

COGNITIVE INTERVIEWING AS A TOOL FOR IMPROVING THE INFORMED CONSENT PROCESS

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ABSTRACT: CONSENT MATERIALS OFTEN CONTAIN complex information, legalese, and other features that render them difficult to comprehend in such a way that consent is truly informed. I propose that researchers adapt *cognitive interviewing*, normally used for the pretesting of survey questionnaires, to evaluate the understandability of consent materials and the way in which subjects use this information to make decisions regarding participation. Cognitive interviewing involves the intensive probing of small samples of volunteer subjects to elucidate thought processes that otherwise remain hidden. Cognitive interviewing can be applied: (a) to further the basic science of informed consent; (b) to pretest materials for a specific study; and (c) as an embedded procedure for assessing subject thought processes in the course of obtaining consent.

KEY WORDS: cognitive interviewing, comprehension, informed consent

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LEVINE (1984) SUGGESTED TWO MEANS for ensuring that study subjects understand the consent process in biomedical and social research: "The pool of prospective subjects can be limited to those who by virtue of their education and experience are most capable of comprehension. Alternatively, one can introduce procedures to enhance the process of informed consent—to make the mysterious items of information more comprehensible" (1984, p. 8). Most investigators would likely reject the first solution, and instead favor the development of consent materials that do not require an advanced degree to understand.¹ Unfortunately, in spite of efforts to inform subjects about their rights, about what the research study entails, and how information will be used, there is ample evidence that these efforts are not particularly effective.

Siminoff (2003) summarizes the state of the art by asserting that "Numerous studies reveal that consent forms packed with technical information are difficult to read and that subjects seriously misunderstand the purpose of research and the implications for individual care ..." (2003, p. S1). Ironically, the tendency to adhere to regulatory and legal requirements appears to preclude rather than to facilitate communication (for a review see Sugarman, Kass, Goodman, Perentesis, Fernandes, & Faden, 1998).

In addition to focusing on the information conveyed to subjects, Siminoff (2003) proposes that researchers consider the process by which potential subjects in turn use that information to make decisions about participating in research protocols. From the perspective of cognitive psychology, we are therefore challenged to better understand both *comprehension processes* necessary to encode materials, and the *decision processes* involved in making reasoned use of them. Further, investigators must consider not just the study consent form, but the *overall consent process*, as challenges to comprehension and decision-making. This involves all research-relevant communications and procedures, such as complex procedures for collection of sensitive personal information in a way that maintains privacy and confidentiality; and advance letters sent to study subjects (Flory & Emanuel, 2004; Grundner, Levine, & Meisel, 1982; Sachs, *et al.*, 2003).

Several categories of potential misunderstanding are relevant to the consent process:

1. Study sponsorship/incentives: Who is doing the study? What is their incentive?
2. Study procedures: What is the subject asked to do? What will be done with information about him/her?
3. Medical and psychosocial risks to study subjects: What are the potential adverse outcomes? How likely are they?
4. Burden on subjects: What are the financial and time costs of participation?
5. Benefits to study subjects: Is the study likely to provide a health benefit to the individual participant?
6. Benefits to others: Is the study likely to improve knowledge about health or disease?

As an example of research that has chronicled troublesome knowledge gaps on the part of study participants, Pace, *et al.* (2005) surveyed 141 individuals in an NIH-sponsored randomized trial of HIV positive adults in Thailand, immediately after obtaining consent. The consent process was extensive, involving a two-hour group discussion led by a trained clinical trial nurse, an individual interview with a physician, and a lengthy (2,600 word) consent document. Despite this, a questionnaire-based assessment determined that 40% mistakenly believed that all study participants would receive the experimental drug evaluated in the trial (in truth, 50% were to receive that intervention), despite high levels of self-perceived knowledge of study details. Further, only 71% of subjects knew that they could withdraw at any time, and 27% reported at least some pressure to join the study. Concerning the latter finding, the authors stated that "... further questioning is necessary to understand the origins of and reasons for such perceptions of pressure" (2005, p. 15).

The notion that further questioning of study subjects is key to understanding subject cognition is the central theme of this paper. To fully assess the thinking of potential subjects, it is vital to probe their thoughts in an intensive, investigative manner, and optimally to do so prior to study recruitment and implementation. To this end, I propose use of a technique—the cognitive interview—that has been widely applied in the survey methods and questionnaire pretesting field to evaluate the cognitive aspects of responses to survey questions.

Cognitive Interviewing: A Review

I borrow from an associated field in which effective communication is paramount—that of questionnaire design—and advocate the adaptation of the *cognitive interview*, a relatively quick and efficient means for establishing that survey questions are understood as intended, ask for appropriate information, and do so in a way that minimizes error in resulting data² (Beatty, 2004; Collins, 2003; DeMaio & Rothgeb, 1996; Jobe, Keller, & Smith, 1996; Redline, Smiley, Lee, DeMaio, & Dillman, 1998; Tourangeau, Rips, & Rasinski, 2000). Brief guides by the U.S. Census Bureau (2003) and by Willis (2005a) outline the conduct of cognitive interviews, and one detailed text exists (Willis, 2005b). In the arena of survey methods, cognitive interviewing is most often used to evaluate the functioning of questionnaires, but is also applied in the evaluation of materials presented in written or auditory form, such as advance letters to survey respondents, and statistical maps and graphs (Landreth, 2001; Pickle, Herrmann, Kerwin, Croner, & White, 1993).

Background Theory

Cognitive interviewing was developed as a formal method in the 1980s as part of a collaboration between cognitive psychologists and survey researchers known as CASM (Cognition and Survey Methodology). The CASM movement emphasizes the fundamental contribution of human cognition, or information processing, to the task of responding to survey questions (Jabine, Straf, Tanur, & Tourangeau, 1984). Cognitive interviews rely on the Four Stage cognitive model introduced by Tourangeau (1984), depicted in Table 1.

For example, when asked the question "How many times in the past year did you go to a dentist?" the respondent must first comprehend the various terms ("past year"; "dentist"), and the entire meaning of the question, in a way that is consistent with the intent of the investigator. Further, he/she must be able to successfully retrieve from memory information corresponding to past visits. Following this, the individual may initiate a decision, judgment, or estimation process related to whether the retrieved memory is both accurate and acceptable (e.g., based on a recall of one visit, the person may think "That can't be right, I know I had more than that"; or, may recall no visits but decide it appropriate to report at least one to the interviewer). Finally, during the response mapping process, the individual must produce a response that is codeable by the data collector (e.g., an answer of "a couple of times" cannot unambiguously be coded as a "2").

The CASM approach is predicated on the notion that survey questions and other materials fail because of problems at some point in the cognitive processing chain. As a result, we obtain faulty data due to survey response error—simply put, answers that are incorrect. Cognitive interviewing is a tool that investigates problems in this processing chain and identifies their source with respect to the evaluated materials. As such, an item may present comprehension problems because it is too lengthy to be well-encoded; or it may request information that the

TABLE 1. Stages of the survey response process (adapted from Tourangeau, 1984).

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1. *Comprehension* of the question
 2. *Retrieval* from memory, or recall, of information the question inquires about
 3. *Decision/Judgment/Estimation* processes, especially concern the adequacy of the answer
 4. *Response*, in which the respondent attempts to match an internally generated answer to the response categories provided or expected by the investigator
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respondent can no longer remember (for example, whether one has had a tetanus shot in the past 10 years). The fundamental purpose of cognitive interviewing is not to gather quantitative data or to focus on the answers to the tested questions, but rather to obtain information—mainly qualitative in nature—concerning the processes involved in answering them. Based on the results of these interviews, questions are modified in an attempt to rectify the problems observed.

Cognitive Interviewing Procedures

Samples used for a set, or “round,” of cognitive interviews often consist of 8-12 individuals. Although these numbers are small by normal standards of empirical research, the major objectives concern the attainment of insights and generation of hypotheses, as opposed to statistical power and hypothesis testing. Further, when testing survey questions, large samples are often unnecessary because it often becomes quickly evident that an evaluated question is flawed. Typically, individuals recruited for cognitive interviews represent a range of characteristics relevant to the evaluated questions (e.g., both current and former smokers, to evaluate a tobacco questionnaire). Finally, the interview is normally conducted by researchers who have received specific training in cognitive interviewing techniques, as opposed to field interviewers.

Cognitive interviewing relies on two basic procedures: (a) the think-aloud, and (b) verbal probing procedures. The think-aloud was advocated by Ericsson and Simon (1980) for use in psychological laboratory experiments that require problem-solving, and was extended to the evaluation of survey questions by Loftus (1984). During think-aloud interviews, the interviewer requests that subjects externalize their thought processes as they respond to tested questions or materials. The interviewer typically instructs the subject to “Tell me what you are thinking”. For instance, in testing the survey question “In the last 12 months have you been to a dentist?” Loftus (1984) reported a subject’s think-aloud response consisting of: “Let’s see ... I had my teeth cleaned six months ago, and so ... and then I had them checked three months ago, and I had a tooth ... yeah, I had a toothache about March ... yeah. So, yeah, I have” (1984; p. 62). To pretest survey questions, or to elucidate the underlying cognitive basis for the survey response process, the resulting record of the subject’s verbal output (the “verbal protocol”) is analyzed to identify potential problems that have a cognitive origin (Bickart & Felcher, 1996; Bolton, 1993). Loftus (1984) asked subjects questions about health care visits and students’ financial deposits to a

meal card plan, and through analysis of the resultant verbal protocols, found that memory retrieval of such autobiographical episodes was predominately in a past-to-present direction (as opposed to the reverse, or in a haphazard retrieval order).

Despite its initial focus on thinking-aloud, cognitive interviewing has come to be characterized increasingly by the use of *verbal probing* (Willis, Royston, & Bercini, 1991). As opposed to think-aloud, verbal probing demands active, directed investigation by the interviewer. For example, after the subject is asked and then answers the tested question, the interviewer follows with probes of the type contained in Table 2.

Probe questions are sometimes oriented toward particular cognitive processes: Comprehension probes assess understanding of the survey question; recall probes target the ability to remember information the question requests. Beyond assessing cognition, however, probing also incorporates “Expansive” or “Elaborative” probes that induce subjects to clarify whether the tested question applies meaningfully to them, and whether the fuller explanation is consistent with the initial answer to the question (Willis, 2005b). For example, the interviewer may first present the item “Would you say your health in general is Excellent, Very Good, Good, Fair, or Poor?”; and no matter the subject’s response, request an elaboration (“Tell me more about your health.”). The researchers can then consider whether the initial close-ended response represents the expanded description in a manner intended by the investigation. Extensive probing of the general health item, above, has revealed it to be very limited as an absolute measure of self-perceived health, in part due to age-dependent context effects. A 25-year-old marathoner may report “fair” health because she has recently suffered a hamstring pull, whereas a 90-year-old with multiple chronic-health conditions may answer “Excellent” and then justify that response based on the fact that he

TABLE 2. Example of evaluated question, with probe questions.

Question: When you shop for food, how often do you buy items that are labeled “low sodium”?

Verbal probes used to test the question:

1. Tell me more about that ...
2. How often do you shop for food?
3. What to you, is “sodium”?
4. What is it that you are looking for, on the label?
5. Do you look for labels that say low sodium, or just choose foods you know are low?

remains alive at the moment (Schechter, Beatty, and Willis, 1999; Willis, 2005b). To adjust to this finding, the item has sometimes included the phrase “Compared to other people your age.”

Verbal probes can be *proactive*, and developed prior to the interview based on the anticipation of problems; or *reactive*, and administered because the subject has provided some indication of difficulty (for example, a long pause) (Willis, 2005b). Probes are usually administered *concurrently*; during the conduct of the interview, and immediately after the subject has answered each tested question. Alternately, researchers sometimes make use of *retrospective* (debriefing) probes, which are administered as a set after the tested questionnaire is completed. A major advantage of concurrent probes is that they obtain information immediately after the subject has answered each tested question, when relevant verbalizable information is still likely to exist in memory. Retrospective probes risk the loss of these memories because they increase the interval between question processing, and probing. On the other hand, the retrospective approach avoids interrupting the interview with additional probing, and leads the subject to reflect back over the entire interview. For the evaluation of self-administered questionnaires and other materials to be read by survey respondents, a common procedure is to allow the subject to complete the instrument undisturbed and then conduct retrospective probing (see Hak, van der Veer, & Jansen (2004); Redline, *et al.*, (1998).

Analysis of Outcomes from Cognitive Interviews

Under any form of probing, cognitive interviews produce data in the form of written notes taken by the interviewer during the interview, observers’ notes, or analysis of audio or video recordings of the interview. Data derived from cognitive interviews are qualitative, consisting of written summaries that describe the problems noted on a question-by-question basis, and which suggest modifications intended to address these defects. Multiple, iterative testing rounds are often used to determine if the modified version then functions as intended, without introducing further problems. Table 3 contains representative results based on the food-shopping question presented in Table 2, with potential modifications.³ Upon further testing, the revised questions may also fail—for example, 12 months may be too long an interval to recall such a mundane behavior. However, at some point the investigators will settle upon a version deemed sufficient to be sent into the field.

TABLE 3. Representative findings from cognitive testing of question illustrated in Table 2, with potential modifications.

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- A. Comments based on cognitive interviews:
1. Some subjects report that they don’t do food shopping themselves;
 2. Some subjects are not sure what “sodium” is; one confused it with low-fat food;
 3. Subjects reported selecting foods that they knew to be low in sodium, rather than by checking for a specific label;
 4. Even those who relied on the label looked for a listing of milligrams of sodium, as opposed to a label specifically saying “low in salt/sodium”;
 5. The timeframe is ungrounded; so interpretations between subjects of the relevant reference period vary greatly;
 6. Asking for a frequency of such label-checking behavior may be unworkable, because subjects cannot confidently report the exact frequency of such a behavior.
- B. Suggested modification, based on testing:
1. In the past 12 months, have YOU gone shopping for groceries five or more times?
 2. IF YES: In the past 12 months, when you shopped for food, have you chosen an item because it had a label saying that it was low in salt or sodium?
 3. IF YES: In general, how often do you select a food because it has a label saying it is low in salt or sodium—frequently, once in awhile, or have you only done this once or twice?
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Proposed Extensions to the Area of Human Subjects Protection

Because obtaining respondent consent is a necessary component of survey research, CASM researchers have begun to address the cognitive aspects of the consent process. Singer (2004) has outlined the general challenge of effectively conveying to survey respondents, in a quick manner, what a survey will be about, what will be done with the information collected, and what rights the subject has. The adaptation of cognitive interviewing methods to study the consent process in surveys, and in medical and social science research more generally, forces an emphasis on subjects’ mental processing of forms, materials, and other consent-related information. In terms of cognitive processes involved, the main focus is comprehension. However, cognitive interviewers will also be interested in decision processes⁴: In particular: Is an individual’s decision as to whether to participate in the protocol determined by the comprehension of its relevant features, or is that decision based on preconception or avoidable misinterpretation?

The remaining two cognitive processes depicted in Table 1—Retrieval, and Response—may also be relevant to the overall consent process. For example, it would

be illuminating to assess whether subjects base their decisions on the recall of information they have received about the study, prior to formal communication with investigators. Further, subjects may exhibit response mapping behaviors which should give the investigator pause, such as signing a consent form, but also stating that “Whatever this study is about, I guess I’ll sign up ... what do I have to lose?” In spite of such possibilities, the focus of the current paper is mainly comprehension and decision, rather than retrieval or response selection.

Using Cognitive Interviews to Assess the Comprehension of Terms Used in Consent Materials

As an overall objective, it may be particularly valuable to apply cognitive interviewing techniques to learn how potential subjects comprehend the terms commonly used by researchers in the consent process, as particular words may convey complex denotative and connotative meanings (Butters, Sugarman, and Kaplan, 2000). Hochhauser (2003) has identified a range of *Concepts Words* used in consent forms that are likely to be misunderstood because they describe general ideas, abstract concepts, or references, for example: “assigned by chance”, “at risk”, “sponsor”, “clinical condition”, and “retrospective study.” Further, he identifies problematic *Category Words* that describe groups of concepts: “abnormal laboratory tests”, “my legal rights”, and “unexpected toxicities”; as well as *Value Judgment Words* such as “absolute confidentiality”, “rare occasions”, and “serious medical events.” In order to investigate whether these terms are problematic, investigators can probe term comprehension; e.g., “What do you think we mean by a ‘clinical condition’?”

Hochhauser (2003) also provides examples of modified wording presumed to be both simpler to understand and more specific (e.g., “assigned by a coin toss” as opposed to “assigned by chance”; “swallow a pill” instead of “oral administration”; “your name and address” rather than “identifiable information”). These potential substitutions are ripe for testing within cognitive interviews. As a precedent, Butters *et al.* (2000) analyzed the transcripts of in-depth interviews (in some ways similar to cognitive interviews) conducted with 26 former medical research subjects to determine their interpretations of common phrases such as “clinical investigation” and “medical experiment.” The former term was found to present confusion and inconsistency, and the latter produced pronounced negative connotations.

Using Cognitive Interviews to Investigate General Comprehension and Decision Processes

As a preface to a second general application of cognitive interviews, consider the following scenario: An epidemiological study is conducted to search for genetic polymorphisms (variants) which mediate the relationship between behavioral risk factors and the development of colon cancer. In one study arm, patients receiving cancer treatment are asked to participate in a separate research study which involves a blood draw; cheek buccal cell collection; administration of a survey questionnaire about diet, physical activity, and family history of cancer; and the indefinite storage of their biological materials for future DNA testing. The research study is described by a study nurse not otherwise involved in the patient’s treatment, and a consent form is presented to the subject. After the nurse addresses any questions, the subject signs the form, and he/she is then enrolled in the study.

This protocol may be entirely appropriate from an ethical point of view and approvable by an institutional IRB as a minimal risk protocol. What assurance do we have, however, that the study subject truly understands the ramifications of participation? Several issues are pertinent; and each can be translated into a cognitive probe to be asked of subjects after they have read the consent form, but prior to signing it (Table 4).

Subject responses to the probe questions in Table 4 would be open-ended in nature, and require that the interviewer listen carefully to ascertain the significance of these responses, and whether any misconceptions need to be resolved. Overall, the intent of cognitive probing is to actively engage the subject beyond the point of simply asking “Do you have any questions?” of someone who may not know precisely what questions to ask. Note that the answers to probe questions may invite further “emergent” probes which are unscripted, and are developed on-the-spot based on informative strands that emerge during the interchange. As such, the cognitive interviewing script serves as a guide that sets the stage for further unstructured conversation.

The implementation of cognitive techniques would not entail a radical change to existing directions in human subjects research, but constitutes a natural extension. The Pace, *et al.* (2005) study cited earlier demonstrates the uses of procedures similar to those of cognitive interviewers. Although the researchers relied upon a standardized questionnaire that was somewhat less flexible or adaptive than the cognitive interview, some of their queries were equivalent to scripted cognitive probes. For example, “How easy was it to understand information about the

TABLE 4. Examples of probes for investigating subject comprehension and decision processes.

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- a. Based on what you just read and been told—What is your understanding of what you are being asked to do?
 - b. Is it your understanding that you are being asked to participate in a research study, or to agree to a medical procedure that may help you?
 - c. IF STUDY in (b): What would you say is the purpose of the study?
 - d. The form mentions the use of blood to test for genes that may increase a person's chances of getting colon cancer. To you, what is a "gene"?
 - e. What is your understanding of how your blood, and cheek cells, will be used in the future?
 - f. Do you remember anything on the form about how your medical care will be affected if you decide to join the study? What about if you decide NOT to join the study?
 - g. Overall, who is this study intended to benefit?
 - h. What did you think of the consent form—did it contain too much information, too little, or the right amount?
 - i. Was the form easy to understand, hard to understand, or somewhere in between? Why?
 - j. At this point, based on your understanding of the study, are you leaning towards participating or not participating? Why do you say that?
 - k. At this point, do you feel ready to make a decision about participation, or would you like more time, or more information, or possibly both?
 - l. Do you feel as though your decision to participate is one that you are making freely, or do you feel pressured in any way?
 - m. Do you feel like your decision to participate is truly your own decision, based on your understanding and what you think is best—or are you relying partly on what others are saying is best for you?
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ESPRIT study in the discussion with the ESPRIT study team?" constitutes a comprehension probe, and "How much pressure, if any, did you feel from other people to join the ESPRIT study?" concerns decision processes. The use of knowledge probes in particular provides a built-in test of accuracy, given that the investigators know the correct answer to the probe. For example, the answer given to the question "In the ESPRIT study, who do you think will get IL-2?" (Everybody ... A few people ... Don't know) can be validated against the information actually presented to subjects.

Three Areas of Application of Cognitive Interviewing

More specifically, to apply cognitive interviews as described above, I propose three particular directions for their use in the area of human subjects protection,

all of which have existing analogs within the survey methods area.

(a) Basic Research to Develop Principles and Practices

The allure of cognitive interviewing is in part based on the possibility that consistent results can be used to develop general principles of questionnaire design that are widely applicable (Schwarz, 1999). Similarly, by applying cognitive techniques to determine how individuals understand the process of informed consent (e.g., investigation of the "Therapeutic Misconception" described by Applebaum, Roth, & Lidz, 1982), researchers can endeavor to develop principles to guide the communication of critical concepts related to consent. Siminoff (2003, p. S2) expresses this notion in terms of "the need to ground informed consent research and interventions in theories of communication and decision-making." We might investigate, for example, the type of wording that leads subjects to erroneously believe that they will receive therapeutic benefit through study participation, and how to disabuse them of this notion. Following Gerber (1999), I also promote the use of ethnographic forms of cognitive interviewing to assess cultural norms associated with obtaining consent (e.g., differential perceptions of the role of the family in the consent process between Western and Asian cultures). Based on these investigative studies, practitioners may be able to suggest detailed principles of communication regarding wording or vehicles for conveying consent information (e.g., paper versus video presentation), or even shared templates for consent material wordings that can be implemented across future studies.

An illustrative investigation by Agre & Rapkin (2003), although not strictly a cognitive interviewing study, indicates the value of basic cognitive research on informed consent. The authors investigated the impact of four consent presentation modes—standard paper consent, booklet consent, video presentation, or computer assisted instruction (CAI)—on comprehension of consent information for 18 clinical oncology protocols (either non-therapeutic or Phase I—III trials). To assess comprehension, a multiple-choice knowledge test was administered to 441 subjects (204 Patients, 109 family members or friends of Patients, and 128 non-Patient surrogates). Overall, the average knowledge test score was 69%, and did not differ significantly among patients, their family members, or surrogates. Knowledge was higher for more complex protocols and for those that offered the possibility of therapeutic benefit. However, comparison of the four presentation conditions failed to produce clear, consistent results. Computer and video produced

somewhat higher levels of comprehension than paper formats, but one cluster of subjects was found to perform very poorly under both computer and video, leading the authors to conclude that media-based tools are not automatically effective for improving the informed consent process (a conclusion supported by a more extensive review by Agre, *et al.*, 2003).

Especially relevant to the current focus, Agre and Rapkin (2003) caution that the overall average knowledge score of 69% correct answers is difficult to interpret, and may not in itself serve as a definitive measure of consent form appropriateness, as the knowledge test may have been difficult, and it might be unnecessary to understand all the study details in order to be well-enough informed to make a reasonable decision concerning participation. This observation is reminiscent of Pace *et al.*'s (2005) suggestion that follow-up questioning may be necessary to investigate the depth of subject understanding—which again is a function potentially satisfied by the conduct of cognitive interviews.

An example of a theory-oriented cognitive interviewing study of comprehension and decision-making is described by Willis, Sirken, and Nathan (1994), who sought to determine how procedures of varying complexity for asking sensitive survey questions are viewed from the subject's perspective. In one experiment, 24 individuals were provided descriptions of two administration procedures involving questions on drug use. In one condition (Envelope), the procedure involved sealing a completed self-administered questionnaire in a pre-addressed envelope, and placing the envelope in a public mailbox. A second, more complex condition described a variant of the Randomized Response Technique (RRT), in which a card containing two survey questions is presented (Horvitz, Shah, & Simmons, 1967). One of these questions is the sensitive item of interest to the researcher (e.g., "In the past 12 month, did you use a needle to inject or 'shoot up' street drugs?"), and the other is a non-sensitive item having a known response distribution ("Was your mother born in January, February, March, April, May, or June?"). The survey respondent is instructed to use a randomizing device (usually a coin) to determine which of the two questions he or she is to answer. Despite the randomness of the procedure, the aggregate results are, in theory, useful to the researchers, who can compute an overall prevalence estimate for the sensitive item alone.

Based on a suspicion that the RRT procedure may not be totally clear to subjects, and may even appear somewhat bizarre, Willis *et al.* (1994) employed cognitive interviews to ask subjects (a) to describe in their own words how each procedure protects them; (b) to indicate

how likely it is that the investigators could breach the individual's anonymity after using each procedure; and (c) to report which procedure they preferred. Although the quantitative data concerning risk assessment were not particularly revealing, and subjects were fairly equally split in terms of preference, the answers to the open-ended cognitive probe were illuminating. For the RRT condition, 9 of 24 spontaneously mentioned that the procedure appeared useless to the researchers, given its essentially random nature. Further, even subjects who felt that the procedure protected them did not universally indicate a willingness to therefore obey the given instructions. On the contrary, several voiced little incentive to pay attention to the outcome of the coin toss, or to answer the assigned question truthfully, given that the entire process seemed random and pointless.

Less anticipated by the researchers was the finding that 9 of 24 subjects answered probe questions by using explanations that emphasized contextual elements, or factors not intended to be components of the administration procedure. For example, subjects suggested that the interviewer might pay attention to the respondent's facial expression, when shown a card containing a drug-related question, to determine if he/she were a drug user. The investigators concluded that "... the cognitive interviewing approach brings to light variables and survey-relevant issues that may be significant determinants of respondent behavior, but that the survey design does not normally consider." As applied to research on the consent process, this finding implies that individuals presented consent materials may be found, through cognitive testing, to have extended the reach of their thinking well beyond what is explicitly stated within these materials, and to make use of inferential processes, assumptions about what the materials are likely to mean, and perhaps even personality characteristics of the individual requesting consent (e.g., "I would consider whether the doctor seemed trustworthy").

*(b) Implementing Cognitive Interviews Prior to the Study:
Applied Materials Development*

The second application of cognitive interviewing to the research consent process mirrors the questionnaire pretesting procedures used in Federal cognitive laboratories (e.g. at the Census Bureau and the National Center for Health Statistics). Rather than relying exclusively on general principles of communication gleaned from basic research, these laboratories strive to evaluate each questionnaire as a case study, and develop materials customized for that investigation. The corresponding

use of cognitive interviewing as a pretesting method in the human subjects protection arena is straightforward, but does beg a significant question: Who should the materials be pretested on? In some cases it may be feasible to recruit members of the eligible study population. For example, within an epidemiological project intended to ascertain diet, any adult may theoretically be eligible, and test subjects would be relatively easy to locate. For studies that involve clinical intervention using patients, it may also be possible to identify pretest subjects from the patient population. On the other hand, it might not be desirable to “waste” difficult-to-recruit patients solely for purposes of materials development. Hence it may be necessary to rely on surrogate subjects, and we must face the critical issue of whether surrogates are appropriate substitutes.

Several authors have investigated the use of surrogates to evaluate consent-oriented materials, although not within the context of cognitive interviewing studies. Agre and Rapkin (2003) indicated that the response tendencies of surrogate patients were not equivalent to those of patients, and in a review of 18 NIH-sponsored projects that empirically investigated informed consent in the research context, Siminoff (2003) found that surrogates tended to make different decisions than did patients. As such, investigators should be wary of asking individuals to put themselves in the position of subjects faced with the prospect of participating in a research study.

However, at a finer-grained level of analysis, a critical issue may be whether the objective of pretesting mainly involves comprehension or decision processes. It is possible that the understandability of consent forms and investigation of alternate wordings is a general concern that can be meaningfully assessed using non-patients; note that Agre and Rapkin (2003) obtained identical mean knowledge measure scores for patients and surrogates.⁵ On the other hand, surrogates may be fundamentally limited in their ability to replicate the (sometimes literally life-and-death) decisions that patients make concerning study participation. The conclusion that comprehension and decision processes diverge in this manner is consistent with the general finding from the cognitive interviewing field that asking judgments based on hypothetical situations (i.e., requesting that the subject predict how he/she would react in a particular circumstance) is fraught with difficulty; whereas assessing basic comprehension of presented materials is a more valid enterprise (Willis, 2005b). Hence, for purposes of assessing understanding of the consent process it may be sufficient to rely on surrogates who exhibit characteristics similar to those of true study subjects, especially with respect to age,

educational level, and other variables likely to impact comprehension.

Assuming the cognitive researcher has cleared the hurdle of subject recruitment, cognitive interviewing provides some clear benefits as a means of tailoring the development and pretesting of consent materials for a particular study. For one, cognitive interviews may provide a clearer picture than completely structured knowledge tests concerning whether subjects truly comprehend the material. Flory and Emanuel (2004) have suggested that knowledge test items are often designed to test memory for the exact wording of the consent materials, and therefore reflect rote memorization. More intensive forms of cognitive probing might alleviate this problem, as they focus on a deeper level of comprehension, rather than on whether subjects can correctly reproduce only superficial items of information.

Most basically, applied cognitive testing is compact in scale and in resource requirements, and therefore practical for use as a developmental step. Although more extensive research efforts of the type reported by Agre and Rapkin (2003), involving large samples and standardized questionnaires, are useful for purposes of quality assurance and for understanding the basic science of consent, these are not as useful as a pretesting tool, as they require too many subjects for that purpose. Also, because they are piggy-backed to an ongoing protocol, large-sample methodological tests are not generally useful for altering the consent process for the evaluated protocol. Cognitive interviewing, on the other hand, can be used prior to the study as an efficient developmental tool that can impact the fielded version of consent materials.

As an illustration, Bates (2005) describes the small-scale application of cognitive interviewing to explore means for requesting subject consent to link administrative records to their survey responses. The scripted request consisted of the following:⁶

The Census Bureau would like to conduct additional research without taking up your time with more questions. We would like your permission to obtain the information that you have given to other agencies on topics such as Social Security and Medicare benefits. All of the additional information collected by the Census Bureau is kept confidential and is protected by the same law that protects your survey information. Would that be ok with you?

This form of the request was tested in twenty cognitive interviews either at the Census Bureau or in local establishments such as a public library or a social service facility. Tested subjects ranged widely in age (18-81), differed

somewhat in educational level (12th grade through Master's degree), and were of varied race. All but two subjects reported that they would grant consent, and few evident problems were observed. However, a somewhat different picture emerged through follow-up probing that assessed subject comprehension by asking them to paraphrase the intent of the request. Based on a review of interview transcripts, 9 of 20 failed to grasp the notion that the Census Bureau intended to engage in sharing of information the respondent had already provided to other Federal agencies. Further, 11 of 20 misunderstood the direction of the transfer, and believed that the request regarded movement of responses *to* (rather than *from*) another agency.

Given such findings, investigators must consider both the significance of the obtained results, and the proper course of action to be taken. The first misinterpretation (concerning the basic nature of the request, related to the fact of data sharing) might be thought more significant than the second (regarding the more subtle issue concerning directionality of sharing). Concerning appropriate actions to be taken, the investigators could script a revised request, and then to conduct a follow-up round of cognitive testing to evaluate the revision, in advance of study data collection.

(c) *Embedded Cognitive Interviews: Interviewing Over the Course of the Study*

I have to this point advocated the conduct of cognitive interviewing (a) as basic research (apart from a particular study), and (b) as a pretesting procedure, prior to study implementation. Butters *et al.* (2000) and Agre and Rapkin (2003) point toward a third application, the latter noting that within the conduct of the study itself, investigators "have a responsibility to assess individuals' understanding more thoroughly than simply asking if they have questions" (2003, p. 6). This statement suggests that the cognitive interview can be conceptualized not only as a means for the development and pretesting of consent materials, but also as a method by which subject cognition can be assessed at multiple points during the course of the ongoing investigation. Because of the flexibility inherent in this application, it is reminiscent of the traditional semi-structured interview within clinical research. For the proposed application, however, the purpose of a less-structured form of interviewing is not data collection, but rather the use of probing to elucidate subject comprehension and decision-making concerning a range of critical elements of the research. Embedded cognitive probing techniques turn an otherwise largely one-way delivery of information

(investigator-to-subject) into a bidirectional exchange with built-in means for identifying misinterpretations.

The introduction of the embedded cognitive interview into the consent process is consistent with the application of a similar procedure within survey research by Friedenreich, Courneya, & Bryant (1997). Friedenreich *et al.* assessed respondent physical activity through a questionnaire that relied on cognitive probes at the time of data collection to embellish an otherwise standardized instrument, and to therefore enrich the interaction between interviewer and study subject. Unfortunately, this approach to interviewing is normally not feasible for large-scale surveys, mainly because of the associated costs imposed by the less-structured interview, such as requirements for interviewer training (as probing demands much more skill than the straight administration of a standardized survey questionnaire) and survey administration time (Schober and Conrad, 1997).

Fortunately, neither of these limitations should be as severe an impediment within the field of human subjects protection. For most research studies, the research coordinator, nurse or other individual seeking subject consent is trained to be familiar with the elements of the study, and the time available to explain the study to subjects should in general be less limited than is typical for a population survey questionnaire. As such, it is potentially feasible and appropriate to conduct, as part of the consent process, a discussion of the study which embeds cognitive interviewing.

For such embedded cognitive interviews, a major issue is whether interviewer probing is concurrent or retrospective, as discussed earlier. As is often done for cognitive testing of self-administered questionnaires, it may be most effective to: (a) wait until the subject finishes reading the consent form (or at least a section of it); (b) probe concerning his or her understanding of critical elements from each section; (c) intervene by correcting misinterpretations that are identified; (d) finally, administer probe questions relating to decision processes, by probing the basis for the subject's tendencies to participate or not. Sample probes relevant to the latter are contained at the bottom of Table 4 (items j-m).

Case Study: The Use of Cognitive Interviewing to Study the Consent Process

No matter which of the three applications of cognitive interviewing described above is adapted to the development and evaluation of consent materials, it is important that cognitive interviewing be integrated into the overall Institutional Review Board (IRB) approval process. The following example illustrates how this objective

can be accomplished. The cognitive investigation (conducted by the author) centered on the desire to collect empirical information to assess the clarity of materials and likely reactions of study subjects, because there was disagreement between the investigator and the IRB on matters of wording prior to final approval of materials. The issue of contention centered on the relative effectiveness of two alternative versions of an advance letter which differed (mainly) with respect to wording used to describe steps to be taken in the event the respondent could not be contacted over the telephone. Version 1 contained a paragraph that was phrased as suggested by the Minutes of IRB review:

VERSION 1: If we are unable to contact you, we plan to use in our research, the information about you from public health records and other sources to check on your health status. If you don't want us to use any information about you, please contact us at the *Family Health Study* Office at 1-800-XXX-XXXX.

Version 2 contained a revision of that paragraph, developed by the investigator in response to the IRB's suggestion, which attempted to "soften" the wording:

VERSION 2: If we try to call but are unable to contact you, you will not be able to take part in our telephone interview. However, it is still important to us to be able to include you in our study. So, we may try to verify your health information by confidentially checking sources such as health registries. If you would rather that we don't use *any* information about you, please contact us at the *Family Health Study* Office at 1-800-XXX-XXXX.

The investigators carried out cognitive testing of letters that contained these wording variants on eight NCI clerical staff members not associated with the protocol. The presentation order of these versions was counterbalanced so that four subjects received Version 1 first, and two initially received Version 2. The cognitive interviewer was careful to avoid the appearance of preferring either letter to avoid introducing bias. The primary goal of pretesting was to determine which of these versions subjects preferred, and why, and to determine ways to further modify the preferred variant. Interviews relied on probes formulated before the interview (*Anticipated probes*), but also allowed the interviewer latitude in applying more emergent forms of probing as appropriate during each interview. A subset of the probes formulated prior to the interview is shown in Table 5.

Because the surrogate subjects were NCI staff members, they were generally more educated and more

TABLE 5. Family Health Study: Probes used to assess comprehension and subject reactions to alternative variants of advance letter.

-
1. ... let's look at each paragraph, one at a time. Read over the first paragraph again ... Now, the next paragraph, starting with "if we are unable"—read that one.
 - a. If we can't call you, what does it say we'll do?
 - b. Where does it sound like we'll look for this information?
 - c. Does this seem ok to you, or is there anything that would bother you about this?
 - d. Would it bother you to have the researchers looking for health information about you, or would this be ok?
 - e. Again, what are you supposed to do if you don't want the researchers to look for information about you?
 2. Now let me show you a different version of the letter—LEAVE BOTH VERSIONS IN VIEW
 - a. First, what differences do you notice between the letters?
 - b. Which letter do you think sounds better—the first one you read, or the second?
 - c. Why do you like that one better? Why?
 - d. Can you think of any way that we could improve either letter?
-

knowledgeable about cancer-related research than the target population for the study. Despite this limitation, a wide range of opinions, concerns, and suggestions was elicited. Most importantly, it was observed that the revised letter (Version 2) was preferred by 6 of the 8 participants. According to their specific comments, it seemed a "gentler" or "nicer" means by which to communicate the necessary information. The original version was generally viewed as overly terse and suggested that investigator access to administrative record data was, as one subjects stated, "a done deal." Another paraphrased this statement as equivalent to "... we're going to do this whether you like it or not"; a third stated spontaneously that this paragraph appeared threatening; and a fourth commented that this "will really tick someone off." Interestingly, the two individuals preferring the original version had no objections or suspicions concerning the researchers' practice of verifying health information through records and registries; they therefore preferred the version that was shorter and more direct.

However, even though the revised letter was preferred overall, it was also found to have several problematic features. In particular, the use of the term "verify" was objectionable to several participants, and conferred a feeling of "being checked up on by the government," in the view of one subject. In response, the investigator replaced "verify" with the phrase "to get a more complete picture of your health." When the investigator presented these results to the IRB with a request that the revised version be approved, the Board did so, and

commended the investigator for empirically assessing critical issues regarding informed consent.

Best Practices

Best practices are those that are both scientifically valid, ethical, and feasible in the applied research setting. From a pragmatic point of view, we need to consider whether results of cognitive interviews can be implemented effectively to study the consent process and to develop materials. Most importantly, as Siminoff (2003, p. S2) points out, “IRBs need to be given the regulatory (and perhaps legal) flexibility to allow investigators to tailor consent forms and consent situations to specific populations.” Given that IRBs typically do have such latitude, it behooves investigators and IRBs to promote the idea that adequate informed consent must ultimately be grounded in the thinking of study subjects as empirically ascertained. Attaining this objective requires that investigators take the initiative in promoting cognitive interviewing techniques among their colleagues and IRB members.

Further, the case study described above, concerning the testing of wording of the Family Health Study advance letter, illustrates that cognitive interviewing need not be elaborate or excessively time-consuming. Even if it is not possible to conduct an extensive series of interviews, it is likely that useful information will emanate from less than a dozen interviews. Practitioners should therefore not be put off by the prospect of interjecting yet another step into their research; in this regard, best practices involve the use of cognitive interviews at even a modest level of effort. As such, IRB members should feel free to encourage investigators to make use of cognitive testing to determine that materials are in fact understood.

Research Agenda

Looking ahead, a productive research agenda would stress the further development of cognitive interviewing techniques that are effective in investigating the manner in which consent materials, with their unique forms of phraseology, legal requirements, and complex descriptions, are understood. To this end, I propose several avenues of methodological research:

(1) Determining Method Reliability and Resistance to Bias

Because cognitive testing relies on small subject samples, a fair question is whether the results obtained are sufficiently robust, as opposed to exhibiting severe variability

across samples or reflecting the biases of particular studied individuals. Experience in the area of cognitive testing of survey questions has not resolved this debate, but has made clear that decision-making based on results of small samples necessarily demands a large dose of investigator judgment. Willis (2005b) suggests that instead of expecting a single round of cognitive testing to speak for itself, researchers must rely on “clinical judgment” in interpreting these results, as is often the case in qualitative research methodology. This issue remains contentious, however, and it is vital to determine the degree to which variation in sample sizes for cognitive interviewing rounds affects the stability of the substantive results. For example, once twenty interviews are completed, how many new issues or problems arise if ten additional are conducted?

(2) Further Developing the Theoretical Basis Underlying Cognitive Interviews

I noted earlier that the theoretical justification for cognitive interviewing has not been especially well-developed, beyond the assertion that multiple cognitive stages are involved in processing responses to survey questions, and that these processes can be tapped through the use of verbal probing techniques. However, the efficacy of verbal probing to externalize cognition is yet another contentious issue. Most welcome would be theoretical development that directly targets the issue of whether subject behavior within cognitive interviews is an adequate representation of mental processes occurring in the environment and context in which those interviews are asserted to apply (e.g., when study subjects are faced with consent materials as part of the fielded study). Evaluation of the degree of carry-over between the cognitive interview and the field environment would optimally involve split sample experiments in which predictions based on the former are tested in the latter, through varying consent materials and then documenting measurable effects on subject comprehension and decision-making processes. As an illustration from the questionnaire design literature, Fowler (2004) found through cognitive testing that a question asking about frequency of strenuous activity over the past 30 days appeared to elicit superior recall if it included specific examples of such activities. When the question was then tested both with and without these examples in a randomized field experiment, the former version produced a substantially higher mean reported frequency. The researcher regarded this finding as evidence of the efficacy of cognitive interviewing, and of the use of split-sample experiments as a means for method evaluation.

(3) *Identifying Relevant Features of the Consent Process that Govern the Use of Cognitive Interviews*

With respect to testing survey questions, a critical parameter that guides cognitive testing practice is questionnaire administration mode; interviewer-administration calls for different approaches than self-administration. As applied to the study consent process, effective cognitive interviewing practice may be found to depend on additional features that vary with the type of study conducted.

For example, minimal and greater-than-minimal risk investigations are likely to present inherently varying cognitive contexts, especially concerning the manner and extent to which study subjects attend to the consent process. In turn, cognitive interviews appropriate for these discrepant categories may vary in systematic and fundamental ways. Further, the particular issues of greatest interest may be somewhat specific to the particular arena of human subjects research. For example, a vital area of concern is minority participation (or lack thereof) in biomedical research, and determination of the key factors that govern participation by racial and ethnic minorities in particular types of studies (Wendler, Kington, Madans, Van Wye, Christ-Schmidt, Pratt, *et al.*, 2006). The development of appropriate cognitive probes can be based on such primary areas of interest.

(4) *Determination of Whether Better-Designed Materials can Improve Response Rates*

A key threat experienced by survey researchers and by others who study human subjects is diminishing response rates to invitations to participate in research. Researchers therefore harbor hopes that particular approaches to devising advance letters, brochures, or wording of consent-related materials will improve subject cooperation. Cognitive testing of such materials may enable investigators to identify elements that capture the interest of potential subjects, as opposed to alienating them. For example, Butters, *et al.* (2000) examined the issue of how particular “emotionally charged” language in consent forms may produce unrealistic fears and disincline subjects to participate; gaining knowledge about the effects of such language through cognitive pretesting would seem in order.

(5) *Determination of Where Cognitive Interviewing Best “Fits”*

I have proposed that cognitive interviewing be applied to the consent arena in three forms: (a) as basic research; (b) as a means for pretesting prior to field implementation; and (c) as a procedure to be embedded

in the fielded study. A final research direction would involve the synthesis of these approaches. It is possible that each variant could serve as a component of an ongoing cycle of process improvement, such that the results of each can be used to inform the currently fielded investigation, and future research cycles.

Educational Implications

Even if researchers and IRBs were convinced that cognitive interviews have potential value, it would still be necessary for investigators to learn how to conduct them effectively. It is possible to become reasonably proficient through a limited course of self-study, making use of available resources (Willis, 2005a; b). Occasionally, short courses are offered through the Joint Program in Survey Methodology, a combined effort of the University of Maryland, University of Michigan, and Westat. If professionals in the arena of human subjects protection were to become adept in use of cognitive techniques, this would set the stage for the development of a cadre of researchers sharing a common language, scientific approach, and set of applicable tools. At that point, a promising further development would be the establishment of means to support ongoing communication between practitioners, in order to share results and possibly to point toward improvements in cognitive methods.

Within the field of cognitive interviewing as applied to survey questions, the last twenty years have evidenced a burgeoning of effort, but unfortunately the results of cognitive investigations have been unsynchronized, largely unpublished, and therefore unlikely to inform and educate other researchers. Miller, Canfield, Beatty, Whitaker, & Wilson (2003) have endeavored to address this problem by developing the Q-BANK database, which chronicles the outcomes of cognitive testing of survey questions across several U.S. Federal agencies. The major intent of Q-BANK is to provide a readily accessible compendium of previous testing results, which can be consulted when new questionnaires are developed. A key contribution to the area of human subjects protection would be an analogous database of results related to the cognitive evaluation of consent forms and processes.

Summary

It is imperative that investigators consider the cognitive world of study subjects as we endeavor to lead them to a level of understanding necessary for consent to be considered truly informed. A promising means for facilitating understanding of the subject’s thought processes is to appropriately adapt cognitive interviewing procedures.

Researchers, ethicists, and institutional review boards are encouraged to make use of cognitive techniques to improve our understanding of the consent process in general, to pretest study-specific consent procedures, and to provide an embedded mechanism to guide our discussions with participants. If successful, we will no longer be faced with Levine's (1984) option of recruiting the few study subjects who we know to be capable of comprehending dense, technical, and possibly mysterious items of information.

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Joint Program in Survey Methodology, and is author of the book *Cognitive Interviewing* (2005, Sage Publications).

End Notes

¹A reviewer has suggested that the former suggestion was perhaps intended as a "straw man" as opposed to a serious possibility, as it would violate the principle of equitable subject selection.

²The term "Cognitive Interview" is also used to describe a procedure intended to improve the recall of information by crime eyewitnesses (Fisher, R. P., & Geiselman, R. E. (1992), *Memory-Enhancing Techniques for Investigative Interviewing: The Cognitive Interview*. Springfield, IL: Thomas); I do not describe that variant.

³Results in Table 3 are derived from an unpublished investigation by the author.

⁴The nature of the decision process as it relates to informed consent diverges somewhat from its conceptualization in the questionnaire design field, as the former mainly involves the decision whether to participate in research, whereas the latter normally relates to decisions concerning responding to survey questions. However, the Decision process can be viewed broadly to encompass a wide range of decisions and judgments that subject may make.

⁵Although internal consistency reliability for the knowledge test was higher for patients and families than for surrogates, again suggesting that surrogates may not behave exactly as patients.

⁶Although the study involved slight variations of this wording, no clear differences between versions were noted.

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