for several seconds. Because of WM’s brief time limit, consent information held in working memory decays quickly and is easily forgotten.

STM: Short-Term Memory
Small amounts of consent information will move from Working Memory into Short-Term Memory, which temporarily (less than a minute) stores this information. While early research suggested STM held about seven items, recent research finds STM storing only three-to-five pieces of information. Like WM, STM decays quickly—unless subjects work at keeping information in STM by repeating consent information over and over again, or by organizing similar pieces of information into more memorable “chunks”.

But information stored in STM will be lost if subjects have to quickly remember new consent information; new information replaced old information. The huge amount of verbal and written consent information means that most subjects will retain very little in WM or STM. If subjects ask questions, the added information from questions and answers wipes out what was in WM or STM, so they may remember very little even a short time later. What was remembered early in the consent process can be forgotten by the end. Remembering and forgetting consent form information will continue throughout the consent process.

“Chemobrain” and short-term memory
Memory problems and mental confusion (“chemobrain”) is often reported by cancer patients who have received chemotherapy. A recent study by Silverman, et al in the online Breast Cancer Research and Treatment (2006, vol. 99) found changes in brain metabolism and impaired short-term verbal memory in some breast cancer patients 5-10 years after chemotherapy. If cancer patients experiencing “chemobrain” later enter clinical trials, their slightly impaired memory and mental confusion may affect their ability to adequately remember and understand the consent process.

LTM: Long-Term Memory
Long-Term Memories can last a lifetime. LTM’s capacity is almost unlimited, but getting consent information from STM to LTM requires subjects to rehearse that information, or to associate new consent information with existing research or medical treatment memories. Consent information that subjects can link to other
memories will be remembered better than information without links because isolated information has no memory associations.

LTM does not decay like STM, but information from STM must be “consolidated” to move it into LTM. For example, there are three stages to remembering consent information:

1) encoding--the coding of what patients hear and read in the consent process into electrical impulses and chemical changes in the brain,

2) storage--where the consent information is placed in the brain, and

3) retrieval--the ability to get the information out when asked.

Prospective subjects who can store consent information in LTM do so because they were able to successfully encode, store, and retrieve that information. But if subjects cannot remember consent information, there’s no way to know if they didn’t successfully encode the information, store it, or just can’t retrieve it. Often memories can be stored, but not easily retrieved, as anyone with a middle-aged memory has experienced. Sometimes you know the answer to a question but you can’t retrieve it when asked (the “tip of the tongue” phenomenon). Remembering with a hint or later spontaneously remembering means that the memory was always there, but couldn’t be retrieved. Thus, poor subject performance on consent comprehension tests could be due to coding or storage or retrieval problems; test scores don’t always reflect what memories people have, only the memories they can retrieve at the time of the test.

Long term memories are permanent because they’re based on brain changes in electrical pathways and neurotransmitters. Ideally subjects should be able to transfer consent information from STM to LTM but that may not happen with current consent procedures. There are a few ways to move STM into LTM, including:

1) rehearsal--repeating key information over and over and over,

2) using mnemonic (memory aid) techniques, or

3) associating information about clinical trials with existing memories.

Based on memory research, “therapeutic misconceptions” may occur if subjects associate and confuse new informed consent information with existing treatment memories. If new information about clinical trial treatments is associated with memories of medical treatments, it’s not surprising that subjects may see links between treatment and research, because that association is how their brain remembers new consent information.
LTM: Recall vs Recognition

Consent comprehension studies don’t distinguish between recall and recognition. In multiple-choice tests where the correct answer is one of four alternatives, subjects only have to recognize the correct answer within the four alternatives. Such recognition memory compares information in the questions and alternatives to LTM information. But the four alternative multiple-choice format allows subjects to get 25% correct by guessing even if they can’t recognize the correct answer.

On the other hand, asking subjects to verbally explain what they know about the clinical trial, or asking open-ended questions, measures subjects’ recall of consent information. Because the correct answer isn’t available, subjects must search their memories to find where the answer is stored, and then retrieve that information to answer the question. Unlike multiple-choice recognition tests, subjects in recall tests cannot get 25% correct by guessing since the correct answer is not available. Because recognition and recall don’t use the same memory processes, comprehension results from consent recognition vs recall studies aren’t comparable.

Older subjects and their memory

Memory capacity begins to decline at about age 30. As clinical trials try to recruit older subjects, their reduced working memory capacity, poorer memory consolidation from STM to LTM and slower retrieval time means that older prospective subjects will find it harder to encode, store, and retrieve consent information than will younger subjects.

Is it ethically sufficient for older subjects to remember consent information very briefly and yet feel comfortable signing the consent form? Or should subjects be able to remember key information about clinical trials days, weeks, or months later? How long does “informed” consent have to last?

What can be done to improve informed consent memory?

LTM for consent is affected by whether consent information is distributed over several meetings (better LTM) or presented all at one time (poorer LTM). A typical consent process presents all the consent information at one time, which means that most information cannot make it into STM or LTM. Getting more consent information into LTM requires spacing the consent process over several meetings to improve memory consolidation—an effective but impractical strategy.

Subjects could better remember consent information if given mnemonic techniques to aid their memory and help them remember aspects of the consent process. Mnemonics should be concrete, visual, memorable, and even ridiculous. For example, consider the eight FDA required “basic elements” of informed consent.

8) Voluntariness— or as the mnemonic “Red Rugs Because A Cream Carpet Contained Vomit” where the first letter of each mnemonic word is the first letter of each of the required elements.

Subjects cannot visualize the “basic elements,” but they can visualize the mnemonic version, making it easier to remember the eight basic elements of informed consent, and perhaps some of the information associated with each element.

Tinkering with a consent form’s grade level, writing in plain English or changing the consent form’s layout can help make the document more understandable. But unless informed consent is consistent with what’s known about memory, subjects will continue to forget much of what they hear and read in the consent process.

Subjects could try to remember them in order as
1) Research,
2) Risks,
3) Benefits,
4) Alternatives,
5) Confidentiality,
6) Compensation,
7) Contact,