

Remembering and Interpreting Informed Consent: A Qualitative Study of Drug Trial Participants

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Background and Objectives: Federal regulations require that research subjects provide informed consent for their participation in biomedical research. Before giving consent, subjects are presented with information about study procedures, risks, benefits, and alternatives. Although investigators have assessed subjects' retention of consent material, little is known about how participants view methodologic dimensions of biomedical research, such as placebos and randomization, or the distinction between medical treatment in a research protocol versus personal health care. These issues were examined with a qualitative interview study.

Methods: Research interviews were conducted with 14 subjects who had recently completed their participation in one of two drug trial studies. The interviews were tape-recorded and transcribed. The transcripts were analyzed and coded for thematic content.

Results: Participants showed a thorough understanding of important study elements, such as randomization and placebos. They described primarily altruistic motives for participating in the drug trial. There was evidence that subjects might not make a clear distinction between personal medical care and treatment in a research protocol.

Conclusions: Participants viewed their involvement in research very positively. They understood most important methodologic dimensions. The findings, however, suggest that the consent process should include greater attention to the distinction between research and clinical practice. (J Am Board Fam Pract 1996; 9:14-22.)

Biomedical research in the United States takes place within the context of regulations designed to protect participants' welfare. An overarching principle is that participants understand a study's purpose as well as attendant risks and benefits.^{1,2} This information, which has come to be called "informed consent," is communicated both orally and in written form to potential study participants. It is assumed that once this information is conveyed, individuals understand relevant aspects of their research participation. Although there have been a reasonable number of investigations of subjects' memory for consent information,³⁻⁶ there have been few examinations of participants' views of their role in biomedical research, their understanding of its purpose, and their perceptions of the consent process itself. The purpose of

the current study was to investigate, through qualitative interviews, participants' understanding of these aspects of a clinical drug trial.

The contemporary concern with informed consent is often traced to a 1966 article in the *New England Journal of Medicine* by Henry Beecher.⁷ Beecher, a professor of anesthesiology at Harvard, presented 22 examples of investigators who had risked the lives or health of their subjects without informing them or obtaining their permission. Some examples of the practices Beecher cited included feeding live hepatitis viruses to residents of a state school for the mentally retarded, injecting live cancer cells into 22 elderly and senile hospitalized patients, and intentional withholding of penicillin from servicemen with streptococcal infections.^{7,8} In part as a product of congressional hearings prompted by Beecher's article, the Department of Health, Education, and Welfare (now the Department of Health and Human Services) developed more detailed guidelines for research with human subjects.¹ These principles are articulated in *The Belmont Report* published by DHEW in 1979.² The basic elements of informed consent include voluntary participation, risks of treatment, benefits of treatment, a description of the treatment, alternatives

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to treatment, and a source to be contacted in the case of an adverse event. DHHS regulations also add that information is to be provided both orally and with a consent form. One of the roles of university and hospital institutional review boards (IRBs) is to monitor and provide corrective feedback about consent forms and how consent information is presented to prospective subjects. While regulatory bodies require that certain information be provided to research participants, there are no guidelines about how investigators are to proceed if a subject's understanding appears deficient. Typically an investigator presents the consent information in both written and verbal forms, a signature is obtained, and the transaction is completed.¹

Within the past 15 years there have been a limited number of quantitative studies of the consent process. These investigations have often focused upon participants' retention and recall of informed consent information. Typically subjects are provided with a consent document and then are tested about the form's content either immediately or at intervals ranging from several hours to days. While specific results vary somewhat from study to study, several patterns have emerged with some consistency. First, with increased time intervals between information presentation and testing, retention declines.³ Second, different types of information are differentially retained by research subjects. For example, adverse events such as medication side effects typically have the poorest retention rates.^{3,9} Third, subject characteristics appear to be associated with recall of consent information. While influenced by the type of consent process used, geriatric patients and those with below-average intellectual functioning appear to show more difficulty with comprehension of study material.^{4,5}

We conducted a series of quantitative studies assessing recall and recognition of informed consent material.^{6,10,11} In our investigations, drug trial subjects have also been asked to evaluate the adequacy of the consent information as well as the extent to which their rights as research participants are protected. Of interest is that while subjects' memories for such information as the drug name, symptoms for which medication can be taken, and side effects are poor, participants unanimously view themselves as well-informed and their rights as well-protected.⁶ For example, simi-

lar to findings reported by others, more than one half of our subjects could not recall any medication side effects.⁶ Because memory has often been inappropriately equated with comprehension, we recently developed an open-ended test covering the eight basic informed consent elements. It is administered immediately after written and verbal study information has been provided. We have found that participants comprehend about 70 percent of the consent material.¹¹

The current study was designed to complement our earlier investigations through qualitative interviews. The standardized, closed-ended questionnaires assessing specific study information did not elicit broader information about how the research process is perceived by subjects. There have been very few investigations of research subjects' motivations for participation, views of informed consent, and perceptions of such design elements as use of placebos and randomization.

Patient care and research are guided by different objectives. A typical patient who signs an informed consent document for a procedure recommended by a personal physician is entering into a contract different from the contract entered into by the biomedical research subject consenting to an experimental procedure. The goal of treatment for the patient is immediately palliative or curative. In the research context the goal often is to use the individual to generate generalizable knowledge without direct benefit to the patient-subject. Because clinical drug studies and other biomedical research take place in clinics and hospitals and include customary medical practices (physical examinations, laboratory tests, radiographs), research participants might not make the distinction between individualized treatment and an investigative protocol.¹² Applebaum et al.¹² have labeled this misunderstanding the "therapeutic misconception," which is characterized by the incorrect inference that study procedures will be of immediate benefit to the participants themselves.¹ In a study of psychiatric patients in a research protocol, it was found that nearly 40 percent of those patients explicitly told that they were receiving a placebo still believed that the experimental procedures would be of direct therapeutic benefit to themselves.¹²

Although recall and recognition of study information can be quantified, these contextual issues are probably not readily amenable to quantitative

investigation. Qualitative inquiry was therefore used to examine these issues. The specific purposes of the current study were to understand how participants in a biomedical research study view (1) their study participation, (2) the informed consent process, (3) placebos, (4) treatment randomization, and (5) participation in a research protocol compared with customary clinical care.

Methods

Participants

The participants were drawn from pools of adults who had completed one of two clinical drug studies. Seven subjects were drawn from approximately 90 who participated in a herpes labialis (cold sore) study, and 7 were drawn from a group of 65 participants in a genital herpes trial. The 14 participants interviewed consisted of 11 women and 3 men who had an average age of 40.5 years. All of the interviewees were white. The participants averaged 14.4 years of formal education. All participants received informed consent information in both written and verbal formats. The consent form was written at an 8th grade reading level and included the elements described in *The Belmont Report*.² A research associate read a standardized version of this material and responded to any questions.

The selection of research participants in qualitative investigations emphasizes inclusion of persons who reflect the phenomenon under study.¹³ Sample sizes are typically much smaller than in quantitative investigations. In analyzing transcripts, the categories or themes that emerge typically reach a saturation point at 6 to 8 subject protocols.¹³ Saturation refers to the point at which analysis of additional protocols does not yield any additional descriptive categories. The sample size in the current investigation was based on these general principles. Preliminary analysis of a subset of eight transcripts indicated that data saturation had occurred. The remaining interviews, however, were conducted to ensure adequate sampling.

Interview

The interview questions selected for this study were influenced by a qualitative informed consent study conducted by Lidz and colleagues¹⁴ in a psychiatric hospital. Their investigation is one of the few systematic qualitative studies of the consent process and subjects' views of their role as

research participants. Examples of questions we used in our current study are listed in Table 1. Interview questions centered around participants' understanding of placebos, randomization, reason(s) for participation in a clinical trial, and the distinction between receiving treatment as part of a research protocol versus customary clinical care.

Methodologically the interview process was guided by ethnographic principles, such as those described by McCracken¹⁵ and Spradley.¹⁶ Participants were initially asked broad questions (Table 1), then questions requesting detailed content.¹⁶ A general format was followed by the interviewer to organize the interactions.¹⁵ The interviews were conducted by the first author in an office adjacent to the research rooms. Participants made a special appointment with the investigator that was unrelated to the clinical trial. The interviewer had had no previous contact with any of the participants.

Data Analysis

All of the interviews were tape-recorded and transcribed. The transcripts were analyzed for consistent themes according to an adaptation of

Table 1. Examples of Questions Used in Informed Consent Interviews.

1. What can you tell me about the study that you were involved in?
2. What types of information were you given when you entered the study?
3. What information did you use to make your decision to participate?
4. At what point did you decide to participate in the study?
5. What were the forms that you signed?
6. One of the forms that you signed was a consent form; why were you asked to sign the consent form? What did it mean when you signed it?
7. In some studies, a placebo is used. What is a placebo? How does a placebo work?
8. How do the investigators decide whether to give the active drug or placebo?
9. What is the difference between having your condition treated through a research study versus having it treated by your personal physician? Do you feel the quality of care differs?
10. Do you feel that the investigators have the same concern for you personally as your physician?
11. Do you feel that you need to understand the care that you receive?

grounded theory¹⁷ for interview data by Rennie et al.¹⁸ This approach involves analysis of semantic segments of narrative data (meaning units). The segments were coded according to their thematic content. The coding process is guided by constant comparison in which the investigator compares each unit with other data. The purpose of this comparison is to discern similarities and differences between categories, as well as the conceptual boundaries of specific categories.^{17,18} The goal of this process is to organize and synthesize narrative data to provide an understanding of how people make sense of a particular subject area. This general method has been used to study such issues as how psychotherapy patients perceive the treatment process,¹⁸ adaptation to chronic illness by patients and their families,¹⁹ and the organization of work roles in a neonatal intensive care unit.²⁰

Although a brief, preliminary analysis was conducted during the interview phase, the formal systematic coding of the data was initiated only after all interviews were completed. After coding, the initial analytic categories were reviewed by the second author, a clinical pharmacist. The initial categories were also presented to a group of clinical pharmacists actively engaged in drug trial studies. Based upon their feedback, categories were refined and clarified.

Results of qualitative interview studies are typically presented in the form of specific themes that emerge from the analysis with supporting narrative data to illustrate each theme. A more abstract story line is presented here in order to integrate and synthesize the findings at a conceptual level.

Results

Domain 1: Motivation for Participation (*"I did it for science, humanity, ... and maybe some cash."*)

Most participants provided specific reasons for participating in the study. They viewed themselves as making a valuable contribution to humanity or medicine. Although all participants were paid for their involvement in the trial, monetary reward was mentioned by a minority of those interviewed. Many participants appeared to believe that they were embarking on a personal mission that would result in finding an effective treatment for their condition. Those participants holding this perspective often emphasized that

they were performing a valuable service by developing a treatment for a chronic condition plaguing them and others. These participants also tended to view themselves as part of a community of fellow sufferers.

It's kind of like saving our environment or preparing our children for the future. It's really a good feeling that you could actually be in on the research.

Well basically, I've used a lot of different products, over-the-counter products, to heal cold sores when I get them. I've used the samples of other creams that are already out there, and they didn't do much for me. So I was just thinking that if I can do something to get something on the market that would help in research, then it would be better for me and lot of other people.

As noted above, a small number mentioned financial compensation, but the financial compensation was almost always an afterthought—usually not the first reason mentioned:

I guess I'd been raised that I might as well do something useful and do research. I find it interesting, and I think somebody might as well do it, and I hope I am giving you something you can use.... Yeah, I'm a cheapskate. I wanted the money. I figured as long as I had it, I might as well get in the study, 'cause I was going to have to treat it anyway. The last check came. I had forgotten totally about it, and it showed up in the mail. Like, wow—so I guess I'm kind of a mercenary, too.

Domain 2: Protection of Human Rights (*"No one pressured me; it was my choice."*)

The participants were unanimous in their perception that their rights as research subjects were well-protected. None of them believed that important information had been withheld prior to their involvement in the study. Likewise, the participants all stated that they had been adequately informed about the purpose of the study and accompanying procedures. All of those interviewed viewed their participation as entirely voluntary, and none felt coerced. In contrast to other aspects of the study, participants provided relatively brief, positive accounts of the quality of the informed consent information. The following excerpts are typical accounts of their perceptions of volunteering:

It was totally my choice, and at any time I could have quit the study with no problems, no hassles, no guilt. It was totally up to me.

At any time I could get out of it if I didn't feel like I wanted to be in it; if I were feeling pressured, or if I just didn't want to participate any longer, I wouldn't have to. I was there as a volunteer. I was there on my own rules. They weren't chaining me to it.

Domain 3: The Consent Form ("It prevents lawsuits.")

The most common perception of the consent form was that it was a tool for protecting the investigators and drug company from legal liability. Participants indicated they recognized that they were being given an experimental drug and that there was some element of accompanying risk involved. Subjects freely acknowledged being guinea pigs (in the words of several respondents). Participants viewed the consent form as a legal document indicating that they were knowledgeable and fully informed guinea pigs. Several respondents also noted that the consent form allowed information about them to be released to pharmaceutical company representatives.

It was extremely rare for participants to describe the informed consent form as having educational benefit. The consent form was primarily seen as a legal document designed to prevent litigation. When asked about the reason for signing the consent form, responses were typically similar to this one:

Well, we live in a litigious society. If it weren't for lawyers, we wouldn't have to worry about most of that.

Another respondent provided somewhat more detail:

Basically, it just acknowledged that I was aware of the entire scope of the study. We all know it really doesn't absolve anybody. The legal responsibility, I mean, one way or another. Courts don't honor blanket consent forms, but they do take them into consideration. Also it's to make sure that nothing is done on the sly, I guess. We all read about how the government injects people with radioactive material without their knowledge.... You also have to release a certain amount of liability. When I was asked to sign it, I understood what I was signing, and I understood I'd be releasing the company from liability and responsibility.

Domain 4: Placebos ("The power of positive thinking.")

All participants could provide a reasonable definition or description of a placebo. Those subjects in placebo-control trials all recognized that placebos were administered. Most descriptions of placebos emphasized the psychological expectancies associated with them:

As health is certainly enhanced by mental attitude, a placebo works for many people, in many instances, because they have the feeling that they are being helped. They think their doctor gave them some medicine that is going to make them better. Mental attitude does help. The body heals itself pretty well anyway; and if you have the right mental attitude, it will heal itself better. Placebos work that way.

About one third of the participants verbalized a more sophisticated rationale for using placebos in drug-trial studies. These participants showed an understanding of the need for a baseline condition, controlling for psychological expectancies against which to compare a new drug:

You cannot measure a medication; you have to have something to measure it against. The placebo will, in some people, tend to get a little bit of improvement or whatever. They get a certain result from it because of mental attitude. But you have to be able to measure against something, and the medication certainly should show more marked improvement than a placebo in order to evaluate it. Otherwise, how do you evaluate what the real medicine has done at all?

Domain 5: Treatment Randomization ("The drug company plays with dice.")

Participants consistently demonstrated an understanding that assignment of the placebo or active drug was randomly determined. Approximately one half of the participants correctly indicated that the local investigators were blinded to the assignment categories. Of those subjects who verbalized an understanding of the double-blind process, most indicated that the pharmaceutical company had information about assignment to active versus placebo drug. Perceptions of the randomization process, however, were sometimes very concrete:

I would imagine they rolled dice for it. As far as I understand how they did it, generally in research, it's just done at random.

It's all random. It was just based on who walked in the door at what time. Like the person right before me could have had active, or they could have had the placebo. It's just random. They just take the next numbered tube.

Domain 6: Personal Care Versus Generalizable Knowledge ("I may have gotten a sugar pill, but they treated me better.")

Participants were nearly unanimous in saying that their medical care was much better and that the research staff cared more about them personally than did their private physician. While some of the participants did acknowledge that there might be a distinction between receiving their care through a research study and receiving care from their personal physician, none believed that they were in any way short-changed by receiving their care as part of a research protocol. This finding is particularly noteworthy in that at least one half of these patients were receiving placebos. Although several respondents alluded to this possibility, this issue did not appear to be troubling to them. In the words of one respondent:

I felt that the research study was more in tune to the individual. They really wanted to make sure you understood completely what you were doing before you left. I've gone to many doctors and left the office saying, "I don't know what the hell he just told me," or "What I am supposed to do?" I'd end up calling back and talking to the nurse. So I felt I was in much better hands with the research study staff than I was in many private physicians' offices.

Several respondents noted that medical treatment in a research study involved only time-limited treatment for one specific condition. Of 14 participants interviewed, however, only 2 seemed to have a firm grasp of the distinction between research for generalizable knowledge and personal medical care.

Discussion

Participants in this clinical drug trial viewed their involvement very positively. They characterized their motivation for participation as altruistic. Respondents believed that through their involvement in the study, they were able to make a personally meaningful contribution to science and curing illness. Participants saw a relation between their participation and possible benefits to others

with their condition. While the monetary gain received was not mentioned by most respondents and appeared to be a secondary factor by those who did mention compensation, it is possible that financial reward played a larger role than described. It could be that subjects experienced dissonance about being paid for a seemingly altruistic act. As a result, participants' narrative accounts might have overstated the broader social motivation to help others.

The respondents unanimously believed that their rights as research subjects were well-protected. They were very satisfied with the breadth and depth of information received before their involvement. Participants felt uniformly unpressured to be part of the study and recognized that they could leave the study at any time without penalty. This understanding extended to the concepts of placebo and treatment randomization. It would appear that these drug trial participants comprehended the important criteria of informed consent.

While specific study content (eg, name of drugs, side effects, and so on) was not addressed in the interviews, the respondents' perceptions and appraisals of the informed consent process were overwhelmingly positive. The thoroughness with which this information was presented—in both written and verbal formats—is likely to have contributed to subjects' positive appraisals. This pattern is consistent with our earlier quantitative findings of the informed consent process.^{6,10} Among adults participating in a drug trial comparing two analgesics, it was found that participants considered themselves to be very well-informed and believed that their rights as research participants were well-protected.⁶ When asked specific content questions about material covered in the consent form and the verbal consent process, however, participants demonstrated relatively poor understanding of factual material. The majority of them were unable to name the drugs being studied. Most subjects could recall fewer than one half of the potential side effects or conditions for which the medication could be taken. Fewer than 1 percent of the participants were able to name correctly all three parties who had access to their records in the study, while fewer than one third could correctly name only one of the parties.⁶

The informed consent document, signed by

participants at a study's outset, is viewed as the primary means through which participants are educated about the investigation and their rights as research subjects.²¹ Often-cited advantages of the consent document include the subjects' opportunity to read the information at their own pace, availability of the material for rereading, and the absence of the investigator's nonverbal influence.¹⁴ Nevertheless, few participants viewed the document as fulfilling these purposes. The consent forms were almost universally seen as a legal document designed to protect the companies from litigation. The study conducted by Lidz and colleagues¹⁴ yielded similar findings. Lidz et al concluded that physicians and patients viewed the consent document as "a form of legalistic mumbo-jumbo to prevent lawsuits."

Applebaum and colleagues¹² have expressed concern that clinical trial participants might not comprehend methodologic aspects of studies, such as randomization and double-blind placebos. Based on their responses, our subjects appeared to have a solid understanding of these issues. The narrative data, however, raise questions about whether participants fully appreciate the distinction between personal medical care and medical procedures performed as part of an investigative protocol. Although research specifically addressing this issue is sparse, one study found that more than two thirds of the participants in a double-blind trial did not understand that treatment assignment was not randomly determined; instead, they believed that therapy was individualized.²² In a psychiatric setting, Applebaum and colleagues¹² found that even though subjects could often define "random" very clearly, they continued to believe that in a randomized trial, they would receive treatment that was of direct, personal benefit.

Even though we did not specifically ask subjects whether they received an active drug or a placebo, a number of participants spontaneously volunteered that they were sure they had received the active drug. This "discovery" suggests that participants in placebo trials might deny or distort important study information to maintain the illusion of personal benefit. Park and Covi²² found that of 15 subjects who were explicitly instructed that they were receiving a placebo, 6 believed that they were receiving the active drug 1 week after being informed.

Participation in research, however, also appears to be associated with a number of nonspecific benefits. These subjects viewed themselves as receiving much better care through the study than from their personal physician. The higher levels of attention and greater amounts of time spent with the research subjects are likely to have contributed to this perception. These nonspecific benefits of research participation have been noted in both medical and behavioral research.²³

The generalizability of these qualitative findings can be limited by respondent characteristics as well as factors specific to the investigatory protocols. It is well-established that patients' perceptions of physicians and health care are often influenced by demographic features, such as age, sex, and ethnicity.^{24,25} While there have been few investigations of the impact of demographic characteristics on perceptions of biomedical research, it is likely that similar contextual influences exist. For example, geriatric subjects have been found to exhibit poorer recall of consent information compared with younger participants.²⁶ Additionally, a recent study involving administration of the Deaconess Informed Consent Comprehension Test to clinical trial participants found that women had higher scores than men.²⁷ This finding is consistent with studies that find better verbal skills among women.²⁸ In the current study, the respondents were all white, well-educated, and disproportionately female. It is unknown whether a similar set of descriptive categories would emerge from a sample with a different sex, age, and ethnic composition. Given that our average subject had almost 2.5 years of college education, however, the failure to distinguish between personal medical care and research is particularly noteworthy.

Another contextual limitation of this study could be the type of illness being treated. Patients in this investigatory protocol had a nonlethal illness that had no known cure. Our participants' relatively benign view of the research protocol might not be shared by subjects with a life-threatening condition or those with an illness for which a cure was available. Quantitative studies have found that recall of informed consent material is poorer with high-risk than with low-risk medical procedures.²⁹ It should be noted that in our study, participants (one half of whom were receiving placebos) were required to refrain from using

their palliative medication while undergoing the investigatory protocol. Nevertheless, it would be valuable to conduct similar qualitative interviews with clinical trial participants who have more serious or life-threatening conditions.

In conclusion, we have found, through both qualitative and quantitative studies, that drug trial participants appeared to have very positive perceptions of their participation. Additionally, from a subjective viewpoint, they perceived their rights to be well-protected and believed that they were well-informed about study procedures. There are suggestions that participants might have been making questionable inferences based upon the clinical setting; there was a pervasive view that participation in the research study would be of direct personal benefit. Our subjects had been in clinical trials for conditions with no well-established standard of care. While this factor might have contributed to a lack of discrimination between research and clinical goals, the interview findings raise concerns about whether more should be done to convey this distinction more explicitly. Although this issue should be explored further, it might be necessary for medical investigators to explain clearly those study dimensions that differ from conventional clinical care.^{1,12} Additionally, study physicians should inform subjects that because of their dual role they will not be focused exclusively on participants' well-being.^{1,12} Our findings suggest that obtaining truly informed consent could require a more complicated and demanding process than currently being implemented.

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